FEDERAL REGISTER

Vol. 82 Tuesday,

No. 227 November 28, 2017

Pages 56151–56528

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.ofr.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.fdsys.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 82 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Contents

Federal Register

Vol. 82, No. 227

Tuesday, November 28, 2017

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR
984.....56151
986.....56152

10 CFR

Proposed Rules:
430.....56181

14 CFR
39 (5 documents) 56156, 56158, 56163, 56165, 56167

17 CFR
23.....56169

18 CFR

Proposed Rules:
40.....56186

33 CFR
165.....56170

Proposed Rules:
Ch. II.....56192

40 CFR
52 (3 documents) 56172, 56173
70.....56173
180.....56173

42 CFR

Proposed Rules:
405.....56336
417.....56336
422.....56336
423.....56336
498.....56336

47 CFR

Proposed Rules:
96.....56193

50 CFR
300.....56177
622.....56178
648 (2 documents) 56180

Proposed Rules:
91.....56201
660.....56204

Rules and Regulations

Federal Register
Vol. 82, No. 227
Tuesday, November 28, 2017

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–17–0035; SC17–984–1 FIR]

Walnuts Grown in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule that implemented a recommendation from the California Walnut Board (Board) to decrease the assessment rate established for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per kernelweight pound of assessable walnuts. The Board is comprised of growers and handlers of walnuts and locally administers the Marketing Order that regulates the handling of walnuts grown in California. The Board also has a public member who has no financial interest in walnut production or handling.

DATES: Effective November 29, 2017.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Terry.Vawter@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses;* or 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 rule is issued under Marketing Order No. 984, as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the ''Order.'' 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 Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this 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).

Under the Order, California walnut handlers are subject to assessments, which provide funds to administer the Order. Assessment rates issued under the Order are intended to be applicable to all assessable California walnuts for the entire marketing year and continue indefinitely until amended, suspended, or terminated. The Board's marketing year began on September 1 and ends on August 31.

In an interim rule published in the **Federal Register** on July 21, 2017, and effective July 24, 2017, (82 FR 33775), § 984.347 was amended by decreasing the assessment rate established for California walnuts for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per hundredweight pound of assessable walnuts. The decrease was recommended by the Board because the 2017–18 crop is expected to be 615,000 tons, which is 62,000 tons larger than the 2016–17 crop. At that crop level, handler assessments, combined with funds from the financial reserve, should provide adequate funds to administer the program.

Final 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 action on small entities. Accordingly, AMS has prepared this final 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 4,700 growers of California walnuts in the production area and approximately 90 handlers subject to regulation under the Marketing Order. The Small Business Administration (SBA) defines small agricultural growers as those having annual receipts of less than $750,000 and small agricultural service firms as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to USDA's National Agricultural Statistics Service's (NASS) 2012 Census of Agriculture, approximately 86 percent of California's walnut farms were smaller than 100 acres. Further, NASS reports that the average yield for 2015 was 2.01 tons per acre, and the average price received for 2015 was $1,620 per ton. A 100-acre farm with an average yield of 2.01 tons per acre would, therefore, have been expected to produce about 201 tons of walnuts. At $1,620 per ton, that farm's production would have had an approximate value of $325,620. This is well below the SBA threshold of $750,000; thus, it can be concluded that the majority of California's walnut growers are considered small growers according to SBA's definition.

According to information supplied by the industry, approximately two-thirds of California's walnut handlers shipped merchantable walnuts valued under $7,500,000 during the 2016–17 marketing year and would, therefore, be considered small handlers according to the SBA definition.

This rule continues in effect the action that decreased the assessment rate collected from handlers for the 2017–18 and subsequent marketing years from $0.0465 to $0.0400 per kernelweight pound of assessable walnuts. The Board unanimously recommended 2017–18 expenditures of $24,140,000 and an assessment rate of $0.0400 per kernelweight pound of assessable walnuts, which is $0.0065 lower than the assessment rate previously in effect. The quantity of assessable walnuts for the 2017–18 marketing year is estimated to be 615,000 tons, 62,000 tons greater than the quantity estimated for the 2016–17 marketing year. Therefore, even at the reduced assessment rate, the Board should collect approximately $22,140,000 in assessment income, which, when combined with $2,000,000 from its reserves, should be adequate to cover its budgeted expenses.

This rule continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on growers.

In addition, the Board's meeting was widely publicized throughout the California walnut industry, and all interested persons were invited to attend the meeting and encouraged to participate in Board deliberations on all issues. Like all Board meetings, the May 31, 2017, meeting was a public meeting, and all entities, both large and small, were able to express views on this issue.

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

This action imposes no additional reporting or recordkeeping requirements on either small or large California walnut 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.

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

Comments on the interim rule were required to be received on or before September 19, 2017. No comments were received.

Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *https://www.regulations.gov/docket?D=AMS-SC-17-0035.*

This action also affirms information contained in the interim rule concerning Executive Orders 12866, 12988, 13175, 13563, and 13771; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Government Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (82 FR 33775, July 21, 2017) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

PART 984—WALNUTS GROWN IN CALIFORNIA

■ Accordingly, the interim rule amending 7 CFR part 984, which was published at 82 FR 33775 on July 21, 2017, is adopted as a final rule, without change.

Dated: November 22, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–25736 Filed 11–27–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 986

[Doc. No. AMS–SC–17–0032, SC17–986–2 FR]

Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas; Establishment of Reporting Requirements and New Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation made by the American Pecan Council (Council) to establish reporting requirements under the Federal marketing order for pecans (Order). The Council locally administers the Order and is comprised of growers and handlers of pecans operating within the production area and one public member. This action requires all pecan handlers to submit two forms to the Council: one for inter-handler transfers and another that includes year-end inventory and pecans handled throughout the year. The Council will use this information to facilitate assessment collection and provide valuable reports to the industry, including the annual marketing policy required by the Order.

DATES: Effective December 28, 2017.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, 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: *Jennie.Varela@ams.usda.gov* or *Christian.Nissen@ams.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 final rule is issued under Marketing Agreement and Order No. 986 (7 CFR part 986) regulating the handling of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas, hereinafter referred to as the ''Order.'' 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 Department of Agriculture (USDA) is issuing this final 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 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 final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Marketing Order now in effect, pecan handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the reporting requirements issued herein will be applicable to all assessable pecans beginning October 1, 2016, to facilitate the collection of assessments.

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 final rule establishes reporting requirements under the Order. This action requires all pecan handlers to submit to the Council reports of inter-handler transfers of pecans, inventory, and a summary of pecans handled. This information will be used to facilitate assessment collection and provide valuable reports to the industry, including the annual marketing policy required by the Order. The Council unanimously recommended this action at its April 17, 2017, meeting.

Section 986.61 of the Order requires all handlers warehousing pecans as of August 31 be identified as the handler of those pecans and pay the assessment rate accordingly. Section 986.62 provides the Council, with the approval of the Secretary of Agriculture (Secretary), authority to establish methods and procedures, including necessary reports, to maintain accurate records for inter-handler transfers. Sections 986.75, 986.76, and 986.77 provide authority to prescribe reports of handler inventory, merchantable pecans handled, and pecans received by handlers, respectively. Section 986.78 further provides the Council, with the approval of the Secretary, authority to collect other reports and information from handlers needed to enable the Council to perform its duties. This final rule would utilize these authorities to establish new §§ 986.162 and 986.175 under the rules and regulations of the Order. These new sections would require handlers of pecans to report to the Council any inter-handler transfers, and the volume of shelled, inshell, and total volume of pecans handled each fiscal year by type using specific Council forms.

At its November 16, 2016, meeting, the first meeting following the Order's promulgation, the Council discussed its initial budget, assessment rates, and necessary reporting requirements in order to set up a program that is efficient and responsive to industry needs. During these discussions, the Council established a Statistics and Reporting Committee (Committee) to develop reporting requirements.

Members of the Committee discussed the reporting needs of the industry, reviewed examples of reporting forms from other marketing orders, and met and worked with the staff of another marketing order in developing the reporting requirements. The Committee also worked with USDA to ensure the recommended information collection would provide the information necessary to facilitate the administration of the Order.

At its February 23, 2017, meeting, the Council reviewed drafts of seven reporting forms as developed and recommended by the Committee. The Council expressed its interest in having as much electronic reporting as possible but recognized that many handlers may prefer a paper submission. The Council also considered the timing of when forms would be due and submission dates that would work for all parts of the industry. After a thorough review and some modifications, seven forms were approved by the Council.

At a meeting on April 17, 2017, the Council revisited the recommended reporting requirements and the accompanying forms. Acknowledging the industry was more than halfway through the fiscal year at that time, the Council took action to move forward with the minimum reports necessary to facilitate the collection of assessments and to provide the other information needed for the 2016–17 fiscal year. Specifically, the Council voted to utilize two forms for that fiscal year: One focusing on inter-handler transfers, and one containing information regarding year-end inventory and pecans handled throughout the fiscal year. The Council agreed it still wanted to move forward with all seven forms for the 2017–18 fiscal year but considered year-end reporting on two forms as the most viable option for the first fiscal year of the Order. The remaining five forms will be proposed in a subsequent rulemaking action.

This final rule adds two new reporting requirements and two new forms to the rules and regulations under the Order by adding §§ 986.162 and 986.175. The pecan industry includes a subset of handlers, defined in the Order as accumulators, who compile pecans for the purpose of resale or transfer to another handler. Additionally, small handlers may also sell or transfer pecans to other handlers. During the formal rulemaking hearing, the industry expressed concern that it may be difficult to track pecans moved through accumulators or transferred between handlers. Further, some handlers and accumulators that are small operations may find reporting, recordkeeping, and paying assessments burdensome.

The report of inter-handler transfers includes information on the month of transfer, type of pecans transferred, the volume transferred, the amount of assessments owed on the pecans transferred, identification information and signatures for the two handlers involved, and whether the transferring handler or receiving handler would be responsible for reporting and paying the assessments. This report helps ensure that transferred pecans are not counted twice for volume reporting purposes and will help facilitate the collection of assessments. It will also allow receiving handlers to assume the reporting burden from smaller entities and ensure payment of corresponding assessments.

The Council selected the tenth day of the month following the month of transfer as the due date for reports of inter-handler transfers. Should the tenth day of the month fall on a weekend or holiday, reports would be due by the first business day following the tenth day of the month. Given that the final rule will publish after the September date, the due date will be extended to December 28, 2017. For subsequent fiscal years, reports of inter-handler transfers will be due on a monthly basis as specified above.

In order to correctly collect assessments, provide industry data, and complete a marketing policy for the coming fiscal year, the Council requires accurate reports of what has been handled and what is in inventory going into the next fiscal year. Based on Council discussions, it is also important for the industry to know the variety and form of the pecans in inventory. This information will be vital to the industry as it enters the next harvest, as the amount and type of inventory impacts

prices of the new crop. Collection of this data was one of the industry's goals in promulgating the Order, as currently there is no source for this type of information across the 15-state production area. This information will be captured in the year-end inventory report.

The year-end inventory report includes information on the handler submitting the form, total pounds by type of pecans inshell and shelled in inventory, inventory committed but not shipped for both export and domestic, and any uncommitted inventory. It also includes information on pecans handled throughout the year, as well as data for total inventory, including both shelled and inshell, with shelled volume converted to an inshell basis using the conversion specified in the order (volume shelled × 2). In addition, it includes information regarding total assessments owed, assessments paid to date, and remaining assessments due for that handler.

The Order specifies that on August 31 of each year, every handler warehousing inshell pecans shall be identified as the first handler of those pecans and shall be required to pay the required assessment rate. The Order also specifies that the marketing policy include an estimate of the handler inventory as of August 31. Consequently, the Council selected September 10 as the due date for the year-end inventory report, or the first business day following the tenth of September, should the tenth fall on a weekend or a holiday. The Council believes this would give all handlers sufficient time to submit the information to the Council after August 31. Further, handlers would be required to pay to the Council all remaining unpaid assessments by the due date of the year-end inventory report. As the recommended September 10 due date has passed, for the 2016–17 fiscal year, this report will be due December 28, 2017.

This action requires all pecan handlers to provide the Council with reports of any inter-handler transfers, year-end inventory, and pecans handled throughout the year. This information will facilitate assessment collections, provide valuable reports to the industry, and allow the Council to complete the annual marketing policy required by the order.

The Council also recommended additional reporting requirements, which would be effective for the 2017–18 fiscal year. These requirements are being considered under a separate action.

Final 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 action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to determine whether the regulatory action will have a significant economic impact on a substantial number of small entities and 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 2,500 growers of pecans in the production area and approximately 250 handlers subject to regulation under the marketing order. Small agricultural growers 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 information from the National Agricultural Statistics Service (NASS), the average grower price for pecans during the 2015–16 season was $2.20 per pound, and 254 million pounds were utilized. The value for pecans that year totaled $558.8 million ($2.20 per pound multiplied by 254 million pounds). Taking the total value of production for pecans and dividing it by the total number of pecan growers provides an average return per grower of $223,520. Using the average price and utilization information, and assuming a normal bell-curve distribution of receipts among growers, the majority of growers receive less than $750,000 annually.

Evidence presented at the formal rulemaking hearing indicates an average handler margin of $0.58 per pound. Adding this margin to the average grower price of $2.20 per pound of inshell pecans results in an estimated handler price of $2.78 per pound. With a total 2015 production of 254 million pounds, the total value of production in 2015 was $706.12 million ($2.78 per pound multiplied by 254 million pounds). Taking the total value of production for pecans and dividing it by the total number of pecan handlers provides an average return per handler of $2,824,480. Using this estimated price, the utilization volume, number of handlers, and assuming a normal bell-curve distribution of receipts among handlers, the majority of handlers have annual receipts of less than $7,500,000. Thus, the majority of growers and handlers of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas may be classified as small entities.

This final rule establishes reporting requirements under the order. This action requires all pecan handlers to provide the Council with reports of any inter-handler transfers, year-end inventory, and pecans handled throughout the year. This information will facilitate the Council's collection of assessments and provide valuable reports to the industry. This rule establishes new §§ 986.162 and 986.175 under the rules and regulations of the order. The authority for this action is provided for in §§ 986.62, 986.75, 986.76, 986.77, and 986.78 of the order.

Requiring reports of transfers, handler inventory, and pecans handled throughout the year will impose an increase in the reporting burden on all pecan handlers. However, this data is already recorded and maintained by handlers as a part of their daily business. Handlers, regardless of size, should be able to readily access this information. Consequently, any additional costs associated with this change would be minimal (not significant) and apply equally to all handlers.

This action should also help the entire industry by providing comprehensive data on pecans handled and year-end inventory. Collection of this data was one of the industry's goals in promulgating the order as there is no other source for this type of data. This information should help with marketing and planning for the industry, as well as provide important information for the collection of assessments and in preparing the annual marketing policy required by the order. The benefits of this rule are expected to be equally available to all pecan growers and handlers, regardless of their size.

The Council discussed other alternatives to this action, including having additional reporting requirements, but determined that in order to efficiently carry out the objectives of the marketing order this first fiscal year, the information collected in these two reports would be sufficient. The Council also considered requiring the inter-handler transfer form

to be submitted for each transfer. However, the Council determined that could be burdensome for some handlers, and a monthly report would provide the necessary documentation. Therefore, the alternatives were rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this collection has been submitted to OMB with the reference number 0581–0303. Upon approval, the collection will be merged with OMB No. 0581–0291, ''Federal Marketing Order for Pecans.'' This final rule establishes the use of two new Council forms, which impose a total annual burden increase of 185 hours. The forms, Report of Inter-Handler Transfer of Pecans and Year End Inventory Report, require the minimum information necessary to effectively carry out the requirements of the order. The information would enable the Council to facilitate assessment collection and provide valuable reports to the industry.

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.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. Further, the public comment received concerning the proposal did not address the initial regulatory flexibility analysis.

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.

The Council's meetings were widely publicized throughout the pecan industry and all interested persons were invited to attend the meetings and participate in Council deliberations on all issues. Additionally, the Council's Committee meetings held February 23, 2017, and April 17, 2017, were also public meetings and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the **Federal Register** on July 21, 2017 (82 FR 33829). Copies of the rule were sent via email to all Council members and known pecan handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending September 19, 2017, was provided to allow interested persons to respond to the proposal.

One comment was received in favor of the proposed information collection. The commenter stated the proposed requirements were necessary in order to better assess the pecan crop. Accordingly, no changes will be made to the rule as proposed, based on the comments received. Minor editorial changes were made to the rule for the purpose of clarity. The name of Subpart B was corrected to read as SUBPART B—Administrative Provisions and the lists in §§ 986.162 and 986.175 now include an ''and.''

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.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Council and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 986

Marketing agreements, Nuts, Pecans, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 986 is amended as follows:

PART 986—PECANS GROWN IN THE STATES OF ALABAMA, ARKANSAS, ARIZONA, CALIFORNIA, FLORIDA, GEORGIA, KANSAS, LOUISIANA, MISSOURI, MISSISSIPPI, NORTH CAROLINA, NEW MEXICO, OKLAHOMA, SOUTH CAROLINA, AND TEXAS

■ 1. The authority citation for 7 CFR part 986 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 986.162 to read as follows:

§ 986.162 Inter-handler transfers.

(a) Inter-handler transfers of inshell pecans, pursuant to § 986.62, shall be reported to the Council on APC Form 4. Handlers shall file reports by the tenth day of the month following the month of transfer. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month; Provided, that for the 2016–17 fiscal year, all inter-handler transfer forms shall be submitted by December 28, 2017. The report shall contain the following information:

(1) Month of transfer;

(2) The type and weight of pecans transferred;

(3) The amount of assessments owed on the pecans transferred;

(4) The names and signatures for both the transferring and receiving handlers; and

(5) Handler assuming the reporting and assessment obligations on the pecans transferred.

■ 3. Add § 986.175 to read as follows:

§ 986.175 Handler inventory.

(a) Handlers shall submit to the Council a year-end inventory report following August 31 each fiscal year. Handlers shall file such reports by September 10. Should September 10 fall on a weekend, reports are due by the first business day following September 10; Provided, that for the 2016–17 fiscal year, all inventory reports shall be submitted by December 28, 2017. Such reports shall be reported to the Council on APC Form 7 and include:

(1) The name and address of the handler;

(2) The total weight and type of inshell pecans in inventory, regardless of country of origin;

(3) The total weight and type of shelled pecans in inventory, regardless of country of origin;

(4) The total weight and type of inshell pecans committed, not shipped, for export and domestic shipments, and any uncommitted inventory, regardless of country of origin;

(5) The total weight and type of shelled pecans committed, not shipped, for export and domestic shipments, and any uncommitted inventory, regardless of country of origin;

(6) The combined total inventory for inshell and shelled pecans calculated on an inshell basis, and combined weight committed, not shipped, for exports and domestic shipments, and any uncommitted inventory;

(7) Total weight and type of domestic pecans handled for the fiscal year; and

(8) Total assessments owed, assessments paid to date, and remaining assessments due to be paid by the due date of the year-end inventory report for the fiscal year.

Dated: November 22, 2017.

Bruce Summers,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2017–25735 Filed 11–27–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0526; Product Identifier 2017–NM–026–AD; Amendment 39–19109; AD 2017–24–05]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This AD was prompted by reports of cracking in the upper aft skin at the rear spar of the wings. This AD requires repetitive inspections for cracking of the upper aft skin of the wings, and repair if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of January 2, 2018.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740; telephone 562–797–1717; Internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0526.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0526; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on June 5, 2017 (82 FR 25744). The NPRM was prompted by reports of cracking in the upper aft skin at the rear spar of the wings. The NPRM proposed to require repetitive inspections for cracking of the upper aft skin of the wings, and repair if necessary.

Comments

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

Effect of Winglets on Accomplishment of the Proposed Actions

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

Southwest Airlines requested clarification that additional alternative method of compliance (AMOC) approvals are not necessary during accomplishment of the actions specified in Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017, if the installation of winglets was done using STC ST01219SE.

We agree with the commenters' statements. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC ST01219SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' AMOC approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Revise Certain Corrective Action Requirements

All Nippon Airways (ANA) asked that we revise paragraph (h) of the proposed AD to change the compliance method for crack repair to allow use of the Boeing 737–500 Structural Repair Manual (SRM) 57–20–10, Repair 7. ANA stated that Boeing has already developed the repair procedure for the outer wing upper aft skin at the trailing edge between wing buttock line (WBL) 160 and WBL 205, as specified in Boeing 737–500 SRM 57–20–10, Repair 7. ANA added that the repair procedure is applicable to part of an inspection area specified in Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017. ANA noted that its request should be considered to reduce AMOC requests.

We disagree with the request. Boeing has indicated that Repair 7 of the SRM is currently being revised. We do not consider that delaying this rulemaking until release of the revised service information is warranted. However, under the provisions of paragraph (j) of this AD, we will consider requests for approval of alternative service information if sufficient data are submitted to substantiate that the service information would provide an acceptable level of safety. Boeing has indicated it intends to request approval of a global AMOC for the revised service information after this AD is published. Therefore, we have made no change to this AD in this regard.

Request To Clarify Certain Requirements

Boeing asked that paragraph (g) of the proposed AD, and the heading for paragraph (g), be changed to include ''corrective actions'' to clarify that corrective actions may be required.

We agree with the commenter's request. We have revised paragraph (g) of this AD accordingly.

Boeing also asked that the header for paragraph (h) of the proposed AD be changed to remove ''repetitive'' because merely specifying ''inspections'' addresses both initial and repetitive inspections.

We agree to clarify the terminology in the header for paragraph (h) of this AD. We do not presume that the term ''repetitive'' necessarily excludes the initial action. An action cannot be repeated without accomplishment of the initial action. Many existing ADs use the term ''repetitive'' actions, which we intend as including the initial action. Therefore, we have not changed this AD regarding this issue.

Conclusion

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

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

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

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017. The service information describes procedures for repetitive surface high frequency eddy current inspections, low frequency eddy current inspections, and detailed inspections on airplanes with or without an external repair, for cracking of the upper aft skin from WBL 159 to WBL 220. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 471 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	Up to 9 work-hours × $85 per hour = up to $765 per inspection cycle.	$0	Up to $765 per inspection cycle.	Up to $360,315 per inspection cycle.

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

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2017–24–05 The Boeing Company: Amendment 39–19109; Docket No. FAA–2017–0526; Product Identifier 2017–NM–026–AD.

(a) Effective Date

This AD is effective January 2, 2018.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to all The Boeing Company Model 737–100, –.200, –.200C, –.300, –.400, and –.500 series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/48e13cdfbbc32cf4862576a4005d308b/$FILE/ST01219SE.pdf*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of cracking in the upper aft skin at the rear spar of the wings. We are issuing this AD to detect and correct cracks in the upper aft skin of the wings, which could result in the inability of a principal structural element to sustain limit load, and consequent reduced structural integrity of the airplane.

(f) Compliance

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

(g) For Group 1 Airplanes: Inspection and Corrective Actions

For airplanes identified as Group 1 in Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017: Within 120 days after the effective date of this AD, do an inspection for cracking of the upper aft skin of the wings, and do all applicable corrective actions, using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(h) For Groups 2 and 3 Airplanes: Repetitive Inspections and Repair

For Groups 2 and 3 airplanes identified in Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017: At the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017, except as required by paragraph (i) of this AD, do the applicable inspection for cracking of the upper aft skin of the wings from wing buttock line (WBL) 159 to WBL 220, in accordance with the Work Instructions of Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017. If any cracking is found, repair before further flight, in accordance with the procedures specified in paragraph (j) of this AD. Repeat the inspection thereafter at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017.

(i) Exceptions to the Service Information

(1) Where Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017, specifies a compliance time ''after the original issue date of this service bulletin,'' paragraph (h) of this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Although Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017, specifies to contact Boeing for repair instructions, and specifies that action as ''RC'' (Required for Compliance), this AD requires repair in accordance with the procedures specified in paragraph (j) of this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (i)(2) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (j)(4)(i) and (j)(4)(ii) of this AD apply.

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

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

(k) Related Information

For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: *payman.soltani@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 737–57A1329, dated January 16, 2017.

(ii) Reserved.

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

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

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

Issued in Renton, Washington, on November 15, 2017.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017–25379 Filed 11–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0478; Product Identifier 2016–NM–174–AD; Amendment 39–19087; AD 2017–22–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This AD was prompted by a report of cracks on frame forks and outer skin on the forward and aft cargo compartment doors. This AD requires repetitive inspections of the frame forks, and corrective actions if necessary. This AD also includes optional modifications that constitute terminating action. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective January 2, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of January 2, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* Internet: *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0478.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0478; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on May 22, 2017 (82 FR 23160) (''the NPRM''). The NPRM was prompted by a report of cracks on frame forks and outer skin on the forward and aft cargo compartment doors. The NPRM proposed to require repetitive inspections of the frame forks, and corrective actions if necessary. The NPRM also included optional modifications that constitute terminating action. We are issuing this AD to detect and correct cracks on the frame forks and outer skin on the forward and aft cargo compartment doors, which could lead to reduced structural integrity and failure of the cargo compartment door, possible decompression of the airplane, and injury to occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016–0187, dated September 19, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

> During full scale fatigue test, cracks have been found on frame forks and outer skin on forward and aft cargo doors.
>
> To improve the fatigue behaviour of the frame forks, Airbus introduced modification (mod) 22948 in production, and issued inspection Service Bulletin (SB) A320–52–1032 and modification SB A320–52–1042, both recommended.
>
> Since those actions were taken, further improved cargo compartment doors have been introduced in production through Airbus mod 26213, on aeroplanes having [manufacturer serial number] MSN 0759 and up. This modification, which is not available for in-service retrofit, also includes provisions that exclude installation of pre-mod 26213 aft and forward compartment cargo doors on an aeroplane.
>
> In the frame of the Widespread Fatigue Damage (WFD) study, it has been determined that repetitive inspections are necessary for aft and forward cargo compartment doors on aeroplanes that do not (or no longer) embody mod 22948 (or SB A320–52–1042), and those that do not embody mod 26213. Failure to detect cracks would reduce the cargo door structural integrity.
>
> This condition, if not detected and corrected, could lead to cargo door failure, possibly resulting in decompression of the aeroplane and injury to occupants.
>
> To address this unsafe condition, Airbus issued SB A320–52–1171 to provide inspection instructions. This SB was later revised to correct the list of affected cargo doors. Airbus also issued SB A320–52–1170, introducing a door modification which constitutes terminating action for the repetitive special detailed inspection (SDI).
>
> For the reason described above, this [EASA] AD requires accomplishment of repetitive SDI by rototest of all frame forks in beam 4 area to detect cracks, and, depending on findings, accomplishment of applicable corrective action(s) [repair or replacement]. This AD also provides an optional [modification that constitutes] terminating action for the repetitive SDI required by this [EASA] AD.

One of the optional modifications includes related investigative and corrective actions. The related investigative action is a high frequency eddy current (HFEC) rotating probe inspection for cracks, and the corrective action is a repair. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0478.

Comments

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

Requests To Refer to Updated Service Information

Delta Air Lines and United Airlines requested that we revise the NPRM to refer to Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017. United Airlines mentioned that Airbus has made number of updates and clarifications in Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017. Additionally, United Airlines pointed out that EASA AD 2016–0187, dated September 19, 2016, quoted in the ''Discussion'' section of the NPRM, allows for use of later approved revisions.

We agree with the commenters for the reasons provided. We have revised this AD to refer to Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017. We have also redesignated paragraph (m) (of the proposed AD) as paragraph (m)(1) of this AD and added paragraph (m)(2) to provide credit for actions done before the effective date of this AD, if those actions were done using Airbus Service Bulletin A320–52–1171, Revision 01, dated September 5, 2016.

Request To Clarify That Certain Service Information Cancels the Requirements of Certain Other Service Information

United Airlines requested that we clarify that Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, cancels the requirements of Airbus Service Bulletin A320–52–1032. The commenter indicated that a statement regarding this subject would clarify the required actions for operators. The commenter also pointed out that a statement is listed in Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, that specifies the cancellation of the requirements of Airbus Service Bulletin A320–52–1032.

We agree to clarify. Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, does include a statement indicating that the actions specified in Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, cancel the actions specified in Airbus Service Bulletin A320–52–1032. However, the actions specified in Airbus Service Bulletin A320–52–1032 are not required by any AD, and therefore, we do not specifically address Airbus Service Bulletin A320–52–1032 in this AD (except for the compliance time reference in paragraph (h)(4) of this AD). We have not changed this AD in this regard.

Request To Update the NPRM To Include Modifications 22948 and 26213

Delta Air Lines requested that we revise paragraphs (c) and (g) of the proposed AD to refer to Modifications 22948 and 26213. Specifically, Delta Air Lines requested that we include information that elaborates on the specific airplanes affected by the NPRM. Delta Air Lines pointed out that EASA AD 2016–0187, dated September 19, 2016, quoted in the ''Discussion'' section of the NPRM, and Airbus Service Bulletin A320–52–1042, Revision 2, dated January 14, 1997, already refer to the modifications. Delta Air Lines also mentioned that it has 40 forward and aft cargo compartment doors affected by the NPRM, which are pre-Modifications 22948 and 26213 and under manufacturer serial number 0758.

We disagree to refer to Modifications 22948 and 26213 in paragraphs (c) and (g) of this AD; however, we agree that clarification is necessary. The applicability of this AD refers to the affected models having manufacturer serial numbers through 0758 inclusive; all airplanes having these serial numbers are affected by the identified unsafe condition. Airbus introduced modification 22948 in production, and issued Airbus Service Bulletin A320–52–1032 for recommended inspections and Airbus Service Bulletin A320–52–1042 for recommended modification 22948. Since that service information was issued, Airbus has introduced further improved forward and aft cargo compartment doors (modification 26213) in production on airplanes having manufacturer serial number 0759 and above; however, this modification is unavailable for in-service retrofit. Modification 26213 includes provisions that prohibit installation of earlier configurations of forward or aft cargo compartment doors (pre-modification 26213). Airplanes having manufacturer serial numbers 0759 and subsequent have modification 26213 installed in production. We have not changed this AD in this regard.

Request To Include Instructions for Rotable Parts

Delta Air Lines requested that we include instructions for rotable parts in paragraph (g) of the proposed AD. The commenter mentioned that forward or aft cargo compartment doors could be migrated from manufacturer serial number 0759 and above to airplanes that are affected, and asked if those airplanes are still affected. The commenter also requested that Airbus provide a list of manufacturer serial numbers that are affected by the proposed AD.

We partially agree with the commenter. Airplanes originally delivered with the affected doors are subject to the requirements of this AD. Paragraph (h) of this AD only requires actions on affected doors. It is not physically possible to install the affected doors on serial numbers 0759 and above; therefore, parts rotability does not need to be addressed in this AD.

In addition, paragraph (n) of this AD provides a parts installation limitation for the forward or aft cargo compartment doors for the airplanes identified in paragraph (c) of this AD. We have no practical method to provide a manufacturer serial number list of affected airplanes on which a non-affected door might have been installed or to predict an airplane configuration in the worldwide fleet. Therefore, we have not changed this AD in this regard.

Request To Clarify Optional Terminating Actions

United Airlines requested that we clarify the optional terminating actions specified in paragraph (j) of the proposed AD. The commenter requested we include a statement that specifies modification of all affected doors of an airplane in accordance with the requirements of paragraphs (j)(1), (j)(2), or (j)(3) of this AD constitutes terminating action. The commenter pointed out that EASA AD 2016–0187, dated September 19, 2016, quoted in the ''Discussion'' section of the NPRM, allows for modification of an airplane as specified in Airbus Service Bulletin A320–52–1042, Revision 2, dated January 14, 1997; or Airbus Service Bulletin A320–52–1170, dated September 5, 2016; and either is considered terminating action for the repetitive inspections.

We agree that clarification is necessary. We have revised paragraph (j) of this AD to include introductory text with the statement: ''Modification of all affected doors of an airplane in accordance with the requirements of paragraph (j)(1), (j)(2), or (j)(3) of this AD constitutes terminating action . . . .''

Request To Include Compliance Times for Optional Terminating Actions

Mr. Petit requested that we add compliance times for the optional terminating actions specified in the proposed AD. Mr. Petit indicated that 14 CFR 26.21 might require a mandatory terminating action before 56,300 flight cycles. Mr. Petit also recommended that the optional terminating action not be embodied before 21,700 flight cycles.

We disagree with the commenter's request to include compliance times for the optional terminating action specified in this AD. 14 CFR 26.21 mandates the limit of validity (LOV) and does not specify compliance times for the optional terminating action specified in this AD. This AD mandates repetitive inspections of the frame forks as specified in the service information provided by the design approval holder (DAH) to meet the LOV. In addition, we do not include compliance times for optional actions in ADs because doing so would make the actions mandatory. We intend for the terminating actions in this AD to be optional, which aligns with the MCAI.

Regarding the commenter's recommendation to prohibit accomplishing the optional terminating action before 21,700 flight cycles, the commenter provided no substantiation for this prohibition. We have received no data indicating that the optional terminating action should not be accomplished before 21,700 flight cycles. Therefore, we have not changed this AD in this regard.

Clarification of Exception

Paragraph (i)(2) of the proposed AD, which refers to Airbus Service Bulletin A320–52–1170, dated September 5, 2016, includes an exception as specified in paragraph (k) of the proposed AD. However, paragraph (k) of the proposed AD does not mention Airbus Service Bulletin A320–52–1170, dated September 5, 2016. We have added Airbus Service Bulletin A320–52–1170, dated September 5, 2016, to the exception specified in paragraph (k) of this AD.

Conclusion

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

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

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

Related Service Information Under 1 CFR Part 51

Airbus has issued the following service information.

• Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, describes procedures for repetitive special detailed inspections of all frame forks in the beam 4 area of any affected door, and corrective actions.

• Airbus Service Bulletin A320–52–1042, Revision 2, dated January 14, 1997, describes procedures for modification of all affected forward and aft cargo compartment doors of an airplane.

• Airbus Service Bulletin A320–52–1170, dated September 5, 2016, describes modification of all affected forward and aft cargo compartment doors of an airplane, including related investigative and corrective actions.

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

Costs of Compliance

We estimate that this AD affects 88 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Special detailed inspection	25 work-hours × $85 per hour = $2,125	$0	$2,125	$187,000

OPTIONAL ACTIONS

Action	Labor cost	Parts cost	Cost per product
Modification	24 work-hours × $85 per hour = $2,040	Up to $240	Up to $2,280.

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

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2017–22–07 Airbus: Amendment 39–19087; Docket No. FAA–2017–0478; Product Identifier 2016–NM–174–AD.

(a) Effective Date

This AD is effective January 2, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes, certificated in any category, manufacturer serial numbers through 0758 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Reason

This AD was prompted by a report of cracks on the frame forks and outer skin on the forward and aft cargo compartment doors. We are issuing this AD to detect and correct cracks on the frame forks and outer skin on the forward and aft cargo compartment doors, which could lead to reduced structural integrity and failure of the cargo compartment door, possible decompression of the airplane, and injury to occupants.

(f) Compliance

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

(g) Definition of Affected Door

For the purpose of this AD, an ''affected door'' is a forward or aft cargo compartment

door, having any part number listed in table 1 to paragraph (g) of this AD, except a cargo compartment door on which Airbus Service Bulletin A320–52–1042 or Airbus Service Bulletin A320–52–1170 is embodied.

Table 1 to Paragraph (g) of this AD – *Affected Part Numbers*

Forward cargo compartment door part Nos.	Aft cargo compartment door part Nos.
D52371000000	D52371900000
D52371000002	D52371900002
D52371000004	D52371900004
D52371000006	D52371900008
D52371000008	D52371900010
D52371000010	D52371900012
D52371000012	D52371900014
D52371000014	D52371900016
D52371000016	D52371900018
D52371000018	D52371900022
D52371000022	

(h) Repetitive Special Detailed Inspection of Frame Forks

At the latest of the compliance times listed in paragraphs (h)(1) through (h)(4) of this AD: Do a special detailed inspection of all frame forks in the beam 4 area of any affected door as defined in paragraph (g) of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, except as specified in paragraphs (k) and (l) of this AD. Repeat the inspection thereafter at intervals not to exceed 3,000 flight cycles. A review of the airplane delivery or maintenance records is acceptable to identify any affected door installed on the airplane, provided that the cargo compartment door part number can be conclusively determined from that review.

(1) Before exceeding 37,500 flight cycles since first installation of the door on an airplane.

(2) Within 900 flight cycles after the effective date of this AD, without exceeding 41,950 flight cycles since first installation of the door on an airplane.

(3) Within 50 flight cycles after the effective date of this AD, for a door having reached or exceeded 41,900 flight cycles since first installation on an airplane.

(4) Within 3,000 flight cycles since the last inspection of the door as specified in Airbus Service Bulletin A320–52–1032.

(i) Corrective Actions

If any crack is found during any inspection required by paragraph (h) of this AD, before further flight, do all applicable corrective actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, except as specified in paragraphs (k) and (l) of this AD. Accomplishment of applicable corrective actions does not constitute terminating action for the repetitive inspections.

(j) Optional Terminating Action

Modification of all affected doors of an airplane in accordance with the requirements of paragraph (j)(1), (j)(2), or (j)(3) of this AD, constitutes terminating action for the repetitive inspections specified in paragraph (h) of this AD for that airplane.

(1) Modification of all affected doors of an airplane in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1042, Revision 2, dated January 14, 1997, constitutes terminating action for the repetitive inspections specified in paragraph (h) of this AD for that airplane, provided that, after modification, no affected door is re-installed on that airplane.

(2) Modification of all affected doors of an airplane including accomplishment of all applicable related investigative and corrective actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–52–1170, dated September 5, 2016, except as specified in paragraph (k) of this AD, constitutes terminating action for the repetitive inspections specified in paragraph (h) of this AD for that airplane, provided that, after modification, no affected door is re-installed on that airplane.

(3) Modification of all affected doors on an airplane, in case of finding damaged frame forks, as specified in an Airbus Repair Design Approval Sheet (RDAS), and done in accordance with a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA); constitutes terminating action for the repetitive inspection specified in paragraph (h) of this AD for that airplane, provided that, after modification, no affected door is re-installed on that airplane.

(k) Exception to Service Information

Where Airbus Service Bulletin A320–52–1170, dated September 5, 2016; or Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017; specifies to contact Airbus for appropriate action, and specifies that action as ''RC'' (Required for Compliance): Before further flight, accomplish corrective actions in accordance with the procedures specified in paragraph (o)(2) of this AD.

(l) No Reporting Requirement

Although Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017, specifies to submit certain information to the manufacturer, and specifies that action as ''RC,'' this AD does not include that requirement.

(m) Credit for Previous Actions

(1) This paragraph provides credit for the actions required by paragraphs (h) and (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–52–1171, dated October 29, 2015, provided that it can be conclusively determined that any part number D52371000018 was also inspected as specified in paragraph (h) of this AD.

(2) This paragraph provides credit for the actions required by paragraphs (h) and (i) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–52–1171, Revision 01, dated September 5, 2016.

(n) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, an affected door specified in paragraph (g) of this AD, unless it has been inspected in accordance with the requirements of paragraph (h) of this AD and all applicable corrective actions have been done in accordance with paragraph (i) of this AD.

(o) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (p)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

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

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

(p) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016–0187, dated September 19, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0478.

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

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

(q) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320–52–1042, Revision 2, dated January 14, 1997 (pages 5, 9, and 19 through 22 of this document are identified as Revision 1, dated November 22, 1993).

(ii) Airbus Service Bulletin A320–52–1170, dated September 5, 2016, including Appendices 01 and 02, dated September 5, 2016.

(iii) Airbus Service Bulletin A320–52–1171, Revision 02, dated April 10, 2017.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 44 51; email: *account.airworth-eas@airbus.com;* Internet: *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

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

Issued in Renton, Washington, on October 17, 2017.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017–23349 Filed 11–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0933; Product Identifier 2017–SW–051–AD; Amendment 39–19106; AD 2017–24–02]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH Helicopters

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Airbus Helicopters Deutschland GmbH (Airbus Helicopters) Model MBB–BK 117 D–2 helicopters. This AD requires amending the rotorcraft flight manual to establish a minimum airspeed limitation for the autopilot cruise height mode. This AD is prompted by two reports of uncommanded helicopter climbs and descents. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD becomes effective December 13, 2017.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of December 13, 2017.

We must receive comments on this AD by January 29, 2018.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0933; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket

contains this AD, the European Aviation Safety Agency AD, any incorporated by reference service information, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.helicopters.airbus.com/Web site/en/ref/Technical-Support_73.html.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0933.

FOR FURTHER INFORMATION CONTACT: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *george.schwab@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2017–0146, dated August 10, 2017, to correct an unsafe condition for Airbus Helicopters Model MBB–BK 117 D–2 helicopters. EASA advises that two incidents of uncommanded helicopter climbs and descents have been reported following activation of the autopilot cruise height (CRHT) mode concurrently with the ground trajectory command in hover mode (GTCH). EASA advises this condition, if not detected and corrected, could lead to temporary loss of control of the helicopter or injury to the helicopter's occupants. To address this unsafe condition, EASA requires a minimum airspeed limitation of 40 knots for the autopilot CRHT mode. Since the rotorcraft cannot enter GTCH mode at speeds above 40 knots, under this limitation, CRHT mode will not be engaged concurrently with GTCH mode. EASA considers its AD interim action, pending an autopilot software upgrade to prevent further occurrences.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

We reviewed Airbus Helicopters BK117 D–2 Flight Manual Temporary Revision No. 1, dated March 28, 2017, for Model BK117 D–2 helicopters, and Airbus Helicopters BK117 D–2 (Helionix Step 2) Flight Manual Temporary Revision No. 1, dated March 28, 2017, for Model BK117 D–2 helicopters with Helionix Step 2. These temporary revisions establish a minimum airspeed limitation of 40 knots for the autopilot CRHT mode.

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

AD Requirements

This AD requires, within 10 hours time-in-service, revising the Operating Limitations section of the rotorcraft flight manual by adding a minimum airspeed limitation for the autopilot of 40 knots when CRHT mode is engaged.

Interim Action

We consider this AD to be an interim action. The design approval holder is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD affects 16 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect that making the required changes to the rotorcraft flight manual will require 0.5 work-hour and no parts are needed for a cost of $43 per helicopter and $688 for the U.S. fleet.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the required corrective actions must be accomplished within 10 hours time-in-service.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for prior public comment before issuing this AD are impracticable and contrary to the public interest and that good cause exists to make this AD effective in less than 30 days.

Authority for This Rulemaking

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

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

products identified in this rulemaking action.

Regulatory Findings

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

For the reasons discussed, I certify that this AD:

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

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

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2017–24–02 Airbus Helicopters Deutschland GmbH: Amendment 39–19106; Docket No. FAA–2017–0933; Product Identifier 2017–SW–051–AD.

(a) Applicability

This AD applies to Airbus Helicopters Deutschland GmbH (Airbus Helicopters) Model MBB–BK 117 D–2 helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a helicopter making an uncommanded climb or descent. This condition could result in loss of helicopter control.

(c) Effective Date

This AD becomes effective December 13, 2017.

(d) Compliance

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

(e) Required Actions

Within 10 hours time-in-service, revise the Operating limitations section of the Rotorcraft Flight Manual by adding the information in Figure 1 to paragraph (e) of this AD under Autopilot Limitations. Inserting Airbus Helicopters BK117 D–2 Flight Manual Temporary Revision No. 1, dated March 28, 2017, or Airbus Helicopters BK117 D–2 (Helionix Step 2) Flight Manual Temporary Revision No. 1, dated March 28, 2017, into the RFM is acceptable for compliance with this AD.

FIGURE 1 TO PARAGRAPH (e)

Operating limitations of the autopilot	
Minimum airspeed with CRHT mode engaged	40 kt

(f) Alternative Methods of Compliance (AMOCs)

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

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

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD 2017–0146, dated August 10, 2017. You may view the EASA AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2017–0933.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 2210, Autopilot System.

(i) Material Incorporated by Reference

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

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

(i) Airbus Helicopters BK117 D–2 Flight Manual Temporary Revision No. 1, dated March 28, 2017.

(ii) Airbus Helicopters BK117 D–2 (Helionix Step 2) Flight Manual Temporary Revision No. 1, dated March 28, 2017.

(3) For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.helicopters.airbus.com/Website/en/ref/Technical-Support_73.html*.

(4) You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

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

Issued in Fort Worth, Texas, on November 9, 2017.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2017–25189 Filed 11–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0491; Product Identifier 2016–SW–020–AD; Amendment 39–19031; AD 2017–19–01]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–76A, S–76B, S–76C, and S–76D helicopters. This AD requires inspecting the main rotor (M/R) servo pushrod (pushrod) assembly and applying slippage marks. This AD was prompted by an accident of a Sikorsky Model S–76C helicopter caused by a failed pushrod assembly. The actions of this AD are intended to prevent an unsafe condition on these products.

DATES: This AD is effective January 2, 2018.

ADDRESSES: For service information identified in this final rule, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-

Winged-S or 203–416–4299; email: *wcs_cust_service_eng.gr-sik@lmco.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0491; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations Office, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Blaine Williams, Aerospace Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7161; email *blaine.williams@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On June 5, 2017, at 82 FR 25748, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 by adding an AD that would apply to Model S–76A, S–76B, S–76C, and S–76D helicopters, serial numbers up to and including 761075, with an M/R pushrod assembly part number (P/N) 76400–00034–059, 76400–00014–074, 76400–00014–076, or 76400–00014–077 installed. The NPRM proposed to require inspecting each pushrod assembly and applying two slippage marks across each control rod and jamnut. Depending on the outcome of the inspection, the NPRM proposed to require replacing the pushrod assembly or inspecting the jamnut. Depending on the outcome of inspecting the jamnut, the NPRM proposed to require replacing the pushrod assembly or applying 140 inch-pounds of torque to the jamnut. The proposed requirements were intended to detect a loose jamnut and prevent failure of the pushrod assembly, loss of M/R flight control, and subsequent loss of control of the helicopter.

Since the NPRM was issued, the FAA's Aircraft Certification Service has changed its organizational structure. The new structure replaces product directorates with functional divisions. We have revised some of the office titles and nomenclature throughout this Final rule to reflect the new organizational changes. Additional information about the new structure can be found in the Notice published on July 25, 2017 (82 FR 34564).

Comments

We gave the public the opportunity to participate in developing this AD, but we did not receive any comments on the NPRM.

FAA's Determination

We have reviewed the relevant information and determined that an unsafe condition exists and is likely to exist or develop on other products of these same type designs and that air safety and the public interest require adopting the AD requirements as proposed.

Related Service Information

We reviewed Sikorksy S–76 Helicopter Alert Service Bulletin 76–67–58, Basic Issue, dated November 19, 2015 (ASB), which specifies a one-time inspection of the M/R forward, aft, and lateral pushrod assemblies and jamnuts for proper installation, condition, and security. If a pushrod or jamnut does not meet criteria specified in the inspections, the ASB specifies replacing the assembly. The ASB also specifies applying torque to each jamnut and applying two slippage marks across each control rod and jamnut.

Differences Between This AD and the Service Information

The Sikorsky ASB specifies returning any removed M/R pushrod assembly to Sikorsky. This AD does not require returning any parts to Sikorsky.

Costs of Compliance

We estimate that this AD affects 198 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at $85 per work-hour. Inspecting the M/R pushrod assemblies takes about 2.2 work-hours for an estimated cost of $187 per helicopter and $37,026 for the U.S. fleet. Replacing an M/R pushrod assembly takes about 2 work-hours for a labor cost of $170. Parts to replace M/R pushrod assembly P/N 76400–00034–059 cost about $2,411 for a total estimated replacement cost of $2,581. Parts to replace M/R pushrod assembly P/N 76400–00014–074 cost about $2,224 for a total estimated replacement cost of $2,394. Parts to replace M/R pushrod assembly P/N 76400–00014–076 cost about $2,488 for a total estimated replacement cost of $2,658. Parts to replace M/R pushrod assembly P/N 76400–00014–077 cost about $2,414 for a total estimated replacement cost of $2,584. It takes a minimal amount of time to apply the slippage marks for a negligible cost.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2017–19–01 Sikorsky Aircraft Corporation: Amendment 39–19031; Docket No. FAA–2017–0491; Product Identifier 2016–SW–020–AD.

(a) Applicability

This AD applies to Model S–76A, S–76B, S–76C, and S–76D helicopters, serial numbers up to and including 761075, with a main rotor (M/R) servo pushrod (pushrod) assembly part number (P/N) 76400–00034–059, 76400–00014–074, 76400–00014–076, or 76400–00014–077 installed, certificated in any category.

Note 1 to paragraph (a) of this AD: M/R pushrod P/N 76400–00034–059 is included in the Applicability section of AD 2015–19–51, Amendment 39–18300 (80 FR 65128, October 26, 2015). This AD does not affect AD 2015–19–51.

(b) Unsafe Condition

This AD defines the unsafe condition as a loose jamnut. This condition could result in failure of a pushrod assembly, loss of M/R flight control, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective January 2, 2018.

(d) Compliance

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

(e) Required Actions

Within 300 hours time-in-service:

(1) Inspect the control rod of each pushrod assembly (control rod) to determine whether 0.020 inch diameter lockwire can pass through the inspection hole.

(i) If the lockwire passes through the inspection hole, before further flight, replace the pushrod assembly.

(ii) If the lockwire does not pass through the inspection hole, inspect the jamnut to determine whether it is seated against the control rod and whether it can be turned with finger pressure.

(A) If the jamnut is not seated against the control rod or can be turned with finger pressure, before further flight, replace the pushrod assembly.

(B) If the jamnut is seated against the control rod and cannot be turned with finger pressure, using a pushrod tool, apply 140 inch-pounds of torque to the jamnut.

(2) Apply two slippage marks across each control rod and jamnut as follows:

(i) Clean the area where a slippage mark is to be applied.

(ii) Apply two slippage marks across the control rod and jamnut, parallel and on opposite sides of each other. Each slippage mark must extend at least 0.5 inch onto the control rod and must not cover the inspection hole. Figure 1 (Sheet 2) of Sikorsky S–76 Helicopter Alert Service Bulletin 76–67–58, Basic Issue, dated November 19, 2015, illustrates a slippage mark across a control rod and jamnut.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Blaine Williams, Aerospace Engineer, Boston ACO Branch, Compliance and Airworthiness Division, 1200 District Avenue, Burlington, Massachusetts 01803; telephone (781) 238–7161; email *blaine.williams@faa.gov.*

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

(g) Additional Information

Sikorksy S–76 Helicopter Alert Service Bulletin 76–67–58, Basic Issue, dated November 19, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Sikorsky Aircraft Corporation, Customer Service Engineering, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800-Winged-S or 203–416–4299; email: *wcs_cust_service_eng.gr-sik@lmco.com.* You may review a copy of this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

Issued in Fort Worth, Texas, on November 17, 2017.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2017–25558 Filed 11–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0690; Product Identifier 2017–NM–061–AD; Amendment 39–19107; AD 2017–24–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are removing Airworthiness Directive (AD) 2017–01–06, which applied to certain Airbus Model A319–115, A319–132, A320–214, A320–232, A321–211, A321–213, and A321–231 airplanes. AD 2017–01–06 required inspection and replacement of certain tie rod assemblies installed on the hinged fairing assembly of the main landing gear (MLG). We issued AD 2017–01–06 to detect and correct the absence of cadmium plating on the rod end threads of the tie rod assemblies. Since we issued AD 2017–01–06, we have determined that although cadmium plating might be absent, the rod end threads of the tie rod assemblies can withstand the expected environmental conditions, therefore the unsafe condition, as initially determined, does not exist.

DATES: This AD is effective January 2, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0690.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0690; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday,

except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to remove AD 2017–01–06, Amendment 39–18773 (82 FR 4773, January 17, 2017) (''AD 2017–01–06''). AD 2017–01–06 applied to certain Airbus Model A319–115, A319–132, A320–214, A320–232, A321–211, A321–213, and A321–231 airplanes. The NPRM published in the **Federal Register** on July 17, 2017 (82 FR 32650). The NPRM was prompted by our determination that, although cadmium plating might be absent, the rod end threads of the tie rod assemblies installed on the hinged fairing assembly of the MLG can withstand the expected environmental conditions, therefore the unsafe condition, as initially determined, does not exist. The NPRM proposed to remove AD 2017–01–06. We are issuing this AD to remove AD 2017–01–06.

The European Aviation Safety Agency (EASA) which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0234–CN, dated April 28, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to cancel EASA AD 2015–0234–CN, which applied to certain Airbus Model A319–115, A319–132, A320–214, A320–232, A321–211, A321–213, and A321–231 airplanes. The MCAI states:

> A production quality issue was identified concerning tie rod assemblies, having [a] Part Number starting with D52840212000 or D52840212002, which are installed on the main landing gear (MLG) hinged fairing assembly. This quality issue affects the cadmium plating surface treatment which was inadvertently omitted from the rod end threads of the assembly. The absence of cadmium plating reduces the corrosion protection scheme.
>
> This condition, if not detected and corrected, was initially assessed as leading to galvanic corrosion of the tie rod end threads, possibly resulting in rod end failure, loss of a MLG door, and consequent injury to persons on ground.
>
> To address this unsafe condition, Airbus identified the affected MSN [manufacturer serial number] and issued SB A320–52–1167 to provide inspection instructions.
>
> Consequently, EASA issued AD 2015–0234 [which corresponds to FAA AD 2017–01–06], requiring a one-time inspection of the affected MLG hinged fairing tie rod assemblies, and, depending on findings, replacement of the affected tie rod assembly.
>
> Since that [EASA] AD was issued, tests performed by the tie rod assembly manufacturers determined that the assemblies, even without cadmium plating surface treatment on the rod end threads, can withstand the expected environmental conditions. The consequence is that the unsafe condition, as initially determined, does not exist.
>
> For the reasons described above, this Notice cancels EASA AD 2015–0234.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0690.

Comments

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

Conclusion

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

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

Related Costs of Compliance

AD 2017–01–06 affected about 20 airplanes of U.S. registry. The estimated cost of the actions required by AD 2017–01–06 for U.S. operators was $3,400, or $170, per product. Removing AD 2017–01–06 eliminates those costs.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority.

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2017–01–06, Amendment 39–18773 (82 FR 4773, January 17, 2017), and adding the following new AD:

2017–24–03 Airbus: Amendment 39–19107; Docket No. FAA–2017–0690; Product Identifier 2017–NM–061–AD.

(a) Effective Date

This rescission is effective January 2, 2018.

(b) Affected AD

This action removes AD 2017–01–06, Amendment 39–18773 (82 FR 4773, January 17, 2017).

(c) Applicability

This action applies to Airbus Model A319–115, A319–132, A320–214, A320–232, A321–211, A321–213, and A321–231 airplanes, certificated in any category, as identified in Airbus Service Bulletin A320–52–1167, dated August 6, 2015.

(d) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) AD 2015–0234–CN, dated April 28, 2017, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0690.

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

(e) Material Incorporated by Reference

None.

Issued in Renton, Washington, on November 15, 2017.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017–25253 Filed 11–27–17; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 23

RIN 3038–AC97

Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants; Correction

AGENCY: Commodity Futures Trading Commission.

ACTION: Correcting amendments.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) is correcting a final rule published in the **Federal Register** on January 6, 2016. The rule, concerning margin requirements for uncleared swaps for swap dealers and major swap participants, took effect on April 1, 2016. This correction rectifies errors in cross-references in a particular section of the final rule.

DATES: Effective on November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Thomas Smith, Deputy Director, 202–418–5495, *tsmith@cftc.gov,* or Mark Bretscher, Attorney-Advisor, 312–596–0529, *mbretscher@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 6, 2016 (81 FR 636), the CFTC published final rules adopting new regulations to implement a particular provision of the Commodity Exchange Act (CEA), as added by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[1] This provision requires the Commission to adopt initial and variation margin requirements for certain swap dealers and major swap participants. In implementing the regulations, staff has discovered cross-reference errors in § 23.156 of the regulations. As published, 17 CFR 23.156(a)(3) includes erroneous cross-references to 17 CFR 23.156(a)(1)(iv). Instead, the cross-references should be to 17 CFR 23.156(a)(1)(v). Accordingly, the Commission is making a correcting amendment to 17 CFR 23.156(a)(3) that removes the erroneous cross-references to 17 CFR 23.156(a)(1)(iv) and replaces them with corrected cross-references to 17 CFR 23.156(a)(1)(v).

List of Subjects in 17 CFR Part 23

Swaps, Swap dealers, Major swap participants, Capital and margin requirements.

Accordingly, 17 CFR part 23 is corrected by making the following correcting amendments:

PART 23—SWAP DEALERS AND MAJOR SWAP PARTICIPANTS

■ 1. The authority citation for part 23 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6b, 6b–1, 6c, 6p, 6r, 6s, 6t, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21.

■ 2. In § 23.156, revise paragraph (a)(3)(i)(B) to read as follows:

§ 23.156 Forms of margin.

(a) * * *

(3) * * *

(i) * * *

(B) The discounts set forth in the following table:

STANDARDIZED HAIRCUT SCHEDULE

Cash in same currency as swap obligation	0.0
Eligible government and related debt (*e.g.,* central bank, multilateral development bank, GSE securities identified in paragraph (a)(1)(v) of this section): Residual maturity less than one-year	0.5
Eligible government and related debt (*e.g.,* central bank, multilateral development bank, GSE securities identified in paragraph (a)(1)(v) of this section): Residual maturity between one and five years	2.0
Eligible government and related debt (*e.g.,* central bank, multilateral development bank, GSE securities identified in paragraph (a)(1)(v) of this section): Residual maturity greater than five years	4.0
Eligible corporate debt (including eligible GSE debt securities not identified in paragraph (a)(1)(v) of this section): Residual maturity less than one-year	1.0
Eligible corporate debt (including eligible GSE debt securities not identified in paragraph (a)(1)(v) of this section): Residual maturity between one and five years	4.0
Eligible corporate debt (including eligible GSE debt securities not identified in paragraph (a)(1)(v) of this section): Residual maturity greater than five years	8.0
Equities included in S&P 500 or related index	15.0
Equities included in S&P 1500 Composite or related index but not S&P 500 or related index	25.0
Gold	15.0
Additional (additive) haircut on asset in which the currency of the swap obligation differs from that of the collateral asset	8.0

[1] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

* * * * *

Issued in Washington, DC, on November 21, 2017, by the Commission.

Christopher J. Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants; Correction—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Quintenz and Behnam voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2017–25627 Filed 11–27–17; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–1053]

RIN 1625–AA00

Safety Zone; Delaware River, Pipeline Removal, Marcus Hook, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 250-yard radius of Commerce Construction vessels and machinery conducting diving and pipeline removal operations in the Delaware River, in the vicinity of Anchorage 7, near Marcus Hook, PA. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by diving and pipeline removal operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Delaware Bay.

DATES: This rule is effective without actual notice from November 28, 2017 through December 8, 2017. For the purposes of enforcement, actual notice will be used from November 21, 2017 through November 28, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–1053 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Petty Officer Amanda Boone, Waterways Management Branch, U.S. Coast Guard Sector Delaware Bay; telephone (215) 271–4889, email *Amanda.N.Boone@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because notification of this pipeline removal project was not given to the Coast Guard until November 15, 2017. It is impracticable to publish an NPRM because we must establish this safety zone by November 21, 2017.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to address the potential safety hazards associated with diving and pipeline removal operations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Delaware Bay has determined that potential hazards associated with diving and pipe removal operations starting November 21, 2017, will be a safety concern for anyone within a 250-yard radius of diving and pipe removal vessels and machinery. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the operations are being conducted.

IV. Discussion of the Rule

This rule establishes a safety zone from 5:00 a.m. to 7:00 p.m., Monday through Sunday, from November 21, 2017 through December 8, 2017. The safety zone will cover all navigable waters within 250 yards of vessels and machinery being used by personnel to conduct diving and pipe removal operations. There are three sections of pipeline that will be removed. The first two sections of pipeline to be removed are in Anchorage No. 7, Marcus Hook Anchorage, in the Delaware River. During removal of these sections of pipeline, the safety zone will restrict vessels from anchoring in the lower portion of Anchorage No. 7. During removal of the third section of pipeline, operations will be conducted within the main navigational channel and vessels will be required to transit through the lower portion of Anchorage No. 7.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Vessels wishing to transit the safety zone in the main navigational channel may do so if they can make satisfactory passing arrangements with the towing vessel JOKER in accordance with the Navigational Rules in 33 CFR subchapter E via VHF–FM channel 13 or 80 at least 1 hour, as well as 30 minutes, prior to arrival to arrange safe passage. If vessels are unable to make satisfactory passing arrangements with the towing vessel JOKER, they may request permission from the COTP, or his designated representative, on VHF–FM channel 16. All vessels must operate at the minimum safe speed necessary to maintain steerage and reduce wake. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16, Local Notice to Mariners, and Marine Safety Information Bulletin further defining specific work locations and traffic patterns.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies

to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Delaware River from 5:00 a.m. to 7:00 p.m., Monday through Sunday from November 21, 2017 through December 8, 2017 Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16, Local Notice to Mariners, and Marine Safety Information Bulletin about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry within 250 yards of vessels and machinery being used by personnel to conduct diving and pipe removal operations. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–1053 to read as follows:

§ 165.T05–1053 Safety Zone, Delaware River; Pipeline Removal; Marcus Hook, PA

(a) *Location.* The following areas are safety zones: all navigable waters within 250 yards of the towing vessel JOKER, Commerce Construction crane barge KELLY, and associated diving and pipe removal vessels, as well as any associated equipment, operating in Marcus Hook Range and Anchorage No. 7 near Marcus Hook, PA, on the Delaware River.

(b) *Definitions.* (1) Captain of the Port means the Commander, Sector Delaware Bay or any Coast Guard commissioned,

warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) Designated representative means any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Delaware Bay, to assist with the enforcement of safety zones described in paragraph (a) of this section.

(c) *Regulations.* The general safety zone regulations found in 33 CFR part 165 subpart C apply to the safety zone created by this section.

(1) Entry into or transiting within either safety zone is prohibited unless vessels obtain permission from the Captain of the Port via VHF–FM channel 16, or make satisfactory passing arrangements via VHF–FM channels 13 or 80, with the towing vessel JOKER per this section and the rules of the Road (33 CFR subchapter E). Vessels requesting to transit shall contact the towing vessel JOKER on channel 13 or 80 at least 1 hour, as well as 30 minutes, prior to arrival.

(2) Vessels granted permission to enter and transit the safety zone must do so in accordance with any directions or orders of the Captain of the Port, his designated representative, or the towing vessel JOKER. No person or vessel may enter or remain in a safety zone without permission from the Captain of the Port or the towing vessel JOKER.

(3) There are three sections of pipeline that will be removed. The first two sections of pipeline to be removed are in Anchorage No. 7, Marcus Hook Anchorage, in the Delaware River. During removal of these sections of pipeline, the safety zone will restrict vessels from anchoring in the lower portion of Anchorage No. 7.

(4) During removal of the third section of pipeline, operations will be conducted within the main navigational channel and vessels will be required to transit through the lower portion of Anchorage No. 7. The Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16, Local Notice to Mariners, and Marine Safety Information Bulletin further defining specific work locations and traffic patterns.

(5) All vessels must operate at the minimum safe speed necessary to maintain steerage and reduce wake.

(6) This section applies to all vessels that intend to transit through the safety zone except vessels that are engaged in the following operations: enforcement of laws, service of aids to navigation, and emergency response.

(d) *Enforcement periods.* This section will be enforced from November 21, 2017, through December 8, 2017.

Dated: November 20, 2017.

Scott E. Anderson,

Captain, U.S. Coast Guard, Captain of the Port, Delaware Bay.

[FR Doc. 2017–25613 Filed 11–27–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2017–0515; FRL–9971–22–Region 7]

Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standard; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comments, the Environmental Protection Agency (EPA) is withdrawing the direct final rule for ''Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standard'' published in the **Federal Register** on October 6, 2017. The direct final rule was an approval of a State Implementation Plan (SIP) revision from the State of Missouri for the 2010 Sulfur Dioxide (SO_2) National Ambient Air Quality Standard (NAAQS). Section 110 of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by EPA. These SIPs are commonly referred to as ''infrastructure'' SIPs. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

DATES: The direct final rule published at 82 FR 46672, October 6, 2017, is withdrawn effective November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Tracey Casburn, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7016, or by email at *casburn.tracey@epa.gov.*

SUPPLEMENTARY INFORMATION: Due to adverse comments, EPA is withdrawing the direct final rule to approve the states ''infrastructure'' SIP revision for the 2010 SO_2 NAAQS. In the direct final rule published on October 6, 2017 (82 FR 46672), EPA stated that if it received adverse comment by November 6, 2017, the rule would be withdrawn and not take effect. EPA received adverse comments. EPA will address the comments in a subsequent final action based upon the proposed action also published on October 6, 2017 at 82 FR 46742. EPA will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: November 16, 2017.

James B. Gulliford,

Regional Administrator, Region 7.

■ Accordingly, the amendment to 40 CFR 52.1320(e) published on October 6, 2017 (82 FR 46672) is withdrawn effective November 28, 2017.

[FR Doc. 2017–25568 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0356; FRL–9971–21–Region 7]

Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2008 Ozone National Ambient Air Quality Standard; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comments, the Environmental Protection Agency (EPA) is withdrawing the direct final rule for ''Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2008 Ozone National Ambient Air Quality Standard'' published in the **Federal Register** on October 6, 2017. The direct final rule was an approval of a State Implementation Plan (SIP) revision from the State of Missouri for the 2008 Ozone National Ambient Air Quality Standard (NAAQS). Section 110 of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each new or revised NAAQS promulgated by EPA. These SIPs are commonly referred to as ''infrastructure'' SIPs. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management

program are adequate to meet the state's responsibilities under the CAA.

DATES: The direct final rule published at 82 FR 46679, October 6, 2017, is withdrawn effective November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Tracey Casburn, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7016, or by email at *casburn.tracey@epa.gov.*

SUPPLEMENTARY INFORMATION: Due to adverse comments, EPA is withdrawing the direct final rule to approve the states ''infrastructure'' SIP revision for the 2008 Ozone NAAQS. In the direct final rule published on October 6, 2017, (82 FR 46679), EPA stated that if it received adverse comment by November 6, 2017, the rule would be withdrawn and not take effect. EPA received adverse comments. EPA will address the comments in a subsequent final action based upon the proposed action also published on October 6, 2017 at 82 FR 46741. EPA will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 52

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

Dated: November 16, 2017.

James B. Gulliford,

Regional Administrator, Region 7.

■ Accordingly, the amendment to 40 CFR 52.1320(e) published on October 6, 2017 (82 FR 46679) is withdrawn effective November 28, 2017.

[FR Doc. 2017–25569 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2017–0485; FRL–9971–15–Region 7]

Approval of Nebraska's Air Quality Implementation Plan, Operating Permits Program, and 112(l) Program; Revision to Nebraska Administrative Code; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to adverse comments, the Environmental Protection Agency (EPA) is withdrawing the direct final rule for ''Approval of Nebraska's Air Quality Implementation Plan, Operating Permits Program, and 112(l) Program; Revision to Nebraska Administrative Code,'' published in the **Federal Register** on October 5, 2017. Nebraska's SIP revision revised two chapters, ''Definitions'' and ''Operating Permit Modifications; Reopening for Cause''. Specifically, these revisions incorporated by reference the list of organic compounds exempt from the definition of volatile organic compound (VOC) found in the Code of Federal Regulations. Notification requirements for the operating permit program were amended to be consistent with the Federal operating permit program requirements, and the definition of ''solid waste'' was revised by the state. However, because the state's definition is inconsistent with the Federal definition, EPA was not approving the definition into the SIP. Finally, the state extended the process of ''off-permit changes'' to Class 1 operating permits. Additional grammatical and editorial changes were made in this revision.

DATES: The direct final rule published at 82 FR 46420, October 5, 2017, is withdrawn effective November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Greg Crable, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7391, or by email at *crable.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: Due to adverse comments, EPA is withdrawing the direct final rule to approve revisions to the Nebraska State Implementation Plan (SIP), Operating Permits Program, and 112(l) program; Revision to Nebraska Administrative Code. In the direct final rule published on October 5, 2017, (82 FR 46420), we stated that if we received adverse comment by November 6, 2017, the rule would be withdrawn and not take effect. EPA received adverse comments. EPA will address the comments in a subsequent final action based upon the proposed action also published on October 5, 2017 (82 FR 46453). EPA will not institute a second comment period on this action.

List of Subjects

40 CFR Part 52

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

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: November 16, 2017.

James B. Gulliford,

Regional Administrator, Region 7.

■ Accordingly, the direct final rule published on October 5, 2017 (82 FR 46420), is withdrawn effective November 28, 2017.

[FR Doc. 2017–25576 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0616; FRL–9970–06]

Polyethyleneimine; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of polyethyleneimine when used as an inert ingredient in a pesticide chemical formulation on growing crops and raw agricultural commodities after harvest. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polyethyleneimine when used as an inert in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

DATES: This regulation is effective November 28, 2017. Objections and requests for hearings must be received on or before January 29, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0616, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC

20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0616 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 29, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0616, by one of the following methods:

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

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

II. Petition for Exemption

In the **Federal Register** of February 7, 2017 (82 FR 9555) (FRL–9956–86), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10981) by Spring Trading Company, LLC, on behalf of BASF Corporation, 100 Campus Drive, Florham, NJ 07932. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of polyethyleneimine (CAS Reg. No. 9002–98–6) when used as an inert ingredient emulsifier, surfactant, adjuvant, dispersant, and/or coating in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert ingredient in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other

exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

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

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Polyethyleneimine conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

2. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

3. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

4. The polymer is manufactured or imported from monomers and/or reactants that are already included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

5. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

6. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria: Specified in 40 CFR 723.250(e):

7. The polymer's number average MW of 1,300 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Polyethyleneimine conforms to the definition of polymer and meets all of the exclusion criteria in 40 CFR § 723.250, as listed in this section, except that it is cationic. Cationic polymers are excluded from the polymer exemption from tolerance under 40 CFR § 723.250 (in which manufacture and distribution of polymers meeting the exemption criteria can take place without submission of a Premanufacture Notice (PMN) or an exemption notice prior to commencement of manufacture for a commercial purpose) because of their potential to cause aquatic toxicity. The petitioner has submitted aquatic toxicity studies and based on these studies, the Agency does not expect toxicity to nontarget aquatic organisms. Because of its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to polyethyleneimine.

V. Aggregate Exposure

For the purposes of assessing potential exposure under this exemption, EPA considered that polyethyleneimine could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of polyethyleneimine is 1,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since polyethyleneimine conforms to the human health criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

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

VII. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of polyethyleneimine, based on its conformance to the human health criteria under 40 CFR 723.250, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VIII. Determination of Safety

Taking into consideration all available information on polyethyleneimine with a minimum number average molecular weight of 1,300 amu, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to polyethyleneimine under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of polyethyleneimine when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, is safe under FFDCA section 408.

IX. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

X. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for polyethyleneimine with a number average molecular weight of 1,300 amu (CAS Reg. No. 9002–98–6) when used as an inert ingredient (emulsifier, surfactant, adjuvant, dispersant, and/or coating) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

XI. Statutory and Executive Order Reviews

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

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

XII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 14, 2017.

Michael Goodis,

Director, Registration Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.910, add alphabetically the inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* *	* * *	* *
Polyethyleneimine (CAS Reg. No. 9002–98–6)	Minimum number average molecular weight 1,300 amu.	Emulsifier, surfactant, adjuvant, dispersant and/or coating.
* *	* * *	* *

[FR Doc. 2017–25715 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 170712657–7999–02]

RIN 0648–BG85

International Fisheries; Pacific Tuna Fisheries; Restrictions on Fishing for Sharks in the Eastern Pacific Ocean

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

ACTION: Final rule.

SUMMARY: NMFS is issuing regulations under the Tuna Conventions Act to implement Resolution C–16–05 (*Resolution on the Management of Shark Species*) of the Inter-American Tropical Tuna Commission (IATTC) adopted in July 2016. Per the Resolution, these regulations require purse seine vessel owners, operators, and crew to follow specified release requirements for sharks in the eastern Pacific Ocean (EPO). These regulations also prohibit longline vessels targeting tuna or swordfish in the EPO from using ''shark lines'' (a type of fishing gear used on longline vessels to target sharks). This rule is necessary for the United States to satisfy its obligations as a member of the IATTC.

DATES: This rule is effective January 1, 2018.

ADDRESSES: Copies of the Regulatory Impact Review and other supporting documents are available via the Federal eRulemaking Portal: *http://www.regulations.gov,* docket NOAA–NMFS–2017–0068, or by contacting the Regional Administrator, Barry A. Thom, NMFS West Coast Region, 1201 NE. Lloyd Boulevard, Suite 1100, Portland, OR 97232–1274, or *RegionalAdministrator.WCRHMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Daniel Studt, NMFS, West Coast Region, 562–980–4073.

SUPPLEMENTARY INFORMATION: On August 7, 2017, NMFS published a proposed rule in the **Federal Register** (82 FR 36724) to implement provisions of Resolution C–16–05 adopted by the IATTC in July 2016. The 30-day public comment period for the proposed rule closed on September 6, 2017, and one comment was received from an individual in support of the proposed rule as drafted. NMFS is finalizing the rule as proposed, except for non-substantive revisions as described below. The preamble to the proposed rule contains additional background information, including information on the IATTC, the international obligations of the United States as an IATTC member, and the need for regulations.

This final rule is implemented under the Tuna Conventions Act (16 U.S.C. 951 *et seq.*), as amended on November 5, 2015, by title II of Public Law 114–81. The recent amendments direct the Secretary of Commerce, in consultation with the Secretary of State, and, with respect to enforcement measures, the U.S. Coast Guard, to promulgate such regulations as may be necessary to carry out the United States' obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. The authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS. This rule implements provisions of Resolutions C–16–05 for U.S. commercial fishing vessels that fish for tuna or tuna-like species in the IATTC Convention Area. The IATTC Convention Area is 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.

This final rule requires that the crew, operator, and owner of a U.S. commercial purse seine fishing vessel promptly release unharmed, to the extent practicable, any shark (whether live or dead) caught in the IATTC Convention Area, as soon as it is seen in the net or on the deck, without compromising the safety of any persons. If a shark is live when caught, the crew, operator, or owner of a U.S. commercial purse seine vessel must follow the release procedures described in the regulatory text at 50 CFR 300.27(k).

This rule also prohibits the towing of a whale shark (*Rhincondon typus*) out of a purse seine net (*e.g.,* using towing ropes).

Furthermore, this rule prohibits longline vessels targeting tuna or swordfish in the IATTC Convention Area from using ''shark lines.''

Lastly, this final rule updates paragraph references in 50 CFR 300.24 for consistency and accuracy with existing regulations.

Public Comment and Response

NMFS received one written comment from an individual during the 30-day public comment period that closed on September 6, 2017. The individual supported the proposed rulemaking and noted shark populations' vulnerability to threats.

Changes From the Proposed Rule

There are no changes to the regulatory text in the final rule from the proposed rule except that 50 CFR 300.27(b) has been revised by removing the phrase in parentheticals, ''other than silky shark, oceanic whitetip shark, and whale shark, which may not be retained for consumption''. NMFS removed this parenthetical language from the regulatory text of the final rule because it was unnecessary: Oceanic whitetip, silky or whale sharks are already required to be released as soon as possible; as a result, those three types of shark may never be retained even for the purpose of consumption. Also, for consistency with other definitions in 50 CFR 300.21, a colon was removed from the shark line definition in the proposed rule. Furthermore, paragraph 50 CFR 300.24(ii) was removed by a final rule on September 29, 2017 (82 FR 45514); therefore, paragraph additions of 50 CFR 300.24(jj) and (kk) have been updated to 50 CFR 300.24(ii) and (jj), respectively.

Classification

The NMFS Assistant Administrator, in consultation with the Department of State and the U.S. Coast Guard, has determined that this final rule is consistent with the Tuna Conventions Act and other applicable laws.

Executive Order 12866

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

Executive Order 13771

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

Paperwork Reduction Act Collection of Information

There are no new collection-of-information requirements associated with this action that are subject to the Paperwork Reduction Act (PRA), and existing collection-of-information requirements still apply under the following Control Numbers: 0648–0148, 0648–0214, and 0648–0593. 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 Office of Management and Budget control number. All

currently approved NOAA collections of information may be viewed at: *http://www.cio.noaa.gov/services_programs/prasubs.html*

Regulatory Flexibility Act

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 that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a Regulatory Flexibility Analysis was not required and none was prepared.

List of Subjects in 50 CFR Part 300

Fish, Fisheries, Fishing, Fishing vessels, International organizations, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: November 21, 2017.

Alan D. Risenhoover,

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

For the reasons set out in the preamble, 50 CFR part 300 is amended as follows:

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, add a definition for ''Shark line'' in alphabetical order to read as follows:

§ 300.21 Definitions.

* * * * *

Shark line means a type of fishing gear used to target sharks and consisting of an individual hooked line or hooked lines attached to the floatline or directly to the floats of longline gear and deployed in the water column at depths shallower than the mainline.

* * * * *

■ 3. In § 300.24, revise paragraphs (w), (x), (cc), and (dd), and add paragraphs (ii) and (jj) to read as follows:

§ 300.24 Prohibitions.

* * * * *

(w) Set or attempt to set a purse seine on or around a whale shark (*Rhincodon typus*) in contravention of § 300.27(g).

(x) Fail to release a whale shark encircled in a purse seine net of a fishing vessel as required in § 300.27(h).

* * * * *

(cc) To retain on board, transship, store, land, sell, or offer for sale any part or whole carcass of a mobulid ray, as described in § 300.27(i).

(dd) Fail to handle or release a mobulid ray as required in § 300.27(j).

* * * * *

(ii) Fail to handle or release a shark as required in § 300.27(k).

(jj) Use a shark line in contravention of § 300.27(l).

■ 4. In § 300.27, revise paragraphs (b) and (h), and add paragraphs (k) and (l) to read as follows:

§ 300.27 Incidental catch and tuna retention requirements.

* * * * *

(b) *Release requirements for non-tuna species on purse seine vessels.* All purse seine vessels must release all billfish, ray (not including mobulid rays, which are subject to paragraph (i) of this section), dorado (*Coryphaena hippurus*), and other non-tuna fish species, except those being retained for consumption aboard the vessel, as soon as practicable after being identified on board the vessel during the brailing operation. 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.

* * * * *

(h) *Whale shark release.* The crew, operator, and owner of a fishing vessel of the United States commercially fishing for tuna in the Convention Area must release as soon as possible, any whale shark that is encircled in a purse seine net, and must ensure that all reasonable steps are taken to ensure its safe release. No whale shark may be towed out of a purse seine net (*e.g.,* using towing ropes).

* * * * *

(k) *Shark handling and release requirements for purse seine vessels.* The crew, operator, and owner of a U.S. commercial purse seine fishing vessel must promptly release unharmed, to the extent practicable, any shark (whether live or dead) caught in the IATTC Convention Area, as soon as it is seen in the net or on the deck, without compromising the safety of any persons. If a shark is live when caught, the crew, operator, or owner must follow release procedures in the following two paragraphs.

(1) Sharks must be released out of the purse seine net by directly releasing the shark from the brailer into the ocean. Sharks that cannot be released without compromising the safety of persons or the sharks before being landed on deck must be returned to the water as soon as possible, either utilizing a ramp from the deck connecting to an opening on the side of the boat, or through escape hatches. If ramps or escape hatches are not available, the sharks must be lowered with a sling or cargo net, using a crane or similar equipment, if available.

(2) No shark may be gaffed or hooked, lifted by the head, tail, gill slits or spiracles, or lifted by using bind wire against or inserted through the body, and no holes may be punched through the bodies of sharks (*e.g.,* to pass a cable through for lifting the shark).

(l) *Shark line prohibition for longline vessels.* Any U.S. longline vessel used to fish for tuna or swordfish is prohibited from using any shark line in the IATTC Convention Area.

[FR Doc. 2017–25617 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 170803719–7719–01]

RIN 0648–XF848

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic; Re-Opening of the Recreational Sector for Red Snapper

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

ACTION: Temporary rule; re-opening.

SUMMARY: NMFS announces the re-opening of the recreational sector for red snapper in the exclusive economic zone (EEZ) of the South Atlantic through this temporary rule. The most recent preliminary recreational harvest information for red snapper indicate the recreational annual catch limit (ACL) for the limited 2017 fishing season has not yet been reached. Therefore, NMFS re-opens the recreational sector for red snapper in the South Atlantic EEZ for 3 days (see DATES) to allow the recreational ACL to be caught, while minimizing the risk of the recreational ACL being exceeded.

DATES: This rule is effective 12:01 a.m., local time, December 8, 2017, and closes

at 12:01 a.m., local time, on December 11, 2017.

FOR FURTHER INFORMATION CONTACT: Nikhil Mehta, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *nikhil.mehta@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes red snapper and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

On November 2, 2017, NMFS published a temporary rule through emergency action for South Atlantic red snapper in the 2017 fishing year (82 FR 50839). The temporary rule authorized the limited harvest and possession of red snapper in or from the South Atlantic EEZ in the 2017 fishing year. The 2017 commercial ACL was set at 124,815 lb (56,615 kg), round weight, and the 2017 recreational ACL was set at 29,656 fish. The recreational season was open for two consecutive weekends made up of Fridays, Saturdays, and Sundays. The recreational season opened for the weekends of November 3 through 5, 2017, and November 10 through 12, 2017. The temporary rule additionally set a 1 fish per person recreational bag limit. No size limits were implemented for either sector through the temporary rule in an effort to decrease regulatory discards. The temporary rule also set a daily commercial trip limit 75 lb (34 kg), gutted weight. The intended effect of the temporary rule through emergency action is to reduce, to the extent practicable, existing adverse socio-economic impacts to fishermen and fishing communities that utilize the red snapper portion of the snapper-grouper fishery, without allowing overfishing or preventing the stock from rebuilding. Additionally, limited commercial and recreational harvest of red snapper in 2017 provides an opportunity to collect fishery-dependent data that will be useful for future red snapper stock assessments and management decisions.

During the limited harvest season in 2017, the South Atlantic states and NMFS collected harvest information through fishing effort and dockside surveys, survey of private anglers and charter and headboat captains, and voluntary donations of fish carcasses from recreational anglers. NMFS notes that the majority of recreational harvest of red snapper occurs off Florida and the majority of the sector landings are attributable to private anglers.

NMFS is required to close the recreational sector for red snapper when the recreational ACL specified at 50 CFR 622.193(aa)(2) is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS previously projected and announced in the **Federal Register** that the recreational ACL for South Atlantic red snapper for the 2017 limited fishing season would be reached by the end of the second recreational open weekend at 12:01 a.m., local time, on November 13, 2017 (82 FR 50839, November 2, 2017). However, preliminary recreational harvest information indicates that the recreational ACL for red snapper was not met as of that date. Based on these preliminary data, NMFS has projected that the recreational sector may reopen for additional 3 days, which is not expected to result in harvest exceeding the 2017 recreational sector ACL.

Therefore, in accordance with 50 CFR 622.8(c), NMFS temporarily re-opens the recreational sector for 3 days (Friday, Saturday, and Sunday) beginning at 12:01 a.m., local time, December 8, 2017, to allow the recreational sector to have the opportunity to harvest the red snapper ACL. The recreational sector will close 3 days later, at 12:01 a.m., local time, December 11, 2017, and will remain closed in accordance with the effectiveness of the implemented emergency measures (82 FR 50839, November 2, 2017). NMFS has determined that this re-opening will allow for an additional opportunity to recreationally harvest red snapper while minimizing the risk of exceeding the recreational ACL. NMFS notes that the commercial harvest of red snapper that was authorized through the temporary rule implementing emergency measures is currently open through December 31, 2017, unless the commercial ACL is projected to be reached prior to that date.

Once the recreational sector closes, the bag and possession limits are zero for red snapper in or from the South Atlantic EEZ. Additionally, these bag and possession limits apply to the harvest of red snapper in both state and Federal waters in the South Atlantic on board a vessel with a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper.

Classification

The Regional Administrator, NMFS Southeast Region, has determined this temporary rule is necessary for the conservation and management of red snapper and the South Atlantic snapper-grouper fishery and is consistent with the temporary rule implementing emergency measures, the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.8(c) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this action to temporarily re-open the recreational sector for red snapper constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the conditions and justification for temporary rule implementing the recreational ACL in 2017 are still in effect, and all that remains is to notify the public of the re-opening. Such procedures are contrary to the public interest because of the need to immediately implement this action to allow recreational fishers to harvest the recreational ACL of red snapper from the EEZ, while minimizing the risk of exceeding the recreational ACL. Prior notice and opportunity for public comment would be contrary to the public interest because it would not allow for harvest of the recreational ACL before the end of the fishing season.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 22, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–25645 Filed 11–22–17; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 161017970–6999–02]

RIN 0648–XF835

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2017 commercial summer flounder quota to the State of Rhode Island. This quota adjustment is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial quotas for Virginia and Rhode Island.

DATES: Effective November 22, 2017, through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Cynthia Hanson, Fishery Management Specialist, (978) 281–9180.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.110. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the initial 2017 allocations were published on December 22, 2016 (81 FR 93842).

The final rule implementing Amendment 5 to the Summer Flounder Fishery Management Plan, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider the criteria in § 648.102(c)(2)(i)(A) through (C) in the evaluation of requests for quota transfers or combinations.

Virginia is transferring 38 lb (17 kg) of summer flounder commercial quota to Rhode Island. This transfer was requested by Virginia to repay landings by a Virginia-permitted vessel that landed in Rhode Island under a safe harbor agreement. The revised summer flounder quotas for calendar year 2017 are now: Virginia, 1,219,874 lb (553,326 kg); and Rhode Island, 887,960 lb (402,772 kg); based on the initial quotas published in the 2017 Summer Flounder, Scup, and Black Sea Bass Specifications and subsequent transfers.

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: November 22, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–25685 Filed 11–22–17; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 151130999–6594–02]

RIN 0648–XF834

Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2017 commercial bluefish quota to the State of Rhode Island. This quota adjustment is necessary to comply with the Atlantic Bluefish Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial bluefish quotas for Virginia and Rhode Island.

DATES: Effective November 22, 2017, through December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Cynthia Hanson, Fishery Management Specialist, (978) 281–9180.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.162 and the initial 2017 allocations were published on March 13, 2017 (82 FR 13402).

The final rule implementing Amendment 1 to the Bluefish Fishery Management Plan published in the **Federal Register** on July 26, 2000 (65 FR 45844), and provided a mechanism for transferring bluefish quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval of a transfer of bluefish commercial quota under § 648.162(e)(1)(i) through (iii). The Regional Administrator must first approve any such transfer based on the criteria in § 648.162(e).

Virginia is transferring 338 lb (153 kg) of Atlantic bluefish commercial quota to Rhode Island. This transfer was requested by Virginia to repay landings by a Virginia-permitted vessel that landed in Rhode Island under a safe harbor agreement. Both states have agreed to the transfer and certified that it meets all pertinent requirements. The revised bluefish quotas for calendar year 2017 are now: Virginia, 1,014,435 lb (460,140 kg); and Rhode Island, 731,901 lb (331,985 kg); based on the initial quotas published in the 2016–2018 Atlantic Bluefish Specifications and subsequent transfers.

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: November 22, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–25697 Filed 11–22–17; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 227
Tuesday, November 28, 2017

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 ENERGY

10 CFR Part 430

[EERE–2017–BT–STD–0059]

RIN 1904–AE11

Energy Conservation Program: Energy Conservation Standards Program Design

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Energy (DOE) is evaluating the potential advantages and disadvantages of additional flexibilities in the U.S. Appliance and Equipment Energy Conservation Standards (ECS) program. Flexibilities could include market-based approaches such as those used to set average efficiency standards, feebate programs, or other approaches that may reduce compliance costs and/or increase consumer choice while preserving or enhancing appliance efficiency. This RFI discusses key issues and requests feedback on the possible design of such a program. DOE additionally requests feedback on possible economic efficiency gains, impacts on consumer and manufacturer costs and on energy savings, and suggestions for a pilot product category and/or phase-in of revisions across the ECS program. DOE also requests feedback on any potential challenges associated with designing and implementing any of these flexible program approaches as well as possible solutions.

DATES: Written comments and information are requested on or before February 26, 2018.

ADDRESSES: Any comments submitted must identify the RFI for Energy Conservation Standards Program Design, and provide docket number EERE–2017–BT–STD–0059 and/or regulatory information number (RIN) number 1904–AE11. Comments may be submitted using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: ProgramDesign2017STD0059@ee.doe.gov.* Include docket number EERE–2017–BT–STD–0059 in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.
- *Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.
- *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Instructions: All submissions received must include the agency name and docket number and/or RIN. No telefacsimiles (faxes) will be accepted.

Docket: The docket is available for review at *http://www.regulations.gov/docket?D=EERE-2017-BT-STD-0059,* including **Federal Register** notices, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket Web page can be found at *http://www.regulations.gov/docket?D=EERE-2017-BT-STD-0059.* This Web page contains a link to the docket for this notice at *http://www.regulations.gov.* The *http://www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket.

For information about how to submit a comment or review other public comments in the docket, send an email to *ApplianceStandardsQuestions@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Appliance and Equipment Standards Program Staff, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1445. Email: *ProgramDesign2017STD0059@ee.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. Background

The purpose of this Request for Information (RFI) is to outline and request feedback on the design, value, and solutions to potential challenges of revising the U.S. Appliance and Equipment Energy Conservation Standards (ECS) program to include additional compliance flexibilities, with the goal of reducing compliance costs, enhancing consumer choice and maintaining or increasing energy savings. Of particular interest are designs that would use market-based policy mechanisms such as averaging, credit trading, or feebates. Market-based policy mechanisms are potentially less burdensome alternatives as they use markets, price, and other economic variables to provide incentives for regulated entities to reduce or eliminate negative environmental externalities in the least cost way. These policy mechanisms recognize that compliance

costs may vary significantly across the regulated sector and allows individual parties to choose the most cost effective compliance option.

An example, discussed further below, of a market-based regulatory program that uses averaging, banking, and trading of credits is the Corporate Average Fuel Economy (CAFE) standards program for light-duty vehicles. The CAFE standards program specifies a fleet-based average fuel efficiency standard that allows manufacturers to trade credits across vehicle classes and manufacturers. This is only one example of how a regulatory program can include some market-based mechanism allowing for more flexibility in compliance. Other examples of market-based mechanisms used in a number of other U.S. energy and environmental programs include standards to which gasoline refineries were subject during the leaded gasoline phase-down,[1] the use of credits, or RINs (Renewable Fuel Identification Numbers) in the U.S. EPA Renewable Fuel Standards program,[2] fuel efficiency standards for heavy duty engines and vehicles, various versions of state-level Renewable Portfolio Standard programs, including those allowing for the use of Tradable Renewable Certificates (TRCs),[3] and several power plant emissions control programs including California's Cap and Trade program.[4]

DOE requests feedback on possible revisions to the ECS to adopt some type of market-based approach and/or other program flexibilities. DOE additionally requests feedback on possible impacts on consumer and manufacturer costs, estimated benefits of the program such as energy savings, design and implementation of such a program, and suggestions for a pilot product category and/or phase-in of revisions across ECS. DOE encourages the public to provide input on measures DOE could take to lower the cost of its regulations consistent with the requirements of EPCA.

Economic theory suggests that the introduction of credit trading into a mandatory regulatory program such as ECS would likely improve economic efficiency (see Coase (1960),[5] Crocker (1966),[6] Dales (1968a, 1968b),[7] and Montgomery (1972) [8]) and subsequent discussions such as Ellerman (2005) [9]). Credit trading, for example, either within a single manufacturer or between manufacturers, would allow a level of flexibility for compliance, and could thereby reduce compliance costs associated with production, and establish a market mechanism to reveal the ''shadow value'' [10] of the efficiency standard through the value of credits on the credit trading market. In principle, the same aggregate level of energy savings could be obtained with reduced compliance cost, because manufacturers with a lower marginal cost of providing efficiency improvements could increase the efficiency of the products they sell even more, and sell credits from their over-compliance to manufacturers with a higher marginal cost of providing efficiency, thereby allowing them to produce products with efficiency levels below the standard. This could reduce the overall manufacturer cost associated with producing the same aggregate level of energy savings. Such a program would allow a degree of flexibility that could accommodate increased consumer choice as well. For example, if there is a small market segment of consumers with a very high willingness to pay for a product that, for whatever reason, cannot be produced to meet a given energy conservation standard level, under a mandatory standard they could not obtain this product. However, under a trading, averaging, or other market-based scheme a manufacturer could choose to produce that product by purchasing credits in the credit market. Furthermore, market-based standards further incentivize even the makers of the most efficient appliances to continue to innovate and improve efficiency, gains once the minimum standard is met.[11] DOE requests comment on which flexible compliance or market-based program scheme might incentivize the most cost-effective improvements in energy efficiency.

Increased flexibility, reduced economic costs, and increased incentives for manufacturers to innovate and improve efficiency across a spectrum of products (*i.e.,* both high efficiency products and products that just meet the standard level) are all possible benefits from introducing average standards and/or market-based approaches, or other compliance flexibilities. These market-based program options will differ from the current DOE compliance structure creating some uncertainty about implementation, interaction with voluntary programs such as ENERGY STAR, certification, and enforcement for both manufacturers and DOE. The scope of a tradable standards program could range from allowing averaging only across each company's appliances within a product category (that is, no trading across product categories or between companies). For example, considering the consumer refrigerator and freezer product category,[12] a company could average the energy efficiency of their products across all of the product classes of equipment that they produce or just average across some of the various residential refrigerator products in different product classes that they produce, but different companies would not be able to average their energy efficiencies between companies. Another program design could allow companies to trade credits across product categories and/or between companies. A feebate program could similarly vary in scope but would have different implementation and administrative requirements and costs. As there are many program design possibilities and potential program flexibilities, DOE requests comment on any potential benefits or costs that may arise with the implementation of these types of policy changes and any

[1] Newell, R.G., & Rogers, K. (2003). The U.S. experience with the phasedown of lead in gasoline. Resources for the Future, Washington, DC, 2.

[2] *https://www.epa.gov/renewable-fuel-standard-program/overview-renewable-fuel-standard.*

[3] Wiser, R., Porter, K., & Grace, R. (2005). Evaluating experience with renewables portfolio standards in the United States. *Mitigation and Adaptation Strategies for Global Change, 10*(2), 237–263.

[4] *https://www.arb.ca.gov/cc/capandtrade/capandtrade.htm.*

[5] Coase, R.H. (1960). The problem of social cost. *The Journal of Law and Economics,* 3, 1–44. [republished as Coase, R.H. (2013). The problem of social cost. *The journal of Law and Economics,* 56(4), 837–877.]

[6] Crocker T.D.W.H. (1966). The structuring of atmospheric pollution control systems. The economics of air pollution: A symposium, New York, W.W. Horton, pg. 61–86.

[7] Dales J.H. (1968a) Land, water, and ownership. *Canadian Journal of Economics/Revue Canadienne d'Economique,* 1(4), 791–804. *Dales, J.H. (1968b). Pollution, property and prices. Toronto, University of Toronto Press.*

[8] Montgomery, W.D. (1972). Markets in licenses and efficient pollution control programs. *Journal of Economic Theory.* 5(3), 395–418.

[9] Ellerman, A.D. (2005). A note on tradeable permits. *Environmental and Resource Economics,* 31(2), 123–131.

[10] Shadow price or shadow value is a term in economics. It refers to the marginal value of a constraint, or the value of relaxing a given constraint by one unit. In the case of a standard with trading, theoretically the price of credits in the credit market would reveal the shadow value of the constraint imposed by the standard.

[11] Note that the voluntary ENERGY STAR program currently provides a separate incentive for increasing efficiency beyond the minimum standards, in a different way than mandatory market-based standards. ENERGY STAR criteria are set above minimum standards to provide a separate incentive to produce products above the minimum.

[12] DOE's current energy efficiency standards for the consumer refrigerators, refrigerator-freezers, and freezers product category are subdivided into forty-two different product classes most of which have unique energy efficiency standards. 76 FR 57516 (September 15, 2011).

recommendations for how the program could be successfully implemented.

B. Background on Market-Based Mechanisms in the Context of Environment Regulation

There are many examples of market-based mechanisms incorporated into environmental regulation. Broadly, prominent examples in the United States include emissions trading systems (ETS, or cap and trade); and performance-based standards with a market-based mechanism or similar allowance for some element of flexibility in compliance. In the case of an ETS, a particular cap, or limit, is placed on the level of emissions. That cap would generally be structured in the form of emissions credits (*e.g.,* a single ton of emissions) allocated to each entity subject to the policy. Several allocation mechanisms are possible, including grandfathering, lottery, or auctioning. There are numerous other examples of ETS policies at the state and federal levels in the United States and across the world.[13]

A successful example of an ETS is EPA's Acid Rain Program, where fossil fuel-fired electric power plant emissions of sulfur dioxide were capped nationwide and power plant owners could either install emissions control technologies to reduce their sulfur dioxide emissions allowing the owner to earn credits for each ton of emissions reduced or the owner could purchase credits to offset their emissions. The Acid Rain Program also included an emissions averaging component for nitrous oxide (NO_X) emissions that allowed owners to use company-wide averaging to meet the emissions standard.

An example of flexible performance standards include the various implementations of vehicle fuel economy standards across the world. Many of these vehicle fuel economy programs incorporate some variation of an average target, allowing flexibility in compliance by enabling manufacturers to sell models that are less efficient than the target as long as they balance it out with sales of models that are more efficient.[14] China is one of the exceptions as they set minimum standards that each vehicle model must achieve. In addition, some programs have also incorporated some degree of flexible compliance or coordination in compliance across manufacturers. A program already implemented in the U.S., is the Department of Transportation's Corporate Average Fuel Economy (CAFE) standards and EPA's greenhouse gas (GHG) standards for passenger vehicles. CAFE standards were first enacted by Congress in 1975. Starting in 1978, each vehicle manufacturer was required to meet a fleet-wide, average fuel economy standard: One for passenger cars and another for light trucks. The Department of Transportation's National Highway Traffic and Safety Administration (NHTSA) administers the CAFE standards, while the Environmental Protection Agency (EPA) administers the greenhouse gas emissions (GHG) standards for passenger cars and light-duty trucks under section 202(a) of the Clean Air Act (42 U.S.C. 7521(a)). The two agencies work together, with the California Air Resources Board, to set CAFE and GHG standards for passenger vehicles in part to harmonize their standards to reduce compliance burdens on manufacturers so manufacturers can produce the same vehicle model across the nation. The current CAFE standards cover light-duty passenger vehicles for model years out to 2021 while EPA's GHG standards go out to 2025 (77 FR 62623).

For all U.S. sales in a given model year, the CAFE standards require each manufacturer's U.S. sales meet a production-weighted harmonic mean fuel economy/emissions target based on vehicle footprint (the vehicle wheelbase times its track width, or the area between its tires). Thus, CAFE is a fleet-based standard, which allows each manufacturer to trade off fuel economy between its own models by altering its product mix (*i.e.,* ''internal trading''). The standards are applied fleetwide for a company so that domestically produced vehicles[15] and imported vehicles, are treated the same for compliance purposes.

Beginning with the standards issued in 2009 for model year 2011 vehicles, the CAFE program allows for trading of credits across manufacturers (74 FR 14195). Manufacturers who fail to meet their fleet-level target may buy credits from manufacturers who achieved greater-than-required fleet-level fuel economy; alternatively, manufacturers failing to meet their fleet-level target may pay a fine. Credits may also be used within a manufacturer's own product mix, trading from passenger cars to light trucks, or from domestic to foreign production. Credits earned by exceeding the fuel economy standard may be banked and used up to five years in the future.

The CAFE calculation incorporates many different complexities and allowances for vehicle design features (*e.g.,* flex-fuel capability, air conditioning, off-cycling technologies, solar panels, engine start/stop, active aerodynamics, etc.), which may or may not have logical analogs in products covered by ECS. It is important when designing a credit program that there is sufficient heterogeneity in the affected product category to leverage the advantages of a market-based approach. For analysis of the impact and effectiveness of credit trading within CAFE, see, *e.g.,* Leard and McConnell (2015)[16] and Greenstone et al. (2017).[17]

Other passenger vehicle fuel economy standards programs around the world also provide some examples for variations on this concept. For example, Japan follows a similar model to the United States, in that their vehicle standards are mandatory and their fuel economy targets are also based on average vehicle fuel economy, where the target is specific to weight classes. Starting in 2001 the regulation was revised to allow manufacturers to transfer credits across weight classes (see An & Sauer 2004).[18]

The European Union (E.U.) program differs significantly from that used in the United States. In the E.U. program the average passenger vehicle fuel economy across the entire industry is to meet a certain target by the compliance date (*i.e.,* there are no manufacturer-specific targets). It is a voluntary standard established through an agreement between manufacturers and the European Commission. Because the target is not specific to each manufacturer, manufacturers can presumably coordinate to enable the entire passenger vehicle fleet to meet the target (An & Sauer 2004).

Another example of a performance standard incorporating a level of flexibility in compliance is a feebate. Examples include the Swedish program to incentivize power plant operators to reduce nitrous oxide emissions, as well as vehicle fuel economy programs in

[13] E.T.S. China (2016). ''Carbon Pricing Watch 2016,'' World Bank Group. *http://www.ecofys.com/en/publications/carbon-pricing-watch-2016/.*

[14] An, F., & Sauer, A. (2004). Comparison of passenger vehicle fuel economy and greenhouse gas emission standards around the world. Pew Center on Global Climate Change, 25.

[15] Vehicles produced with more than 75 percent U.S., Canadian, or post-NAFTA Mexican content.

[16] Leard, B. and V. McConnell (2015). ''New Markets for Pollution and Energy Efficiency: Credit Trading under Automobile Greenhouse Gas and Fuel Economy Standards,'' Resources for the Future, RFF DP 15–16.

[17] Greenstone, M. et al. (2017). ''The Next Generation of Transportation Policy,'' The Hamilton Project, Policy Proposal 2017–02.

[18] An, F., & Sauer, A. (2004). Comparison of passenger vehicle fuel economy and greenhouse gas emission standards around the world. Pew Center on Global Climate Change, 25.

several countries.[19] [20] Under a feebate program, an efficiency ''pivot-point'' is set, below which manufacturers pay a fee and above which manufacturers receive a payment from the regulating body or government entity. The fee or payment is based on the efficiency of products sold relative to the pivot point. So, for example, the highest efficiency products generate higher payments than products also above the pivot point but that are lower efficiency (see for example Gillingham 2013 [21]). Feebates may be easier to administer than tradable standards because tracking of permits is not required and credit market liquidity is not a concern, though other implementation challenges may arise.[22]

Regardless of the specific program design, the general concept with existing programs is to establish a target level, and allow manufacturers to have the flexibility to meet that target in the least cost way. That flexibility can include a penalty or payment based on if a manufacturer under- or over-performs relative to the target (*i.e.,* feebate), a credit market (*e.g.,* CAFE), or allowing for other forms of collaboration in compliance (*e.g.,* E.U. vehicle standard program). DOE seeks feedback on what type of approach would best serve the ECS program. In the remainder of this document CAFE is used as an example to discuss some of the specific points on which DOE seeks feedback, although DOE is interested in feedback regarding any other potential policy approaches.

II. Key Issues

A. Translation to Energy Conservation Standards

The markets for consumer products and commercial equipment covered by the ECS program will inform the way a market mechanism or allowance for compliance flexibility could possibly be established for ECS's consumer products and commercial equipment.

First, the scope of the ECS program covers a broad range of consumer products and commercial equipment. The ECS program currently covers more than 60 types of products, each of which have a number of product classes. For this full scope of products, there are a large number of manufacturers controlling hundreds of brands across a wide range of sectors and industries that may facilitate averaging or trading amongst manufacturers. The EPCA definition of manufacturer applies not only to original equipment manufacturers, but also retailers, distributors, installers, or importers, some of which rebrand products manufactured by other distributors. All of these regulated entities would have to submit sales data on covered models in order to track compliance with such a program. The current program of mandatory energy conservation standards for each model currently requires that manufacturers certify and report to DOE the efficiency level of all covered models. Production or sales data are not collected.

Careful consideration should be given to the scope of additional program flexibilities, for example the range of product categories across which trading under a tradable standard could occur. One potential approach could be to maintain a single standard level as is currently the case for covered appliances and commercial equipment. The standard level would still be set separately for each product category and each class within that product category. Trading could be allowed within a single product class or across all product classes within a particular product category both for a given manufacturer (they could sell some models exceeding the standard as long as they also have sufficient sales below the standard to offset that difference) and across manufacturers so that those with excess credits could bank them or sell them to those with a deficit for a given year. As is the case for CAFE standards, such a system incentivizes manufacturers already producing efficient models to continue improving efficiency [23] Another potential approach could be requiring both a minimum efficiency level and an average standard above the minimum efficiency level that can be met through a more flexible approach, although that approach may reduce the potential cost savings.[24]

While maintaining the same sets of product classes would likely be desirable in most cases, the introduction of trading could allow a degree of freedom and flexibility that could potentially allow for simplification in other dimensions of the program. For example, some product classes could be consolidated, or volume-based standards, such as are established for refrigerators currently, might be simplified to no longer depend on volume. Product classes were defined in order to ensure preservation of consumer choice and product utility/functionality, effectively mandating a degree of flexibility to the program. If the trading introduced a market-driven allowance for flexibility, some of the mandated features may be redundant, and further simplification might be beneficial. This would have to be carefully assessed.

B. Scope of Standards

As discussed above, defining the products across which credit trading would be allowed or a single feebate set must be carefully considered. In the case of a tradable standard, trading could be allowed across product categories using the same type of fuel. For example, a manufacturer could trade credits for room air conditioners with electric clothes dryers, with the common metric being kilowatt hours saved over a product's expected lifetime. Alternatively, trading could be allowed only across product classes for a particular product category (*e.g.,* across all room air conditioner product classes), product classes could be consolidated or eliminated for a single product (*e.g.,* a single standard for all room air conditioners), or trading could be allowed across product categories using similar technologies (room air conditioners and commercial air conditioners, and perhaps consumer refrigerators as well). One of the key program design elements would be ensuring a standardized definition of credits across product classes to the extent trading was allowed across products with differing fuel sources, requiring a normalization of energy savings, though most covered products use electricity. Program administration and compliance costs, potential efficiency gains, credit market liquidity, and potential impacts on competition in product markets are important

[19] Johnson, K.C. (2006). Feebates: An effective regulatory instrument for cost-constrained environmental policy. Energy policy, 34(18), 3965–3976.

[20] German, J. and Dan Meszler (2010). Best practices for feebate program design and implementation. International Council on Clean Transportation. *http://www.theicct.org/sites/default/files/publications/ICCT_feebates_may2010.pdf.*

[21] Gillingham, K. (2013). The Economics of Fuel Economy Standards versus Feebates. National Energy Policy Institute (NEPI) Working Paper. *http://www.ourenergypolicy.org/wp-content/uploads/2013/07/Gillingham-CAFE-Standards-vs-Feebates-Apr-20131.pdf.*

[22] For example feebate programs may require tax and subsidy authority and are not guaranteed to be revenue neutral.

[23] It should be noted that programs such as ENERGY STAR and product rebates by utilities and other program administrators incentivize efficiency in consumer products and industrial equipment outside of the ECS program. The interaction of additional program flexibilities with other programs such as ENERGY STAR is an important consideration.

[24] Retaining a minimum standard could be one way to comply with the anti-backsliding provision in current law.

considerations in setting the scope of the program.

As a final note, for one product currently covered under the ECS program (central air conditioners), the standard level for this product varies regionally. If this feature were present for a product category included in the scope of trading, trading would have to reflect region-specific product sales as well.

C. Normalizing Across Energy Sources

Credit trading across appliances with different fuel sources (*e.g.,* electric versus natural gas dryers) would require normalizing energy metrics across fuel types. CAFE currently does this for alternative fuel vehicles (including those that run on electricity, natural gas, hydrogen and other fuels) by generating energy-equivalent fuel economy values. So for instance a natural gas vehicle that travels 30 miles on 100 cubic feet of natural gas is given a gasoline-fuel-equivalent miles per gallon value by multiplying the natural gas fuel economy by an energy content conversion factor representing the relative energy content of 100 cubic feet of gas and one gallon of gasoline. Appliance fuels could similarly be converted into energy-equivalent values, or trading could be restricted to appliances of the same fuel type. DOE seeks feedback on this point.

D. Distributional Impacts Across Consumers and Manufacturers

Incorporating elements of a market-based or flexible approach to the ECS program in order to enable more flexible compliance could have significant benefits for consumer's manufacturers, such as providing manufacturers flexibility to comply with the efficiency target in the least cost way. However, even if overall costs decline, the distribution of costs among regulated firms could change, and some firms might face higher costs than under the current program. Administrative costs for firms may increase while overall compliance costs may be reduced, for instance as a result of reductions in production costs or larger profits from better targeting of consumer preferences. DOE seeks feedback on the potential for distributional asymmetries in costs and benefits that could be relevant. For example, would a credit trading mechanism significantly change administrative costs associated with complying with the ECS? Would these cost changes disproportionately impact some types and sizes of firms relative to others (*e.g.,* would some firms potentially have a compliance advantage, in that they may be better equipped to establish designated personnel to manage participation in the credit market)? How would different approaches to program flexibility impact those costs (*e.g.,* credit trading versus feebates?). What are the likely net gains to consumers and manufacturers of a more flexible approach?

E. Enforcement

The establishment of credit trading would require additional data collection and monitoring to set standards and ensure compliance.[25] As under the current CAFE program, calculating credit holdings would depend on accurate sales data for every covered model. In cases where standards vary regionally, these data would also need to be broken out by region. These data would be necessary to support accurate and consistent calculations for the determination of appropriate energy conservation standard levels as part of the rulemaking, and would be essential for enabling and monitoring the credit market and ensuring compliance.

F. Potential Challenges

For several product markets, particularly for large appliances, the set of manufacturers is relatively small. This level of concentration in the product market, if replicated in the credit market, implies manufacturers may be able to exercise market power (*i.e.,* the market would not be perfectly competitive).[26] Competitive credit markets are an important factor in design of programs that include trading. The extent to which market power could be exercised in credit markets, and the potential impact on appliance program outcomes and on consumers, would need to be carefully considered in design of a program. In general, liquid and competitive credit markets would be more likely if trading was allowed across many product categories.[27] Approaches that do not involve credit markets, such as a feebate, would not generate the same credit trading concerns. More broadly, the interaction of standards and market power in product markets is an important consideration.[28] For a discussion of how market power has the potential to impact a credit market in an emissions trading context see Fowlie, Reguant, and Ryan (2016).[29]

Second, as with the current appliance program, the impact of special provisions on program goals would have to be carefully considered. For example, CAFE standards allow a mpg benefit for flex-fuel vehicles regardless of the actual fuel used by the vehicles.[30] The resulting incentive to produce flex-fuel vehicles that do not for the most part actually use alternative fuels results in smaller reductions in petroleum fuel use. This provision is being phased out as a result.

Third, introduction of efficiency incentives like tradable performance standards or feebates into the ECS program would mean that manufacturers that specialize in more efficient products may experience higher sales, while those that specialize in lower efficiency products may have added costs and lower sales. As noted above, the impact on small firms must be carefully considered.

G. Potential Pilot Program and Assessment

DOE requests input on potential scope for a market-based pilot. For example, is there a product or equipment type that would be appropriate for such a pilot? Is there a particular industry with a structure more amenable to a market-based pilot than others? Are any potential policy approaches identified in this RFI more suitable to certain industries or products than others? Could this pilot be successfully applied to an industry voluntary program (*e.g.,* set-top boxes)?

[25] For the current ECS program, DOE has published certification, compliance, and enforcement regulations for covered products and equipment in the Code of Federal Regulations (CFR) at 10 CFR part 429. These regulations describe how manufacturers must establish certified ratings based on conducting DOE test procedures on a sample of units of a given basic model and subsequently apply DOE's statistical sampling plans. The regulations also describe how manufacturers must submit certification reports to DOE, and how manufacturers must maintain records underlying the certification. Finally, the regulations describe processes for DOE-initiated testing and enforcing compliance with the certification provisions and the energy and water conservation standards.

[26] For a summary of recent work on this topic see: Houde, S. and C.A. Spurlock (2016). ''Minimum Energy Efficiency Standards for Appliances: Old and New Economic Rationales,'' *Economics of Energy & Environmental Policy,* 5(2).

[27] For discussion in the context of emissions trading markets, see, *e.g.,* Godby, R. (2000). ''Market Power and Emissions Trading: Theory and Laboratory Results,'' *Pacific Economic Review,* 5(3):349–363.

[28] See for example Carolyn Fischer, ''Imperfect Competition, Consumer Behavior, and the Provision of Fuel Efficiency in Light-Duty Vehicles,'' Resources for the Future Discussion Paper 10–60, December 2010.

[29] Fowlie, M., Reguant, M., & Ryan, S.P. (2016). Market-based emissions regulation and industry dynamics. Journal of Political Economy, 124(1), 249–302.

[30] For discussion of the flex-fuel provision and what its use can reveal about manufacturer costs, see, *e.g.,* Anderson, S. and J. Sallee (2011). ''Using Loopholes to Reveal the Marginal Cost of Regulation: The Case of Fuel-Economy Standards,'' *American Economic Review,* 101: 1375–1409.

DOE also requests feedback on how to assess pilot program results. In particular, how could DOE identify the counterfactual or control group for comparison with the existing mandatory ECS program? How could DOE best conduct a retroactive assessment of costs and benefits to manufacturers under the existing ECS program and the market-based pilot? How could DOE identify distributional impacts across manufacturers? How could DOE determine if a broader or narrower scope of trading, if allowed, would have been more beneficial? DOE also requests input on what data it would need to collect to properly assess pilot program results.

III. Public Participation

DOE invites all interested parties to submit in writing by February 26, 2018, comments and information on matters addressed in this RFI and on other matters relevant to DOE's evaluation of the potential advantages and disadvantages of additional compliance flexibilities in energy conservation standards, such as tradable average standards, feebates or other market-based approaches. DOE requests feedback on program design, possible economic efficiency gains, impacts on consumer and manufacturer costs and on energy savings, and potential challenges associated with designing and implementing such a program, including suggestions for a pilot and/or phase-in of a revised ECS.

DOE considers public participation to be a very important part of the process for developing new and/or amended energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this RFI should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Issued in Washington, DC, on November 21, 2017.

Daniel R Simmons,

Principal Deputy Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 2017–25663 Filed 11–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM16–22–000]

Coordination of Protection Systems for Performance During Faults and Specific Training for Personnel Reliability Standards

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to approve Reliability Standards PRC–027–1 (Coordination of Protection Systems for Performance During Faults) and PER–006–1 (Specific Training for Personnel) submitted by the North American Electric Reliability Corporation (NERC). The purpose of proposed Reliability Standard PRC–027–1 is to maintain the coordination of protection systems installed to detect and isolate faults on bulk electric system elements, such that those protection systems operate in the intended sequence during faults. The purpose of proposed Reliability Standard PER–006–1 is to ensure that personnel are trained on specific topics essential to reliability to perform or support real-time operations of the bulk electric system. In addition, the Commission proposes to direct NERC to develop certain modifications to proposed Reliability Standard PRC–027–1.

DATES: Comments are due January 29, 2018.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways:

- Electronic Filing through *http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures Section of this document.

FOR FURTHER INFORMATION CONTACT:
Juan Villar (Technical Information), Office of Electric Reliability, Division of Reliability Standards and Security, 888 First Street NE., Washington, DC 20426, Telephone: (772) 678–6496, *Juan.Villar@ferc.gov.*

Alan Rukin (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502–8502, *Alan.Rukin@ferc.gov.*

SUPPLEMENTARY INFORMATION:

1. Pursuant to section 215 of the Federal Power Act (FPA), the Commission proposes to approve proposed Reliability Standards PRC–027–1 (Coordination of Protection Systems for Performance During Faults) and PER–006–1 (Specific Training for Personnel), which were submitted for approval by the North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO).[1] As discussed below, however, the Commission also proposes to direct NERC to modify proposed Reliability Standard PRC–027–1 to require an initial protection system coordination study to ensure that applicable entities will perform (or have performed), as a baseline, a study demonstrating proper coordination of its protection systems. We propose to direct NERC to submit the modified Reliability Standard for Commission approval within 12 months following the effective date of a final rule in this proceeding.

2. The Commission also proposes to approve the associated violation risk factors, violation severity levels, implementation plans, and effective dates proposed by NERC for Reliability Standards PRC–027–1 and PER–006–1. The Commission further proposes to approve the retirement of currently-effective Reliability Standard PRC–001–1.1(ii) (System Protection Coordination).[2]

3. In addition, the Commission proposes to approve new and revised definitions submitted by NERC for incorporation in the NERC Glossary of Terms Used in NERC Reliability Standards (''NERC Glossary'') for the following terms: (1) ''protection system coordination study;'' (2) ''operational planning analysis;'' and (3) ''real-time assessment.''

[1] 16 U.S.C. 824o.

[2] The Commission approved Reliability Standard PRC–001–1.1(ii) on May 29, 2015. *North American Electric Reliability Corporation,* 151 FERC ¶ 61,186 (2015).

I. Background

A. Section 215 and Mandatory Reliability Standards

4. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval.[3] Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight or by the Commission independently.[4] In 2006, the Commission certified NERC as the ERO pursuant to section 215 of the FPA.[5]

B. Order No. 693

5. On March 16, 2007, the Commission issued Order No. 693, approving 83 of the 107 Reliability Standards filed by NERC, including Reliability Standard PRC–001–1.[6] In addition, the Commission directed NERC to develop modifications to Reliability Standard PRC–001–1 that:

> (1) Correct the references for Requirements, and [*sic*] (2) include a requirement that upon the detection of failures in relays or protection system elements on the Bulk-Power System that threaten reliable operation, relevant transmission operators must be informed promptly, but within a specified period of time that is developed in the Reliability Standards development process, whereas generator operators must also promptly inform their transmission operators; and (3) clarifies that, after being informed of failures in relays or protection system elements that threaten reliability of the Bulk-Power System, transmission operators must carry out corrective control actions, *i.e.,* return a system to a stable state that respects system requirements as soon as possible and no longer than 30 minutes after they receive notice of the failure.[7]

C. NERC Petition and Proposed Reliability Standards PRC–027–1 and PER–006–1

6. On September 2, 2016, NERC submitted a petition seeking Commission approval of proposed Reliability Standards PRC–027–1 and PER–006–1.[8] NERC states that the proposed Reliability Standards, new and revised NERC Glossary terms, and the retirement of Reliability Standard PRC–001–1.1(ii) satisfy the Commission's criteria in Order No. 672 and are just, reasonable, not unduly discriminatory or preferential, and in the public interest.[9] NERC explains that the intent of the proposed Reliability Standards and changes to the NERC Glossary are to maintain the coordination of protection systems installed to detect and isolate faults on bulk electric system elements and require registered entities to provide training to their relevant personnel on protection systems and remedial action schemes. NERC asserts that the proposed Reliability Standards are an improvement over currently-effective Reliability Standard PRC–001–1.1(ii) and will ensure that appropriate personnel are trained on protection systems and that protection systems are appropriately studied, coordinated, and monitored.

1. Proposed Reliability Standard PER–006–1

7. NERC states that proposed Reliability Standard PER–006–1 requires generator operators to use a systematic approach to develop and implement training for dispatch personnel at centrally-located dispatch centers.[10] NERC explains that proposed Reliability Standard PER–006–1 will also cover plant personnel who are responsible for real-time control of a generator. NERC maintains that it is appropriate to train plant personnel [in] the functionality of protection systems and remedial action schemes. NERC observes that proposed Reliability Standard PER–006–1 replaces the phrase ''purpose and limitations'' used in currently-effective Reliability Standard PRC–001–1(ii) with the phrase ''operational functionality'' to clearly identify the objective of the training.[11] NERC also observes that proposed Reliability Standard PER–006–1 replaces the phrase ''applied in its area'' in Reliability Standard PRC–001–1.1(ii) with the phrase ''that affect the output of the generating facility(ies) it operates'' to properly tailor the scope of the required training. NERC notes that proposed Reliability Standard PER–006–1 does not specify a periodicity for the required training.

2. Proposed Reliability Standard PRC–027–1

8. NERC asserts that proposed Reliability Standard PRC–027–1:

> provides a clear set of Requirements that obligate entities to (1) implement a process for establishing and coordinating new or revised Protection System settings, and (2) periodically study Protection System settings that could be affected by incremental changes in Fault current to ensure the Protection Systems continue to operate in their intended sequence.[12]

According to NERC, proposed Reliability Standard PRC–027–1, Requirement R1 mandates that each transmission owner, generator owner, and distribution provider establish a process for developing new and revised protection system settings for bulk electric system elements.[13]

9. NERC states that proposed Reliability Standard PRC–027–1, Requirement R2 mandates that every six years, applicable entities must either: (1) Perform a protection system coordination study to determine whether the protection systems continue to operate in the intended sequence during faults; (2) compare present fault current values to an established fault current baseline and, only if the comparison identifies a 15 percent or greater deviation in fault current values (either three phase or phase to ground) at a bus to which the bulk electric system is connected, perform a protection system coordination study; or (3) use a combination of options 1 and 2.[14]

10. NERC explains that proposed Reliability Standard PRC–027–1, Requirement R3 will require applicable entities to use the process established under proposed Reliability Standard PRC–027–1, Requirement R1 for the development of any new or revised protection system settings.

3. Proposed Retirement of Reliability Standard PRC–001–1.1(ii)

11. NERC states that Reliability Standard PRC–001–1.1(ii) includes six requirements that are either addressed by Reliability Standards approved by the Commission or by the proposed Reliability Standards. Specifically, NERC explains that Reliability Standard PRC–001–1.1(ii), Requirement R1 has been partially replaced by currently-effective Reliability Standards PER–003–1 and PER–005–2. NERC continues that proposed Reliability Standard PER–006–1 and the proposed revised definitions of operational planning

---

[3] *Id.* 824o(c), (d).

[4] *Id.* 824o(e).

[5] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *order on compliance,* 118 FERC ¶ 61,190, *order on reh'g,* 119 FERC ¶ 61,046 (2007), *aff'd sub nom. Alcoa Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[6] *Mandatory Reliability Standards for the Bulk-Power System,* Order No. 693, FERC Stats. & Regs. ¶ 31,242, at PP 1433–1449, *order on reh'g,* Order No. 693–A, 120 FERC ¶ 61,053 (2007).

[7] Order No. 693, FERC Stats. & Regs. ¶ 31,242 at P 1449.

[8] Proposed Reliability Standards PRC–027–1 and PER–006–1 are not attached to this Notice of Proposed Rulemaking. The proposed Reliability Standards are available on the Commission's eLibrary document retrieval system in Docket No. RM16–22–000 and are posted on the NERC Web site, *http://www.nerc.com.*

[9] NERC Petition at 10.

[10] *Id.* at 13.

[11] *Id.* at 15.

[12] *Id.* at 26.

[13] *Id.* at 27.

[14] *Id.* at 26.

analysis and real-time assessment will replace the remaining portions of Reliability Standard PRC–001–1.1(ii), Requirement R1. NERC asserts that Reliability Standard PRC–001–1.1(ii), Requirement R2 has been addressed by Reliability Standards IRO–001–4, IRO–008–2, IRO–010–2, TOP–001–3, and TOP–003–3, which the Commission approved in Order No. 817.[15] NERC states that Reliability Standard PRC–001–1.1(ii), Requirements R3 and R4 will be replaced with proposed Reliability Standard PRC–027–1. NERC also explains that Reliability Standard PRC–001–1.1(ii), Requirement R5 has been replaced with several Reliability Standards developed after Reliability Standard PRC–001–1(ii) became effective.[16] NERC further states that Reliability Standard PRC–001–1.1(ii), Requirement R6 has been replaced with Reliability Standards TOP–001–3 and TOP–003–3.

II. Discussion

12. Pursuant to section 215(d)(2) of the FPA, we propose to approve proposed Reliability Standards PER–006–1 and PRC–027–1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest, as both proposed Reliability Standards improve upon currently-effective Reliability Standard PRC–001–1.1(ii) in important ways.[17] Specifically, proposed Reliability Standard PRC–027–1 does so by (1) modifying the applicability section to include the appropriate functional entity types with the responsibilities, resources, and skill sets to conduct the studies required to coordinate protection systems, and (2) listing the protection system functions on all bulk electric system elements that require coordination. Proposed Reliability Standard PER–006–1, along with existing formal training requirements in the PER group of Reliability Standards, also improves upon Reliability Standard PRC–001–1.1(ii), Requirement R1 by ensuring that the necessary personnel are familiar with and understand the purpose and limitations of protection systems schemes while providing more precise and auditable requirements. However, proposed Reliability Standard PRC–027–1, Requirement R2, Option 2 does not appear to ensure coordination of all bulk electric system elements with protection system functions. Accordingly, pursuant to section 215(d)(5) of the FPA, we propose to direct that NERC develop modifications to proposed Reliability Standard PRC–027–1 that address our concern regarding this gap, as discussed below.

13. In addition, we propose to approve NERC's associated violation risk factors, violation severity levels, implementation plans, and effective dates. We also propose to approve the revised definitions for inclusion in the NERC Glossary. Further, we propose to approve the retirement of Reliability Standard PRC–001–1.1(ii), as requested by NERC.

14. Pursuant to 215(d)(5) of the FPA, we propose to direct that NERC develop modifications to proposed Reliability Standard PRC–027–1 addressing our concern that applicable entities that choose Requirement R2, Option 2 perform (or have already performed) an initial baseline study demonstrating proper coordination of their protection systems. Any additional protection system coordination studies would be necessary only if an applicable entity is confronted with 15 percent or greater fault current deviations from the prior baseline study amounts, as currently proposed in Reliability Standard PRC–027–1, Requirement R2, Option 2. We propose to direct NERC to submit the modified Reliability Standard within 12 months following the effective date of a final rule in this proceeding.

15. Proposed Reliability Standard PRC–027–1, Requirement R2 does not require an initial protection system coordination study if an applicable entity elects Option 2. Unlike Option 1, which requires performance of protection system coordination studies every six years, Option 2 requires applicable entities to ''[c]ompare present Fault current values to an established Fault current baseline and perform a Protection System Coordination Study when the comparison identifies a 15 percent or greater deviation.'' The proposed Reliability Standard and NERC's petition do not indicate that the ''Fault current baseline'' must be established through an initial protection system coordination study. Instead, NERC's petition states that the baseline must be established ''by the effective date of the standard based on short-circuit studies.'' [18] The proposed Reliability Standard provides that ''the initial Fault current baseline(s) shall be established by the effective date of this Reliability Standard and updated each time a Protection System Coordination Study is performed,'' but this language does not require establishing the ''initial Fault current baseline'' through an initial protection system coordination study.[19] NERC's petition reinforces this understanding, as noted above, by explicitly allowing the use of short-circuit studies to establish the initial Fault current baseline.

16. While they are related terms, we understand there to be a difference between short-circuit studies and protection system coordination studies. NERC defines protection system coordination study as an ''analysis to determine whether Protection Systems operate in the intended sequence during Faults.'' [20] By comparison, proposed Reliability Standard PRC–027–1 explains that a short-circuit study is ''an analysis of an electrical network that determines the magnitude of the currents flowing in the network during an electrical fault . . . [and] are used as the basis for protection device coordination studies.'' [21] Therefore, while short-circuit studies are inputs to protection system coordination studies, it appears that a short-circuit study differs in scope from a protection system coordination study. Based on this record, it would be incorrect to conclude that proposed Reliability Standard PRC–027–1, Requirement R2, Options 1 and 2 afford the same level of protection system coordination because the former requires a protection system coordination study while the latter does not.

17. While we generally support permitting flexibility in the Reliability Standards to achieve required performance goals, the possibility that some bulk electric system elements may never undergo a protection system coordination study raises reliability concerns. In past serious Bulk-Power System events, mis-coordination was a contributing factor to misoperations and outages. For example, the Arizona Southern California September 8, 2011 Outage Report identified an instance

[15] *Id.* at 5 (citing *Transmission Operations Reliability Standards and Interconnection Reliability Operations and Coordination Reliability Standards,* Order No. 817, 153 FERC ¶ 61,178 (2015)).

[16] *Id.* at 6.

[17] 16 U.S.C. 824o(d)(2).

[18] NERC Petition at 36 n.35.

[19] Proposed Reliability Standard PRC–027–1, Requirement R2, Option 2 n.1. Footnote 1 further states that if an ''initial baseline was not established by the effective date of this Reliability Standard because of the previous use of an alternate option or the installation of a new BES Element, the entity *may* establish the baseline by performing a Protection System Coordination Study'' (emphasis added). *Id.*

[20] NERC Petition, Exhibit A–3, Proposed Definitions. This definition is consistent with the definition of coordination of protection in IEEE Std. C37.113–1999 (stating that the ''process of choosing settings or time delay characteristics of protective devices, such that operation of the devices will occur in a specified order to minimize customer service interruption and power system isolation due to a power system disturbance'').

[21] Proposed Reliability Standard PRC–027–1, Supplemental Material at 8.

where a transmission owner did not perform a protection system coordination study prior to the implementation of a protection system.[22] The 2011 Outage Report stated that this omission negatively affected the reliable operation of the Bulk-Power System during the 2011 event.[23]

18. Over the past eleven years, several NERC reports have addressed the importance of protection system coordination to Bulk-Power System reliability. Proposed Reliability Standard PRC–027–1 addresses some of the issues raised in these reports; but without requiring an initial protection system coordination study, the proposed Reliability Standard does not address all of them. In 2006, for example, the NERC System Protection Control Task Force assessed Reliability Standard PRC–001.[24] The report recommended requiring the coordination of all existing protection systems.[25]

19. In 2009, in a letter from the NERC President to the NERC Board of Trustees and stakeholders, NERC identified generation and transmission mis-coordination as responsible for 30 percent of the misoperations that occurred between 2005 and 2008.[26] The 2009 letter stated that mis-coordination between generation and transmission protection systems ''has caused two significant system disturbances in the past two years, and resulted in the unnecessary loss of generation during seven additional disturbances in that timeframe.'' [27] The letter explained that the 2009 NERC System Protection Initiative would initially focus on the area of protection system coordination.[28]

20. In 2013, NERC issued a Misoperations Report prepared by the Protection System Misoperations Task Force.[29] The Misoperations Report identified ''ways to potentially reduce the amount of future misoperations'' and concluded that ''[m]isoperations due to setting errors can potentially be reduced.'' [30] The identified techniques to reduce incorrect settings, included: Peer reviews, increased training, more extensive fault studies, standard templates for setting standard schemes using complex relays, and periodic review of existing settings when there is a change in system topography.[31] In the ReliabilityFirst region, NERC identified a category of misoperations caused by ''Engineering/Design Issues,'' which specifically included setting mis-coordination.[32] This category of misoperations was one of the three most common causes of misoperations for above 200 kV facilities within the ReliabilityFirst region.[33] The positive impact on Bulk-Power System reliability of reducing misoperations because of ''Incorrect setting/logic/design errors'' is found in NERC's 2015 Analysis of System Protection Misoperations:

> The State of Reliability 2015 report found that protection system misoperations continued to be a significant contributor to automatic transmission outage severity. In general, transmission system events with protection system misoperations were more impactful than other transmission events. They were also a significant contributor to transmission outage severity, indicating that a reduction in protection system misoperations would lead to an improvement in system reliability.[34]

21. In 2014, a NERC ''lessons learned'' document on ''Generation Relaying—Underfrequency Protection Coordination'' identified a 2014 incident where underfrequency relay trip settings were installed on the system unnecessarily and were not coordinated with a generator's relay trip setting.[35] The document explained that ''[u]nintended generator tripping during an underfrequency event can exacerbate the condition.'' [36] The document also stated that ''generator relay protection should be coordinated with all auxiliary power system relaying with specific regard to time-delay settings'' in order to ensure reliable generator operation.[37]

22. The 2016 State of Reliability Report noted that while protection system misoperations declined in 2015, misoperations showed a ''statistically significant positive correlation with transmission outage severity and show[ed] a higher relative transmission risk.'' [38] Misoperations showed the strongest correlation of the factors considered. In addition, the 2016 State of Reliability Report identified that ''over 40 percent of the incorrect setting/logic/design misoperations were due to the miss coordination [*sic*] of ground overcurrent settings'' found by ERCOT.[39]

23. The 2017 State of Reliability Report recognized the significance of protection system misoperations to Bulk-Power System reliability by observing that ''[p]rotection system misoperations should remain an area of focus as it continues to be one of the largest contributors to the severity of transmission outages.'' [40]

24. For the reasons discussed above, we propose to direct that NERC develop modifications to proposed Reliability Standard PRC–027–1 to address our concern by requiring that applicable entities perform an initial protection coordination study under Requirement R2, Option 2. We propose that applicable entities would have six years from the effective date of a modified Reliability Standard to complete the analysis. An applicable entity could use pre-existing protection system coordination studies to satisfy the proposed requirement provided it was reasonable (*i.e.,* no intervening system changes that would render the earlier work obsolete). After conducting the initial protection system coordination study, subsequent protection system coordination studies would only be required when an applicable entity is confronted with 15 percent or greater fault current deviations from the prior baseline study amounts, as currently proposed in Reliability Standard PRC–027–1, Requirement R2, Option 2. We seek comments on this proposal.

25. Separately, we seek comment from NERC and other interested entities explaining the technical basis for

[22] Arizona Southern California September 8, 2011 Outage Report at 101–103, *https://www.ferc.gov/legal/staff-reports/04-27-2012-ferc-nerc-report.pdf.*

[23] *Id.* at 100–102.

[24] NERC SPCTF Assessment of Standard PRC–001–0—System Protection Coordination (2006), *http://www.nerc.com/pa/Stand/Project200706SystemProtectionCoordinationDL/NERC_SPCTF_Assessment_of_Standard_PRC.pdf.*

[25] *Id.* at 3–4.

[26] NERC Letter from Rick Sergel, NERC President, Regarding System Protection Initiative at Figure 2 (April 24, 2009).

[27] *Id.* at 1.

[28] *Id.* at 1–2.

[29] NERC Misoperations Report (2013), *http://www.nerc.com/comm/PC/Protection%20System%20Misoperations%20Task%20Force%20PSMTF%202/PSMTF_Report.pdf.*

[30] *Id.* at 3.

[31] *Id.*

[32] *Id.* at 14–15. The 2013 Misoperations Report elaborated that the ''Engineering/Design Issues'' category included:

> Incorrect short circuit values and coordination errors. The incorrect short circuit values included outdated or incorrect data used to calculate relay settings. The coordination errors in these cases all involved pilot protection either of insufficient carrier blocking trip delays or of improper choice of ground pickup values used in a blocking scheme. *Id.* at 15.

[33] *Id.* at 14.

[34] NERC, Analysis of System Protection Misoperations at 1 (Dec. 2015) (citations omitted), *http://www.nerc.com/pa/RAPA/PA/Performance%20Analysis%20DL/2015_Analysis_of_System_Protection_Misoperations_Final.pdf* (finding that 31 percent of all misoperations were due to ''Incorrect setting/logic/design errors'').

[35] NERC, Lesson Learned, Generation Relaying—Underfrequency Protection Coordination (2014), *http://www.nerc.com/pa/rrm/ea/Lessons%20Learned%20Document%20Library/LL20140601_Generation_Relaying_Underfrequency_Protection_Coordination_final.pdf.*

[36] *Id.*

[37] *Id.*

[38] 2016 State of Reliability Report at 17, *http://www.nerc.com/pa/RAPA/Pages/default.aspx.*

[39] *Id.* at 166.

[40] 2017 State of Reliability Report at 2.

employing a 15 percent deviation threshold in proposed Reliability Standard PRC–027–1, Requirement R2, Option 2. We seek to better understand the basis for this threshold to ensure an adequate record in the proceeding on this matter.

III. Information Collection Statement

26. The collection of information addressed in this Notice of Proposed Rulemaking is subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[41] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[42] Upon approval of a collection(s) of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of a rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

27. The Commission will submit the information collection requirement to OMB for its final review and approval. We solicit public comments on the need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

28. The information collection requirements in this Notice of Proposed Rulemaking in Docket No. RM16–22–000 are associated with FERC–725A,[43] FERC–725G6,[44] and FERC–725Y, as discussed below.

29. *Public Reporting Burden:* The number of respondents below is based on an examination of the NERC compliance registry on April 7, 2017, for transmission owners, generator owners, generator operators, and distribution providers within the United States and an estimate of how many entities from that registry will be affected by the Reliability Standards proposed for adoption and implementation. At the time of Commission review of proposed Reliability Standards PRC–027–1 and PER–006–1, 334 transmission owners, 913 generator owners, 875 generator operators, and 365 distribution providers in the United States were registered in the NERC compliance registry. However, under NERC's compliance registration program, entities may be registered for multiple functions, so these numbers incorporate some double counting. We note that many generation sites share a common generator owner or generator operator. The following table provides the estimated proposed annual burden and cost related to information collection requirements in this Notice of Proposed Rulemaking.[45]

PROPOSED CHANGES IN THE NOPR IN DOCKET NO. RM16–22–000

Respondent category and requirement[46]	Number of respondents	Annual number of responses per respondent	Total number of annual responses	Average burden hours and cost per response[47]	Annual burden hours and total annual cost (rounded)[48]
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
FERC–725G6 (Covering Proposed Reliability Standard PRC–027–1)[49]					
TO; Reporting Reqs. R1, R2, & R3	334	1	334	60 hrs.; $3,941.40 ..	20,040 hrs.; $1,316,428.
TO; Recordkeeping Reqs.	334	1	334	40 hrs.; $1,565.60 ..	13,360 hrs.; $522,910.
GO; Reporting Reqs. R1, R2, & R3	913	1	913	10 hrs.; $656.90	9,130 hrs.; $599,750.
GO; Recordkeeping Reqs.	913	1	913	10 hrs.; $391.40	9,130 hrs.; $357,348.
DP; Reporting Reqs R1, R2, & R3	365	1	365	10 hrs.; $656.90	3,650 hrs.; $239,769.
DP; Recordkeeping Reqs.	365	1	365	10 hrs.; $391.40	3,650 hrs.; $142,861.
Sub-Total for Reporting Reqs. for FERC–725G6.					32,820 hrs.; $2,155,947.
Sub-Total for Recordkeeping Reqs. for FERC–725G6.					26,140 hrs.; $1,023,119.
Total Proposed Increase for FERC–725G6.					58,960 hrs.; $3,179,066.
FERC–725Y (Covering Proposed Reliability Standard PER–006–1)					
GOP; Reporting Req. R1	875	1	875	5 hrs.; $328.45	4,375 hrs.; $287,394.
GOP; Recordkeeping Req.	875	1	875	10 hrs.; $391.40	8,750 hrs.; $342,475.
Total Proposed Increase for FERC–725Y					13,125 hrs.; $629,869.
Reductions to FERC–725A (Covering Proposed Retirement of Reliability Standard PRC–001–1.1)[50]					
GOP; Reporting Req.	875	1	875	40 hrs.; $2,627.60 ..	35,000 hrs.; $2,299,150.
GOP; Recordkeeping Req.	875	1	875	50 hrs.; $1,957.00 ..	43,750 hrs.; $1,712,375.

[41] 44 U.S.C. 3507(d).

[42] 5 CFR 1320.11.

[43] FERC–725A (OMB Control No. 1902–0244) currently includes the information collection requirements associated with Reliability Standard PRC–001–1.1(ii), which is proposed for retirement. Only one item per OMB Control No. may be pending OMB review at a time, and an unrelated item affecting FERC–725A is pending OMB review. We are providing estimates of the burden reduction related to FERC–725A for review and comment. However, to submit this Notice of Proposed Rulemaking timely to OMB, the Commission is being conservative and not reducing the burden estimates associated with FERC–725A at this time.

[44] The information collection requirements related to proposed Reliability Standard PRC–027–1 would normally be included in FERC–725G (OMB Control No. 1902–0252). However, only one item per OMB Control No. may be pending OMB review at a time, and an unrelated item affecting FERC–725G is pending OMB review. For this Notice of Proposed Rulemaking and the related submittal to OMB, we use a placeholder information collection no. of FERC–725G6.

[45] TO = transmission owner; TOP = transmission operator; GO = generator owner; GOP = generator operator; DP = distribution provider; and BA = balancing authority.

PROPOSED CHANGES IN THE NOPR IN DOCKET NO. RM16–22–000—Continued

Respondent category and requirement [46]	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of annual responses (1) * (2) = (3)	Average burden hours and cost per response [47] (4)	Annual burden hours and total annual cost (rounded) [48] (3) * (4) = (5)
TOP; Reporting Req.	177	1	177	60 hrs.; $3,941.40 ..	10,620 hrs.; $697,628.
TOP; Recordkeeping Req.	177	1	177	70 hrs.; $2,739.80 ..	12,390 hrs.; $484,945.
BA; Reporting Req.	99	1	99	32 hrs.; $2,102.08 ..	3,168 hrs.; $208,106.
BA; Recordkeeping Req.	99	1	99	20 hrs.; $782.80	1,980 hrs.; $77,497.
Reduction Sub-Total Reporting Reqs. for FERC–725A.	.....	.....	.....	.....	48,788 hrs.; $3,204,884.
Reduction Sub-Total Recordkeeping Reqs. for FERC–725A.	.....	.....	.....	.....	58,120 hrs.; $2,274,817.
Reduction, Sub-Total for FERC–725A	.....	.....	.....	.....	106,908 hrs.; $5,479,701 (reduction).
NET TOTAL REDUCTION FOR PROPOSED CHANGES IN NOPR IN RM16–22–000.	.....	.....	.....	.....	34,823 hrs.; $1,670,766 (reduction).

Titles: FERC–725G6 (Mandatory Reliability Standard PRC–027–1) and FERC–725Y (Mandatory Reliability Standards: Operations Personnel Training (PER–005–2 and PER–006–1).

Action: Revision to existing collections and proposed new information collection.

OMB Control Nos.: To be determined (FERC–725G6) [51] and 1902–0279 (FERC–725Y).

Respondents: Business or other for profit, and not for profit institutions.

Frequency of Responses: Annual recordkeeping and reporting requirements, with some reporting requirements being at least once every six years.

Necessity of the Information: Proposed Reliability Standards PRC–027–1 and PER–006–1 set forth requirements for coordination of protection systems and personnel training on specific topics essential to reliability. The Commission proposes to approve proposed Reliability Standards PRC–027–1 and PER–006–1, which will replace Commission-approved Reliability Standard PRC–001–1.1(ii). The proposed Reliability Standards PRC–027–1 and PER–006–1 improve upon the existing Reliability Standard PRC–001–1.1(ii) because the proposed Reliability Standards assign responsibilities to entities with more appropriate resources and skill sets to conduct studies required to coordinate protection systems. The proposed Reliability Standards also provide additional clarity to the applicable entities.

Internal review: The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

30. Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, Office of the Executive Director, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

31. Comments concerning the information collection proposed in this Notice of Proposed Rulemaking and the associated burden estimates should be sent to the Commission in this docket and may also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs [Attention: Desk Officer for the Federal Energy Regulatory Commission]. For security reasons, comments should be sent by email to OMB at the following email address: *oira_submission@omb.eop.gov.* Please refer to OMB Control Nos. to be determined (FERC–725G6) and 1902–0279 (FERC–725Y) in your submittal.

IV. Environmental Analysis

32. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[52] The action proposed here falls within the categorical exclusion in the Commission's regulations for rules that are clarifying, corrective or procedural, for information gathering, analysis, and dissemination.[53]

V. Regulatory Flexibility Act

33. The Regulatory Flexibility Act of 1980 (RFA) generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities.[54] The Small Business Administration (SBA) defines

[46] For each Reliability Standard, the Measure shows the acceptable evidence for the associated Reporting Requirement, and the Compliance section details the related Recordkeeping Requirement.

[47] Based on data from the Bureau of Labor Statistics, the average hourly cost (wages plus benefits) is $65.69/hour for an engineer, and $39.14/hour for a record clerk. The hourly cost for an engineer is used for reporting requirements; the hourly cost for a record clerk is used for recordkeeping requirements.

[48] For display purposes, the cost figures in column 5 have been rounded.

[49] Some of the reporting requirements are required at least every six calendar years. In this table, the Commission assumes that respondents might work on some of their elements each year; the annual burden estimate shown is one sixth of the burden associated with one complete six-year cycle. For example, for each transmission owner: (a) the annual reporting burden associated with Requirements R1, R2, and R3 is shown as 60 hours per year, and (b) the burden for the six-year cycle would be six times that, or a total of 360 hours.

[50] The estimates for average annual burden hours per response are based on Order No. 693, FERC Stats. & Regs. ¶ 31,242 at PP 1906, 1907. The numbers of respondents and estimated hourly costs are based on current figures.

[51] OMB will assign a Control No. when it issues a decision.

[52] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[53] 18 CFR 380.4(a)(2)(ii).

[54] 5 U.S.C. 601–612.

which utilities are small businesses based on the number of employees that a utility and its affiliates employ.[55]

34. The proposed Reliability Standard PRC–027–1 (included in FERC–725G6) will apply to approximately 1,612 entities (334 transmission owners, 913 generator owners, and 365 distribution providers) in the United States.[56] Pursuant to SBA regulations, the employment threshold for transmission is 500 employees, for generator owners is between 250 and 750 employees (depending on the fuel source), and for distribution providers is 1,000 employees. We estimate that the annual cost for each entity will be $1,048 for each generator owner and distribution provider and $5,507 for each transmission owner.

35. The proposed Reliability Standard PER–006–1 (included in FERC–725Y) will apply to approximately 875 generator operators in the United States. Pursuant to SBA regulations the employment threshold for generator operators is between 250 and 750 employees (depending on the fuel source). We estimate that the annual cost for each generator operator will be $719.

36. In addition, this Notice of Proposed Rulemaking proposes the retirement of Reliability Standard PRC–001–1.1(ii) (included in FERC–725A). That retirement would decrease the annual estimated cost for 875 generator operators by $4,585 each, for 177 transmission operators by $6,681 each, and for 99 balancing authorities by $2,885 each. For the generator operators affected by this retirement and the proposed Reliability Standard PER–006–1, the net annual effect would be a decrease of $3,866 each. We estimate the net annual cost of this Notice of Proposed Rulemaking would vary, by type of entity, from an annual decrease of $6,681 (for each transmission operator) to an annual increase of $5,507 (for each transmission owner). We view this as a minimal economic impact for each entity. Accordingly, we certify that the proposed Reliability Standards PRC–027–1 and PER–006–1 and retirement of Reliability Standard PRC–001–1.1 (ii) will not have a significant economic impact on a substantial number of small entities.

VI. Comment Procedures

37. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due January 29, 2018. Comments must refer to Docket No. RM16–22–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

38. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

39. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

40. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

41. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

42. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

43. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

By direction of the Commission.

Issued November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25586 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

[55] 13 CFR 121.201, Subsector 221.

[56] Many respondents serve multiple roles in the NERC compliance registry, so there is likely double counting in the estimates.

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Chapter II

Report on Potential Actions To Reduce Regulatory Burdens on Domestic Energy Production

AGENCY: Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers (Corps) has issued a report that examined actions it could take to modify existing regulations that potentially burden the development and use of domestically produced energy resources, such as oil, natural gas, coal, and nuclear energy, as well as renewable energy. The report was required by Executive Order 13783, Promoting Energy Independence and Economic Growth. The report identifies changes that could be made to several nationwide permits that authorize activities under section 10 of the Rivers and Harbors Act of 1899 and section 404 the Clean Water Act that are associated with domestic energy production and use.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW–CO–R, 441 G Street NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson at 202–761–4922 or access the U.S. Army Corps of Engineers Regulatory Home Page at *http://www.usace.army.mil/Missions/CivilWorks/RegulatoryProgramandPermits.aspx*.

SUPPLEMENTARY INFORMATION: Executive Order (E.O.) 13783, Promoting Energy Independence and Economic Growth, was published in the **Federal Register** on March 31, 2017 (82 FR 16093). That E.O. requires federal agencies to immediately review existing regulations that may burden the development or use of domestically produced energy resources. Section 2 of E.O. 13783 requires federal agencies to prepare and issue reports with specific recommendations to change their regulations that could reduce or eliminate burdens to domestic energy production.

On October 25, 2017, the Corps issued a report recommending changes to nine nationwide permits to reduce burdens on domestic energy producers. The report is available at: *http://www.usace.army.mil/Portals/2/docs/civilworks/nwp/NWP_13783_25sept2017_castle.pdf?ver=2017-10-25-092532-813.*

The Corps issues nationwide permits to authorize certain categories of activities that require Department of the Army permits under section 404 of the Clean Water Act and/or section 10 of the Rivers and Harbors Act of 1899. Nationwide permits are general permits that authorize activities across the country that result in no more than minimal individual and cumulative adverse environmental effects. Nationwide permits can be issued for a period of 5 years, and the current nationwide permits were issued on December 21, 2016. Those nationwide permits were published in the **Federal Register** on January 6, 2017 (82 FR 1860) and went into effect on March 19, 2017. Those nationwide permits expire on March 18, 2022. There are 52 nationwide permits, and the report identifies 12 nationwide permits that authorize activities associated with domestic energy production and use. The report suggests modifications to nine of those nationwide permits to reduce burdens on domestic energy producers.

The nine nationwide permits (NWPs) recommended for changes include: NWP 3, Maintenance; NWP 12, Utility Line Activities; NWP 17, Hydropower Projects; NWP 21, Surface Coal Mining Activities; NWP 39, Commercial and Institutional Developments; NWP 49, Coal Remining Activities; NWP 50, Underground Coal Mining Activities; NWP 51, Land-Based Renewable Energy Generation Projects; and NWP 52, Water-Based Renewable Energy Generation Pilot Projects.

The Corps will coordinate with the administration to determine if the recommended changes in the report will be pursued. Any modifications to the nine nationwide permits identified in the report would require rulemaking to change those nationwide permits. That rulemaking process requires publishing a proposed rule in the **Federal Register** to solicit comments on the proposed changes to the nationwide permits, evaluating the comments received, and issuing a final rule to modify those nationwide permits. Modification of those nationwide permits will also require, as applicable, water quality certifications under section 401 of the Clean Water Act and consistency determinations under the Coastal Zone Management Act.

Dated: November 17, 2017.

Thomas P. Smith,

Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2017–25554 Filed 11–27–17; 8:45 am]

BILLING CODE 3720–58–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 96

[GN Docket No. 17–258; FCC 17–134]

Promoting Investment in the 3500–3700 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes and seeks comment on reforms of its licensing rules governing Priority Access Licenses (PALs) in the 3550–3700 MHz band (3.5 GHz Band). Specifically, the Commission proposes extending PAL license terms from three years to 10 years, with the possibility for renewal; seeks comment on increasing the PAL geographic licensing area; proposes to allow portioning and disaggregation of PALs on the secondary market; and proposes to amend the rules governing assignment of PALs. The Commission also proposes to remove a rule requiring public disclosure of device registration information, and seeks comment on changes to the technical rules to allow operation over wider bandwidths.

DATES: Interested parties may file comments on or before December 28, 2017, and reply comments on or before January 29, 2018.

ADDRESSES: You may submit comments, identified by GN Docket No. 17–258, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS): *http://fjallfoss.fcc.gov/ecfs2/. See* Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (1998).
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Generally, if more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Commenters are only required to file copies in GN Docket No. 13–111.
- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: Jessica Greffenius, *Jessica.Greffenius@fcc.gov,* of the Wireless Telecommunications Bureau, Mobility Division, (202) 418–2896.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (*NPRM*) in GN Docket No. 17–258, FCC 17–134, released on October 24, 2017. The complete text of the *NPRM* is available for viewing via the Commission's ECFS Web site by entering the docket number, GN Docket No. 17–258. The complete text of the *NPRM* is also available for public inspection and copying from 8:00 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 202–488–5300, fax 202–488–5563.

Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Government Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

The proceeding this *NPRM* initiates shall be treated as a ''permit-but-

disclose'' proceeding in accordance with the Commission's *ex parte* rules (47 CFR 1.1200 *et seq.*). Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules. We find that all *ex parte* presentations made by NTIA or Department of Defense representatives are exempt under our exemption for presentations by federal agencies sharing jurisdiction with the Commission (*see* 47 CFR 1.1204(a)(5)).

Synopsis

I. Introduction and Background

In this Notice of Proposed Rulemaking in GN Docket No. 17–258 (*NPRM*), the Commission seeks comment on several proposed changes to the rules governing Priority Access Licenses (PALs) that will be issued in 3550–3700 MHz band (3.5 GHz Band)—including longer license terms, renewability, larger geographic license areas, and auction methodology. These changes are consistent with the service rules and license assignment models that helped foster the development of 4G and LTE services in the United States. We anticipate that adopting similar rules for the 3.5 GHz Band similarly will encourage robust investment in network deployment. We also seek comment on changes to the technical rules that could facilitate operations over wider bandwidths while ensuring that current and future incumbent operations continue to be protected from interference. In addition, we seek changes to the information security requirements that would help safeguard private information and protect critical infrastructure.

In 2015, the Commission adopted rules for commercial use of 150 megahertz in the 3.5 GHz Band. Specifically, the *First Report and Order* in GN Docket No. 12–354, adopted April 15, 2015 and released April 21, 2015 (FCC 15–47), created a three-tiered framework to coordinate shared federal and non-federal use of the band. Incumbents comprise the highest tier and receive protection from all other users, followed by PAL, the second tier, and General Authorized Access (GAA), the third tier. PALs receive protection from GAA operations; GAA is licensed-by-rule and must accept interference from all other users. Automated frequency coordinators, known as Spectrum Access Systems (SASs), will coordinate operations between and among users in different access tiers. The service and technical rules governing the 3.5 GHz Band were adopted as the new Part 96 of the Commission's rules.

In June 2017, both CTIA and T-Mobile (together, Petitioners) filed petitions for rulemaking, which ask the Commission to reexamine several of the PAL licensing rules. CTIA proposes several changes to the PAL licensing rules; T-Mobile supports CTIA's proposals and makes additional proposals, including proposed changes to the amount of spectrum available for PALs and to the technical rules governing the 3.5 GHz Band. Petitioners argue that these changes are necessary to promote 5G network deployment in the Citizens Broadband Radio Service.

The Wireless Telecommunications Bureau and Office of Engineering and Technology sought comment on the Petitions—and on related issues raised in *ex parte* communications—on June 22, 2017 (DA 17–609), and received comments and reply comments from more than 120 parties.

II. NPRM

A. PAL Licensing Rules

1. License Term and Renewability

The rules adopted in the *First Report and Order* established a three-year license term for PALs. Under the current rules, at the end of its term, a PAL will terminate automatically and may not be renewed. During the first application window, however, an applicant may apply for up to two consecutive three-year terms for a given PAL. During subsequent regular application windows, only the next three-year license term will be made available for any given PAL.

Petitioners ask the Commission to increase the PAL license term to ten years, and to include an expectation of renewal. Petitioners and some commenters argue that a longer, renewable license term will better encourage investment in the 3.5 GHz Band, stressing that a three-year term with automatic termination creates a risk that Priority Access licensees will face stranded investment in just three (or, initially, six) years. Petitioners and some commenters also disagree with the assumption underlying the current rule—that a user's ability to switch between Priority Access and GAA use will provide sufficient incentives for investment. T-Mobile argues that the current rule does not account for challenges ''that providers have reported experiencing in the real world today'' that can delay network deployment. For example, CTIA cites difficulties in obtaining siting approvals, which they argue are magnified in this band, given the complexity of rolling out a high number of small cell deployments.

CTIA and several commenters also note that a ten-year, renewable licensing scheme is consistent with the Commission's ''proven approach'' in most other licensed mobile bands, including the bands at issue in the *Spectrum Frontiers* proceeding which, like the 3.5 GHz Band, ''will see network deployments comprised mostly of small cells.'' Others argue that ten-year terms would harmonize the U.S. approach with the global approach to actively encourage 5G network deployment in the mid-band spectrum.

Other commenters, however, support the existing rules. They argue that that a longer, renewable license—combined with other potential rule changes sought by the Petitioners—would make PALs economically viable investments only for large entities, and would convert the 3.5 GHz Band from an innovative framework into a traditionally licensed

band. These commenters also argue that the investments already made in the band based on the current rules belie concerns about barriers to investment and that any changes to the band should permit a diversity of deployment models and use cases and not be solely designed for the benefit of one (*i.e.,* 5G).

We propose to revise our rules by increasing the PAL license term from three years to ten years and by eliminating the requirement that PALs automatically terminate at the end of the license term. We also seek comment on this change and on the appropriate performance requirements and renewal standards for PALs. This approach is consistent with that adopted for other wireless services and will afford each licensee sufficient time to design and acquire the necessary equipment and devices and to deploy facilities across the license area. We invite detailed comments on this proposal from all stakeholders.

We seek comment on whether the proposed rule changes will affect investment already made, as well as how they will incentivize future investment, in this band. What specific impact will a longer, renewable license have on investments and business plans already underway? How will the proposal affect investment in the future, particularly given the longer term of ten years and the possibility of renewal? To what extent would a longer license term with the possibility of renewal facilitate the deployment of a wide array of technologies?

We also seek comment on how a longer, renewable license term for PALs could affect deployments in rural areas. Does the proposed rule change effectively promote the development and rapid deployment of new technologies, products, and services to benefit the public, including those residing in rural areas? Given concerns raised by the Wireless Internet Service Providers Association (WISPA) and other commenters about access to spectrum in rural areas, does the proposed rule change appropriately balance the objectives in Section 309(j) (47 U.S.C. 309(j))? Do these arguments present a persuasive case for maintaining the current three-year license term for PALs in rural areas? Further, does extending the license term to ten years lead to barriers to exit for companies that could impede innovation and investment or is the ability to return a license to the Commission sufficient to allay such concerns?

Additionally, we seek comment on alternative approaches to the length of the license term, including different, hybrid approaches for particular subsets of PALs (*e.g.,* three years for some PALs, five years for some, and ten for yet others). Many of these other approaches are already in the record. For example, Charter proposes a six-year renewable term, Motorola Solutions proposes a five-year term with only a single renewal allowed, and Southern Linc and WISPA suggest that a subset of PALs could have a five-year term, with PALs seeking renewal paying a fee. What other alternative licensing terms and conditions might be appropriate for this band? What impact would these alternatives have on investment, deployment, and on smaller or rural entities seeking PALs? Commenters that submit alternative proposals should include a cost-benefit analysis to support their approach.

If the license term is increased to ten years with the possibility of renewal, PALs would more closely resemble other licenses issued by the Commission under its auction authority. Such licenses include performance requirements—typically construction requirements—and many services also include renewal standards. Some commenters argue that, if PALs are licensed for a ten-year, renewable term, the Commission should impose construction requirements on Priority Access licensees, as it has for other licensed wireless services. We seek comment on whether, if we adopt longer term, renewable PALs, it would serve the public interest to adopt certain performance requirements to ensure that the spectrum is put to its best use in an efficient and effective manner. If so, what types of performance requirements would be appropriate? Which performance metrics (*e.g.,* population coverage, geographic coverage) and benchmarks would be appropriate? Does the opportunistic GAA use of the band—including unused PAL channels—alleviate concerns involving spectrum warehousing or otherwise satisfy the Commission's statutory obligations? If so, how can we take that into account in determining performance requirements for longer term, renewable PALs?

In addition, to obtain renewal, a licensee generally must show that it has continued to provide at least the initially-required level of service necessary to satisfy its performance requirement, and that it has substantially complied with the Communications Act and Commission rules. If we adopt the proposed changes to PALs, what standard, if any, would be appropriate for the Commission to apply at the end of the PAL license term to determine whether renewal is warranted? Would such a requirement be appropriate in this band? If so, how should it be applied and what level of service should be used as a renewal standard?

Some commenters have argued that, instead of renewability, the licenses should be reauctioned at the end of the license term. For example, Paul Milgrom describes an auction format under which an incumbent would be required to bid for a renewal of its license at the end of the license term, but it would be given a bidding credit so that, if it won, it would have to pay only a fraction of the auction-determined price. Moreover, if the incumbent loses, it would be compensated with a transferable bidding credit to apply to the purchase of other outcomes. Milgrom argues that this would mitigate the risk that the incumbent licensee's investments may become stranded. We seek comment on this approach and its assumptions, as well as on other approaches that might offer an alternative to renewability and still encourage robust investment in the band. Could this approach promote competition and efficient use of spectrum?

2. Geographic License Area

The *First Report and Order* defined the geographic license area for each PAL as one census tract. Petitioners request that the Commission increase the geographic licensing area from census tracts to Partial Economic Area (PEAs). T-Mobile argues that doing so would ''be consistent with the geographic licensing area that the Commission has already identified as best for 5G operations'' in the Spectrum Frontiers proceeding. Petitioners and some commenters contend that licensing PALs on a census tract-basis—which could result in over 500,000 PALs—will be challenging for SAS Administrators, the Commission, and licensees to manage, and will create unnecessary interference risks due to the large number of border areas that will need to be managed and maintained. Petitioners and some commenters contend that these challenges ultimately will make PALs unattractive to licensees and reduce investment. They argue that PEAs are small enough to allow for flexible and targeted networks, but large enough to reduce border areas and decrease administrative burdens. Some commenters also contend that a larger license area (along with a longer, renewable license term) will promote global harmonization of the 3.5 GHz Band for 5G development.

Many commenters oppose expanding the geographic license area of PALs

from census tracts to PEAs or other larger areas. These commenters argue that PEAs—especially in combination with other potential changes to the PAL licensing rules—could foreclose smaller entities from participating in the PAL auction. Some commenters similarly contend that enlarging the geographic area and extending the license term will effectively grant permanent spectrum rights to large carriers, and upend planned business models for targeted, local, and rural uses. Some of these commenters—including, Google and Sony, which have applied to be SAS Administrators—argue that managing licenses in over 70,000 geographic areas would not pose an undue burden ''given the meaningful advances in database management, cloud computing, and other technologies and engineering systems in recent years.''

NCTA and Charter suggest that county-sized license areas could strike a balance between preserving low barriers to entry and minimizing administrative burdens. Some commenters propose using a hybrid approach to offer more than one PAL license size (*e.g.,* offering some licenses by PEAs and others by county or census tracts). GeoLinks similarly asks us to consider whether rural areas would benefit more from using census tracts or counties to ensure more timely broadband access to rural communities, while more urban areas could benefit from using PEAs.

We seek comment on increasing the geographic licensing area of PALs to stimulate additional investment, promote innovation, and encourage efficient use of spectrum resources. We seek comment on this proposal and on the potential effects of this change on investment in and use of the 3.5 GHz Band. We also seek comment on whether a larger license area would provide additional flexibility to facilitate the deployment of a wide variety of technologies, including 5G.

We seek comment on Petitioners' specific request to increase the license size of PALs to PEAs, and how this would affect investment in PALs—both investments currently underway and future PAL investment—and diversity of PAL uses and users. Would PEAs strike an appropriate balance between facilitating access to spectrum by both large and small providers while incentivizing investment in, and rapid deployment of, new technologies? We also note that, like census tracts, counties nest into PEAs, which in turn nest into EAs. This nesting would make it easier for operators to combine or partition their PEAs into the license area of their choice. Would the larger size of PEAs and the ability to combine and partition licenses to customize service areas effectively address the concerns raised by commenters and promote robust deployment in the band? Commenters should include cost-benefit analyses when comparing licensing PALs on a PEA-basis versus a census tract-basis, as well as for options in between these choices (*e.g.,* licensing on a county-basis). Would PEAs effectively balance the objectives set forth in Section 309(j) of the Act (47 U.S.C. 309(j)), including encouraging ''efficient and intensive'' use of the 3.5 GHz spectrum and prescribing license area designations that promote ''an equitable distribution of licenses and services among geographic areas'' and ''economic opportunity for a wide variety of applications''? What impact would licensing PALs using PEAs have on smaller entities, rural deployments, and existing investments? Would PEA-based licensing facilitate compatible, authorized users and uses occupying the same spectrum?

We also seek comment on alternatives or hybrid approaches, including those already in the record. Would counties, or a combination of PAL license areas (*e.g.,* a hybrid combination of PEAs in urban areas and census tracts in rural areas, offering PALs of different sizes, such as PEAs and census tracts, or some other combination) ensure a diversity of auction participants, differing technologies, and rural deployments? Since we are offering seven PALs, commenters in favor of offering different license sizes in rural and urban areas should discuss what would be the appropriate balance between larger geographic areas and census tracts. Are there other possibilities that could promote such objectives? Should the Commission reconsider package bidding of census tracts or other geographic areas for a limited number of PALs? Would this approach promote our objectives? Would package bidding, bidding credits for certain bidders or areas, or other auction design mechanisms be appropriate for us to consider if we were to increase the license area? Specifically, we seek comment on whether we should adopt the bidding credits we used in the 600 MHz Band (Incentive Auction). Commenters should include a cost-benefit analysis of their proposed alternatives or hybrid approaches and discuss how their proposed approach appropriately balances the objectives set forth in Section 309(j) of the Act (47 U.S.C. 309(j)).

In addition, we seek comment generally on how changes to the license area (on their own, and in combination with changes to the license term) could affect auction complexity. How might such changes affect bidding strategies? How would a combination of license areas affect the auction mechanism and bidding strategies? Are there insights from bidders' experience during recent auctions that may be relevant in this context?

In light of the proposed change to modify the geographic license area, as well as any other changes considered in this *NPRM,* should the Commission modify the current 40 megahertz spectrum aggregation limit? Should we remove it altogether? What are the costs and benefits of higher or lower limits? How would changes affect competition and new entrants?

3. Secondary Markets

In the *Second Report and Order* in GN Docket No. 12–354 (FCC 16–55), the Commission prohibited Priority Access licensees from partitioning or disaggregating their licenses because the Commission found typical reasons for permitting partitioning and disaggregation in more traditionally licensed bands were not present in the 3.5 GHz Band. The Commission also determined that a light-touch leasing process could achieve the goal of making PAL spectrum use rights available in secondary markets—on a targeted, flexible basis—without the need for the Commission oversight required of partitioning and disaggregation.

In its Petition, T-Mobile asks the Commission to consider allowing partitioning and disaggregation of PALs, if it permits licensing on a PEA basis. Several commenters agree that allowing partitioning and disaggregation will help ensure that PAL spectrum rights flow to their best use and support a wide variety of deployments. These commenters also argue that partitioning and disaggregation will encourage service to targeted areas, mitigating concerns that licensing larger area PALs might result in in inefficient spectrum use.

Several commenters oppose the concept of secondary market transactions as a replacement for smaller geographic areas and shorter term PALs to encourage efficient use of spectrum by a variety of users. They argue that there is no guarantee that the licensee will lease or sell idle spectrum in the secondary market. Other commenters, however, suggest that, if the Commission were to make changes to the PAL license term, renewability, and geographic area, then the ability of a PAL licensee to partition or disaggregate its license on the secondary market could be a useful tool to ensure

robust and targeted use of the spectrum throughout the license area.

We propose to allow partitioning and disaggregation of PALs in secondary market transactions. Allowing partitioning and disaggregation would be consistent with other changes considered in this *NPRM,* and is consistent with the licensing paradigm for other similarly licensed services. We also anticipate that the ability to partition and disaggregate a PAL will be an effective way to improve spectral efficiency and facilitate targeted network deployments, particularly if the Commission adopts a longer license term or larger license area for PALs. We seek comment on this proposal and its underlying assumptions. If we were to adopt a larger geographic license area for some or all PALs, would allowing partitioning and disaggregation of PALs enable prospective PAL licensees to acquire PAL rights in smaller geographic areas where their business needs call for it? Are partitioning and disaggregation effective means to facilitate the ability of small entities to access the spectrum they desire for targeted, local deployments? If the Commission does not adopt some or all of the other proposed revisions to PALs, should we still allow partitioning and disaggregation? If so, why? To what extent would partitioning and disaggregation help the Commission facilitate the objectives of Section 309(j) (47 U.S.C. 309(j)), which, among other considerations, asks us to promote ''economic opportunity for a wide variety of applications''?

We note that several commenters argue the PAL licensees will lack an incentive to disaggregate or partition a larger, longer-term PAL. T-Mobile, in response, suggests that this ''can be remedied by adopt[ing] reasonable performance requirements associated with renewal expectations.'' We seek comment on the relationship between secondary market transactions and performance requirements. What types of requirements would be appropriate to encourage a robust secondary market for PALs to facilitate targeted and intensive spectrum use? How would requirements related to secondary markets interplay with construction requirements for PALs more broadly? How could performance requirements and secondary markets incentivize users to provide service to rural and other difficult-to-serve areas?

4. SAS Public Disclosure of CBSD Registration Information

In the *First Report and Order,* the Commission required that SAS Administrators make Citizens Broadband Radio Service Device (CBSD) registration information available to the general public. When doing so, however, SAS Administrators must ''obfuscate the identities of the licensees.'' In doing so, the Commission acknowledged ''the concerns raised by commenters about disclosure of confidential business information to the public.''

Both CTIA and T-Mobile, supported by several commenters, ask the Commission to eliminate the rule requiring public disclosure of CBSD registration information. Petitioners assert that the rule raises both competitive concerns and ''cybersecurity and national security concerns.'' AT&T also claims that ''the SAS will be required to collect extensive data regarding users' network configuration, uses, and technical parameters''—data that ''amounts to critical infrastructure data'' that must be adequately protected to avoid competitive and cybersecurity concerns.'' In addition, Petitioners and commenters argue that obfuscating the licensees' identities does not adequately address these concerns because it still may be possible to uncover the identities of individual licensees based on publicly available information. Petitioners and commenters also contend that, since potential GAA operators can coordinate directly with the SAS Administrators to deploy GAA services, the public disclosure requirement is unnecessary to ensure that operations in the band are effectively coordinated.

Google, Open Technology Institute and Public Knowledge (OTI/PK), and WISPA support retention of the current rule, arguing that it benefits potential operators that need to investigate the feasibility of deploying GAA or PAL service before incurring the cost of attempting to reserve or auction spectrum. OTI/PK contends that meaningful transparency allows incumbents and public advocacy groups to play a productive role in holding SAS Administrators and other stakeholders accountable for responsibilities such as military radar protection and ensuring that valuable PAL spectrum does not lie fallow. Google denies that anonymized public registration data presents security or competitive concerns and argues that such information is already available, as wireless carriers' transceiver locations are visible to a passerby, logged by crowd-sourced applications, and publicly documented. Google also notes that several aspiring SAS Administrators—including CTIA—already have negotiated a model sharing agreement, and that CTIA itself has stated that the agreement ''provides the necessary protections for SAS customers' proprietary and competitively sensitive information, as well as end users' private information.'' In response, AT&T argues that the model sharing agreement that Google references addresses SAS-to-SAS information sharing, not public availability of information, and that Google incorrectly assumes that licensees plan network deployment based on activities of others rather than on internal objectives and consumer behavior.

Charter, Federated Wireless, and NCTA encourage the Commission to seek comment on how it could ensure that prospective users of the band can obtain sufficient information to execute network deployments without disclosing detailed CBSD registration information to the public.

We propose to amend the current rules to prohibit SASs from disclosing publicly CBSD registration information that may compromise the security of critical network deployments or be considered competitively sensitive. We seek comment on the proposal and ask which specific information should be withheld from public disclosure to address the concerns raised by Petitioners and Commenters. We ask commenters to address the potential competitive, security, or other forms of risk presented by the rule, as well as on specific and actionable suggestions to mitigate these risks. Nothing we propose here will affect SAS-to-SAS information sharing requirements.

We also note that some commenters claim that potential GAA and PAL users will use registration information to plan deployments. As such, we seek comment on how to appropriately balance the potential competitive and security risks with potential users' need for information about CBSD deployment. Is there a mechanism—other than full public disclosure of CBSD registration information—for potential users to plan future GAA and/or PAL deployments? For example, could potential users communicate with an SAS on a confidential basis? We also seek comment on whether there is certain information that the SAS can publicly provide while balancing data sensitivity and security concerns.

5. Competitive Bidding Procedures for PALs

a. Assignment of PALs

Section 309(j) of the Communications Act (47 U.S.C. 309(j)) requires that the Commission assign licenses using competitive bidding when ''mutually

exclusive applications are accepted for any initial license,'' subject to certain exemptions not applicable to this band. Because of the ''generic'' nature of PAL frequency assignments, mutual exclusivity exists when multiple applicants apply to bid on more PALs than exist in a given census tract. In the *First Report and Order,* the Commission decided that, when there are two or more applicants for PALs in a given census tract, it will make available one fewer PAL than the total number of PALs for which all applicants have applied in that license area, up to a maximum of seven PALs. The Commission also concluded that assigning PALs on a non-auctioned basis would not result in the most efficient assignment of the spectrum. It therefore decided that, where there is only a single applicant for one or more PALs in a license area, it would not proceed to an auction or assign any PALs for that license area and there would only be shared GAA access to that spectrum until the next filing window for competitive bidding. In its *Order on Reconsideration* in GN Docket No. 12–354 (FCC 16–55), the Commission granted a limited exception for certain rural areas, finding it in the public interest to assign a PAL even if there is only a single applicant, given the likelihood of lower demand in rural areas.

T-Mobile and several commenters ask the Commission to make all PALs available, regardless of the number of applications the Commission receives in any given license area. GeoLinks argues that, by prohibiting the assignment of PALs when there is only one interested carrier, the Commission will ''surely create gaps in rural, sparsely populated parts of the country that could benefit from an interested service provider.'' Further, several commenters, like AT&T and Ericsson, argue that the Commission's current policy will eventually phase out PAL licenses in a market with each subsequent auction if there is no renewal expectancy, rendering the auctions ''essentially a game of musical chairs for PAL licensees.'' No commenter opposes T-Mobile's mutual exclusivity proposal specifically.

United States Cellular Corporation (USCC) argues that the Commission should assign PALs in any given license area by subjecting all PALs to a minimum opening bid and the existing spectrum aggregation limit of four PALs. If the aggregate demand in a license area does not exceed seven PALs, USCC suggests that the applicant(s) would receive the number of PALs for which they applied, subject to the payment of the minimum opening bid for those PALs, and remaining spectrum would be available on a GAA basis.

Consistent with our proposals to lengthen the PAL license term, make them renewable, and increase the PAL geographic license area, we also propose to employ our standard practice for finding mutual exclusivity among accepted applications. We propose to eliminate the rule that limited the number of PALs the Commission would make available. We also propose to assign PALs even when there is only one applicant in a given license area, assuming the applicant is otherwise qualified. We seek comment on these changes, which appear consistent with the broad opposition to the current requirements already in the record. The other proposed changes to PAL licensing discussed in this *NPRM*—including longer, renewable license terms and a larger geographic area—would make PALs more similar to licenses offered in the Incentive Auction and other recent spectrum auctions, where there was no need for the requirements in Sections 96.29(c) and 96.29(d) of our rules (47 CFR 96.29(c) and 47 CFR 96.29(d)). We seek comment on this proposal. What are the costs and benefits of removing these requirements? Are these changes consistent with the statutory objectives of Section 309(j) (47 U.S.C. 309(j)), including to ''promot[e]economic opportunity and competition,'' ''ensur[e] that new and innovative technologies are readily accessible,'' ''avoid[ ] excessive concentration of licenses'' and ''disseminat[e] licenses among a wide variety of applicants''; ''recover[ ] for the public of a portion of the value of the of the public spectrum''; and promote ''efficient and intensive use of electromagnetic spectrum.'' Additionally, as fully described below, we also seek comment on whether a PAL for any given license area is mutually exclusive to GAA use in that area such that the Commission would have the authority to assign PALs by auction in those situations.

In the *First Report and Order,* the Commission adopted these two limitations on the assignment of PALs because it concluded that assigning PALs on a non-auctioned basis would not result in as efficient an assignment of the spectrum as licensing the spectrum for shared GAA use. The Commission found that ensuring widespread GAA use of spectrum in any geographic area for which it had not received mutually exclusive PAL applications was the best way to discharge its statutory obligation to ''encourage the larger and more effective use of radio in the public interest.'' However, the Commission reached these conclusions regarding nonrenewable PALs that had substantially shorter license terms than we are now proposing to adopt for PALs. Under our current proposals, the use case for PALs could vary more significantly from GAA use than under our current rules. The Commission also noted in the First Report and Order that the determination of mutual exclusivity of PAL applications would not be a one-time event for this band, because PALs would be licensed for three-year, non-renewable terms and the Commission would periodically open application windows for new PALs, as well as interim filing windows to accept applications for unassigned PALs. If we adopt our proposal to increase PAL license terms to 10 years, such frequent application or filing windows likely would not be necessary. We seek comment on whether the circumstances that will pertain if our proposals regarding license term, renewability, and geographic area are adopted warrant our elimination of the current limits on the number of PALs we make available.

Moreover, the record indicates that PALs will be more useful to a wide variety of potential licensees if PALs are renewable, longer term, and/or licensed for a larger geographic area. USCC suggests that, if the Commission adopts PEA-based license areas and a ten-year license period with a renewal expectancy, ''it will be far less likely that the aggregate demand in any license area will be less than seven PALs.'' We seek comment on whether our proposed changes in the term, renewability, and service area of PALs would make them more useful to a wider range of potential licensees and, if so, whether that would reduce the benefit of limiting the number of PALs available in a given license area or not assigning PALs in any area for which there is only one applicant.

We note that, if we adopt the above proposal to make all of the PALs in a given license area available for assignment regardless of the number of applicants that have applied in that area, it would still be possible, albeit less likely, for the number of PALs being offered to exceed applicant demand in a given area. Similarly, if we were to assign PALs in a license area for which only a single applicant applied for a PAL, as some commenters advocate, in those instances we would not have accepted mutually exclusive PAL applications, which is the prerequisite for assigning PALs by auction. While the Commission has the authority in both situations to assign the PALs on a

non-auctioned basis, we seek comment on whether it would be consistent with our statutory objectives to do so on a non-auctioned basis given the nature of the changes we propose to adopt for PALs. Such a circumstance raises questions of how to accommodate GAA use such that the sharing envisioned within this band could occur. To the extent necessary and as an alternative, we also seek comment on whether we nevertheless have authority to assign PALs by auction in these situations because a PAL for any given area is mutually exclusive to GAA use in that area. If we were to assign PALs by auction in these situations, applicants would be required to submit at least the minimum opening bid for each PAL consistent with the Commission's general competitive bidding procedures. Would such an approach be consistent with our statutory requirements and objectives under Section 309 of Act (47 U.S.C. 309(j))? Commenters that support this proposal should describe in detail the mechanism by which such a change would work, particularly within the sharing regime contemplated in the 3.5 GHz Band, and how it would fit within the Commission's statutory requirements.

b. Bidding on Specific PAL License Blocks

Under the current rules, Priority Access licensees do not bid on specific spectrum blocks. Rather, SAS Administrators assign frequencies based on the amount of spectrum that the PAL licensee is authorized to use in a given license area. Licensees may request a particular channel or frequency range from the SAS, but are not guaranteed a particular assignment. The SAS will ''assign geographically contiguous PALs held by the same Priority Access Licensee to the same channels in each geographic area'' and ''assign multiple channels held by the same Priority Access Licensee to contiguous frequencies within the same License Area'' when it is feasible to do so. T-Mobile instead asks the Commission to allow applicants to bid on particular channels, rather than bidding solely on an amount of spectrum that will later be assigned by the SAS.

A few commenters support T-Mobile's proposal. Ericsson argues that this approach would ensure a ''stable and predictable'' spectrum environment, while 5G Americas and GSMA argue that it would encourage robust use of the band for 5G and would align with what other countries have planned for the band.

Commenters opposing this proposal question how it would work given the need to protect incumbent rights. Vivint Wireless calls it ''unnecessary and a bit confusing,'' arguing that it ''would seem to limit the available channels should a PAL licensee need to move to avoid interfering with a protected incumbent.'' Google argues that, if the Commission permitted parties to manually select frequencies, an operator could position itself in the middle of the PAL spectrum, preventing other PAL holders from aggregating contiguous blocks. It argues that ''the current SAS dynamic assignment framework allows protection of federal incumbent and Priority Access operations while enabling a seamless experience for end users of [Citizens Broadband Radio Service] services.''

We seek comment on the feasibility and desirability of allowing PAL licensees to bid on specific channel assignments. How could the Commission accomplish this given the other constraints of the band, including the need to protect incumbents? Would having a separate voluntary channel assignment phase of the auction—as was done recently in the Incentive Auction—work in this context? For example, could we first allow applicants to bid on the amount of PAL spectrum they desire, then in a separate round, allow PAL bidders to value and bid on specific channel assignments? Would this allow PAL bidders to value their PAL spectrum more accurately by knowing their primary location vis-a-vis federal and other incumbents and adjacent band licensees? Would the Commission need to make changes to the assignment phase framework used in the Incentive Auction to accommodate interference protection of federal incumbents by PALs? And if so, what changes would it need to make? Should the Commission adopt rules to ensure that bidders are assigned to contiguous frequencies within a geographic area, where possible? We also seek comment on what alternative auction methodologies might be appropriate to balance the SAS Administrator's need to dynamically avoid interference with Priority Access licensees' desire for certainty and the ability to aggregate contiguous spectrum. Are there other auction designs that could better balance interests in this context? We seek comment on the costs and benefits of any proposed approaches.

B. Emissions and Interference Limits

In the *First Report and Order,* the Commission adopted the following emission limits:

- −13 dBm/MHz from 0 to 10 megahertz from the assigned channel edge;
- −25 dBm/MHz beyond 10 megahertz from the assigned channel edge down to 3530 megahertz and up to 3720 megahertz;
- −40 dBm/MHz below 3530 megahertz and above 3720 megahertz.

In the *Second Report and Order,* the Commission denied petitions for reconsideration that requested changes to these limits.

T-Mobile's Petition requests changes to the emission limits that it claims are necessary to support channels wider than 10 megahertz without power reduction. Specifically, T-Mobile argues that the −13 dBm/MHz limit should apply from 0–20 megahertz outside the channel edge, and the −25 dBm/MHz requirement should be eliminated (or, alternatively, apply at least 20 megahertz from the channel edge). Outside of the 3550–3700 MHz band, T-Mobile contends that the −40 dBm/MHz limit should be eliminated (or, alternatively, the transition gap should be 40 megahertz instead of 20 megahertz).

Qualcomm agrees that the emission limits should be relaxed to facilitate wider channels without power reduction. Qualcomm argues that, for single or aggregated channels that are the channel bandwidth (B) megahertz wide (up to 40 megahertz), the −13 dBm/MHz requirement should apply from 0 to B megahertz above and below the channel edges, and the −25 dBm/MHz requirement should apply at frequencies beyond B megahertz. Qualcomm does not request changes to the −40 dBm/MHz emission limit outside of the 3550–3700 megahertz band. Several other commenters also support relaxation of the emission limits.

Others, including Motorola Solutions and Vivint Wireless, support the current emissions limits. Motorola Solutions argues that no changes are necessary because current technologies can be utilized to meet the existing limits, and the existing rules allow higher power with wider bandwidth which helps counteract the need for power reduction. Vivint Wireless asserts that relaxing the emissions limits will increase the risk of interference between adjacent channel operations.

Our current rules were designed to accommodate 10 megahertz and 20 megahertz channels. We propose to relax the emissions mask in a manner that will be scalable to accommodate wider bandwidth channels. Petitioners and commenters agree on the value of the first step of attenuation at −13

dBm/MHz—starting at the channel edge—and many of them agree on the value of the lowest attenuation in the band at −25 dBm/MHz. We believe that relaxation of the current emission limits, while enabling efficient frequency and power assignments, would promote innovation and investment in the band and allow operators to make use of wider channels without reducing their transmit power. However, we are not persuaded by T-Mobile's proposals to eliminate the −25 dBm/MHz limit or to eliminate the −40 dBm/MHz limit below 3530 megahertz and above 3720 megahertz. We also are not persuaded by T-Mobile's proposal to increase the transition bandwidth to 40 megahertz outside of the band, because of the impact these changes would have on protecting adjacent operations. Rather, we seek comment on two alternative proposals. First, we seek comment on Qualcomm's proposal to: (1) Extend the −13 dBm/MHz limit from 0 to 100% of B; (2) apply the −25 dBm/MHz limit beyond 100% of B; and (3) not change the −40 dBm/MHz limit specified in Section 96.41(e)(2). Second, we seek comment on a more graduated reduction of the emission limits in Qualcomm's proposal, with the addition of an attenuation step between the channel edge and a full channel bandwidth from the channel edge, as follows:

- −13 dBm/MHz from 0 to B/2 (*i.e.,* 50% of B) megahertz from the assigned channel edge;
- −20 dBm/MHz from B/2 to B (*i.e.,* 100% of B) megahertz from the assigned channel edge;
- −25 dBm/MHz beyond B megahertz from the assigned channel edge, down to 3530 megahertz and up to 3720 megahertz;
- −40 dBm/MHz below 3530 megahertz and above 3720 megahertz.

We seek comment on these two proposals and on the tradeoffs in the number and levels of the attenuation steps. A more relaxed mask gives more margin to accommodate bandwidths wider than 10 megahertz, although this could raise the potential for increased interference to users operating on adjacent channels. We seek quantitative analysis of these tradeoffs and we seek comment on whether alternative attenuation steps could balance these tradeoffs more effectively. What is the balance between vendor cost, radio performance, and spectrum efficiency? For example, are there tradeoffs in the design complexity of out-of-band signal reduction techniques, balanced with flexible and efficient spectrum sharing? Will either or both of the proposed masks facilitate the use of wider channels in the band without requiring power reduction?

In the second proposal above, we seek comment on an attenuation step of −20 dBm/MHz between −13 dBm/MHz and −25 dBm/MHz, between one-half channel (50% of B) and one channel bandwidth (100% of B) from the channel edge. This additional attenuation step may enable more efficient SAS-based frequency and power assignments while facilitating wider channel bandwidths. Without this step, frequency separation between PAL channels (and other GAA/PAL channels) may be larger under some operational use cases. We seek comment on the capabilities of current and future CBSDs and end user devices to meet these masks, and the attenuation steps used in other bands for other wireless services. We also seek quantitative analysis of TDD interference scenarios to assess the tradeoff and balance between the emission mask and the statistical likelihood of interference between licensees.

We note that studies have shown that device output power and out-of-band emissions are likely to be lower than regulatory limits or industry standards. For instance, an Ofcom study describes a case where the actual out-of-band emissions is lower than the minimum requirements specified in 3GPP by ~8 dB in the first adjacent channel. The study also shows the non-linear effect of out-of-band emissions at maximum power, and higher reduction in out-of-band emissions for every dB of reduction in fundamental transmit power. Ofcom notes that the increased emission leakage that accompanies increasing fundamental power is due to the non-linear behavior of the power amplifier when it is driven into saturation. What are the likely effects of this behavior in devices that will be deployed in the 3.5 GHz Band? We seek comment and quantitative evidence that actual out-of-channel emissions in the 3.5 GHz Band will be substantially lower than worst case values. Are the margins found in the Ofcom study typical and representative of the margins that can be expected in 3.5 GHz?

We also seek comment on the tradeoffs inherent in any change to the emission mask(s) in the band. Specifically, what are the tradeoffs between the margins of actual emissions, and the spectral efficiency of frequency assignments in the 3.5 GHz Band? Will either or both of the proposed masks meet the more restrictive 3GPP Adjacent Channel Leakage Ratio (ACLR) emissions limit (*i.e.,* 30 dBc for user devices and 45 dBc for base stations)? Finally, given the existing OOBE limits that apply above 3720 MHz and below 3530 MHz—which we do not propose to change—we seek comment on whether either of these proposals would facilitate the use of wider bandwidth channels at or near the band edges.

III. Procedural Matters

Initial Regulatory Flexibility Act Analysis

As required by the Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 603), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) for this *NPRM,* of the possible significant economic impact on small entities of the policies and rules addressed in this document. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed on or before the dates on the first page of this *NPRM.* The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of the *NPRM,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

Initial Paperwork Reduction Act Analysis

The *NPRM* contains proposed modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget OMB to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

List of Subjects in 47 CFR Part 96

Telecommunications, Radio.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 96 as follows:

PART 96—CITIZENS BROADBAND RADIO SERVICE

■ 1. The authority citation for part 96 continues to read as follows:

Authority: 47 U.S.C. 154(i), 303, and 307.

■ 2. Section 96.25 is amended by revising paragraphs (a) and (b)(3) to read as follows:

§ 96.25 Priority access licenses.

(a) An applicant must file an application for an initial authorization for all PALs desired. Initial authorizations shall be granted in accordance with Section 96.29. Priority Access Licensees must operate CBSDs consistent with the technical rules and interference protection requirements set for in this part.

(b) * * *

(3) *License term.* Each PAL has a ten-year license term. Licensees must file a renewal application in accordance with the provisions of Section 1.949.

* * * * *

§ 96.27 [Removed and Reserved]

■ 3. Remove and reserve § 96.27.

■ 4. Section 96.29 is revised to read as follows:

§ 96.29 Competitive bidding procedures.

Mutually exclusive initial applications for Priority Access Licenses are subject to competitive bidding. The general competitive bidding procedures set forth in part 1, subpart Q of this chapter will apply unless otherwise provided in this subpart.

■ 5. Section 96.32 is amended by revising paragraph (b) to read as follows:

§ 96.32 Priority access assignments of authorization, transfer of control, and leasing arrangements.

* * * * *

(b) Priority Access Licensees may partition or disaggregate their licenses and partially assign or transfer their licenses and may enter into de facto leasing arrangements for a portion of their licenses.

* * * * *

■ 6. Section 96.41 is amended by revising paragraph (e)(2) to read as follows:

§ 96.41 General radio requirements.

(e) * * *

(2) *Additional protection levels.* Notwithstanding paragraph (e)(1) of this section, the conducted power of any emissions below 3530 MHz or above 3720 MHz shall not exceed −40dBm/MHz.

* * * * *

§ 96.55 [Amended].

■ 7. Section 96.55 is amended by removing and reserving paragraph (a)(3).

[FR Doc. 2017–25672 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 91

[Docket No. FWS–HQ–MB–2015–0161; FXMB12330900000//189//FF09M13200]

RIN 1018–BB23

Revision of Federal Migratory Bird Hunting and Conservation Stamp (Duck Stamp) Contest Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Revised proposed rule; request for comments.

SUMMARY: We, the Fish and Wildlife Service (Service), are revising our previous proposal to revise regulations governing the annual Migratory Bird Hunting and Conservation Stamp Contest (also known as the Federal Duck Stamp Contest (contest)). The proposals in this document are revisions to our February 11, 2016, proposed rule and consist of further updates to the scientific names of species on our list of contest design subjects, updates to recognize technological advances in stamp design and printing, and proposed requirements specific to the 2018 contest.

DATES: We will accept comments that we receive on or before December 28, 2017. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–MB–2015–0161, which is the docket number for this proposed rule. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct rulemaking before submitting your comment.
- *By hard copy:* Submit by U.S. mail or hand delivery to: Public Comments Processing, Attn: FWS–HQ–MB–2015–0161; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: BPHC; Falls Church, VA 22041–3803.

We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Public Comment Procedures and Public Availability of Comments under **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Suzanne Fellows, (703) 358–2145, *suzanne_fellows@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

History of the Federal Migratory Bird Hunting and Conservation Stamp (Duck Stamp) Program

On March 16, 1934, Congress passed, and President Franklin D. Roosevelt signed, the Migratory Bird Hunting Stamp Act. Popularly known as the Duck Stamp Act, it required all waterfowl hunters 16 years or older to buy a stamp annually. The revenue generated was originally earmarked for the Department of Agriculture, but 5 years later was transferred to the Department of the Interior and the Service.

In the years since its enactment, the Federal Duck Stamp Program has become one of the most popular and successful conservation programs ever initiated. Today, some 1.8 million stamps are sold each year, and as of 2017, Federal Duck Stamps have generated more than $1 billion for the preservation of more than 6 million acres of waterfowl habitat in the United States. Numerous other birds, mammals, fish, reptiles, and amphibians have similarly prospered because of habitat protection made possible by the program. An estimated one-third of the Nation's endangered and threatened species find food or shelter in refuges preserved by Duck Stamp funds. Moreover, the protected wetlands help dissipate storms, purify water supplies, store flood water, and nourish fish hatchlings important for sport and commercial fishermen.

History of the Duck Stamp Contest

The first Federal Duck Stamp was designed at President Roosevelt's request by Jay N. ''Ding'' Darling, a nationally known political cartoonist for the Des Moines Register and a noted hunter and wildlife conservationist. In subsequent years, noted wildlife artists were asked to submit designs. The first

Federal Duck Stamp Contest was opened in 1949 to any U.S. artist who wished to enter, and 65 artists submitted a total of 88 design entries. Since then, the contest has attracted large numbers of entrants, and it remains the only art competition of its kind sponsored by the U.S. Government. The Secretary of the Interior appoints a panel of noted art, waterfowl, and philatelic authorities to select each year's winning design. Winners receive no compensation for the work, except a pane of their stamps, but winners may sell prints of their designs, which are sought by hunters, conservationists, and art collectors.

Theme of 2019–2020 Stamp

Throughout the history of the Federal Duck Stamp, there has been an effort to increase its messaging capabilities. For example, in 1959, the theme of the contest was ''Retrievers Save Game,'' and artists were required to produce a design which illustrated this theme. The resulting 1959–1960 stamp, the ''King Buck,'' featuring a black Labrador Retriever and a mallard, is arguably among the most identifiable Federal Duck Stamps. With the introduction of the 1998–1999 pressure-sensitive adhesive stamp, the Service developed a dollar-bill sized stamp carrier which provided additional area for visual and verbal messages. Additional opportunities exist for messages on the back of the stamp as well as on the appreciation certificates that are available to customers interested in the Duck Stamp Program.

To address Executive Order 13443 (Facilitation of Hunting Heritage and Wildlife Conservation; 72 FR 46537, August 20, 2007) and Department of the Interior Secretary's Order 3356 (Hunting, Fishing, Recreational Shooting, and Wildlife Conservation Opportunities and Coordination with States, Tribes, and Territories; September 15, 2017), the theme of the 2019–2020 stamp and accompanying certificate of appreciation will be ''celebrating our waterfowl hunting heritage.'' This will provide visual and verbal recognition to the contributions waterfowl hunters make to habitat conservation. As the only ones required to purchase a Federal Duck Stamp, waterfowl hunters have been the primary supporters of the Federal Duck Stamp program and have enabled the purchase of wetland habitats that support both hunted and nonhunted species, assist in flood control and water purification, and provide communities with an economic stimulus. By celebrating our waterfowl hunting heritage and showing hunters in a positive light as active wildlife conservationists on the 2019–2020 stamp, we will celebrate their contributions to providing public lands and robust wildlife populations. Through additional messaging, we also hope to engage Americans of all ages and backgrounds who may not have traditionally realized the benefits of wetland conservation.

Revised Proposed Changes to the Regulations at 50 CFR Part 91

On February 11, 2016, we published a proposed rule (81 FR 7279) to revise the regulations at 50 CFR part 91 governing the annual Federal Duck Stamp Contest. Specifically, we proposed to update our contact information; update common names and spelling of species on our list of contest design subjects; correct minor grammar errors; and specify the requirement to include a second, appropriate, migratory bird species in the artwork design beginning with the 2016 contest. We did not make that rule final. Now, with this document, we are revising that proposed rule.

Retained Provisions of the February 11, 2016, Proposed Rule

As set forth in the February 11, 2016, proposed rule (81 FR 7279), we continue to propose to:

- Update §§ 91.1(b) and 91.11 to provide current and accurate contact information for the Service's Duck Stamp Office.
- Update the scientific and common names on our list at § 91.4 of species that are potential contest design subjects to ensure that list contains names currently accepted by the American Ornithological Society (AOS) *http://www.americanornithology.org/;* see also the AOS Checklist at *http://checklist.aou.org/taxa/;* this checklist is our standard reference on taxonomy, nomenclature, and capitalization). Some of the names differ in this revised proposed rule from those set forth in our February 11, 2016, proposed rule. Those differences are explained in Revised Provisions, below.
- Correct minor grammar errors in our regulations at 50 CFR part 91.

For the proposed text of §§ 91.1(b), 91.4, and 91.11, refer to our February 11, 2016, proposed rule (81 FR 7279).

Revised Provisions

The revisions to our February 11, 2016, proposed rule contained in this document consist of:

- Further updates to the scientific names of species on our list at § 91.4;
- Updates to recognize technological advances in stamp design and printing;
- Addition of judging and subject matter regulations to require that each depiction illustrates the theme ''celebrating our waterfowl hunting heritage'' for the 2018 contest.

Further Updates to Species' Scientific Names

Section 91.4 contains our list of eligible waterfowl species. For each year's contest, we choose five or fewer species from the list; one or more of those species (or a combination thereof; see § 91.14) are the only acceptable subjects for entries during that contest year. We announce each year's eligible species on our Web site and in an annual contest brochure. Our list at § 91.4 contains scientific and common names accepted by the AOS.

Since we last revised our regulations, and again since we published our proposed rule on February 11, 2016, the AOS has changed the listing order among species and updated several species names. The further updates contained in this revised proposed rule are to two categories: (1) Geese, and (2) dabbling ducks. For geese, the revised proposed changes would correct the genus name of Emperor, Snow, and Ross's geese to Anser, so that they would read, ''Emperor Goose (Anser canagicus),'' ''Snow Goose (Anser caerulescens),'' and ''Ross's Goose (Anser rossii),'' respectively.

For dabbling ducks, the revised proposed changes would correct the genus name of Blue-winged and Cinnamon teal and Northern Shoveler to Spatula, so that they would read, ''Blue-winged Teal (Spatula discors),'' ''Cinnamon Teal (Spatula cyanoptera),'' and ''Northern Shoveler (Spatula clypeata),'' respectively. We would also correct the genus name of Gadwall and American Wigeon to Mareca, so that the entries read, ''Gadwall (Mareca strepera)'' and ''American Wigeon (Mareca americana).''

We propose these further changes to our list at § 91.4 to reflect the most current scientific names of eligible waterfowl species.

Updating Technological Advances in Stamp Design and Printing

Currently both § 91.15 and § 91.23 contain regulations and references to a stamp production process that is no longer used. We propose to remove these outdated statements to reflect current technology in this revised proposed rule.

Depicting the Theme ''Celebrating our Waterfowl Hunting Heritage'' in 2018 Artwork Entries

Current § 91.14 explains that a live portrayal of any bird(s) of the five or fewer identified eligible waterfowl species must be the dominant feature of the design, but that the design may depict other appropriate elements such as hunting dogs, as long as an eligible waterfowl species is in the foreground and clearly the focus of attention. In this revised proposed rule, we propose that, for 2018, contest entries must include one or more elements that reflect the theme ''celebrating our waterfowl hunting heritage.''

Section 91.21(b) outlines the qualification of the judging panel. We also propose that, for 2018, all selected contest judges must have an understanding and appreciation of the waterfowl hunting heritage and be able to recognize scenery or objects related to waterfowl hunting.

Finally, § 91.23 sets forth the scoring criteria for the contest. We propose to specify that, for 2018, entries will also be judged on how well they illustrate the theme of ''celebrating our waterfowl hunting heritage.''

The proposed changes to the regulations concerning the theme of ''celebrating our waterfowl hunting heritage'' would be in effect only for the 2018 contest.

Public Comments Procedures

To ensure that any final action resulting from this proposed rule will be as accurate and as effective as possible, we request that you send relevant information for our consideration. We will accept public comments we receive on or before the date listed above in **DATES**. We are striving to ensure that any amendments to the regulations resulting from our February 11, 2016, proposed rule (81 FR 7279) and this revised proposed rule would be in effect with sufficient time for artists to prepare submissions by the June opening of the 2018 contest. The comments that will be most useful are those that you support by quantitative information or studies and those that include citations to, and analyses of, the applicable laws and regulations. Please make your comments as specific as possible and explain the basis for them. In addition, please include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

You must submit your comments and materials concerning this proposed rule by one of the methods listed above in **ADDRESSES**. We will not accept comments sent by email or fax or to an address not listed in **ADDRESSES**. If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information, such as your address, telephone number, or email address—will be posted on the Web site. Please note that comments submitted to this Web site are not immediately viewable. When you submit a comment, the system receives it immediately. However, the comment will not be publically viewable until we post it, which might not occur until several days after submission.

If you mail or hand-carry a hardcopy comment directly to us that includes personal information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. To ensure that the electronic docket for this rulemaking is complete and all comments we receive are publicly available, we will post all hardcopy comments on *http://www.regulations.gov.*

In addition, comments and materials we receive, as well as supporting documentation used in preparing this proposed rule, will be available for public inspection in two ways:

(1) You can view them on *http://www.regulations.gov.* In the Search box, enter FWS–HQ–MB–2015–0161, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, select the type of documents you want to view under the Document Type heading.

(2) You can make an appointment, during normal business hours, to view the comments and materials in person by contacting the person listed above under **FOR FURTHER INFORMATION CONTACT**.

Public Availability of Comments

As stated above in more detail, 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 publically 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.

Required Determinations

For this revised proposed rule, we affirm the following required determinations provided in our February 11, 2016, proposed rule (81 FR 7279):

- Regulatory Planning and Review (Executive Orders 12866 and 13563);
- Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2));
- Federalism (Executive Order 13132);
- Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*);
- Takings (Executive Order 12630);
- Civil Justice Reform (Executive Order 12988);
- Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*);
- National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);
- Government-to-Government Relationship with Tribes (Executive Order 13175); and
- Energy Supply, Distribution, or Use (Executive Order 13211).

We provide new required determinations as follows:

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions) (5 U.S.C. 601 *et seq.*). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities. The changes we propose are intended primarily to clarify the requirements for the contest. These changes would affect individuals, not businesses or other small entities as defined in the Regulatory Flexibility Act.

We therefore certify that, if adopted, this rule would not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act. A Regulatory Flexibility Analysis is not required.

Accordingly, a Small Entity Compliance Guide is not required.

Executive Order 13771

This rule is not an Executive Order (E.O.) 13771 (82 FR 9339, February 3, 2017) regulatory action because this rule is not significant under E.O. 12866.

Clarity of This Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

List of Subjects in 50 CFR Part 91

Hunting, Wildlife.

Proposed Regulation Promulgation

For the reasons stated in the preamble, we propose to further amend 50 CFR part 91, as proposed to be amended at 81 FR 7279 (February 11, 2016), as set forth below:

PART 91—MIGRATORY BIRD HUNTING AND CONSERVATION STAMP CONTEST

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 718j; 31 U.S.C. 9701.

■ 2. Amend § 91.4 by revising paragraphs (b) and (d) to read as follows:

§ 91.4 Eligible species.

* * * * *

(b) Geese.

(1) Emperor Goose (Anser canagicus)

(2) Snow Goose (including ''white'' and ''blue'' morphs) (Anser caerulescens)

(3) Ross's Goose (Anser rossii)

(4) Greater White-fronted Goose (Anser albifrons)

(5) Brant (Branta bernicla)

(6) Cackling Goose (Branta hutchinsii)

(7) Canada Goose (Branta canadensis)

* * * * *

(d) Dabbling Ducks.

(1) Wood Duck (Aix sponsa)

(2) Blue-winged Teal (Spatula discors)

(3) Cinnamon Teal (Spatula cyanoptera)

(4) Northern Shoveler (Spatula clypeata)

(5) Gadwall (Mareca strepera)

(6) American Wigeon (Mareca americana)

(7) Mallard (Anas platyrhynchos)

(8) American Black Duck (Anas rubripes)

(9) Mottled Duck (Anas fulvigula)

(10) Northern Pintail (Anas acuta)

(11) Green-winged Teal (Anas crecca)

* * * * *

■ 3. Revise § 91.14 to read as follows:

§ 91.14 Restrictions on subject matter for entry.

(a) A live portrayal of any bird(s) of the five or fewer identified eligible waterfowl species must be the dominant feature of the design. The design may depict more than one of the eligible species. The judges' overall mandate is to select the best design that will make an interesting, useful, and attractive duck stamp that will be accepted and prized by hunters, stamp collectors, conservationists, and others. The design must be the contestant's original hand-drawn creation. The entry design may not be copied or duplicated from previously published art, including photographs, or from images in any format published on the Internet. Photographs, computer-generated art, or art produced from a computer printer or other computer/mechanical output device (airbrush method excepted) are not eligible to be entered into the contest and will be disqualified. An entry submitted in a prior contest that was not selected for a Federal or State stamp design may be submitted in the current contest if the entry meets the criteria set forth in this section.

(b) The 2018 Contest. In addition to the restrictions set forth in paragraph (a), in 2018 only, designs will also be required to include appropriate hunting-related accessories and/or scenes celebrating the Federal Duck Stamp's long-standing connection as part of our Nation's waterfowl hunting heritage and the contributions to conservation made by waterfowl hunters. Designs may include, but are not limited to, hunting dogs, hunting scenes, hunting equipment, waterfowl decoys, managed waterfowl areas as the background of habitat scenes, or other designs that represent our waterfowl hunting heritage. The design chosen will clearly meet the theme of ''celebrating our hunting heritage.''

§ 91.15 [Removed and Reserved]

■ 4. Remove and reserve § 91.15.

■ 5. In § 91.21, designate the text in paragraph (b) after the paragraph header as paragraph (b)(1) and add paragraph (b)(2) to read as follows:

§ 91.21 Selection and qualification of contest judges.

* * * * *

(b) Qualifications. (1) * * *

(2) The 2018 Contest. In 2018 only, it will also be mandatory that all selected judges have an understanding and appreciation of the waterfowl hunting heritage and be able to recognize waterfowl hunting paraphernalia.

* * * * *

■ 6. Revise § 91.23 to read as follows:

§ 91.23 Scoring criteria for contest.

(a) Entries will be judged on the basis of anatomical accuracy, artistic composition, and suitability for reduction in the production of a stamp.

(b) The 2018 Contest. In 2018 only, entries will also be judged on how well they illustrate the theme of ''celebrating our hunting heritage.''

Dated: November 8, 2017.

Jason Larrabee,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2017–25661 Filed 11–27–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 170901861–7861–01]

RIN 0648–BH08

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Biennial Specifications

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

ACTION: Proposed rule.

SUMMARY: NMFS proposes to implement annual harvest specifications and management measures to establish the allowable catch levels for Pacific mackerel in the U.S. exclusive economic zone (EEZ) off the West Coast (California, Oregon and Washington) for the fishing years 2017–2018 and 2018–2019. This rule is proposed pursuant to the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The proposed harvest guideline (HG) and

annual catch target (ACT) for the 2017–2018 fishing year are 26,293 metric tons (mt) and 25,293 mt respectively. The proposed HG and ACT for the 2018–2019 fishing year are 23,840 mt and 22,840 mt respectively. If the fishery attains the ACT in either fishing year, the directed fishery will close, reserving the difference between the HG and ACT as a 1,000 mt set-aside for incidental landings in other CPS fisheries and other sources of mortality. If the HG is reached, all retention would be prohibited through the end of the fishing year. This rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Comments must be received by December 28, 2017.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0134, by any of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0134,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Barry A. Thom, Regional Administrator, West Coast Region, NMFS, 501 W. Ocean Blvd., Ste. 4200, Long Beach, CA 90802–4250; Attn: Joshua Lindsay.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments 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 report, ''Pacific Mackerel Biomass Projection Estimate for USA Management in 2017–2018 and 2018–2019'' may be obtained from the West Coast Regional Office.

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.,* NMFS manages the Pacific mackerel fishery in the U.S. EEZ off the West Coast in accordance with the CPS FMP. The CPS FMP and its implementing regulations require NMFS to set annual harvest specifications for the Pacific mackerel fishery based on the annual specification framework and control rules in the FMP. The purpose of this proposed rule is to implement these harvest specifications, which include allowable harvest levels (ACT/HG/annual catch level [ACL]), as well as annual catch reference points (overfishing limit [OFL] and acceptable biological catch [ABC]) that take into consideration uncertainty surrounding the current biomass estimates for Pacific mackerel for the 2017–2018 and 2018–2019 fishing years.

During public meetings each year, biomass estimates for Pacific mackerel are presented to the Pacific Fishery Management Council's (Council) CPS Management Team (CPSMT), the Council's CPS Advisory Subpanel (CPSAS) and the Council's Scientific and Statistical Committee (SSC), where the biomass estimates and the status of the fisheries are reviewed and discussed. These biomass estimates are then presented to the Council along with the calculated OFL, ABC, ACL, HG and ACT recommendations and comments from the CPSMT, CPSAS and SSC. Following review by the Council and after hearing public comment, the Council adopts biomass estimates and makes its harvest specification recommendations to NMFS. Biennial specifications published in the **Federal Register** establish these allowable harvest levels (*i.e.,* ACT/ACL/HG) for the upcoming two Pacific mackerel fishing years. This is the first proposed rule where harvest specifications are being adopted for the upcoming two fishing years (2017–2018 and 2018–2019) per the recently published final rule (82 FR 35687; August 1, 2017) that changed the CPS FMP management framework so that Pacific mackerel harvest specifications could be adopted biennially instead of annually.

The control rules in the CPS FMP include the HG control rule, which in conjunction with the OFL and ABC rules, are used to manage harvest levels for Pacific mackerel. According to the FMP, the quota for the principal commercial fishery, the HG, is determined using the FMP-specified HG formula. The HG is based, in large part, on the current estimate of stock biomass. The biomass estimate is an explicit part of the various harvest control rules for Pacific mackerel, and as the estimated biomass decreases or increases from one year to the next, the resulting allowable catch levels similarly trend. The harvest control rule in the CPS FMP is HG = [(Biomass-Cutoff) * Fraction * Distribution] with the parameters described as follows:

1. *Biomass.* The estimated stock biomass of Pacific mackerel for the 2017–2018 management season is 143,403 mt. The estimated stock biomass of Pacific mackerel for the 2018–2019 management season 131,724 mt.

2. *Cutoff.* This is the biomass level below which no commercial fishery is allowed. The FMP established this level at 18,200 mt.

3. *Fraction.* The harvest fraction is the percentage of the biomass above 18,200 mt that may be harvested. This is set in the FMP at 30 percent.

4. *Distribution.* The average portion of the Pacific mackerel biomass estimated in the U.S. EEZ off the Pacific coast is 70 percent and is based on the average historical larval distribution obtained from scientific cruises and the distribution of the resource according to the logbooks of aerial fish-spotters.

The Council has recommended and NMFS is proposing, Pacific mackerel harvest specifications and management measures for both the 2017–2018 and 2018–2019 fishing years. For the 2017–2018 Pacific mackerel fishing year these include an OFL of 30,115 metric tons (mt), an ABC and ACL of 27,510 mt, a HG of 26,293 mt, and an annual ACT of 25,293 mt. For the 2018–2019 Pacific mackerel fishing year these include an OFL of 27,662 mt, and ABC and ACL of 25,269 mt, a HG of 23,840 mt, and an ACT of 22,840 mt. The Pacific mackerel fishing season runs from July 1 to June 30. These catch specifications are based on the control rules established in the CPS FMP and biomass estimates of 143,403 mt (2017–2018) and 131,724 mt (2018–2019); these biomass estimates are the result of a full stock assessment completed in June 2015 and a subsequent catch-only projection estimate completed in June 2017 by NMFS Southwest Fisheries Science Center and approved by the Council's SSC and the Council at their June 2017 meeting as best available science (see **ADDRESSES**).

Under this proposed action, upon the unlikely attainment of the ACT in either fishing year, directed fishing would close, reserving the difference between the HG and ACT (1,000 mt) as a set aside for incidental landings in other fisheries and other sources of mortality. For the remainder of the fishing year, incidental landings would be constrained to a 45-percent incidental

catch allowance when Pacific mackerel are landed with other CPS (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel) or up to 3 mt of Pacific mackerel could be landed incidentally in non-CPS fisheries.[1] Upon attainment or projected attainment of the HG, no retention of Pacific mackerel would be allowed even as incidental catch. The purpose of the incidental set-aside and allowance of an incidental fishery is to allow for the restricted incidental landings of Pacific mackerel in other fisheries, particularly other CPS fisheries, when the directed fishery is closed to reduce potential discard of Pacific mackerel and allow for continued prosecution of other important stocks that may school with Pacific mackerel.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** announcing the date of any closure of either (1) directed fishing (when harvest levels near or take the ACT) or (2) retention—including by incidental fishing (when harvest levels near or attain the HG). Additionally, to ensure the regulated community is informed of any closure, NMFS will also make announcements through other means available, including fax, email, and mail to fishermen, processors, and state fishery management agencies. This rule would also add paragraph (p) to the prohibitions section at 50 CFR 660.505 referencing the prohibition on retention, possession, or landing of Pacific mackerel for the remainder of the year after the closure date specified in the **Federal Register** notice published by the Regional Administrator.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the following reasons:

For Regulatory Flexibility Act (RFA) purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

Pacific mackerel are principally caught off southern California within the limited entry portion (south of 39 degrees N. latitude; Point Arena, California) of the CPS fishery and is one component of CPS fisheries off the U.S. West Coast, which also includes the fisheries for Pacific sardine, northern anchovy and market squid. The small entities that would be affected by the proposed action are those vessels that harvest Pacific mackerel as part of the West Coast CPS purse seine fleet and are all considered small business under the above size standards. Currently there are 58 vessels permitted in the Federal CPS limited entry fishery off California. The average annual per vessel revenue in 2016 for those vessels was well below the threshold level of $11 million; therefore, all of these vessels are considered small businesses under the RFA. Therefore, this rule would not create disproportionate costs between small and large vessels/businesses.

NMFS used the ex-vessel revenue information for a profitability analysis, as the cost data for the harvesting operations of CPS finfish vessels was limited or unavailable. For the 2016–2017 fishing year, the HG was 21,161 mt and was divided into an ACT of 20,161 mt and an incidental set-aside of 1,000 mt. Approximately 1,492.16 mt of Pacific mackerel was harvested in the 2016–2017 fishing year with an estimated ex-vessel value of approximately $417,616.

The HG for the 2017–2018 Pacific mackerel fishing year is 26,293 mt, with an ACT of 25,293 mt and an incidental set-aside of 1,000 mt. The HG for the 2018–2019 Pacific mackerel fishing year is 23,840 mt with an ACT of 22,840 mt and an incidental set-aside of 1,000 mt. These proposed ACTs are similar to the ACT established for the 2016–2017 fishing year (20,161 mt), thus it is highly unlikely that the ACTs proposed in this rule will limit the potential profitability to the fleet from catching Pacific mackerel compared to last season or recent catch levels, as shown below. The annual average U.S. Pacific mackerel harvest in recent years (2010–2015) has been about 5,000 mt. In this period, the landings have not exceeded 11,800 mt. Additionally, annual average landings during the last decade (2005–2015) have not been restricted by the applicable quota. Accordingly, vessel income from fishing is not expected to be altered as a result of this rule as it compares to recent catches in the fishery, including under the previous season's regulations.

Based on the disproportionality and profitability analysis above, the proposed action, if adopted, will not have adverse or disproportional economic impact on these small business entities. As a result, an Initial Regulatory Flexibility Analysis is not required, and none has been prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: November 21, 2017.

Alan D. Risenhoover,

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

For the reasons set out in the preamble, 50 CFR part 660 is proposed to be amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.505, add paragraph (p) to read as follows:

§ 660.505 Prohibitions.

* * * * *

(p) Retain, possess or land Pacific mackerel after an announcement under § 660.511(j) that the harvest guideline has been taken or is projected to be reached soon.

■ 3. In § 660.511, add paragraphs (i) and (j) to read as follows:

§ 660.511 Catch restrictions.

* * * * *

(i) The following harvest specifications apply for Pacific mackerel:

(1) For the Pacific mackerel fishing season July 1, 2017, through June 30, 2018, the harvest guideline is 26,293 mt and the ACT is 25,293 mt;

(2) For the Pacific mackerel fishing season July 1, 2018, through June 30,

[1] Live bait fishing is excluded from closures of the directed fishery, and Amendment 16 to the CPS FMP, if approved, would allow very small directed fisheries to continue even when most directed were closed.

2019, the harvest guideline is 23,840 mt and the ACT of 22,840 mt.

(j) When an ACT in paragraph (i) of this section has been reached or is projected to be reached soon, then for the remainder of the Pacific mackerel fishing season, Pacific mackerel may not be targeted and landings of Pacific mackerel may not exceed 45 percent of landings when Pacific mackerel are landed with other CPS (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel), except that up to 3 mt of Pacific mackerel may be landed without landing any other CPS. When a harvest guideline in paragraph (i) of this section has been reached or is projected to be reached soon, no further retention of Pacific mackerel is allowed through the end of the Pacific mackerel fishing season. The Regional Administer shall announce in the **Federal Register** the date that an ACT or the harvest guideline is reached or is expected to be reached, and the date and time that the restrictions described in this paragraph go into effect.

[FR Doc. 2017–25614 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 82, No. 227
Tuesday, November 28, 2017

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.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Louisiana Advisory Committee To Discuss Hearing Preparations for Barriers to Voting Report

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Louisiana Advisory Committee (Committee) will hold a meeting on Tuesday, November 28, 2017, at 11:00:00 a.m. Central for a discussion on Hearing preparations for the Barriers to Voting in Louisiana report.

DATES: The meeting will be held on Tuesday, November 28, 2017, at 11:00 a.m. Central. Public Call Information: Dial: 800–279–9534, Conference ID: 4587545

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or 312–353–8311

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the following toll-free call-in number: 800–279–9534, conference ID: 4587545. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 55 W. Monroe St., Suite 410, Chicago, IL 60615. They may also be faxed to the Commission at (312) 353–8324, or emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Louisiana Advisory Committee link (*http://www.facadatabase.gov/committee/committee.aspx?cid=251&aid=17*). Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Welcome and Roll Call
Discussion of Barriers to Voting—
Hearing preparations
Next Steps
Public Comment
Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance that this project will inform the Commission's FY2018 statutory enforcement report on voting rights and is therefore under a very tight timeline.

Dated: November 22, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–25635 Filed 11–27–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Participant Statistical Areas Program.

OMB Control Number: 0607–XXXX.

Form Number(s):

20PSAP–F–500—State Recognized Tribes Update Form.
20PSAP–F–510—Contact Update Form.
20PSAP–F–511—Product Preference Form.
20PSAP–F–520—State Tribal Liaison Contact Update Form.
20PSAP–F–530—Federally Recognized Tribe Contact Update Form.
20PSAP–F–540—Federally Recognized Tribe Product Preference Form.

Type of Request: Regular submission.

Number of Respondents: 3,801.

Average Hours per Response: varies per Fiscal Year (FY).

Average Time per Response per FY 2018: 5.

Average Time per Response per FY 2019: 25.

Average Time per Response per FY 2020: 10.

Burden Hours: 152,040 (All Phases, All FYs).

FY 2018 Burden Hours (Internal Review Phase): 19,005

FY 2019 Burden Hours (Delineation Phase): 95,025

FY 2020 Burden Hours (Verification Phase): 38,010

Needs and Uses

The Partnership Statistical Areas Program (PSAP) is one of many voluntary geographic partnership programs. PSAP collects suggested statistical boundaries to update the U.S. Census Bureau's geographic database of addresses, streets, and boundaries. The Census Bureau uses its geographic database to link demographic data from surveys and the decennial Census to locations and areas, such as cities, school districts, and counties. To tabulate statistics by localities, the Census Bureau must have accurate addresses and boundaries.

The boundaries collected in PSAP and other geographic programs will

create census blocks, which are the building blocks for all Census Bureau geographic boundaries. The addresses collected in the 2020 Census Local Update of Census Addresses Operation (LUCA) will place households in a specific census block. While the geographic programs differ in requirements, timeframe, and participants, PSAP and the other geographic programs all follow the same basic process:

1. The Census Bureau invites eligible participants to the program. For PSAP, the Census Bureau invites federally recognized tribes, Alaska Native Regional Associations, local or regional planning agencies, and council of government officials.

2. If they elect to participate in the program, participants receive a copy of the boundaries or addresses the Census Bureau has on file. PSAP participants receive a free customized mapping software.

3. Participants review the boundaries or addresses in the Census Bureau provided software and update them if needed. For PSAP, the Census Bureau strongly recommends that PSAP participants reach out to local governments to collect updates.

4. Participants return their updates to the Census Bureau.

5. The Census Bureau updates their geographic database with boundary updates from participants.

6. The Census Bureau uses the newly updated boundaries and addresses to tabulate statistics.

PSAP allows participants to review and suggest modifications to the boundaries for block groups, census tracts, census county divisions (CCDs), and census designated places (CDPs). Additionally, tribal governments can review or propose changes for tribal statistical areas, which include: Tribal block groups (TBGs), tribal census tracts (TCTs), CDPs, tribal designated statistical areas (TDSAs), state designated tribal statistical areas (SDTSAs), state reservations,[1] Alaska Native village statistical areas (ANVSAs), Oklahoma tribal statistical areas (OTSAs), and OTSA tribal subdivisions.

The PSAP geographies represent statistical units for the tabulation and dissemination of small area data from the decennial census, the American Community Survey (ACS), and other Census Bureau programs and surveys. While legal boundaries, such as cities and counties, allow the Census Bureau to publish data by those areas, local governments often need data for planning by smaller units. PSAP is a unique program initiated and executed by the Census Bureau to allow local and regional governments to break larger geographic areas into smaller units so that they can receive 2020 Census and ACS data by these smaller units and better plan local services. The Census Bureau uses the information collected in PSAP from participating governments and agencies to tabulate and disseminate small area data from the decennial census, the American Community Survey (ACS), and other Census Bureau programs and surveys. In addition, these statistical geographies and the data they provide serve as input to governing, allocating federal funding, and planning of capital expenditures and basic infrastructure investment at the tribal, state, and county levels.

The 2020 Census PSAP occurs between March 2018 and October 2020 and has three primary components:

1. PSAP Internal Review.
2. PSAP Delineation.
3. PSAP Verification.

1. PSAP Internal Review

Census Bureau staff performs an internal review of PSAP entities prior to the distribution of materials to PSAP participants. This internal review ensures each of the statistical areas meets the population, housing, and geographic criteria as defined by the program. During the internal review process, the Census Bureau reviews, revises, and updates a draft plan of these statistical areas. This geographic plan aims to help participants efficiently identify and prioritize areas that need to be reviewed and revised for their local areas.

From March 2018 through May 2018, Census Bureau staff initially contacts the 2010 Census PSAP participants to solicit participation in the 2020 Census PSAP. If 2010 Census PSAP participants decline to participate in the 2020 Census PSAP, the Census Bureau will reach out and invite local or regional planning agencies (RPAs) that can cover relatively large areas. To obtain coverage nationwide, the Census Bureau works with federally recognized tribes, Alaska Native Regional Associations (ANRAs), local or regional planning agencies, and councils of government officials (COGs). The Census Bureau strongly recommends PSAP participants to seek input from other census data users and stakeholders regarding 2020 Census PSAP statistical area delineations. Participants reach out to local governments for additional inputs and coordinate the multiple interests and requests that arise. Local governments that are interested in participating may contact the participants covering their area. The Census Bureau will publish the contact information of the 2020 Census PSAP participants on the PSAP Web site. The Census Bureau will contact federally recognized tribes to solicit their participation in the 2020 Census PSAP. For state recognized tribes, the Census Bureau will invite state governors to designate or appoint a state tribal liaison for the 2020 Census PSAP. The Census Bureau will also contact State Data Centers to help build the 2020 Census PSAP invitation and communication lists.

In July 2018, participants receive an official invitation package with a Contact Update Form that they fill out and return to the Census Bureau by mail. The Census Bureau then sends reminder packages to participants who do not respond in the time period mentioned on the Contact Update Form.

2. PSAP Delineation

In January 2019, the Census Bureau notifies program participants of the start of the delineation phase. The Census Bureau conducts the delineation phase of the 2020 Census PSAP boundaries using the web-based Geographic Update Partnership Software (GUPS), a customized geographic information system (GIS) based on an open-source platform. Participants can either download the materials and software online from the Census Bureau's Web site or have them shipped on DVDs. Participants have a maximum of 120 days from the date of receipt of materials to complete and submit statistical geography updates to the Census Bureau.

3. PSAP Verification

The verification phase starts January 2020 and allows participants to review the proposed edits from Census Bureau geographers. The Census Bureau sends a prepaid postcard to participants asking them to verify, accept, or reject the final version of the proposed plan, which is available online or by paper maps for tribal participants. Participants have 90 calendar days to review updates. Census Bureau staff contacts non-respondents through a follow-up mail-out and follow-up telephone calls. Once the Census Bureau receives the postcard with a participant's approval or acceptance of the final verification plan, the Census Bureau finalizes the 2020 statistical boundaries.

Method of Collection: The Census Bureau offers two methods of collection for the 2020 Census PSAP:

[1] State reservations are not statistical areas, but they are included in PSAP for administrative reasons.

1. GUPS submission (electronic): The Census Bureau uses several formats to collect information and updates for statistical boundaries during the internal review, delineation, and verification phases. The Census Bureau collects updated contact information from participants who choose to participate in the program online, by email, and by telephone. The Census Bureau-provided software, GUPS, is the only method of response for state and local governments. However, tribal participants reviewing TBGs, TCTs, or CDPs may elect to use GUPS or Census Bureau provided paper map products to review and edit tribal statistical geographies.

2. Paper map submission: Participants reviewing ANVSAs, OTSAs, OTSA tribal subdivisions, TDSAs, or SDTSAs are provided Census Bureau paper map products to review and edit tribal statistical areas.

2020 CENSUS PSAP SCHEDULE

Date	Event
March–May 2018	Contact 2010 Census PSAP participants to inquire about 2020 Census PSAP participation.
July 2018	PSAP invitation materials sent to PSAP participants.
January 2019	PSAP delineation phase begins. Participants have 120 calendar days to submit updates.
February 2019	PSAP Webinar trainings begin.
July 2019	Send PSAP participants communication notifying closeout of delineation phase.
January 2020	PSAP verification phase begins. Participants have 90 calendar days to review updates.

Affected Public: All federally or state recognized American Indian tribes and Alaska Natives in the United States, states, counties, local governments, and planning agencies.

Frequency: PSAP occurs once per decade in order to support the Decennial Census, the American Community Survey, and other Census Bureau programs and surveys.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 6.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2017–25644 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–73–2017]

Foreign-Trade Zone (FTZ) 39—Dallas/Fort Worth, Texas; Notification of Proposed Production Activity; Dallas Airmotive, Inc (Aircraft Engine Disassembly), DFW Airport, Texas

Dallas Airmotive, Inc (DAI) submitted a notification of proposed production activity to the FTZ Board for its facility in DFW Airport, Texas. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 20, 2017.

The DAI facility is located within Site 1 of FTZ 39. The facility is used for the disassembly of aircraft engines. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and 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 DAI from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, DAI would be able to choose the duty rates during customs entry procedures that apply to: AC generators; accumulators; linear actuators; valve and gear adapters; airflow control regulators; aluminum tubes and pipe fittings; fuel control arms; attenuators; autostart kits; auxiliary power units; rubber gearshaft baffles; mounting ball assemblies; aluminum ball floats; exhaust duct bands; roller bearing assemblies; ball bearings; roller bearings; cylindrical roller bearings; spherical roller bearings; bellcranks; metal bellows; turbofan and rotorcraft fan blades; insulation blankets; metal blocks for turbofans; nickel and steel bolts; container and engine brackets; fabric braids; plastic bumpers; plastic and metal bushing; bypass ducts; electric cables; steel cables; bearing cages; cam propeller controller engines; plastic and aluminum fuel caps; carbon face seal assemblies; oil seal carriers; turbofan and rotorcraft cases; turbofan chambers; chip detectors; signaling sensor chips; steel circlips; circuit breakers; steel clamps; clevis rod ends; sprag clutches; turbofan coils; turbofan pump collars; turbine module combusters; temperature compensators; turbine stator compressors; electrical conduits; turbofan cones; plug and field connectors; electrical contacts; universal torque, bleed valve and starting controls; ceramic fiber cords; steel cotter pins; turbofan and rotorcraft counter weights; magnesium and steel couplings; turbofan and rotorcraft covers; silicon and rubber cushions; torquemeter cylinders; steel vibration dampers; data collections units; paper, aluminum and steel decals; pump and gear deflectors; bagged, 8-unit dessicants; turbofan, valve and gear diaphragms; turbofan discs; steel dowels; dynamostarters; ejector pumps; tank assemblies; magnesium gear elbows; electronic engine controls; plastic envelopes; exciters; fairings; steel ferrules; filler caps; water and fuel filters; aluminum flanges; valve and automatic fuel controls; fuel pumps; fuel shut off cables; fuel/oil heat exchangers; oil tank gauges; silicone, rubber, paper, stone, asbestos, steel, copper, nickel, turbofan, valve and two-layer gaskets; gear; gearshafts; glow plugs; pin-valve guides; harness clips; heat shields; non-metallic hoses; turbofan, pump, gearbox and check valve housings; turbofan pump impellers; mechanical, humidity, oil level and electrical indicators; injectors; inner compressor modules; steel and nickel inserts; seal retaining plate insulation; thermocouple insulators; ITT indicators; ITT probes; steel keys; air pressure valves; rubber O-ring kits; fuel pump and filter seals parts kits; electrical leads; negative lead thermocouples; turbofan and overspeed control levers; turbofan and bleed valve liners; steel lock tabs; stainless steel locking nuts; logbooks; measurement interfaces; metering plugs; pushrod modification kits; heated P3 line modification kits; monitors; rubber,

shipping container and vibration mounts; steel nipples; turbo and rotorcraft nozzles; steel, nickel and titanium nuts; oil coolers; turbofan orifices; overspeed governors; overtorque limiters; aluminum packing; turbofan pad assemblies; turbofan panels; oil filter replacement parts kits; filter parts kits; fuel filter replacement parts kits; steel, copper, nickel and aluminum pins; turbofan pipes; turbofan valve pistons; plastic, glass, steel, identification, pump, gear and thermocouple plates; shipping, metal, electrical, chip and collector plugs; plungers; potentiometers; power section modules; pressure transmitters; propeller governor controls; oil and fuel pumps; turbofan quadrants; steel turbofan receptacles; reducing unions; reduction gear boxes; oil level indicator reflectors; regulators; variable and fixed resistors; retainer turbofans; plastic, rubber, steel and nickel turbofan rings; steel, nickel and aluminum tubular rivets; plain bearing rod ends; steel, nickel, turbofan, pump and valve rods; roller bearings; turbo and rotorcraft rotors; turbine helicopter engines; pulse pick-up runners; scavenge pumps; oil scoops; turbofan pump and valve screens; steel, nickel and aluminum screws; silicon, rubber, textile, nickel, turbofan, valve, mechanical, oil and electrical motor seals; turbofan and valve seats; oil, rotational speed and option sensors; air-oil separators; turbofan and rotorcraft shafts; fuel nozzle sheaths; electrical connector shells; shield assemblies; aluminum, turbofan and rotorcraft shims; shipping container skid base assemblies; plastic, steel, turbofan, rotorcraft, valve, gear and insulated sleeves; slider blocks; steel snap rings; turbofan and rotorcraft spacers; speed sensors and probes; steel spindles; spinners; steel springs; starter generators; power turbine stators; bleed check valve stoppers; oil strainers; plastic and steel straps; felt and fiberglass strips; steel and nickel studs; sump accessory gearboxes; rotorcraft and turbofan supports; shock absorber suspenders; switch assemblies; swivel joint casings; tape with a width less than 20cm; insulating, electrical and rubber tape; steel and aluminum tees; temperature sensors; plastic plate templates; terminal assemblies; terminal boards; terminal lugs; thermal couplings; immersion and T6 thermocouples; tie rods; torque transducers; bearing tracks; train idlers; transducers; transformer liners; transmitters; turbofan traps; steel trunnions; plastic, steel and aluminum tubes; turbine stator assemblies; turbofan engines; turboshaft gas turbine A/C engine; vacuum capsules; pressure reducing, hydraulic, safety, solenoid and regulator valves; turbo and rotorcraft vanes; silicone, fabric, steel locking, steel, copper, nickel and aluminum washers; wheels; nickel wire; steel wire rope; wiring harnesses; wrapper assemblies; and, yokes (duty rate ranges from duty-free to 49.5¢/kg + 7.5%). DAI 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 components and materials sourced from abroad include: Turbojet aircraft engines; and, turbopropeller engines (duty rate ranges from duty-free to 2.5%).

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 January 8, 2018.

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 Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25651 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–185–2017]

Foreign-Trade Zone 144—Brunswick, Georgia; Application for Subzone Orgill, Inc. Tifton, Georgia

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Brunswick and Glynn County Development Authority, grantee of FTZ 144, requesting subzone status for the facility of Orgill, Inc. (Orgill), located in Tifton, Georgia. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on November 22, 2017.

The proposed subzone (50 acres) is located at 260 Jordan Road, Tifton, Georgia (Tift County). The proposed subzone would be subject to the existing activation limit of FTZ 144. No authorization for production activity has been requested at this time.

In accordance with the Board's regulations, Qahira El-Amin of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

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 January 8, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 22, 2018.

A copy of the application 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 Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Qahira El-Amin at *Qahira.El-Amin@trade.gov* or (202) 482–5928.

Dated: November 22, 2017.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2017–25652 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–48–2017]

Foreign-Trade Zone (FTZ) 230—Piedmont Triad Area, North Carolina; Authorization of Production Activity Klaussner Home Furnishings (Upholstered Furniture) Asheboro and Candor, North Carolina

On July 24, 2017, Klaussner Home Furnishings submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 230D, in Asheboro and Candor, North Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (82 FR 37191–37192, August 9, 2017). On November 21, 2017, 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, and further subject to a restriction requiring that lithium ion batteries be admitted to the subzone in privileged foreign status (19 CFR 146.41) or domestic status (19 CFR 146.43).

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25657 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–74–2017]

Foreign-Trade Zone (FTZ) 204—Tri-Cities Area, TN/VA; Notification of Proposed Production Activity Eastman Chemical Company (Acetic Anhydride and Acetic Acid) Kingsport, Tennessee

The Tri-Cities Airport Authority, grantee of FTZ 204, submitted a notification of proposed production activity to the FTZ Board on behalf of Eastman Chemical Company (Eastman Chemical), located in Kingsport, Tennessee. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 21, 2017.

The Eastman Chemical facility is located within Site 12 of FTZ 204. The facility is used for the separation via vacuum distillation of an imported blend of acetic anhydride and acetic acid. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and 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 Eastman Chemical from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status material/component noted below, Eastman Chemical would be able to choose the duty rates during customs entry procedures that apply to acetic acid and acetic anhydride (duty rate ranges from 1.8 to 3.5%). Eastman Chemical 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 component/material sourced from abroad is a blend of acetic anhydride and acetic acid (duty rate 5%).

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 January 8, 2018.

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 Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25654 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–68–2017]

Foreign-Trade Zone (FTZ) 241—Fort Lauderdale, Florida; Notification of Proposed Production Activity; Marine Industries Association of South Florida (Yacht Repair/Refitting), Fort Lauderdale, Florida

The City of Fort Lauderdale, grantee of FTZ 241, submitted a notification of proposed production activity to the FTZ Board on behalf of the Marine Industries Association of South Florida (MIASF), located in Fort Lauderdale, Florida. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 17, 2017.

MIASF's facilities are located within Subzone 241A. The facilities are used for yacht repair and refitting. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and 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 MIASF from customs duty payments on the foreign-status components used in export production (estimated 95 percent of production). On its domestic sales, for the foreign-status materials/components noted below, MIASF would be able to choose the duty rates during customs entry procedures that apply to yachts, inflatable boats, boat tenders, and outboard motor tenders (duty-rate ranges from 1% to 2.4%). MIASF 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 components and materials sourced from abroad include: Diesel marine propulsion engines; fuel pumps; fuel coolers; oil pumps; oil coolers; fuel injectors; fuel injector pumps; heat exchangers for marine propulsion engines; fine mesh screen filters; cast iron cylinder liners; cylinder heads; pistons; piston rings; engine mounts; crank shafts; cam shafts; thrust bearings; linear bearings; seal kits; cylinder head gaskets; rubber hoses; aluminum piping; zinc anode kits; turbochargers; aluminum exhausts; rubber v-belts combined with textiles; air filters; thermostats; raw water pumps; valves; starters; alternators/generators; electric control boxes; sending units; sensors; instrument clusters; stainless steel propellers; brass propellers; stainless steel propeller shafts; brass propeller shafts; stainless steel couplings; brass spool pieces; stainless steel spool pieces; bushings for propeller shafts; gear boxes for propellers; gear box mounts; gear coolers; gear box pumps; shaft struts; strut bearings; heat exchangers for running gear; hydraulic valves; stainless steel sprayer rings for running gear; gear legs for bow thrusters; mounting hardware; hydraulic filters; power take offs for bow thrusters; electrical control heads for bow thrusters; marine steering systems; brass rudders; fiberglass rudders; stainless steel tie bars; rubber lined naval brass bearings; stainless steel quadrants; steel hydraulic fittings; rubber hydraulic hoses; hydraulic pumps; hydraulic rams; electrical power packs; marine stabilizers; hydraulic power packs; fins for stabilizers; gyroscopes; cabling; pulsation dampeners; marine generators; generator mounts; electrical wire windings; aluminum sound shields; fuel water separators; aluminum tank fittings; rubber gaskets; fresh water system; fresh water pumps; stainless steel water valves; copper water valves; freshwater maker units; hot water tanks; bath and sink taps/faucets; copper piping; lube oil systems; lubricating oil pumps; stainless steel flow control oil valves; fuel systems; fire control spray heads; fire and smoke

detectors; ventilation systems; ceiling fans; wall fans; metal ducting; programmable logic controllers; dampeners; moisture eliminators; electrical systems; electrical wire-plastic covered copper; automatic circuit breakers; electric switches; surge suppressors; junction boxes and enclosures (electrical system); programmable logic controller modules; monitoring systems; lighting fixtures and lamp holders; light bulbs; compressors and pumps (air conditioning); copper evaporator coils; fan coil units and blowers; enclosures (shore power system); heat exchangers (air conditioning system); deck winches; captive winches; mast and exhaust stack outlets; hot tubs; swimming pools; aluminum booms; boom vang; aluminum masts; sails; aluminum spreaders; EC6 carbon rigging; aluminum solid rods; furlers; mandrels; yokes; bulb keels; fins for sailboats; stainless steel anchors; stainless steel chains for anchors; electric windlasses; stainless steel snubber hooks; life rafts; helm stations; double and single loudspeakers; davits; inflatable motorboats (tender); outboard motorboats (tender); spotlights; stainless steel fairleads; stainless steel bollards; stainless steel stanchions; synthetic fiber lifelines; inflatable water toys; water skies, surfboards and paddleboards; fuel spill kits; stainless steel tender chocks; boat dock fenders; safety equipment including life jackets and belts; stainless steel freeing port scuppers; outdoor cushions made of man-made fibers; awnings and canvas covers; helm screens; radars; control modules; automatic identification systems; global marine distress and safety systems; bridge computers; navigation software; vinyl helm or captain chairs; navigational charts; electronic components (navigational and radio aid); gyro compasses; satellite domes; communication domes; depth sounders; sonars; binoculars; wood laminate flooring; ceramic tile flooring; marble flooring; carpet flooring; textile and vinyl wall coverings; vinyl ceilings; refrigerators; microwave ovens; ovens and cooktops; toasters; water heaters; coffee makers; dishwashers; blinds; curtains; shades (window treatments); leather, polyester, polyurethane fabric, and PVC coated vinyl upholstery replacements; electric door closer; manual door hinges; self-enclosed saunas; elevators; dumb waiters; kitchen, bedroom, bathroom, and cabinetry hardware; wood veneers; desk and table lamp lighting; wall mounted lighting; soft furnishings including sofas, chairs, wood tables, wall units, bedroom sets, and mattresses; stainless steel cutlery; lead crystal glassware; glassware (other); bathroom and kitchen fixtures and fittings; toilets; marble countertops; bathtubs; shower enclosures; glass partitions; computer equipment racks; computers; programmable data communication processors; televisions; television lifts and enclosures; DVD players; digital movie and music storage; remote controls for electronics; digital media switches; IT switches; in room AV processors; infrared pick-ups; AC rack coolers; coaxial cabling; docking stations; video projectors; custom theater seating; sound installations; control pads; patch panels; grounding plates; aerial-antennas for radio reception; cell modules; lighting modules; mounting hardware; projector screens; internal and external communication telephone systems; cabling wire for telephone systems; steel sheets; aluminum sheets; aluminum profiles; carbon fiber sheets; glass reinforced plastic-fiberglass for repairs; epoxy fairing compound; polyurethane paint for yachts; enamel paint for yachts; and aliphatic hydrocarbon based anti-fouling paint (duty rate ranges from duty free to 22.5%).

The request indicates that thrust, linear, and strut bearings; naval brass bearings; steel sheets; aluminum sheets; aluminum profiles, and wood laminate flooring are subject to antidumping/countervailing duty (AD/CVD) orders when 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 the following components will be admitted to the zone in privileged foreign status (thereby precluding inverted tariff benefits on those components): Aluminum piping; rubber v-belts combined with textiles; gear box mounts; aluminum sound shields; aluminum tank fittings; aluminum booms; aluminum masts; aluminum spreaders; aluminum solid rods; synthetic fiber lifelines; awnings and canvas covers; carpet flooring; textile wall coverings; blinds; curtains; shades-window treatments; leather, polyester and polyurethane fabrics; PVC coated vinyl upholstery replacements; electric door closers; manual door hinges; kitchen, bedroom and bathroom cabinetry; cabinetry hardware; wood veneers; television lifts and enclosures; and, mounting hardware.

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 January 8, 2018.

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 Web site, which is accessible via *www.trade.gov/ftz*.

For further information, contact Qahira El-Amin at *Qahira.El-Amin@trade.gov* or (202) 482–5928.

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25656 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–75–2017]

Proposed Reestablishment and Expansion of Site—Foreign-Trade Zone 276 Kern County, California

Pursuant to the provisions of the Foreign-Trade Zones (FTZ) Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400), an application has been submitted to the FTZ Board by Kern County, grantee of Foreign-Trade Zone 276, requesting to reestablish the zone adjacent to the Los Angeles/Long Beach U.S. Customs and Border Protection port of entry. The reestablished zone would be comprised of previously approved Site 2, which the application proposes to expand.

FTZ 276 was initially approved on January 19, 2010, as a new zone adjacent to the Meadows Field user-fee airport (Board Order 1653, 75 FR 8920–8921, February 26, 2010). A user-fee airport may serve as a port of entry for purposes of establishing, operating and maintaining a FTZ pursuant to the FTZ Board's regulations (see 15 CFR 400.2(m)). The grantee now proposes to reestablish the zone as an additional zone adjacent to the Los Angeles/Long Beach U.S. Customs and Border Protection port of entry. The reestablished zone would be comprised of Site 2—within the Tejon Ranch Commerce Center, located at the

intersection of Interstate 5 and Highway 99, Lebec, California—which the application proposes to expand from 247 to 1,093 acres.

The application was formally docketed on November 21, 2017. The applicant is authorized to make the proposal under the California Government Code, Sections 6300–6305. The application indicates a need for expanded zone designation within the Tejon Ranch Commerce Center. Specific manufacturing approvals are not being sought at this time. Such requests would be made to the FTZ Board on a case-by-case basis.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is January 8, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 22, 2018.

A copy of the application 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 FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25655 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–135–2017]

Approval of Subzone Status; Ekornes Inc.; Somerset, New Jersey

On September 7, 2017, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the New Jersey Department of State, grantee of FTZ 44, requesting subzone status subject to the existing activation limit of FTZ 44, on behalf of Ekornes Inc., in Somerset, New Jersey.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (82 FR 42784, September 12, 2017). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 44J was approved on November 13, 2017, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 44's 407.5- acre activation limit.

Dated: November 21, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–25653 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–822–806, A–821–824, A–520–808]

Certain Carbon and Alloy Steel Wire Rod From Belarus, the Russian Federation, and the United Arab Emirates: Affirmative Final Determinations of Sales at Less Than Fair Value and Partial Affirmative Finding of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of carbon and alloy steel wire rod (wire rod) from Belarus, the Russian Federation (Russia), and the United Arab Emirates (the UAE) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The final estimated dumping margins of sales at LTFV are shown in in the ''Final Determinations'' section of this notice.

DATES: Applicable November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Rebecca Janz at (202) 482–2972 (Belarus), Kaitlin Wojnar at (202) 482–3857 (Russia), Carrie Bethea (UAE) at (202) 482–1491, 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 September 12, 2017, the Department published the preliminary affirmative determination of critical circumstances concerning Russia and the preliminary determinations of sales at LTFV in the investigations of wire rod from Belarus, Russia, and the UAE.[1] We invited interested parties to comment on these preliminary determinations. We received no comments on the *Preliminary LTFV Determinations* but did receive comments on the scope of these investigations. Additionally, no interested party requested a hearing.

Scope of the Investigations

The products covered by these investigations are wire rod from Belarus, Russia, and the UAE. For a complete description of the scope of the Belarus, Russia, and the UAE investigations, *see* the Appendix to this notice.

Scope Comments

During the course of these investigations, the Department received numerous scope comments from interested parties. Prior to the *Preliminary LTFV Determinations,* the Department issued a Preliminary Scope Decision Memorandum to address these comments. As a result of these comments, the Department made no changes to the scope of these investigations as it appeared in the *Initiation Notice.*[2]

In September 2017, we received scope case and rebuttal briefs. On November 20, 2017, we issued the Final Scope Decision Memorandum in response to these comments in which we did not

[1] *See Certain Carbon and Alloy Steel Wire Rod from the Russian Federation and the United Arab Emirates: Affirmative Preliminary Determinations of Sales at Less Than Fair Value, and Affirmative Preliminary Determination of Critical Circumstances for Imports of Certain Carbon and Alloy Steel Wire Rod from the Russian Federation,* 82 FR at 42794 (September 12, 2017) (*Preliminary LTFV Determinations Russia & UAE*), and accompanying Preliminary Decision Memorandum (PDM); and *Carbon and Alloy Steel Wire Rod from Belarus: Preliminary Determination of Sales at Less Than Fair Value,* 82 FR 42796 (September 12, 2017) (*Preliminary LTFV Determination Belarus*), and accompanying PDM (collectively, *Preliminary LTFV Determinations*).

[2] For discussion of these comments, *see* Memorandum, ''Carbon and Alloy Steel Wire Rod from Belarus, Italy, the Republic of Korea, the Russian Federation, South Africa, Spain, the Republic of Turkey, Ukraine, the United Arab Emirates, and the United Kingdom: Scope Comments Decision Memorandum for the Preliminary Determination'' (Preliminary Scope Decision Memorandum), dated August 7, 2017; *see also Carbon and Alloy Steel Wire Rod from Belarus, Italy, the Republic of Korea, the Russian Federation, South Africa, Spain, the Republic of Turkey, Ukraine, United Arab Emirates, and United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 19207 (April 20, 2017) (*Initiation Notice*).

change the scope of these investigations.[3]

Period of Investigations

The period of investigation (POI) is January 1, 2016, through December 31, 2016, for Russia and the UAE. Because Belarus is a non-market economy (NME) country, the POI for that investigation is July 1, 2016, through December 31, 2016.

Verification

Because the mandatory respondents in the Russian and UAE investigations did not provide the information requested, and the Department determined that Byelorussian Steel Works (BSW) was uncooperative, the Department did not conduct verifications under section 782(i)(1) of the Act.

Analysis of Comments Received, Use of Adverse Facts Available, and Changes Since the Preliminary Determinations

As noted above, we received no comments pertaining to the *Preliminary LTFV Determinations.*

As stated in the *Preliminary LTFV Determination Belarus,* we found that BSW is not eligible for separate rate status because it is wholly-owned by the Government of Belarus. We also found in the *Preliminary LTFV Determinations* that the Belarus-wide entity, as well as the mandatory respondents in the investigations involving Russia and the UAE,[4] withheld information that the Department requested and failed to provide information by the specified deadlines. This significantly impeded the proceedings, and accordingly, resulted in the Department relying on facts otherwise available, pursuant to sections 776(a)(1) and 776(a)(2)(A)–(C) of the Tariff Act of 1930, as amended (the Act). Further, we found that these respondents did not cooperate to the best of their abilities to comply with our requests for information, and, accordingly, we determined it appropriate to apply adverse inferences in selecting from the facts available, pursuant to section 776(b) of the Act and 19 CFR 351.308(a).[5] For the purposes of the final determinations, we continue to find that, in accordance with sections 776(a)–(b) of the Act, application of facts otherwise available with adverse inferences is appropriate. Accordingly, the Department has made no changes to the *Preliminary LTFV Determinations,* and no decision memoranda accompany this **Federal Register** notice.

Final Affirmative Determinations of Critical Circumstances

For Russia, in accordance with section 733(e)(1) of the Act and 19 CFR 351.206, we preliminarily found that critical circumstances exist with respect to mandatory respondents, Abinsk and NLMK Ural, and all other producers and exporters of wire rod from Russia (All Others).[6] As stated above, the Department received no comments concerning the *Preliminary LTFV Determinations.* Thus, for these final determinations, we continue to find that, in accordance with section 735(a)(3) of the Act and 19 CFR 351.206, critical circumstances exist for imports from all producers and exporters of wire rod from Russia.

All-Others Rate

As discussed in the *Preliminary LTFV Determinations,* the Department based the selection of the ''All-Others'' rates in Russia and the UAE, on the dumping margins alleged in the Petitions,[7] in accordance with section 735(c)(5)(B) of the Act. We made no changes to the selection of these rates for these final determinations.[8]

Final Determinations

The final estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margin (percent)
Belarus	
Belarus-Wide Entity[9]	280.02
Russia	
Abinsk Electric Steel Works Ltd	756.93
JSC NLMK-Ural	756.93
All-Others	436.80
UAE	
Emirates Steel Industries PJSC	84.10
All-Others	84.10

[9] The Belarus-wide entity includes BSW, the sole mandatory respondent in the investigation of wire rod from Belarus.

Continuation of Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, for these final determinations, we will direct U. S. Customs and Border Protection (CBP) to suspend liquidation of all entries of wire rod from Russia, as described in the Appendix to this notice, which were entered, or withdrawn from warehouse, for consumption on or after June 14, 2017 (90 days prior to the date of publication of the *Preliminary LTFV Determinations*), because we continue to find that critical circumstances exist with regard to imports from all producers and exporters of wire rod from Russia.

In accordance with section 735(c)(1)(B) of the Act, for these final determinations, the Department will instruct CBP to continue to suspend liquidation of all entries of wire rod from Belarus and the UAE, as described in the Appendix to this notice, which were entered or withdrawn from warehouse, for consumption on or after September 12, 2017, the date of publication of the preliminary determinations of the Belarus and UAE investigations in the **Federal Register**.

With respect to entries from Belarus, pursuant to section 735(c)(1)(B) of the Act and 19 CFR 351.210(d), CBP shall require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price as shown above.

With respect to entries from Russia, pursuant to section 735(c)(1)(B)(ii) of the Act, CBP shall require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) For Abinsk and NLMK Ural, the cash deposit rate will be equal to the estimated weighted-average dumping margin which the Department determined in this final determination; (2) if the exporter is not a firm identified in this investigation

[3] For discussion of these comments, *see* Memorandum, ''Carbon and Alloy Steel Wire Rod from Belarus, Italy, the Republic of Korea, the Russian Federation, South Africa, Spain, the Republic of Turkey, Ukraine, the United Arab Emirates, and the United Kingdom: Final Scope Memorandum'' (Final Scope Decision Memorandum), dated November 20, 2017.

[4] Abinsk Electric Steel Works Ltd. (Abinsk) and JSC NLMK-Ural (NLMK Ural) (Russia), and Emirates Steel Industries PJSC (Emirates Steel) (UAE).

[5] *See Preliminary LTFV Determinations Russia and UAE,* 82 FR at 42794, and accompanying PDM at 4–6; and *Preliminary LTFV Determination Belarus,* 82 FR at 42797, and accompanying PDM at 6–10.

[6] *See Preliminary LTFV Determinations Russia and UAE,* 82 FR at 42795.

[7] *See* the Petitions for the Imposition of Antidumping Duties on Carbon and Alloy Steel Wire Rod from Belarus, Italy, the Republic of Korea, the Russian Federation, the Republic of South Africa, Spain, Turkey, Ukraine, United Arab Emirates, and the United Kingdom, dated March 28, 2017 (the Petitions).

[8] *See Preliminary LTFV Determinations Russia and UAE,* 82 FR at 42795.

but the producer is, then the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the producer of the subject merchandise; (3) the cash deposit rate for all other producers or exporters will be 436.80 percent, as discussed in the ''All-Others Rate'' section, above.

With respect to entries from the UAE, pursuant to section 735(c)(1)(B)(ii) of the Act, CBP shall require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) For Emirates Steel, the cash deposit rate will be equal to the estimated weighted-average dumping margin which the Department determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, then the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the producer of the subject merchandise; (3) the cash deposit rate for all other producers or exporters will be 84.10 percent, as discussed in the ''All-Others Rate'' section, above.

These instructions suspending liquidation will remain in effect until further notice.

Disclosure

The estimated weighted-average dumping margins assigned to the mandatory respondents in these investigations in the *Preliminary LTFV Determinations* were based on adverse facts available. As we made no changes to these margins since the *Preliminary LTFV Determinations,* no disclosure of calculations is necessary for these final determinations.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of our final determination of sales at LTFV for Belarus, Russia, and the UAE and final affirmative determination of critical circumstances for Russia. Because the final determinations in these proceedings are affirmative, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of wire rod from Belarus, Russia, and the UAE no later than 45 days after our final determination, in accordance with section 735(b)(2) of the Act. If the ITC determines that such injury does not exist, these proceedings will be terminated and all cash deposits posted will be refunded or cancelled. If the ITC determines that such injury exists, the Department will issue antidumping duty orders directing CBP to assess upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension liquidation.

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an 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.

Notification to Interested Parties

These determinations are issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).

Dated: November 20, 2017.

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

Scope of the Investigations

The merchandise covered by these investigations are certain hot-rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, less than 19.00 mm in actual solid cross-sectional diameter. Specifically excluded are steel products possessing the above-noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (HTSUS) definitions for (a) stainless steel; (b) tool steel; (c) high-nickel steel; (d) ball bearing steel; or (e) concrete reinforcing bars and rods. Also excluded are free cutting steel (also known as free machining steel) products (*i.e.,* products that contain by weight one or more of the following elements: 0.1 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorous, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium). All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under investigation are currently classifiable under subheadings 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3093; 7213.91.4500, 7213.91.6000, 7213.99.0030, 7227.20.0030, 7227.20.0080, 7227.90.6010, 7227.90.6020, 7227.90.6030, and 7227.90.6035 of the HTSUS. Products entered under subheadings 7213.99.0090 and 7227.90.6090 of the HTSUS also may be included in this scope if they meet the physical description of subject merchandise above. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

[FR Doc. 2017–25659 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold an open meeting via teleconference on Thursday, December 14, 2017. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to consider recommendations being developed by the National Goal Subcommittee, the Secure Travel Partnership Operations Subcommittee, and the Secure Travel Partnership Communications Subcommittee. The final agenda will be posted on the Department of Commerce Web site for the Board at *http://trade.gov/ttab* at least one week in advance of the meeting.

DATES: Thursday, December 14, 2017, 1:00 p.m.–2:00 p.m. EST. The deadline for members of the public to register, including requests to make comments during the meeting and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on Thursday, December 7, 2017.

ADDRESSES: The meeting will be held via conference call. The call-in number and passcode will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW., Room 10003, Washington, DC 20230 or by email to *TTAB@trade.gov.* Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Brian Beall, the United States Travel

and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Ave. NW., Room 10003, Washington, DC 20230; telephone: 202–482–5634; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may not be possible to grant. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public speaking time may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting speaking time is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EST on Thursday, December 7, 2017, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Brian Beall at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EST on Thursday, December 7, 2017, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

Dated: November 16, 2017.

Brian Beall,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2017–25668 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 99–12A05]

Export Trade Certificate of Review

ACTION: Notice of Application To Amend the Export Trade Certificate of Review Issued to California Almond Export Association, LLC (''CAEA''), Application No. 99–12A05.

SUMMARY: The Office of Trade and Economic Analysis (''OTEA'') of the International Trade Administration, Department of Commerce, received an application to amend an Export Trade Certificate of Review (''Certificate''). This notice summarizes the proposed amendment and requests comments relevant to whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its application.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the amended Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 99–12A05.''

Summary of the Application

Applicant: CAEA, 4800 Sisk Road Modesto, CA 95356.

Contact: Bill Morecraft, Senior Vice President, Blue Diamond Growers, Telephone: (916) 446–8537.

Application No.: 99–12A05.

Date Deemed Submitted: November 14, 2017.

Proposed Amendment: CAEA seeks to amend its Certificate as follows:

- Add Stewart & Jasper Marketing, Inc. as a Member

CAEA's proposed amendment of its Certificate would result in the following Members list:

Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Blue Diamond Growers, Sacramento, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Livingston, CA
Fair Trade Corner, Inc., Chico, CA
Fisher Nut Company, Modesto, CA
Hilltop Ranch, Inc., Ballico, CA
Hughson Nut, Inc., Hughson, CA
Mariani Nut Company, Winters, CA
Nutco, LLC d.b.a. Spycher Brothers, Turlock, CA
P–R Farms, Inc., Clovis, CA
Roche Brothers International Family Nut Co., Escalon, CA
RPAC, LLC, Los Banos, CA
South Valley Almond Company, LLC, Wasco, CA
Stewart & Jasper Marketing, Inc., Newman, CA
SunnyGem, LLC, Wasco, CA
Western Nut Company, Chico, CA
Wonderful Pistachios & Almonds, LLC, Los Angeles, CA

Dated: November 22, 2017.

Amanda Reynolds,

Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2017–25695 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–469–818]

Ripe Olives From Spain: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) preliminarily determines that countervailable subsidies are being provided to producers and exporters of ripe olives from Spain. The period of investigation is January 1, 2016, through December 31, 2016.

DATES: Application November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, Lana Nigro, or Jennifer Shore, 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) 482–1785, (202) 482–1779, (202) 482–2778, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). The Department published the notice of initiation of this investigation on July 19, 2017.[1] On August 30, 2017, the Department postponed the preliminary determination of this investigation to November 20, 2017.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov*, and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are ripe olives from Spain. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to the Department's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation*.

Methodology

The Department is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, the Department preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[6]

The Department notes that, in making these findings, it relied, in part, on facts available pursuant to section 776(a) of the Act because information necessary for our analysis was not available on the record. For further information, *see* ''Partial Use of Facts Available'' in the Preliminary Decision Memorandum.

Alignment

As noted in the Preliminary Decision Memorandum, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), the Department is aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of Ripe Olives from Spain, based on a request made by the petitioner.[7] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than April 3, 2018, unless postponed.

All-Others Rate

Sections 703(d) and 705(c)(5)(A) of the Act provide that in the preliminary determination, the Department shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act. In this investigation, the Department calculated individual estimated countervailable subsidy rates for Aceitunas Guadalquivir S.L.U. (Aceitunas Guadalquivir), Agro Sevilla Aceitunas S.Coop.And. (Agro Sevilla), Angel Camacho Alimentación, S.L. (Camacho), that are not zero, *de minimis,* or based entirely on facts available. The Department calculated the all-others rate using a weighted-average of the estimated subsidy rates calculated for the individually examined respondents using each company's business proprietary data for the merchandise under consideration.[8]

Preliminary Determination

TheDepartment preliminarily determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Aceitunas Guadalquivir S.L.U.[9]	2.31
Agro Sevilla Aceitunas S.Coop.And	2.47
Angel Camacho Alimentación, S.L.[10]	7.24
All-Others	4.47

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, the

[1] *See Ripe Olives from Spain: Initiation of Countervailing Duty Investigation,* 82 FR 33050 (July 19, 2017) (*Initiation Notice*).

[2] *See Ripe Olives from Spain: Postponement of Preliminary Determination in the Countervailing Duty Investigation,* 82 FR 41210 (August 30, 2017).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination of the Countervailing Duty Investigation of Ripe Olives from Spain,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] *See* Letter from the petitioner, ''Request for Alignment of Final Determination,'' dated November 16, 2017.

[8] For a complete analysis of the data, please *see* the All-Others Calculation Memorandum dated concurrently with this notice.

[9] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Aceitunas Guadalquivir S.L.U.: Coromar Inv., S.L., AG Explotaciones Agricolas, S.L.U., and Grupo Aceitunas Guadalquivir, S.L.

[10] As discussed in the Preliminary Decision Memorandum, the Department has found the following companies to be cross-owned with Angel Camacho Alimentación, S.L.: Grupo Angel Camacho Alimentacíon, Cuarterola S.L., and Cucanoche S.L.

Department will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), the Department will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

The Department intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, the Department intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

In accordance with section 703(f) of the Act, the Department will notify the International Trade Commission (ITC) of its determination. If the final determination is affirmative, the ITC will make its determination before the later of 120 days after the date of this preliminary determination or 45 days after the final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: November 20, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The products covered by this investigation are certain processed olives, usually referred to as ''ripe olives.'' The subject merchandise includes all colors of olives; all shapes and sizes of olives, whether pitted or not pitted, and whether whole, sliced, chopped, minced, wedged, broken, or otherwise reduced in size; all types of packaging, whether for consumer (retail) or institutional (food service) sale, and whether canned or packaged in glass, metal, plastic, multi-layered airtight containers (including pouches), or otherwise; and all manners of preparation and preservation, whether low acid or acidified, stuffed or not stuffed, with or without flavoring and/or saline solution, and including in ambient, refrigerated, or frozen conditions.

Included are all ripe olives grown, processed in whole or in part, or packaged in Spain. Subject merchandise includes ripe olives that have been further processed in Spain or a third country, including but not limited to curing, fermenting, rinsing, oxidizing, pitting, slicing, chopping, segmenting, wedging, stuffing, packaging, or heat treating, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in Spain.

Excluded from the scope are: (1) Specialty olives[12] (including ''Spanish-style,'' ''Sicilian-style,'' and other similar olives) that have been processed by fermentation only, or by being cured in an alkaline solution for not longer than 12 hours and subsequently fermented; and (2) provisionally prepared olives unsuitable for immediate consumption (currently classifiable in subheading 0711.20 of the Harmonized Tariff Schedule of the United States (HTSUS)).

The merchandise subject to this investigation is currently classifiable under subheadings 2005.70.0230, 2005.70.0260, 2005.70.0430, 2005.70.0460, 2005.70.5030, 2005.70.5060, 2005.70.6020, 2005.70.6030, 2005.70.6050, 2005.70.6060, 2005.70.6070, 2005.70.7000, 2005.70.7510, 2005.70.7515, 2005.70.7520, and 2005.70.7525 HTSUS. Subject merchandise may also be imported under subheadings 2005.70.0600, 2005.70.0800, 2005.70.1200, 2005.70.1600, 2005.70.1800, 2005.70.2300, 2005.70.2510, 2005.70.2520, 2005.70.2530, 2005.70.2540, 2005.70.2550, 2005.70.2560, 2005.70.9100, 2005.70.9300, and 2005.70.9700. Although HTSUS subheadings are provided for convenience and US Customs purposes, they do not define the scope of the investigation; rather, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2017–25660 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[12] Some of the major types of specialty olives and their curing methods are:

• ''Spanish-style'' green olives. Spanish-style green olives have a mildly salty, slightly bitter taste, and are usually pitted and stuffed. This style of olive is primarily produced in Spain and can be made from various olive varieties. Most are stuffed with pimento; other popular stuffings are jalapeno, garlic, and cheese. The raw olives that are used to produce Spanish-style green olives are picked while they are unripe, after which they are submerged in an alkaline solution for typically less than a day to partially remove their bitterness, rinsed, and fermented in a strong salt brine, giving them their characteristic flavor.

• ''Sicilian-style'' green olives. Sicilian-style olives are large, firm green olives with a natural bitter and savory flavor. This style of olive is produced in small quantities in the United States using a Sevillano variety of olive and harvested green with a firm texture. Sicilian-style olives are processed using a brine-cured method, and undergo a full fermentation in a salt and lactic acid brine for 4 to 9 months. These olives may be sold whole unpitted, pitted, or stuffed.

• ''Kalamata'' olives: Kalamata olives are slightly curved in shape, tender in texture, and purple in color, and have a rich natural tangy and savory flavor. This style of olive is produced in Greece using a Kalamata variety olive. The olives are harvested after they are fully ripened on the tree, and typically use a brine-cured fermentation method over 4 to 9 months in a salt brine.

• Other specialty olives in a full range of colors, sizes, and origins, typically fermented in a salt brine for 3 months or more.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–891]

Carbon and Alloy Steel Wire Rod From the Republic of Korea: Amended Preliminary Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On October 31, 2017, the Department of Commerce (Department) published in the **Federal Register** the *Preliminary Determination* [1] of the antidumping duty investigation of carbon and alloy steel wire rod (wire rod) from the Republic of Korea (Korea). The Department is amending the *Preliminary Determination* of the investigation to correct a significant ministerial error.

DATES: Effective November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Lingjun Wang, 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) 482–2316.

SUPPLEMENTARY INFORMATION:

Background

On October 31, 2017, the Department published in the **Federal Register** the *Preliminary Determination* of wire rod from Korea. On November 1, 2017, Gerdau Ameristeel US Inc., Keystone Consolidated Industries, Inc., and Charter Steel (collectively, the petitioners) alleged that the Department made a significant ministerial error in the *Preliminary Determination.*

Scope of the Investigation

The product covered by this investigation is wire rod from Korea. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' in the Appendix to this notice.

Significant Ministerial Error

A ministerial error is defined in 19 CFR 351.224(f) as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.'' A significant ministerial error is defined in 19 CFR 351.224(g) as a ministerial error, the correction of which, singly or in combination with other errors, would result in: (1) A change of at least five absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin calculated in the original (erroneous) preliminary determination; or (2) a difference between a weighted-average dumping margin of zero or *de minimis* and a weighted-average dumping margin of greater than *de minimis* or vice versa. Further, 19 CFR 351.224(e) provides that the Department ''will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination.''

Ministerial Error Allegation

The petitioners allege that the Department failed to convert the product matching control number (CONNUM)-specific per-unit import duty cost amounts that were denominated in Korean won to U.S. dollars when it granted POSCO a duty drawback adjustment to U.S. price.[2] The petitioners also maintain that correcting this error results in an increase of more than five absolute percentage points in, but not less than 25 percent of, the weighted-average dumping margin, thereby meeting the definition of ''significant'' pursuant to 19 CFR 351.224(g)(1).[3]

We agree with the petitioners' allegation. The CONNUM-specific per-unit duty cost amount that forms the basis of our duty-drawback adjustment was in Korean won.[4] The Department inadvertently failed to convert CONNUM-specific per-unit duty cost amount to U.S. dollars when adjusting U.S. price in the margin calculation program.[5] This error constitutes a ministerial error within the meaning of 19 CFR 351.224(f).[6] Moreover, correcting this ministerial error changes the margin from 10.09 percent to 40.80 percent, thereby making this error significant pursuant to 19 CFR 351.224(g)(1).[7]

Amended Preliminary Determination

We are amending the preliminary determination of sales at less-than-fair-value for wire rod from Korea to reflect the correction of a ministerial error made in the margin calculation for POSCO. In addition, because the preliminary ''All-Others'' rate was based on the estimated weighted-average dumping margin calculated for POSCO, we are also amending the ''All-Others'' rate. As a result of the correction of the ministerial error, the revised weighted-average dumping margins are as follows:

Exporter/manufacturer	Weighted-average dumping margin (percent)
POSCO	40.80
All-Others	40.80

Amended Cash Deposits and Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be revised according to the rates established in this amended preliminary determination, in accordance with section 733(d) and (f) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.224. Because the rates are increasing from the *Preliminary Determination,* the amended cash deposit rates will be effective on the date of publication of this notice in the **Federal Register**.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we notified the International Trade Commission of our amended preliminary determination.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the amended preliminary determination, in accordance with 19 CFR 351.224.

[1] *See Carbon and Alloy Steel Wire Rod from the Republic of Korea: Preliminary Affirmative Determination of Sales at Less Than Fair Value, and Preliminary Negative Determination of Critical Circumstances,* 82 FR 50386 (October 31, 2017) (*Preliminary Determination*); *see also* the petitioners' November 1, 2017 letter, ''Petitioners' Ministerial Error Allegations Concerning POSCO'' (Ministerial Error Allegation).

[2] *See* DOC October 24, 2014 Memorandum: ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—POSCO,'' and DOC October 24, 2014 Memorandum ''Preliminary Determination Margin Calculation for POSCO.''

[3] *See* Ministerial Error Allegation.

[4] *See* POSCO August 23, 2017 Response to Supplemental Section D Questionnaire at SD–12 and Exhibit SD–10, and POSCO October 11, 2017 Response to Second Supplemental Section D Questionnaire at SD2–6 and Exhibit SD2–7.

[5] *See* DOC October 24, 2017 Memorandum: ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—POSCO'' at 4, and DOC October 24, 2017 Memorandum: ''Preliminary Determination Margin Calculation for POSCO'' at 5.

[6] *See* DOC Memorandum: ''Allegation and Analysis of Ministerial Error in the Preliminary Determination,'' dated concurrently with this memorandum (Ministerial Error Analysis Memorandum).

[7] *See* DOC Memorandum: ''Amended Preliminary Determination Margin Calculation for POSCO,'' dated concurrently with this memorandum (Amended Preliminary Calculation Memorandum).

This amended preliminary determination is issued and published in accordance with sections 733(f) and 777(i) of the Act and 19 CFR 351.224(e).

Dated: November 20, 2017.

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

Scope of the Investigation

The products covered by this investigation are certain hot-rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, less than 19.00 mm in actual solid cross-sectional diameter. Specifically excluded are steel products possessing the above-noted physical characteristics and meeting the Harmonized Tariff Schedule of the United States (HTSUS) definitions for (a) stainless steel; (b) tool steel; (c) high-nickel steel; (d) ball bearing steel; or (e) concrete reinforcing bars and rods. Also excluded are free cutting steel (also known as free machining steel) products (*i.e.,* products that contain by weight one or more of the following elements: 0.1 percent or more of lead, 0.05 percent or more of bismuth, 0.08 percent or more of sulfur, more than 0.04 percent of phosphorous, more than 0.05 percent of selenium, or more than 0.01 percent of tellurium). All products meeting the physical description of subject merchandise that are not specifically excluded are included in this scope.

The products under investigation are currently classifiable under subheadings 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3093; 7213.91.4500, 7213.91.6000, 7213.99.0030, 7227.20.0030, 7227.20.0080, 7227.90.6010, 7227.90.6020, 7227.90.6030, and 7227.90.6035 of the HTSUS. Products entered under subheadings 7213.99.0090 and 7227.90.6090 of the HTSUS also may be included in this scope if they meet the physical description of subject merchandise above. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

[FR Doc. 2017–25658 Filed 11–27–17; 8:45 am]

BILLING CODE 3510–DS–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (''PRA''), this notice announces that the Information Collection Request (''ICR'') abstracted below has been forwarded to the Office of Management and Budget (''OMB'') for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before December 28, 2017.

ADDRESSES: Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (''OIRA'') in OMB, within 30 days of the notice's publication, by either of the following methods. Please identify the comments by OMB Control No. 3038–0091.

- *By email addressed to: OIRAsubmissions@omb.eop.gov* or
- *By mail addressed to:* The Office of Information and Regulatory Affairs, Office of Management and Budget, Attention Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503.

A copy of all comments submitted to OIRA should be sent to the Commodity Futures Trading Commission (the ''Commission'') by either of the following methods. The copies should refer to ''OMB Control No. 3038–0062.''

- *By mail addressed to:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581;
- By Hand Delivery/Courier to the same address; or
- Through the Commission's Web site at *http://comments.cftc.gov.* Please follow the instructions for submitting comments through the Web site.

A copy of the supporting statements for the collection of information discussed herein may be obtained by visiting *http://RegInfo.gov.*

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations. The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Lauren Bennett, Special Counsel, 202–418–5290, email: *lbennett@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission and refer to OMB Control No. 3038–0062.

SUPPLEMENTARY INFORMATION:

Title: Off-Exchange Foreign Currency Transactions (OMB Control No. 3038–0062). This is a request for an extension of a currently approved information collection.

Abstract: Part 5 of the Commission's regulations under the CEA establishes rules applicable to retail foreign exchange dealers (''RFEDs''), futures commission merchants (''FCMs''), introducing brokers (''IBs''), commodity trading advisors (''CTAs''), and commodity pool operators (''CPOs'') engaged in the offer and sale of off-exchange forex contracts to retail customers. Specifically:

- *Regulation 5.5* requires RFEDs, FCMs, and IBs to distribute risk disclosure statements to new retail forex customers.
- *Regulation 5.6* requires RFEDs and FCMs to report any failures to maintain the minimum capital required by Commission regulations.
- *Regulation 5.8* requires RFEDs and FCMs to calculate their total retail forex obligation.
- *Regulation 5.10* requires RFEDs to maintain and preserve certain risk assessment documentation.
- *Regulation 5.11(a)(1)* requires RFEDs to submit certain risk assessment documentation to the Commission within 60 days of the effective date of their registration.
- *Regulation 5.11(a)(2)* requires RFEDs to submit certain financial documentation to the Commission within 105 calendar days of the end of each fiscal year. RFEDs must also submit additional information, if requested, regarding affiliates' financial impact on an RFED's organizational structure.
- *Regulation 5.12(a)* requires RFED applicants to submit a Form 1–FR–FCM concurrently with their registration application.

• *Regulation 5.12(b)* requires registered RFEDs to file a Form 1–FR–FCM on a monthly and annual basis.

• *Regulation 5.12(g)* states that, in the event that an RFED cannot file its Form 1–FR–FCM for any period within the time specified in Regulation 5.12(b), the RFED may file an application for an extension of time with its self-regulatory organization.

• *Regulation 5.13(a)* requires RFEDs and FCMs to provide monthly account statements to their customers.

• *Regulation 5.13(b)* requires RFEDs and FCMs to provide confirmation statements to their customers within one business day after the execution of any retail forex or forex option transaction.

• *Regulation 5.14* requires RFEDs and FCMs to maintain current ledgers of each transaction affecting its asset, liability, income, expense and capital accounts.

• *Regulation 5.18(g)* requires each RFED, FCM, CPO, CTA, and IB subject to Part 5 to maintain a record of all communications received that give rise to possible violations of the Act, rules, regulations or orders thereunder related to their retail forex business.

• *Regulation 5.18(i)* requires each RFED and FCM to prepare and maintain on a quarterly basis a calculation of non-discretionary retail forex customer accounts open for any period of time during the quarter that were profitable, and the percentage of such accounts that were not profitable.

• *Regulation 5.18(j)* requires the CCO of each RFED and FCM to certify annually that the firm has in place processes to establish, maintain, review, modify and test policies and procedures reasonably designed to achieve compliance with the Act, rules, regulations and orders thereunder.

• *Regulation 5.19* requires each RFED, FCM, CPO, CTA, and IB subject to Part 5 to submit to the Commission copies of any dispositive or partially dispositive decision for which a notice of appeal has been filed in any material legal proceeding (1) to which the firm is a party to or to which its property or assets is subject with respect to retail forex transactions, or (2) instituted against any person who is a principal of the firm arising from conduct in such person's capacity as a principal of that firm.

• *Regulation 5.20* requires RFEDs, FCMs and IBs to submit documentation requested pursuant to certain types of special calls by the Commission.

• *Regulation 5.23* requires RFEDs, FCMs and IBs to notify the Commission regarding bulk transfers and bulk liquidations of customer accounts.

The rules establish reporting and recordkeeping requirements that are necessary to implement the provisions of the Food, Conservation, and Energy Act of 2008 [1] regarding off-exchange transactions in foreign currency with members of the public. The rules are intended to promote customer protection by providing safeguards against irresponsible or fraudulent business practices.[2]

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. On September 18, 2017, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 82 FR 43527. The Commission received no relevant comments.

Burden Statement: The Commission is revising its estimate of the burden for this collection to reflect the current number of affected registrants and revised burden estimates. Accordingly, the respondent burden for this collection is estimated to be as follows:

• *Number of Registrants:* 169.

• *Estimated Average Burden Hours per Registrant:* 777.

• *Estimated Aggregate Burden Hours:* 131,259.

• *Frequency of Recordkeeping:* As applicable.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 22, 2017.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2017–25698 Filed 11–27–17; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0082, Whistleblower Provision

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is announcing an opportunity for public comment on the extension of a proposed collection of certain information by the agency. Under the Paperwork Reduction Act (''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 August 2011, the Commission adopted a final rule, as required by Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''), requiring the submission of whistleblower information to the Commission on the Forms TCR and WB–APP. This notice solicits comments on the proposed Information Collection Request (''ICR'') titled: Renewal for Whistleblower Provision; OMB Control Number 3038–0082.

DATES: Comments must be submitted on or before January 29, 2018.

ADDRESSES: You may submit comments, identified by OMB Control No. 3038–0082 by any of the following methods:

• The Agency's Web site, via its Comments Online process: *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

• *Mail:* Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail above.

• *Federal eRulemaking Portal: http://www.regulations.gov/search/index.jsp.* Follow the instructions for submitting comments.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on

[1] Public Law 110–246, 122 Stat. 1651, 2189–220 (2008).

[2] *See* Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55410, 55416 (Sept. 10, 2010).

[1] 17 CFR 145.9.

the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Christopher Ehrman, Director, Whistleblower Office, Commodity Futures Trading Commission, (202) 418–7650; email: *cehrman@cftc.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA, 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, the CFTC is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

Title: The Whistleblower Provision of Section 23 of the Commodity Exchange Act, OMB Control Number 3038–0082. This is a request for extension of a currently approved information collection.

Abstract: 17 CFR 165.3(a) requires the submission of information to the Commission on a Form TCR. The Form TCR, ''Tip, Complaint, or Referral,'' and the instructions thereto, are designed to capture basic identifying information about a complainant and elicit sufficient information to determine whether the conduct alleged suggests a violation of the Commodity Exchange Act. 17 CFR 165.7(b)(1) requires the submission of information to the Commission on a Form WB–APP. The Form WB–APP, ''Application for Award for Original Information Provided Pursuant to Section 23 of the Commodity Exchange Act,'' and the instructions thereto, are designed to elicit sufficient information to determine whether and to what extent a claimant qualifies for a whistleblower award.

Burden Statement: The respondent burden for this collection is estimated to be 0.5 hours per response.

- *Respondents/affected entities:* Individuals.
- *Estimated number of respondents:* 600 per year.
- *Estimated total annual burden on respondents:* 300 hours.
- *Frequency of collection:* Once.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 17, 2017.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2017–25704 Filed 11–27–17; 8:45 am]

BILLING CODE 6351–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2017–0035]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is proposing to renew with change the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Consumer Response Intake Form''.

DATES: Written comments are encouraged and must be received on or before December 28, 2017 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *OMB:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 or fax to (202) 395–5806. Mailed or faxed comments to OMB should be to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review'', use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov*. Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *CFPB_PRA@cfpb.gov*. *Please do not submit comments to this email box.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Consumer Response Intake Form.

OMB Control Number: 3170–0011.

Type of Review: Extension with change of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 3,000,000.

Estimated Total Annual Burden Hours: 387,500.

Abstract: The Intake Form is designed to aid consumers in the submission of complaints, inquiries, and feedback and to help the Bureau fulfill its statutory requirements.[1] Consumers (also referred to as ''respondents'') will be able to complete and submit information through the Intake Form electronically on the Bureau 's Web site. Alternatively, respondents may request that the Bureau mail a paper copy of the Intake Form, and then mail or fax it back to the

[1] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, Title X, sections 1013(b)(3), 1021(c)(2), and 1034, codified at 12 U.S.C. 5493(b)(3), 5511(c)(2), and 5534.

Bureau; or call to submit a complaint by telephone. The questions within the Intake Form prompt respondents for a description of, and key facts about, the complaint at issue, the desired resolution, contact and account information, information about the company they are submitting a complaint about, and previous action taken to attempt to resolve the complaint.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on July 19, 2017, (82 FR 33070), Docket Number: CFPB–2017–0019. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Dated: November 21, 2017.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2017–25717 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2017–0036]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is proposing to renew the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Generic Information Collection Plan for Consumer Complaint and Information Collection System (Testing and Feedback)''.

DATES: Written comments are encouraged and must be received on or before December 28, 2017 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *OMB:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503 or fax to (202) 395–5806. Mailed or faxed comments to OMB should be to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review'', use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov*. Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *CFPB_PRA@cfpb.gov. Please do not submit comments to this email box.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Generic Information Collection Plan for Consumer Complaint and Information Collection System (Testing and Feedback).

OMB Control Number: 3170–0042.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 710,000.

Estimated Total Annual Burden Hours: 118,334.

Abstract: Over the past several years, the Bureau has undertaken a variety of service delivery-focused activities contemplated by the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–2013 (Dodd-Frank Act). These activities, which include consumer complaint and inquiry processing, referral, and monitoring, involve several interrelated systems.[1] The streamlined process of the generic clearance will continue to allow the Bureau to implement these systems efficiently, in line with the Bureau's commitment to continuous improvement of its delivery of services through iterative testing and feedback collection.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on July 19, 2017, (82 FR 33071), Docket Number: CFPB–2017–0022. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Dated: November 21, 2017.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2017–25716 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0144]

Agency Information Collection Activities; Comment Request; Charter School Facilities National Questionnaire

AGENCY: Office of Innovation and Improvement (OII), Department of Education (ED).

ACTION: Notice.

[1] These interrelated systems include secure, web-based portals that allow consumers, companies, and agencies to access complaints and an online ''Tell Your Story'' feature that allows consumers to share feedback about their experiences in the consumer financial marketplace.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 29, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0144. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–32, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sathya Soumya, 202–260–0819.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Charter School Facilities National Questionnaire.

OMB Control Number: 1855–0024.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 200.

Total Estimated Number of Annual Burden Hours: 300.

Abstract: The Charter School Program needs reliable data to understand the current facilities landscape for charter schools. The Charter Schools Program, through the National Charter School Resource Center, administers a questionnaire conducted by the Colorado League of Charter Schools to gather data on charter schools facilities. This data helps to assess the true facilities challenges of the charter schools and what actions ED and the SEAs must take to better financially support the facilities needs of quality charter schools.

This survey can incite positive change, increase the involvement of state legislature to mitigate the financial issues of charter schools to obtain equitable facilities, and ensure charter schools receive an amount for facilities that is more commensurate with the amount provided for traditional public schools. CSOs in participating states have reported that the survey results have provided the charter school facilities discussion in their states credibility regarding the problems facing charter schools and have resulted in legislative and other gains in their state towards charter school facility equity. CSOs have also reported that the results allow them to continue to push the facilities discussion forward for future changes. ED would like to continue to use and administer this survey in additional states and compile the data from all states into a facilities database. ED plans to conduct this survey in approximately three to four states per year, depending on the size of the state and local resources of the CSO to support the survey. This database will provide comprehensive information about the facilities for charter schools and the issues that charter school face in trying to obtain adequate facilities. The League will produce a report and an analysis summarizing the findings per state. The attached survey currently represents about 90% of the questions that will be asked to each state. The survey will be customized to include state-specific questions.

Dated: November 21, 2017.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–25597 Filed 11–27–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0145]

Agency Information Collection Activities; Comment Request; SEA and LEA Self-Assessment and Monitoring Protocol

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 29, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0145. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 216–32, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Patrick Carr, 202–708–8196.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the

Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: SEA and LEA Self-Assessment and Monitoring Protocol.

OMB Control Number: 1810–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 16,800.

Abstract: OSS administers Title I, Sections 1001–1004 (School Improvement); Title I, Part A (Improving Basic Programs Operated by Local Educational Agencies); Title I, Part B (Enhanced Assessments Grants (EAG), and Grants for State Assessments and Related Activities); Title II, Part A (Supporting Effective Instruction); Title III, Part A (English Language Acquisition, Language Enhancement, and Academic Achievement); and School Improvement Grants (SIG). Annual fiscal reviews—annual phone or on-site conversations with a purposeful sample of SEA and LEA program directors and coordinators—help ensure that an SEA and its LEAs are making progress toward improving student achievement and the quality of instruction for all students and are ensuring requirements are met through the review of fiscal requirements to safeguard public funds from waste, fraud, and abuse. The information shared with the OSS also informs the selection and delivery of technical assistance to SEAs and aligns structures, processes, and routines so the OSS can regularly monitor the connection between grant administration and intended outcomes. Because grantees are monitored on a multiyear cycle, administration of this information collection, including the publication of fiscal review results, is necessary to enable the OSS to identify potential areas of noncompliance ahead of formal monitoring visits, decreasing the need for enforcement actions and minimizing burden for SEAs.

Dated: November 22, 2017.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–25649 Filed 11–27–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Charter Renewals: National Coal Council

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of Renewal.

SUMMARY: Pursuant to the Federal Advisory Committee Act and in accordance with Title 41 of the Code of Federal Regulations, section 102–3.65, and following consultation with the Committee Management Secretariat of the General Services Administration, notice is hereby given that the National Coal Council has been renewed for a two-year period. The Council will continue to provide advice, information, and recommendations to the Secretary of Energy on a continuing basis regarding general policy matters relating to coal issues.

FOR FURTHER INFORMATION CONTACT: Daniel Matuszak at (202) 287–6915 or by email at: *daniel.matuszak@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: Council members are chosen to assure a well-balanced representation from all sections of the country, all segments of the coal industry, including large and small companies, and commercial and residential consumers. The Council also has diverse members who represent interest outside the coal industry, including the environment, labor, research, and academia. Membership and representation of all interests will continue to be determined in accordance with the requirements of the Federal Advisory Committee Act, and implementing regulations.

The renewal of the Council has been deemed essential to the conduct of the Department's business and in the public interest in conjunction with the performance of duties imposed upon the Department of Energy by law. The Council will continue to operate in accordance with the provisions of the Federal Advisory Committee Act and implementing regulations.

Issued at Washington, DC, on November 20, 2017.

Shena Kennerly,

Acting Committee Management Officer.

[FR Doc. 2017–25664 Filed 11–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Notice of Orders Issued Under Section 3 of the Natural Gas Act During October 2017

	FE Docket Nos.
UNITED ENERGY TRADING CANADA, ULC	17–126–NG
CANNAT ENERGY INC	17–129–NG
DTE ENERGY TRADING, INC	17–122–NG
DIRECT ENERGY MARKETING INC	17–123–NG
VERMONT GAS SYSTEMS, INC	17–127–NG
CANADA IMPERIAL OIL LIMITED	17–124–NG
GAZ METRO GNL, S.E.C	17–128–LNG
AUX SABLE CANADA	17–133–NG
ROCHESTER GAS AND ELECTRIC CORPORATION	17–132–NG
ENBRIDGE GAS DISTRIBUTION INC	17–130–NG
SUNCOR ENERGY MARKETING INC	17–131–NG
PAA NATURAL GAS CANADA ULC	16–78–NG
IRVING OILS TERMINALS OPERATIONS LLC	17–134–NG
CITY OF PORTAL, INCORPORATED	17–121–NG
EDF TRADING NORTH AMERICA, LLC	17–119–NG
SEVEN STRATEGIC CONSULTING LLC	17–112–NG

	FE Docket Nos.
GREENFIELD ENERGY CENTRE LP	17–125–NG
CONSTELLATION ENERGY GAS CHOICE, LLC	16–31–NG
IRVING OIL COMMERCIAL GP AND IRVING OIL TERMINALS OPERATIONS LLC (formerly IRVING OIL COMMERCIAL GP AND IRVING OIL TERMINALS OPERATIONS INC.).	15–165–NG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during October 2017, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), to amend long-term authority, and to vacate authority. These orders are summarized in the attached appendix and may be found on the FE Web site at *http://energy.gov/fe/listing-doefe-authorizationsorders-issued-2017.*

They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation and International Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on November 21, 2017.

Robert J. Smith,

Deputy Assistant Secretary for Oil and Natural Gas (Acting).

Appendix

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

4100	10/10/17	17–126–NG	United Energy Trading Canada, ULC.	Order 4100 granting blanket authority to import/export natural gas from/to Canada.
4101	10/10/17	17–129–NG	Cannat Energy Inc	Order 4101 granting blanket authority to import/export natural gas from/to Canada, and vacating prior authorization.
4102	10/10/17	17–122–NG	DTE Energy Trading, Inc	Order 4102 granting blanket authority to import/export natural gas from/to Canada.
4103	10/10/17	17–123–NG	Direct Energy Marketing Inc	Order 4103 granting blanket authority to import/export natural gas from/to Canada.
4104	10/10/17	17–127–NG	Vermont Gas Systems, Inc	Order 4104 granting blanket authority to import natural gas from Canada.
4105	10/18/17	17–124–NG	Canada Imperial Oil Limited	Order 4105 granting blanket authority to import/export natural gas from/to Canada.
4106	10/18/17	17–128–LNG	Gaz Metro GNL, S.E.C	Order 4106 granting blanket authority to import LNG from Canada by truck.
4107	10/18/17	17–133–NG	Aux Sable Canada	Order 4107 granting blanket authority to import natural gas from Canada.
4108	10/18/17	17–132–NG	Rochester Gas and Electric Corporation.	Order 4108 granting blanket authority to import/export natural gas from/to Canada.
4109	10/18/17	17–130–NG	Enbridge Gas Distribution Inc	Order 4109 granting blanket authority to export natural gas to Canada.
4110	10/18/17	17–131–NG	Suncor Energy Marketing Inc	Order 4096 granting blanket authority to import/export natural gas from/to Canada.
3858–A	10/18/17	16–78–NG	PAA Natural Gas Canada ULC.	Order 3858–A vacating blanket authority to import/export natural gas from/to Canada.
4111	10/24/17	17–134–NG	Irving Oil Terminals Operations LLC.	Order 4111 granting blanket authority to import/export natural gas from/to Canada, and vacating prior authority.
4099	10/24/17	17–121–NG	City of Portal, Incorporated	Order 4099 granting blanket authority to import natural gas from Canada.
4112	10/27/17	17–119–NG	EDF Trading North America, LLC.	Order 4112 granting blanket authority to import/export natural gas from/to Canada/Mexico, to import/export LNG from/to Canada/Mexico by truck, to export LNG to Canada/Mexico by vessel, and to import LNG from various international sources by vessel.
4113	10/27/17	17–112–NG	Seven Strategic Consulting LLC.	Order 4113 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4114	10/27/17	17–125–NG	Greenfield Energy Centre LP	Order 4114 granting blanket authority to import/export natural gas from/to Canada/Mexico.
3791–A	10/27/17	16–13–NG	Constellation Energy Gas Choice, LLC.	Order 3791–A vacating blanket authority to import natural gas from Canada.
3765–A	10/27/17	15–165–NG	Irving Commercial GP and Irving Oil Terminals Operations LLC (formerly Irving Commercial GP and Irving Oil Terminals Operations Inc.).	Order 3765–A amending long-term authority to import/export natural gas from/to Canada.

[FR Doc. 2017–25634 Filed 11–27–17; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–505–003.
Applicants: South Central MCN LLC.
Description: Compliance filing: SCMCN Compliance Filing Docket No. ER16–505–00_to be effective N/A.
Filed Date: 11/20/17.
Accession Number: 20171120–5166.
Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER17–892–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2017–11–21_Calculations for SRIC and SREC Compliance Filing to be effective 2/1/2017.
Filed Date: 11/21/17.
Accession Number: 20171121–5096.
Comments Due: 5 p.m. ET 12/12/17.

Docket Numbers: ER18–320–000.
Applicants: South Central MCN LLC.
Description: Compliance filing: SCMCN Compliance Filing to be effective N/A.
Filed Date: 11/20/17.
Accession Number: 20171120–5128.
Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–321–000.
Applicants: Exelon Generation Company, LLC.
Description: Initial rate filing: Nuclear Operating Services Agreement Filing to be effective 11/30/2017.
Filed Date: 11/21/17.
Accession Number: 20171121–5040.
Comments Due: 5 p.m. ET 12/12/17.

Docket Numbers: ER18–322–000.
Applicants: Public Service Company of New Mexico.
Description: Tariff Cancellation: Notice of Cancellation of Service Agreement between PNM and Navopache to be effective 1/1/2018.
Filed Date: 11/21/17.
Accession Number: 20171121–5051.
Comments Due: 5 p.m. ET 12/12/17.

Docket Numbers: ER18–323–000.
Applicants: Exelon FitzPatrick, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence, Nuclear Operating Services Agreement (NOSA) to be effective 11/30/2017.
Filed Date: 11/21/17.
Accession Number: 20171121–5085.
Comments Due: 5 p.m. ET 12/12/17.

Docket Numbers: ER18–324–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Second Revised Service Agreement No. 3476, Queue Position No. R11/Z2–109/AC1–029 to be effective 10/23/2017.
Filed Date: 11/21/17.
Accession Number: 20171121–5100.
Comments Due: 5 p.m. ET 12/12/17.

Docket Numbers: ER18–325–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of WMPA SA No. 3916; Queue No. Z2–020 to be effective 10/30/2017.
Filed Date: 11/21/17.
Accession Number: 20171121–5101.
Comments Due: 5 p.m. ET 12/12/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 21, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25626 Filed 11–27–17; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–22–000.
Applicants: CXA Sundevil Power I, Inc., CXA Sundevil Power II, Inc.
Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited and Confidential Treatment of CXA Sundevil Power I, Inc., et. al.
Filed Date: 11/17/17.
Accession Number: 20171117–5167.
Comments Due: 5 p.m. ET 12/8/17.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–17–000.
Applicants: ORNI 39 LLC.
Description: Self-Certification of Exempt Wholesale Generator of ORNI 39 LLC.
Filed Date: 11/20/17.
Accession Number: 20171120–5044.
Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: EG18–18–000.
Applicants: ORNI 41 LLC.
Description: Self-Certification of Exempt Wholesale Generator of ORNI 41 LLC.
Filed Date: 11/20/17.
Accession Number: 20171120–5045.
Comments Due: 5 p.m. ET 12/11/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2253–014; ER10–3319–018; ER11–2370–006.
Applicants: Astoria Energy LLC, Astoria Energy II LLC, Cambria CoGen Company.
Description: Supplement to June 29, 2017 Joint MBR Triennial of Astoria Energy LLC, et al., and June 28, 2017 Triennial MBR Report of Cambria CoGen Company.
Filed Date: 11/20/17.
Accession Number: 20171120–5112.
Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER12–1436–012; ER10–2329–009; ER10–2740–011; ER10–2742–010; ER12–1260–011; ER13–1793–009; ER14–152–007.
Applicants: Eagle Point Power Generation LLC, Elgin Energy Center, LLC, Hazle Spindle, LLC, Rocky Road Power, LLC, Stephentown Spindle, LLC, Tilton Energy LLC, Vineland Energy LLC.
Description: Supplement to June 30, 2017 Triennial Market-Based Rate Update Filing for the Northeast Region of the Rockland Sellers.
Filed Date: 11/17/17.
Accession Number: 20171117–5168.
Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER16–262–001.
Applicants: Uniper Global Commodities North America LLC.
Description: Data Response to November 13, 2017 letter requesting additional information.
Filed Date: 11/17/17.
Accession Number: 20171117–5160.
Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER16–1346–003.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Compliance filing: 2017–11–20_SA 2911 LEPA–MISO External

NRIS (J373) Compliance (3rd Sub) to be effective 4/6/2016.

Filed Date: 11/20/17.

Accession Number: 20171120–5099.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER16–1817–004.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2017–11–20_Compliance filing of E–NRIS pro forma (4th) to be effective 4/5/2016.

Filed Date: 11/20/17.

Accession Number: 20171120–5098.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER17–933–001.

Applicants: Exelon Generation Company, LLC.

Description: Compliance Filing of Exelon Generation Company, LLC.

Filed Date: 11/20/17.

Accession Number: 20171120–5058.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–155–001.

Applicants: EnPowered.

Description: Tariff Amendment: EnPowered USA, Inc. Market Based Rate Tariff to be effective 10/31/2017.

Filed Date: 11/20/17.

Accession Number: 20171120–5119.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–315–000.

Applicants: Wildwood Lessee, LLC.

Description: Baseline eTariff Filing: Wildwood Lessee, LLC MBR Application to be effective 12/10/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5144.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–316–000.

Applicants: The Connecticut Light and Power Company.

Description: § 205(d) Rate Filing: Interconnection Agreement with Woods Hill Solar, LLC to be effective 11/30/2017.

Filed Date: 11/20/17.

Accession Number: 20171120–5051.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–317–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Wholesale Market Participation Agreement SA No. 4846; Queue No. AC2–144 to be effective 11/4/2017.

Filed Date: 11/20/17.

Accession Number: 20171120–5054.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–318–000.

Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.

Description: Compliance filing: Dominion submits Compliance Filling per Opinion No. 555 in EL10–49–005 to be effective 10/19/2017.

Filed Date: 11/20/17.

Accession Number: 20171120–5095.

Comments Due: 5 p.m. ET 12/11/17.

Docket Numbers: ER18–319–000.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Compliance Filing to Docket No. EL16–110 to be effective 10/19/2017.

Filed Date: 11/20/17.

Accession Number: 20171120–5097.

Comments Due: 5 p.m. ET 12/11/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 20, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25582 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–296–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; Phibro Americas LLC

This is a supplemental notice in the above-referenced proceeding Phibro Americas LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is December 6, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25578 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1585–010; ER10–1594–010; ER16–733–001; ER10–1617–010; ER16–1148–001; ER12–60–012; ER10–1632–012; ER10–1626–007; ER10–1628–010.

Applicants: Alabama Electric Marketing, LLC, California Electric Marketing, LLC, LQA, LLC, New Mexico

Electric Marketing, LLC, Tenaska Energía de Mexico, S. de R. L. d, Tenaska Power Management, LLC, Tenaska Power Services Co., Tenaska Virginia Partners, L.P., Texas Electric Marketing, LLC.

Description: Supplement to June 28, 2016 Updated Market Power Analysis of the Tenaska Northeast MBR Sellers.

Filed Date: 11/16/17.

Accession Number: 20171116–5099.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–295–001.

Applicants: Louisville Gas and Electric Company.

Description: Tariff Amendment: Refiling EKPC NITSA Under Correct Record ID to be effective 10/16/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5059.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–302–000.

Applicants: Tampa Electric Company.

Description: § 205(d) Rate Filing: Section 205 Requirements Depreciation Rates—Polk 2 Buildout to be effective 2/1/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5060.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–303–000.

Applicants: South Jersey Energy ISO2, LLC.

Description: Tariff Cancellation: Cancel market-based rate tariff to be effective 11/17/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5061.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–304–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: LGIA Sienna Solar Farm Project SA No. 199 to be effective 11/17/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5063.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–305–000.

Applicants: Bishop Hill Energy LLC.

Description: § 205(d) Rate Filing: Revised Rate Schedule to be effective 10/15/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5109.

Comments Due: 5 p.m. ET 12/7/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25590 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–21–000.

Applicants: Michigan Electric Transmission Company, LLC.

Description: Application Pursuant to Section 203 of the Federal Power Act to Acquire Assets of Michigan Electric Transmission Company, LLC.

Filed Date: 11/17/17.

Accession Number: 20171117–5006.

Comments Due: 5 p.m. ET 12/8/17.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–16–000.

Applicants: Red Dirt Wind Project, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Red Dirt Wind Project, LLC.

Filed Date: 11/16/17.

Accession Number: 20171116–5139.

Comments Due: 5 p.m. ET 12/7/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–234–005.

Applicants: Kentucky Utilities Company.

Description: Compliance filing: Tariff Records to Reflect CCR ARO Settlement to be effective 1/1/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5100.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER17–2565–001.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Amendment No. 1 to WAPA Lease for Hoover to Mead Transmission Lines to be effective 9/30/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5095.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–306–000.

Applicants: CenterPoint Energy Houston Electric, LLC.

Description: § 205(d) Rate Filing: TFO Tariff Interim Rate Revision to Conform with PUCT-Approved Rate to be effective 11/9/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5140.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–307–000.

Applicants: AEP Oklahoma Transmission Company, Inc.

Description: § 205(d) Rate Filing: AEPOTC-Wildhorse Wind Preliminary Development Agreement to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5026.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–308–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original Service Agreement No. 4827, Queue Position No. AC1–010 to be effective 10/18/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5030.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–309–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Bull Branch Solar LGIA Filing to be effective 11/7/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5035.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–310–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Southern Power (Lacrosse Road Solar) LGIA Filing to be effective 11/7/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5036.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–311–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Southern Power (Shellman Solar) LGIA Filing to be effective 11/7/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5037.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–312–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: MAIT submits Engineering and

Construction Services Agreement SA No. 4798 to be effective 12/1/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5069.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–313–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to OATT, Sch. 12-Appdx A re: RTEP Projects Approved by Board Oct. 2017 to be effective 2/15/2018.

Filed Date: 11/17/17.

Accession Number: 20171117–5096.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ER18–314–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2017–11–17_Order 825 Price Formation Request change in Effective Date to be effective 7/1/2018.

Filed Date: 11/17/17.

Accession Number: 20171117–5110.

Comments Due: 5 p.m. ET 12/8/17

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES18–9–000.

Applicants: PJM Interconnection, L.L.C.

Description: Application of PJM Interconnection, L.L.C. Under Section 204 of the Federal Power Act for an Order Authorizing the Issuance of Securities.

Filed Date: 11/17/17.

Accession Number: 20171117–5097.

Comments Due: 5 p.m. ET 12/8/17.

Docket Numbers: ES18–10–000.

Applicants: PJM Settlement, Inc.

Description: Application of PJM Settlement, Inc. Under Section 204 of the Federal Power Act for an Order Authorizing Issuances of Securities and Approving Guaranty.

Filed Date: 11/17/17.

Accession Number: 20171117–5098.

Comments Due: 5 p.m. ET 12/8/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 17, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25579 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3297–011.

Applicants: Powerex Corp.

Description: Notice of Change in Status and Request for Confidential Treatment of Powerex Corp.

Filed Date: 11/15/17.

Accession Number: 20171115–5236.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER11–3417–013; ER11–2292–019; ER11–3942–018; ER11–2293–019; ER10–2917–018; ER11–2294–017; ER12–2447–017; ER13–1613–011 ER10–2918–019; ER10–2920–018; ER11–3941–016; ER10–2921–018; ER10–2922–018; ER13–1346–009; ER10–2966–018; ER11–2383–013; ER10–3178–010; ER12–161–018; ER12–2068–014; ER12–645–019; ER10–2460–014; ER10–2461–015; ER12–682–015; ER10–2463–014; ER11–2201–018; ER13–1139–017; ER13–17–012; ER14–25–014; ER14–2630–010; ER12–1311–014; ER10–2466–015; ER11–4029–014; ER10–2895–018; ER14–1964–009; ER16–287–004; ER13–2143–011; ER10–3167–010; ER13–203–010; ER17–482–003.

Applicants: Alta Wind VIII, LLC, Bear Swamp Power Company LLC, BIF II Safe Harbor Holdings, LLC, BIF III Holtwood LLC, Black Bear Development Holdings, LLC, Black Bear Hydro Partners, LLC, Black Bear SO, LLC, BREG Aggregator LLC, Brookfield Energy Marketing Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Power Piney & Deep Creek LLC, Brookfield Renewable Energy Marketing US LLC, Brookfield Smoky Mountain Hydropower LLC, Brookfield White Pine Hydro LLC, Carr Street Generating Station, L.P., Erie Boulevard Hydropower, L.P., Granite Reliable Power, LLC, Great Lakes Hydro America, LLC, Hawks Nest Hydro LLC, Mesa Wind Power Corporation, Rumford Falls Hydro LLC, Safe Harbor Water Power Corporation, Windstar Energy, LLC, Bishop Hill Energy LLC, Blue Sky East, LLC, California Ridge Wind Energy LLC, Canandaigua Power Partners, LLC, Canandaigua Power Partners II, LLC, Erie Wind, LLC, Evergreen Wind Power, LLC, Evergreen Wind Power III, LLC, Imperial Valley Solar 1, LLC, Niagara Wind Power, LLC, Prairie Breeze Wind Energy LLC, Regulus Solar, LLC, Stetson Holdings, LLC, Stetson Wind II, LLC, Vermont Wind, LLC.

Description: Notice of Change in Status of the Brookfield Companies and TerraForm Companies.

Filed Date: 11/15/17.

Accession Number: 20171115–5251.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1657–000.

Applicants: Armstrong Power, LLC.

Description: Report Filing: Refund Report—Informational Filing (EL16–79) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5227.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1658–000.

Applicants: Calumet Energy Team, LLC.

Description: Report Filing: Refund Report—Informational Report (EL16–80–000) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5217.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1659–000.

Applicants: Northeastern Power Company.

Description: Report Filing: Refund Report—Informational Filing (EL16–81–000) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5220.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1660–000.

Applicants: Pleasants Energy, LLC.

Description: Report Filing: Refund Report—Informational Filing (EL16–82–000) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5228.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1661–000.

Applicants: Troy Energy, LLC.

Description: Report Filing: Refund Report—Informational Filing (EL16–83–000) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5229.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER17–1663–000.

Applicants: Elwood Energy LLC.

Description: Report Filing: Refund Report—Informational Report (EL16–98–000) to be effective N/A.

Filed Date: 11/15/17.

Accession Number: 20171115–5192.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER18–299–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original Service Agreement No. 4841; Queue No. AC2–136 (WMPA) to be effective 10/25/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5004.

Comments Due: 5 p.m. ET 12/7/17.

Docket Numbers: ER18–300–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Limited waiver request of Midcontinent Independent System Operator, Inc. under ER18–300.

Filed Date: 11/15/17.

Accession Number: 20171115–5240.

Comments Due: 5 p.m. ET 12/6/17.

Docket Numbers: ER18–301–000.

Applicants: Ormesa LLC.

Description: Baseline eTariff Filing: Petition for Approval of Initial Market-Based Rate Tariff to be effective 11/30/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5017.

Comments Due: 5 p.m. ET 12/7/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25589 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–315–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization; Wildwood Lessee, LLC

This is a supplemental notice in the above-referenced proceeding Wildwood Lessee, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is December 11, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 20, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25583 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17–1082–000.

Applicants: Enable Mississippi River Transmission, LLC.

Description: 2017 Annual Penalty Revenue Credit Filing of Enable Mississippi River Transmission, LLC.

Filed Date: 9/25/17.

Accession Number: 20170925–5020.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–164–000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing: Negotiated Rate Service Agreement—Mercuria 11–16–2017 to be effective 11/16/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5084.

Comments Due: 5 p.m. ET 11/28/17.

Docket Numbers: RP18–165–000.

Applicants: Alliance Pipeline L.P.

Description: § 4(d) Rate Filing: Contract Extensions October 31 2017 to be effective 11/16/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5152.

Comments Due: 5 p.m. ET 11/28/17.

Docket Numbers: RP18–166–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Pivotal 34691–15) to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5000.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–167–000.

Applicants: Energy Corporation of America,Greylock Production, LLC.

Description: Request for Temporary Waiver and Expedited Action of Energy Corporation of America, et al.

Filed Date: 11/16/17.

Accession Number: 20171116–5159.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP17–397–001.

Applicants: Dominion Energy Transmission, Inc.

Description: Compliance filing DETI—Nonconforming Service Agreement Compliance Filing to be effective 6/1/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5025.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–168–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Virginia Natural 34695–15) to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5001.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–169–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—NJ Natural 910230 eff 11–17–2017 to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5045.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–170–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rates—Spotlight Energy 911468 eff 11–17–2017 to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5061.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–171–000.

Applicants: Horizon Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Elgin Energy Center Negotiated Rate Filing to be effective 12/1/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5062.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–172–000.

Applicants: WBI Energy Transmission, Inc.

Description: § 4(d) Rate Filing: 2017 Non-Conforming Service Agreement FT–1285—Rainbow to be effective 11/17/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5078.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–173–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Bayway Lateral Project In-Service Filing CP16–473 to be effective 12/20/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5119.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–174–000.

Applicants: Enable Mississippi River Transmission, LLC.

Description: § 4(d) Rate Filing: Non-Conforming Negotiated Rate Agreements—WRB to be effective 1/1/2018.

Filed Date: 11/17/17.

Accession Number: 20171117–5129.

Comments Due: 5 p.m. ET 11/29/17.

Docket Numbers: RP18–175–000.

Applicants: Alliance Pipeline L.P.

Description: § 4(d) Rate Filing: Warranty of Title November 2017 to be effective 12/18/2017.

Filed Date: 11/17/17.

Accession Number: 20171117–5133.

Comments Due: 5 p.m. ET 11/29/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 20, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25580 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–301–000]

Ormesa LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Ormesa LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is December 6, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25581 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR17–66–000.

Applicants: Worsham-Steed Gas Storage, LLC.

Description: Five Year Updated Market Power Assessment of Worsham-Steed Gas Storage, LLC.

Filed Date: 5/9/17.

Accession Number: 201705095146.

Comments/Protests Due: 5 p.m. ET 12/7/17.

Docket Numbers: RP18–161–000.

Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (EOG 34687 to Tenaska 48776) to be effective 11/16/2017.

Filed Date: 11/15/17.

Accession Number: 20171115–5086.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–162–000.

Applicants: Discovery Gas Transmission LLC.

Description: § 4(d) Rate Filing: 2018 HMRE Surcharge Filing to be effective 1/1/2018.

Filed Date: 11/15/17.

Accession Number: 20171115–5147.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–163–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: TETLP Nov2017 Cleanup—Remove Terminated Negotiated Rates to be effective 12/16/2017.

Filed Date: 11/16/17.

Accession Number: 20171116–5021.

Comments Due: 5 p.m. ET 11/28/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25588 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP11–1591–000.

Applicants: Golden Pass Pipeline LLC.

Description: Report Filing: 2017 Annual Report of Penalty Revenues and Costs of Golden Pass Pipeline.

Filed Date: 11/14/17.

Accession Number: 20171114–5058.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP17–1052–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: Report Filing: Fuel Refund Report in Docket No. RP17–1052.

Filed Date: 11/14/17.

Accession Number: 20171114–5096.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–158–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 111417 Negotiated Rates—St. Lawrence Gas Company, Inc. R–1640–23 to be effective 12/1/2017.

Filed Date: 11/14/17.

Accession Number: 20171114–5030.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–159–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Compliance filing Annual Operational Flow Order Report 2017.

Filed Date: 11/14/17.

Accession Number: 20171114–5057.

Comments Due: 5 p.m. ET 11/27/17.

Docket Numbers: RP18–160–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: Compliance filing Annual Report on Operational Transactions 2017.

Filed Date: 11/15/17.

Accession Number: 20171115–5026.

Comments Due: 5 p.m. ET 11/27/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–25587 Filed 11–27–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9971–09-Region 1]

Proposed Cercla Administrative Cost Recovery Settlement; Rowayton Trading Company, Inc., Bridgeport Fire Site, Bridgeport, Connecticut

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comments.

SUMMARY: In accordance with Section 122(i) of the Comprehensive Environmental Response Compensation, and Liability Act, as amended (''CERCLA''), notice is hereby given of a proposed administrative settlement for recovery of response costs under CERCLA Section 122(h) and 104(e), concerning the Bridgeport Fire Superfund Site in Bridgeport, Connecticut with the following settling party: Rowayton Trading Company, Inc. The settlement requires Rowayton Trading Company, Inc. to pay $50,000 to the Hazardous Substance Superfund, and, if timely paid, shall include no interest.

For 30 days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The United States will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at 5 Post Office Square, Boston, MA 02109–3912.

DATES: Comments must be submitted by December 28, 2017.

ADDRESSES: Comments should be addressed to Cynthia Lewis, Senior

Enforcement Counsel, U.S. Environmental Protection Agency, 5 Post Office Square, Suite 100 (OES04–3), Boston, MA 02109–3912 (Telephone No. 617–918–1889) and should refer to: In re: Grant Street Fire Superfund Site, U.S. EPA Docket No. CERCLA 01–2017–0026.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed settlement may be obtained from Cynthia Lewis, Senior Enforcement Counsel, U.S. Environmental Protection Agency, 5 Post Office Square, Suite 100 (OES04–3), Boston, MA 02109–3912; (617) 918–1889; l*ewis.cindy@epa.gov).*

SUPPLEMENTARY INFORMATION: In this proposed administrative settlement for recovery of response costs under CERCLA Section 122(h)(1) and 104(e)(6), concerning the Bridgeport Fire Superfund Site in Bridgeport, Connecticut, requires settling party, Rowayton Trading Company, Inc. to pay $50,000 to the Hazardous Substance Superfund, and, if timely paid, shall include no interest. The settlement includes a covenant not to sue pursuant to Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607, relating to the Site, and protection from contribution actions or claims as provided by Sections 113(f)(2) and 122(h)(4) of CERCLA, 42 U.S.C. 9613(f)(2) and 9622(h)(4). The settlement has been approved by the Environmental and Natural Resources Division of the United States Department of Justice.

Dated: October 30, 2017.

Bryan Olson,

Director, Office of Site Remediation and Restoration.

[FR Doc. 2017–25707 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2016–0439; FRL–9971–18–OW]

Peer Review To Inform the Safe Drinking Water Act Decision Making on Perchlorate in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final peer reviewer selection and public peer review meeting.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a public peer review meeting and the final list of expert peer review panelists assembled by EPA's contractor, Versar, Inc. Versar is conducting the external peer review of scientific materials contained in the report titled ''Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water'' (draft MCLG Approaches Report).

DATES: The public peer review meeting will be held on January 29 and 30, 2018. The meeting will be held from approximately 8:30 a.m. to 5 p.m., eastern time, on January 29, and from approximately 8:30 a.m. to 3 p.m., eastern time, on January 30. The registration deadline to attend the meeting in-person or via teleconference or to request to make a brief oral statement at the meeting is January 17, 2018. See the **SUPPLEMENTARY INFORMATION** section for instructions of how to register.

ADDRESSES: The peer review meeting will be held at the Crystal City Marriott at Reagan National Airport, located at 1999 Jefferson Davis Highway, Arlington, VA 22202. The phone number for the teleconference line will be provided to registered observers prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Questions regarding logistics or registration for the public peer review meeting should be directed to Versar, Inc., at 6850 Versar Center, Springfield, VA 22151 (ATTN: Tracey Cowen); by email: *perchlorate@versar.com* (subject line: Perchlorate Peer Review); or by phone: (301) 304–3121 (ask for Tracey Cowen). For additional information concerning the draft MCLG Approaches Report, please contact Samuel Hernandez at the U.S. EPA, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone: (202) 564–1735; or email: *hernandez.samuel@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Registration Instructions

To attend the peer review meeting as an observer, either in-person or via teleconference, register no later than January 17, 2018. You may register (1) by sending an email to *perchlorate@versar.com* (subject line: Perchlorate Peer Review Registration) and include your name, title, affiliation, full address, email, and phone number; or (2) by calling Versar at (301) 304–3121 (ask for Tracey Cowen); or (3) by mailing Versar, Inc., at 6850 Versar Center, Springfield, VA 22151 (ATTN: Tracey Cowen). Please indicate which day(s) you plan to attend the meeting and whether you plan to attend via teleconference or in-person. Space is limited, and registrations will be accepted on a first-come, first-served basis. There will be a limited amount of time for oral statements from the public at the beginning of the peer review meeting on the first day. If you wish to make an oral statement during the meeting, you must notify Versar of your request to speak no later than January 17, 2018. Versar will notify speakers of specific time limits for their oral statements. Versar will accept requests to make oral statements on a first-come, first-served basis, and may limit the amount of time for each speaker as well as the number of speakers due to time constraints. Please be advised that public comments are subject to release under the Freedom of Information Act.

II. Information on Draft Approaches To Inform the Derivation of a Perchlorate MCLG

EPA announced the release of the draft MCLG Approaches Report for public comment on September 15, 2017, in the **Federal Register** (82 FR 43354); on October 12, 2017 (82 FR 47507), EPA announced a 21-day extension of the public comment period on the draft MCLG Approaches Report. The 66-day public comment period on the draft report ended on November 20, 2017. The draft report and public comments received during the comment period are publicly available at *http://www.regulations.gov* (Docket ID No. EPA–HQ–OW–2016–0438). EPA will consider public comments and peer review recommendations in future revisions to the draft MCLG Approaches Report.

III. Information on Final Peer Review Charge Questions

EPA announced a request for public comments on the draft peer review charge questions on September 15, 2017, in the **Federal Register** (82 FR 43361). The 21-day public comment period on the draft charge questions ended on October 6, 2017. EPA considered public comments as it finalized the peer review charge questions. The final peer review charge questions are available through the docket at *http://www.regulations.gov* (Docket ID No. EPA–HQ–OW–2016–0439).

IV. Information About the Peer Reviewers

Consistent with agency guidelines for the peer review of highly influential scientific assessments, EPA tasked its contractor, Versar, to assemble a panel of experts to evaluate the draft MCLG Approaches Report. Versar evaluated 12 candidates for the peer review panel and solicited public comments on an

interim list of peer review panelists on September 15, 2017, in the **Federal Register** (82 FR 43361).

After review and consideration of public comments and consultation with EPA's Scientific Integrity Official, Versar has selected eight peer reviewers, who will, collectively, best provide expertise spanning the previously mentioned areas of knowledge and experience and, to the extent feasible, best provide a balance of perspectives. The final list of eight selected expert peer reviewers is provided as follows:

Name of Nominee, Degree, Place of Employment

1. Hugh A. Barton, Ph.D., Pfizer, Inc.
2. Nancy Carrasco, M.D., Yale School of Medicine
3. Jonathan Chevrier, Ph.D., McGill University Faculty of Medicine
4. Claude Emond, Ph.D., University of Montreal
5. Dale Hattis, Ph.D., George Perkins Marsh Institute, Clark University
6. Angela M. Leung, M.D., M.Sc., UCLA David Geffen School of Medicine
7. Stephen M. Roberts, Ph.D., University of Florida
8. Joanne F. Rovet, Ph.D., The Hospital for Sick Children (Toronto)

EPA requests that no individual or organization contact in any way Versar or the peer review panel members regarding the subject of the peer review meeting, send them written materials regarding the subject of the meeting, or make any offers or requests to any of them that appear to be linked to their participation in the peer review. Versar will direct the peer review panel members to report any such contacts to Versar, Inc., who will take appropriate action in consultation with EPA to ensure the independence and impartiality of the peer review.

V. Information About the Peer Review Meeting

Versar, Inc., has charged the peer review panelists with evaluating and preparing written comments on the draft MCLG Approaches Report. Specifically, reviewers will provide general comments, their overall impressions of the document, and responses to charge questions. Reviewers will also consider the appropriateness of the quality, accuracy, and relevance of the data in the document. Prior to the meeting, Versar will provide copies of the public comments submitted to EPA's public docket (Docket ID No. EPA–HQ–OW–2016–0438) on the draft MCLG Approaches Report to the peer review panelists for their consideration.

Dated: November 17, 2017.

Michael H. Shapiro,

Acting Assistant Administrator, Office of Water.

[FR Doc. 2017–25714 Filed 11–27–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0754]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 29, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0754.

Title: Form Number: FCC Form 2100, Schedule H.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities.

Number of Respondents and Responses: 2,176 respondents; 8,704 responses.

Estimated Time per Response: 12 hours.

Frequency of Response: Recordkeeping requirement; Quarterly reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 104,448 hours.

Total Annual Cost: $5,222,400.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Commercial full-power and Class A television broadcast stations are required to file FCC Form 2100, Schedule H (Formerly FCC Form 398) (Children's Television Programming Report) each calendar quarter. FCC Form 2100, Schedule H is a standardized form that:

(a) Provides a consistent format for reporting the children's educational

television programming aired by licensees to meet their obligation under the Children's Television Act of 1990 (CTA), and

(b) facilitates efforts by the public and the FCC to monitor compliance with the CTA.

Commercial full-power and Class A television stations are required to complete FCC Form 2100, Schedule H each calendar quarter and file the form with the Commission. The Commission places the form in the station's online public inspection file maintained on the Commission's database (*www.fcc.gov*). Stations use FCC Form 2100, Schedule H to report, among other things, the core children's educational and informational programs the station aired the previous calendar quarter and the core programs they plan to air in the upcoming calendar quarter. FCC Form 2100, Schedule H also includes a ''Preemption Report'' that must be completed for each core program that was preempted during the quarter. This ''Preemption Report'' requests information on the date of each preemption, the reason for the preemption and, if the program was rescheduled, the date and time the program was re-aired.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2017–25609 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0120]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 29, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0120.

Type of Review: Extension of a currently approved collection.

Title: Broadcast EEO Program Model Report, FCC Form 396–A.

Form Number: FCC Form 396–A.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents and Responses: 5,000 respondents; 5,000 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain benefits. The statutory authority for this collection of information is contained in Sections 154(i) and 303 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Total Annual Burden: 5,000 hours.

Total Annual Cost: None.

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: The Broadcast Equal Employment Opportunity (EEO) Model Program Report, FCC Form 396–A, is filed in conjunction with applicants seeking authority to construct a new broadcast station, to obtain assignment of construction permit or license and/or seeking authority to acquire control of an entity holding construction permit or license. This program is designed to assist the applicant in establishing an effective EEO program for its station.

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2017–25678 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0573]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility;

the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before December 28, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov*; and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–0573.

Title: Application for Franchise Authority Consent to Assignment or Transfer of Control of Cable Television Franchise, FCC Form 394.

Form Number: FCC Form 394.

Type of Review: Extension of a currently approved collection.

Respondents: Business of other for-profit entities; State, Local or Tribal Government.

Number of Respondents and Responses: 2,000 respondents; 1,000 responses.

Estimated Time per Response: 1–5 hours.

Frequency of Response: Third Party Disclosure Requirement.

Total Annual Burden: 7,000 hours.

Total Annual Costs: $750,000.

Privacy Impact Assessment(s): No impact(s).

Needs and Uses: FCC Form 394 is a standardized form that is completed by cable operators in connection with the assignment and transfer of control of cable television systems. On July 23, 1993, the Commission released a Report and Order and Further Notice of Proposed Rulemaking in MM Docket No. 92–264, FCC 93–332, Implementation of Sections 11 and 13 of the Cable Television Consumer Protection and Competition Act of 1992, Horizontal and Vertical Ownership Limits, Cross-Ownership Limitations and Anti-Trafficking Provisions. Among other things, this Report and Order established procedures for use of the FCC Form 394.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2017–25610 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678]

Information Collection Approved by the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for a revision of a currently approved public information collection pursuant to the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid control number. Comments concerning the accuracy of the burden estimates and any suggestions for reducing the burden should be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: Cathy Williams, Office of the Managing Director, at (202) 418–2918, or email: *Cathy.Williams@fcc.gov.*

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

OMB Control Number: 3060–0678.

OMB Approval Date: November 7, 2017.

OMB Expiration Date: November 30, 2020.

Title: FCC Form 312, Application for Satellite Space and Earth Station Authorizations, Exhibit.

Form Number: FCC Form 312; Schedule A; Schedule B; Schedule S; FCC Form 312–EZ; FCC Form 312–R.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 4,924 respondents; 4,981 responses.

Estimated Time per Response: .5 hours to 80 hours per response.

Frequency of Response: On occasion, one time, and annual reporting requirements; third party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605 and 721.

Total Annual Burden: 34,140 hours.

Total Annual Cost: 10,625,120.

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with this collection of information. Certain information collected regarding international coordination of satellite systems is not routinely available for public inspection pursuant to 5 U.S.C. 552(b) and 47 CFR 0.457(d)(vii).

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Federal Communications Commission received approval from the Office of Management and Budget (OMB) for a revision of the information collection titled ''Part 25 of the Federal Communications Commission's Rules Governing the Licensing of, and Spectrum Usage By, Commercial Earth Stations and Space Stations'' under OMB Control No. 3060–0678, as a result of a recent rulemaking discussed below.

On April 25, 2017, the Commission released a Third Report and Order in IB Docket No. 06–123, FCC 17–49, titled ''Establishment of Policies and Service Rules for the Broadcasting-Satellite Service at the 17.3–17.7 GHz Frequency Band and at the 17.7–17.8 GHz Frequency Band Internationally, and at the 24.75–25.25 GHz Frequency Band for Fixed Satellite Services Providing Feeder Links to the Broadcasting-Satellite Service and for the Satellite Services Operating Bi-directionally in the 17.3–17.8 GHz Frequency Band.'' In the Report and Order, the Commission adopted rules requiring applicants for new licenses for Digital Broadcasting Satellite Service (DBS) feeder-link earth stations in the 17.3–17.8 GHz band to file with the Commission coordination agreements with affected Broadcasting-Satellite Service (BSS) licensees prior to licensing, and to provide technical information on their proposed feeder-link earth stations to a third-party coordinator to facilitate the coordination process (see 47 CFR 25.203(m)). The changes adopted in the Report and Order will result in a net annualized increase of 41 burden hours to applicants and licensees under Part 25. This submission amends the previous submission to the OMB of July 1, 2014, to reflect these changes.

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2017–25677 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1053]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 29, 2018. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1053.

Title: Captioned Telephone Declaratory Ruling; Two-Line Captioned Telephone Order; IP CTS Declaratory Ruling; and IP CTS Reform Order, CG Docket Nos. 13–24 and 03–123.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 60,010 respondents; 180,012 responses.

Estimated Time per Response: 0.25 hours (15 minutes) to 8 hours.

Frequency of Response: Annual, every five years, monthly, and ongoing reporting requirements; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found at Sec. 225 [47 U.S.C. 225] Telecommunications Services for Hearing-Impaired Individuals; The Americans with Disabilities Act of 1990, (ADA), Public Law 101–336, 104 Stat. 327, 366–69, was enacted on July 26, 1990.

Total Annual Burden: 105,088 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information by the FCC from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On August 1, 2003, the Commission released *Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CC Docket No. 98–67, Declaratory Ruling, 68 FR 55898, September 28, 2003, clarifying that one-line captioned telephone voice carry over (VCO) service is a type of telecommunications relay service (TRS) and that eligible providers of such services are eligible to recover their costs from the Interstate TRS Fund (Fund) in accordance with section 225 of the Communications Act.

On July 19, 2005, the Commission released *Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CC Docket No. 98–67 and CG Docket No. 03–123, Order, 70 FR 54294, September 14, 2005, clarifying that two-line captioned telephone VCO service, like one-line captioned telephone VCO service, is a type of TRS eligible for compensation from the Fund.

On January 11, 2007, the Commission released *Telecommunications Relay*

Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123, Declaratory Ruling, 72 FR 6960, February 14, 2007, granting a request for clarification that Internet Protocol (IP) captioned telephone relay service (IP CTS) is a type of TRS eligible for compensation from the Fund.

On August 26, 2013, the Commission issued *Misuse of Internet Protocol (IP) Captioned Telephone Service; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 13–24 and 03–123, Report and Order, 78 FR 53684, August 30, 2013, to regulate practices relating to the marketing of IP CTS, impose certain requirements for the provision of this service, and mandate registration and certification of IP CTS users.

This notice and request for comments pertains to the extension of the currently approved information collection requirements for one-line and two-line captioned telephone service (CTS) and Internet Protocol captioned telephone service (IP CTS) rules and update the estimates of existing burdens that were included in the January 2015 Paperwork Reduction Act (PRA) submission to the Office of Management and Budget (OMB).

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2017–25675 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 92–237; DA 17–1123]

Next Meeting of the North American Numbering Council

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission released a public notice announcing the meeting and agenda of the North American Numbering Council (NANC). The primary agenda of this meeting will be to introduce members of the Committees, set out initial assignments, and provide more information about the Working Groups. The NANC will also begin discussing how to modernize and foster more efficient number administration in the United States. The agenda may be modified at the discretion of the NANC Chair and the Designated Federal Officer (DFO). The NANC meeting is open to the public. The FCC will accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will also provide audio coverage of the meeting. Other reasonable accommodations for people with disabilities are available upon request. Request for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer and governmental Affairs Bureau @(202) 418–0530 (voice) (202) 418–0432 (TTY). Such requests should include a detailed description of the accommodation needed. In addition, please allow at least five days advance notice for accommodation requests; last minute requests will be accepted but may not be possible to accommodate. Members of the public may submit comments to the NANC in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the NANC should be filed in CC Docket No. 92–237.

More information about the NANC is available at *https://www.fcc.gov/about-fcc/advisory-committees/general/north-american-numbering-council.*

DATES: Thursday, December 7, 2017, 9:30 a.m.

ADDRESSES: Requests to make an oral statement or provide written comments to the NANC should be sent to Carmell Weathers, Competition Policy Division, Wireline Competition Bureau, Federal Communications Commission, Portals II, 445 12th Street SW., Room 5–C162, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Marilyn Jones, NANC DFO, at *marilyn.jones@fcc.gov,* or (202) 418–2357, Michelle Sclater, Alternate DFO, at *michelle.sclater@fcc.gov,* or (202) 418–0388; or Carmell Weathers, Special Assistant to the DFO, at *carmell.weathers@fcc.gov,* or (202) 418–2325. The fax number is: (202) 418–1413. The TTY number is: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document in CC Docket No. 92–237, DA 17–1123 released November 20, 2017. The complete text in this document is available for public inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160 or (202) 863–2893, facsimile (202) 863–2898, or via the Internet at *http://www.bcpiweb.com.* It is available on the Commission's Web site at *http://www.fcc.gov.*

Federal Communications Commission.

Marilyn Jones,

Senior Counsel for Number Administration, Wireline Competition Bureau.

[FR Doc. 2017–25633 Filed 11–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (OMB No. 3064–0177)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before January 29, 2018.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Jennifer Jones (202–898–6768), Counsel, MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jennifer Jones, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collections of Information

1. *Title:* Conservator or Receiver of Financial Assets Transferred by an Insured Depository Institution in Connection With a Securitization or Participation After September 30, 2010.

OMB Number: 3064–0177.

Form Number: None.

Affected Public: Insured Depository Institutions.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN AND INTERNAL COST

[3064–0177]

	Type of burden	Estimated number of respondents	Estimated number of responses (average number of trans-actions)	Estimated time per response	Estimated frequency	Frequency of response	Total annual estimated burden
Disclosures:							
360.6(b)(2)(i)(A), (D) Ongoing.							
Private Transactions Non Reg AB Compli-ant.	Disclosure	19	1.895	37	12.0	Monthly	15,984
360.6(b)(2)(i)(D)	Disclosure	35	1.971	3	1.0	On Occasion	207
360.6(b)(2)(ii)(B) Initial/One-Time	Disclosure	1	6.000	1	1.0	On Occasion	6
360.6(b)(2)(ii)(C)	Disclosure	1	6.000	1	1.0	On Occasion	6
Total Disclosure Burden							16,203
Recordkeeping:							
360.6(c)(7)	Recordkeeping	35	1.971	1	1.0	On Occasion	69
Total Recordkeeping Burden							69
TotalB Burden							16,272

SUMMARY OF CAPITAL/START-UP COSTS

[3064–0177]

360.6(b)(2)(i)(A), (B)—Initial/One-Time—Capital/Start-Up Costs—# of sponsors that have never done a registered transaction in particular asset class since November 23, 2016—effective date for compliance with new Reg AB—and prior to doing a private transaction		Estimated number of respondents	Estimated hours per respondent [(a + b) * c]	Total start up hours	Cost per hour	Total cost of annual estimated burden (Internal)
Private Transactions—Auto	Disclosure	1	2,760	2,760	$250	$690,000
Private Transactions—CMBS	Disclosure	17	3,040	51,680	250	$12,920,000
Private Transactions—RMBS*	Disclosure	1	5,400	5,400	250	$1,350,000
Total						$14,960,000
(a) Existing systems and procedures for each required data point for all three asset classes = 10					# of respondents	19
(b) The number of hours required to adjust systems to provide asset level data in XML format for each required data point = 10					cost/respondent	$787,368.42
(c) Estimated number of data points (per SEC Reg AB Rule PRA) = for auto 138, for CMBS 152, for RMBS 270						

*For RMBS transactions, the sponsors will also incur an external cost in connection with securing a third-party due diligence report on compliance with 360.6(b)(2)(ii)(B). This cost is estimated to be $500,000 per transaction.

General Description of Collection: To facilitate better ongoing evaluation of the quality of lending by banks and to reduce risks to the Deposit Insurance Fund from the opaque securitization structures and the poorly underwritten loans that led to the onset of the recent financial crisis, insured depository institutions must require compliance with certain disclosure and other requirements (including compliance with the U.S. Securities and Exchange Commission (SEC) Regulation AB) for securitizations (other than grandfathered transactions) as a prerequisite for the transfer of financial assets by an insured depository institution in connection with a securitization transaction to be eligible for the benefits provided by Part 360.6 of the FDIC's Regulations. Requirements for safe harbor treatment of loan participations are also set forth.

There is no change to the FDIC's Part 360.6. The change in hourly burden and initial start-up costs are mostly attributed to the SEC's changes to Regulation AB in its September 24, 2014 final rule.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 22nd day of November 2017. Federal Deposit Insurance Corporation

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2017–25638 Filed 11–27–17; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 012301–004.

Title: Siem Car Carrier AS/Volkswagen Konzernlogistik GmbH & Co. OHG Space Charter Agreement.

Parties: Siem Car Carrier AS and Volkswagen Konzernlogistik GmbH & Co. OHG.

Filing Party: Ashley W. Craig, Esq.; Venable LLP; 600 Massachusetts Ave. NW.; Washington, DC 20001.

Synopsis: The amendment removes limits on the quantity of charter space that may be used by either Party on an ad-hoc basis on vessels owned or chartered by the other Party.

Dated: November 22, 2017.

By Order of the Federal Maritime Commission.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2017–25699 Filed 11–27–17; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10661]

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 January 29, 2018.

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' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

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–10661 Limit on Federal Financial Participation for Durable Medical Equipment in Medicaid

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Limit on Federal Financial Participation for Durable Medical Equipment in Medicaid; *Use:* Section 1903(i)(27) of the Social Security Act prohibits federal Medicaid reimbursement to states for certain durable medical equipment (DME) expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. To comply with the statute, each state must demonstrate that it is not spending in excess of what Medicare would have paid for the relevant DME items. We would require the minimal amount of information be collected from states to comply with this statute (at 8 hours per state per year). More specifically, we would ask states to demonstrate compliance by filling in their DME fee schedules onto the new spreadsheet page with the relevant information—HCPCS code series A, K, and E only, that are relevant to this information collection of durable medical equipment. *Form Number:* CMS–10661 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 448. (For policy questions regarding this collection contact Richard Kimball at 410–786–2278.

Dated: November 21, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–25621 Filed 11–27–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–185, CMS–437 and CMS–10515]

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 December 28, 2017.

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' Web site address at Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are ''deemed'' to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: Determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements. *Form Number:* CMS–R–185 (OMB control number: 0938–0686); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9; *Total Annual Responses:* 9; *Total Annual Hours:* 5,464. (For policy questions regarding this collection contact Arlene Lopez at 410–786–6782.)

2. *Type of Information Collection Request:* Reinstatement with Change of a previously approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet; *Use:* Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Inpatient Medicare Prospective Payment System (IPPS) and be paid at a different rate. These specialty hospitals and distinct-part units of hospitals include Inpatient Rehabilitation Facilities (IRFs) units, Inpatient Rehabilitation Facilities (IRFs) hospitals and Inpatient Psychiatric Facilities (IPFs).

CMS regulations at 42 CFR 412.20 through 412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS. Form CMS–437 is used by Inpatient Psychiatric Facilities (IPFs) to attest to meeting the necessary requirements that make them exempt for receiving payment from Medicare under the IPPS. These IPFs must use CMS–437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. The IPFs must re-attest to meeting the exclusion criteria annually. *Form Number:* CMS–437 (OMB control number: 0938–0358); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,616; *Total Annual Responses:* 1,616; *Total Annual Hours:* 1,212. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Payment Collections Operations Contingency

Plan; *Use:* Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the Affordable Care Act to the issuer of the QHP in which the individual enrolls. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The data collection will be used by HHS to make payments or collect charges from issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Marketplace user fees. The template will be used to make payments in January 2014 and for a number of months thereafter, as may be required based on HHS's operational progress. *Form Number:* CMS–10515 (OMB control number: 0938–1217); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits and not-for-profit institutions); *Number of Respondents:* 575; *Total Annual Responses:* 7,475; *Total Annual Hours:* 51,175. (For policy questions regarding this collection contact Jaya Ghildiyal at 301–492–5149).

Dated: November 21, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–25612 Filed 11–27–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–0533 and FDA–2016–E–0534]

Determination of Regulatory Review Period for Purposes of Patent Extension; RAPIVAB

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for RAPIVAB and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–E–0533 and FDA–2016–E–0534 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RAPIVAB.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product RAPIVAB (peramivir). RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. Subsequent to this approval, the USPTO received patent term restoration applications for RAPIVAB (U.S. Patent Nos. 6,503,745 and 6,562,861) from BioCryst Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 29, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RAPIVAB represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RAPIVAB is 3,287 days. Of this time, 2,925 days occurred during the testing phase of the regulatory review period, while 362 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 21, 2005. FDA has verified the BioCryst Pharmaceuticals, Inc. claims that December 21, 2005, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 23, 2013. FDA has verified the applicant's claims that the new drug application (NDA) for RAPIVAB (NDA 206426) was initially submitted on December 23, 2013.

3. *The date the application was approved:* December 19, 2014. FDA has verified the applicant's claim that NDA 206426 was approved on December 19, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,824 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25676 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled

''Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology.'' The purpose of the public workshop is to engage stakeholders and solicit input from experts in oncology precision medicine on how to best weigh and evaluate evidence for classification and interpretation of sequencing results for precision oncology.

DATES: The public workshop will be held on January 29, 2018, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Hisani Madison, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5547, Silver Spring, MD 20993, 240–402–6581, *hisani.madison@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The goal of precision oncology is to use a cancer patient's genetic data to help determine which therapeutic(s) might be most effective in treating their disease. Next generation sequencing is increasingly employed in oncology because the technology can be used to screen a large number of mutations simultaneously to optimize and personalize patient care. The increasing number of reported mutations may lead to uncertainty for clinicians in the interpretation and prioritization of the variants with respect to the clinical significance and optimal course of action, respectively.

In January 2017, the Association for Molecular Pathology, the American Society of Clinical Oncology, and the College of American Pathologists published a joint consensus recommendation for standards and guidelines for the interpretation and reporting of sequence variants in cancer. However, the implementation of these recommendations is not consistently applied across all stakeholders. FDA is holding this public workshop to engage stakeholders and solicit input from internal and external experts in precision oncology to discuss how genetic sequencing data is best implemented in patient management so that innovative regulatory strategies can be advanced to support the development of safe and effective precision-based drugs and devices for marketing.

II. Topics for Discussion

Topics for discussion at the public workshop include:

- An overview of the state of the science for sequence variant classification in oncology and its practical use in treating patients;
- The level of evidence required for reporting variants and/or guiding patient treatment;
- Best practices for the use of public/private databases for variant classification and interpretation in oncology; and
- Future directions for data sharing, standardization, and establishing consistency in precision oncology.

The workshop will include a series of brief presentations to provide information to frame the main topics and interactive discussions via several panel sessions. Following the presentations, there will be a moderated discussion where speakers and additional panelists may be asked to provide their individual perspectives.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by January 19, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Peggy Roney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5671, email: *Peggy.Roney@fda.hhs.gov* no later than January 10, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration Web page after January 10, 2018. Organizations are requested to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.).

Dated: November 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25584 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–2374]

Determination of Regulatory Review Period for Purposes of Patent Extension; YONDELIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for YONDELIS and is publishing this notice of that determination as required

by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–E–2374 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; YONDELIS.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product YONDELIS (trabectedin). YONDELIS is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen. Subsequent to this approval, the USPTO

received a patent term restoration application for YONDELIS (U.S. Patent No. 7,420,051) from Pharma Mar, S.A., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 25, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of YONDELIS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for YONDELIS is 7,107 days. Of this time, 6,773 days occurred during the testing phase of the regulatory review period, while 334 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 10, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 10, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 24, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for YONDELIS (NDA 207953) was initially submitted on November 24, 2014.

3. *The date the application was approved:* October 23, 2015. FDA has verified the applicant's claim that NDA 207953 was approved on October 23, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,471 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25683 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0384]

Pediatric Information for X-Ray Imaging Device Premarket Notifications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' This guidance document outlines FDA's current thinking on information that should be provided in premarket notification submissions for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. FDA intends for this guidance to minimize uncertainty during the premarket review process of premarket notification submissions for x-ray imaging devices for pediatric use to encourage the inclusion of pediatric indications for use for x-ray imaging device premarket notification submissions and to provide recommendations on information to support such indications. Both new devices and modifications of existing x-ray imaging devices that require submission of a new premarket notification are included within the scope of this guidance document, regardless of whether the device is a complete x-ray imaging system, a component part of an x-ray imaging device, or an accessory (*e.g.,* detectors and software).

DATES: The announcement of the guidance is published in the **Federal Register** on November 28, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–

2012–D–0384 for ''Pediatric Information for X-ray Imaging Device Premarket Notifications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Laurel Burk, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4268, Silver Spring, MD 20993–0002, 301–796–5933.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document outlines the current thinking of FDA regarding information that should be provided in premarket notification submissions (510(k)s) and device labeling for x-ray imaging devices that are indicated for pediatric populations or general use x-ray imaging devices for which considerable pediatric application is anticipated. General use x-ray imaging devices typically neither include nor exclude specific populations in the indications for use and may be expected to be used in any population. Because a large percentage of the hundreds of millions of x-ray examinations performed annually in the United States are exams of pediatric patients, FDA expects that most general use x-ray imaging devices will be used for a considerable quantity of pediatric examinations unless a device's design precludes use in smaller sized patients. This guidance is intended to enhance clarity regarding the premarket review process of 510(k)s for x-ray imaging devices, to encourage the inclusion of pediatric indications for use for x-ray imaging device 510(k)s, and to provide recommendations regarding labeling, including the instructions for use.

In February 2010, FDA launched an ''Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (*https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm*); and on March 30 and 31, 2010 (75 FR 8375, February 24, 2010), the Agency held a public meeting entitled ''Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging'' (*https://www.federalregister.gov/documents/2010/02/24/2010-3674/device-improvements-to-reduce-unnecessary-radiation-exposure-from-medical-imaging-public-meeting*). At the meeting, FDA sought advice on ''steps that manufacturers of computerized tomography (CT) and fluoroscopic devices could take to reduce unnecessary radiation exposure through improved product design, enhanced labeling, or improved instructions and training for equipment use and quality assurance at medical imaging facilities.'' The Agency asked whether manufacturers should incorporate special provisions for pediatric patients, particularly with regard to hardware and software features. Recommendations received by FDA, which apply to all general-use x-ray imaging modalities, included making available pediatric protocols and control settings, targeted instructions, and educational materials emphasizing pediatric dose reduction, quality assurance tools for facilities emphasizing radiation dose management, and dose information applicable to pediatric patients. Many of the recommendations from pediatric experts focused on expanding the flexibility or range of features already available on x-ray imaging devices, which may also improve adult imaging for nonstandard applications.

In the **Federal Register** of May 10, 2012 (77 FR 27461), the Agency announced the issuance of the draft guidance entitled ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' and interested persons were invited to comment by September 7, 2012. On July 16, 2012 (77 FR 27463, May 10, 2012), the Agency held a public meeting entitled ''Device Improvements for Pediatric X-ray Imaging'' (*https://www.regulations.gov/document?D=FDA-2012-N-0385-0002*) where FDA also solicited public feedback on the draft of this guidance. FDA has considered the comments received and has incorporated changes suggested by the comments, as appropriate. In addition, FDA requested help in identifying issues relevant to radiation safety in pediatric x-ray imaging that might benefit from standards development or further research at this workshop. FDA requested specific comments on technical device design and pediatric safety questions. Since the 2012 meeting, many recommended device design improvements have been incorporated into FDA-recognized consensus standards, and others are under consideration for future revisions of such standards.

In 2014, the Agency issued a revised general pediatric guidance entitled ''Premarket Assessment of Pediatric Medical Devices.'' The guidance, which applies to all devices, defines pediatric subpopulations and the general information that should be provided for

different types of premarket submissions for devices intended for use in pediatric populations.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on pediatric information for x-ray imaging device 510(k)s. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Pediatric Information for X-ray Imaging Device Premarket Notifications'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1771 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR parts 1002, 1010, 1020, 1030, 1040, and 1050 have been approved under OMB control number 0910–0025. The collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756. In addition, FDA concludes that the Indications for Use warning label does not constitute a ''collection of information'' under the PRA. Rather, the labeling statements are ''public disclosure(s) of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2).)

Dated: November 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25632 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–1195 and FDA–2016–E–1534]

Determination of Regulatory Review Period for Purposes of Patent Extension; Senza Spinal Cord Stimulation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Senza Spinal Cord Stimulation System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–E–1195 and FDA–2016–E–1534 for Determination of Regulatory Review Period for Purposes of Patent Extension; SENZA SPINAL CORD STIMULATION 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device Senza Spinal Cord Stimulation System. Senza Spinal Cord Stimulation System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: Failed back surgery syndrome, intractable low back pain, and leg pain. Subsequent to this approval, the USPTO received patent term restoration applications for Senza Spinal Cord Stimulation System (U.S. Patent Nos. 8,712,533 and 8,768,472) from Nevro Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of SENZA Spinal Cord Stimulation System represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Senza Spinal Cord Stimulation System is 1,136 days. Of this time, 820 days occurred during the testing phase of the regulatory review period, while 316 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* March 30, 2012. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was March 30, 2012.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* June 27, 2014. FDA has verified the applicant's claim that the premarket approval application (PMA) for SENZA SPINAL CORD STIMULATION SYSTEM (PMA P130022) was initially submitted June 27, 2014.

3. *The date the application was approved:* May 8, 2015. FDA has verified the applicant's claim that PMA P130022 was approved on May 8, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 312 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984). Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25684 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–1237]

Determination of Regulatory Review Period for Purposes of Patent Extension; SAVAYSA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SAVAYSA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–E–1237 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SAVAYSA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts

with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product SAVAYSA (edoxaban tosylate monohydrate). SAVAYSA is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation and is also indicated for the treatment of deep vein thrombosis and pulmonary embolism following 5–10 days of initial therapy with a parenteral anticoagulant. Subsequent to this approval, the USPTO received a patent term restoration application for SAVAYSA (U.S. Patent No. 7,365,205) from Daiichi Sankyo Co., Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SAVAYSA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SAVAYSA is 3,845 days. Of this time, 3,479 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 1, 2004. FDA has verified the applicant's claim that July 1, 2004, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 8, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for SAVAYSA (NDA 206316) was initially submitted on January 8, 2014.

3. *The date the application was approved:* January 8, 2015. FDA has verified the applicant's claim that NDA 206316 was approved on January 8, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,406 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25703 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–0623]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZERBAXA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ZERBAXA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by January 29, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 29, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

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

Instructions: All submissions received must include the Docket No. FDA–2016–E–0623 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZERBAXA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ZERBAXA (ceftolozane sulfate and tazobactam sodium). ZERBAXA is indicated for the treatment of the following infections caused by designated susceptible micro-organisms:

• Complicated intra-abdominal infections, used in combination with metronidazole and

• Complicated urinary tract infections, including pyelonephritis.

Subsequent to this approval, the USPTO received a patent term restoration application for ZERBAXA (U.S. Patent No. 7,129,232) from Astellas Pharma, Inc. and Wakunaga Pharmaceutical Co. Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 10, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZERBAXA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZERBAXA is 2,360 days. Of this time, 2,117 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 5, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 5, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 21, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for ZERBAXA (NDA 206829) was initially submitted on April 21, 2014.

3. *The date the application was approved:* December 19, 2014. FDA has verified the applicant's claim that NDA 206829 was approved on December 19, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,302 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25682 Filed 11–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, December 11, 2017, 1:00 p.m. to December 11, 2017, 3:30 p.m., National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Bethesda, MD 20892 which was published in the **Federal Register** on November 17, 2017, 82 FR 54389.

This notice is amended to change the meeting date from December 11, 2017 to December 13, 2017. The meeting time and location remains the same. The meeting is closed to the public.

Dated: November 21, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–25631 Filed 11–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1755]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 26, 2018.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1755, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide

recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 2, 2017.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Racine County, Wisconsin and Incorporated Areas	
Project: 15–05–3520S Preliminary Dates: February 14, 2017 and August 23, 2017	
Village of Caledonia	Village Hall, 5043 Chester Lane, Racine, WI 53402.
Village of Mount Pleasant	Village Hall, 8811 Campus Drive, Mount Pleasant, WI 53406.

[FR Doc. 2017–25615 Filed 11–27–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1757]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before February 26, 2018.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1757, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been

engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://www.fema.gov/preliminaryfloodhazarddata* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 2, 2017.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Las Animas County, Colorado and Incorporated Areas	
Project: 13–08–0163S Preliminary Date: February 17, 2017	
City of Trinidad	City Government Office, 135 North Animas Street, Trinidad, CO 81082.
Town of Aguilar	Las Animas County Land Use Office, 200 East 1st Street, Room 102, Trinidad, CO 81082.
Town of Starkville	Town Hall, 8531 Pinon Street, Starkville, CO 81082.
Unincorporated Areas of Las Animas County	Las Animas County Land Use Office, 200 East 1st Street, Room 102, Trinidad, CO 81082.
Dixie County, Florida and Incorporated Areas	
Project: 12–04–7915S Preliminary Date: November 30, 2016	
Town of Cross City	Town Hall, 99 Northeast 210th Avenue, Cross City, FL 32628.
Town of Horseshoe Beach	Town Hall, 18 5th Avenue East, Horseshoe Beach, FL 32648.
Unincorporated Areas of Dixie County	Dixie County Building and Zoning Department, 387 Southeast 22nd Avenue, Cross City, FL 32628.
Levy County, Florida and Incorporated Areas	
Project: 12–04–7915S Preliminary Date: August 12, 2016	
City of Cedar Key	City Hall, 490 2nd Street, Cedar Key, FL 32625.
Town of Inglis	Town Hall, 135 Highway 40 West, Inglis, FL 34449.
Town of Yankeetown	Town Hall, 6241 Harmony Lane, Yankeetown, FL 34498.
Unincorporated Areas of Levy County	Levy County Development Department, 622 East Hathaway Avenue, Bronson, FL 32621.
Taylor County, Florida and Incorporated Areas	
Project: 12–04–7915S Preliminary Date: December 23, 2016	
City of Perry	City Hall, 224 South Jefferson Street, Perry, FL 32347.
Unincorporated Areas of Taylor County	Taylor County Courthouse Annex, 201 East Green Street, Perry, FL 32347.
Caldwell County, Texas and Incorporated Areas	
Project: 16–06–1113S Preliminary Date: April 7, 2017	
City of Luling	City Hall, 509 East Crockett Street, Luling, TX 78648.
City of Martindale	City Hall, 409 Main Street, Martindale, TX 78655.
City of San Marcos	City Hall, 630 East Hopkins Street, San Marcos, TX 78666.
Unincorporated Areas of Caldwell County	Caldwell County Courthouse, 110 South Main Street, Lockhart, TX 78644.
Gonzales County, Texas and Incorporated Areas	
Project: 16–06–1113S Preliminary Date: April 7, 2017	
City of Gonzales	City Hall, 820 St. Joseph Street, Gonzales, TX 78629.
Unincorporated Areas of Gonzales County	Gonzales County Courthouse, 414 St. Joseph Street, Suite 200, Gonzales, TX 78629.
Guadalupe County, Texas and Incorporated Areas	
Project: 16–06–1113S Preliminary Date: April 7, 2017	
City of Luling	City Hall, 509 East Crockett Street, Luling, TX 78648.

Community	Community map repository address
City of Staples	Civic Center, 9615 FM 621, Staples, TX 78670.
Unincorporated Areas of Guadalupe County	Guadalupe County Environmental Health Department, 2605 North Guadalupe Street, Seguin, TX 78155.
Hays County, Texas and Incorporated Areas	
Project: 16–06–1113S Preliminary Date: April 7, 2017	
City of Austin	Watershed Engineering Division, 505 Barton Springs Road, 12th Floor, Austin, TX 78704.
City of Buda	City Hall, 121 Main Street, Buda, TX 78610.
City of Dripping Springs	Public Works Department, 511 Mercer Street, Dripping Springs, TX 78620.
City of Hays	Hays City Hall, 520 Country Lane, Buda, TX 78610.
City of Kyle	Engineering Department, 100 West Center Street, Kyle, TX 78640.
City of Mountain City	City Hall, 101 Mountain City Drive, Mountain City, TX 78610.
City of San Marcos	City Hall, 630 East Hopkins Street, San Marcos, TX 78666.
City of Wimberley	Public Works Department, 221 Stillwater, Wimberley, TX 78676.
City of Woodcreek	City Hall, 41 Champions Circle, Woodcreek, TX 78676.
Unincorporated Areas of Hays County	Hays County Development Services Department, 2171 Yarrington Road, San Marcos, TX 78666.
Village of Bear Creek	Bear Creek Community Map Repository, 8600 North Madrone Trail, Austin, TX 78737.

[FR Doc. 2017–25618 Filed 11–27–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The date of February 16, 2018 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 2, 2017.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Cameron County, Texas and Incorporated Areas Docket No.: FEMA–B–1546 and FEMA–B–1655	
City of Brownsville	Building and Permitting Division, 1034 East Levee Street, Brownsville, TX 78520.
City of Harlingen	Lon C. Hill Building, 502 East Tyler Avenue, Harlingen, TX 78550.
City of La Feria	City Hall, 115 East Commercial Avenue, La Feria, TX 78559.
City of Los Fresnos	City Hall, 200 North Brazil Street, Los Fresnos, TX 78566.
City of Los Indios	City Hall, 109 East 6th Street, Los Indios, TX 78567.
City of Port Isabel	City Hall, 305 East Maxan Street, Port Isabel, TX 78578.
City of Rio Hondo	Municipal Building, 121 North Arroyo Boulevard, Rio Hondo, TX 78583.
City of San Benito	Planning and Development Department, 400 North Travis Street, San Benito, TX 78586.
City of Santa Rosa	City Hall, 413 South Santa Cruz Avenue, Santa Rosa, TX 78593.
City of South Padre Island	City Hall, 4601 Padre Boulevard, South Padre Island, TX 78597.
Town of Bayview	Town Office, 104 South San Roman Road, Bayview, TX 78566.
Town of Combes	Town Hall, 21626 Hand Road, Combes, TX 78535.
Town of Indian Lake	Indian Lake Town Hall, 62 South Aztec Cove Drive, Los Fresnos, TX 78566.
Town of Laguna Vista	Town Hall, 122 Fernandez Street, Laguna Vista, TX 78578.
Town of Rancho Viejo	Town Hall, 3301 Carmen Avenue, Rancho Viejo, TX 78575.
Town of Rangerville	Harlingen Irrigation District, 301 East Pierce Avenue, Harlingen, TX 78550.
Unincorporated Areas of Cameron County	Cameron County, San Bentio Annex, 1390 West Expressway 83, San Benito, TX 78586.

[FR Doc. 2017–25619 Filed 11–27–17; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: TSA Customer Comment Card

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0030, abstracted below to OMB for a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. This collection allows customers to provide feedback to TSA about their experiences with TSA's processes and procedures, to request information or request assistance at the TSA checkpoint, and to report security threats and vulnerabilities.

DATES: Send your comments by December 28, 2017. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@dhs.gov*.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on September 26, 2017 (82 FR 44836).

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (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 valid OMB control number. The ICR documentation will be made available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: TSA Customer Comment Card.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0030.

Forms(s): NA.

Affected Public: Travelling public.

Abstract: The ICR is a voluntary program for airport passengers to provide feedback to TSA regarding their experiences with TSA. The collection of information allows TSA to evaluate and address customer concerns about security procedures and policies.

TSA Customer Comment Cards collect feedback, compliments, and complaints and the passenger may voluntarily provide contact information. TSA uses the contact information to respond to the passenger's comments. For

passengers who deposit their cards in the designated drop-boxes, TSA staff at airports collect the cards, categorize comments, enter the results into an online system for reporting, and respond to passengers as appropriate.

In addition, passengers may reach the TSA Contact Center (TCC) online at *www.tsa.gov/contact/contact-forms.* This site provides electronic forms of the comment card and are intended for the same purpose; to allow passengers to provide feedback to TSA regarding their experiences with TSA security procedures. Passengers may also use the electronic form to file Disability or Civil Rights and Liberties complaints. TCC provides a receipt to any person who submits an electronic form. The information obtained from the electronic forms allows TSA to evaluate and address customer concerns about security procedures and policies with an electronic interface.

TSA is revising the collection to add three new electronic forms: Request for Assistance, Request for Information, and Security Issue. The Request for Assistance electronic form allows passengers to request assistance at the TSA checkpoint as part of the TSA Cares Program. This program was developed for passengers with disabilities, medical conditions, and other special circumstances who may need additional assistance during the security screening process. The program is available to all members of the public and is separate from the Military Severely Injured Joint Support Operations Center (MSIJSOC) and the Travel Protocol Office (TPO) programs which support and facilitate the movement of wounded warriors, severely injured military personnel, veterans and other travelers requiring an escort through the airport security screening process. The Request for Information electronic form allows passengers to submit an inquiry about TSA policies and procedures such as traveling with medical conditions, prohibited & permitted items, and security screening. The Security Issue electronic form allows passengers to play a critical role in identifying and reporting suspicious activities and threats. TCC will also provide receipts to any person who uses the three new electronic forms. TSA is required to provide a receipt to any person who reports a security problem, deficiency, or vulnerability. *See* 49 CFR 1503.3(a).

Number of Respondents: An estimated 203,659 respondents annually.

Estimated Annual Burden Hours: An estimated 18,431 hours annually.

Dated: November 22, 2017.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2017–25670 Filed 11–27–17; 8:45 am]

BILLING CODE 9110–52–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: Exercise Information System

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0057, abstracted below to OMB for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden for the TSA Exercise Information System (EXIS).

DATES: Send your comments by December 28, 2017. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov*.

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on August 22, 2017, 82 FR 39900. EXIS is a web portal designed to serve stakeholders in the transportation industry in regard to security training exercises. EXIS provides stakeholders with transportation security exercise scenarios and objectives, best practices and lessons learned, and a repository of the user's own historical exercise data for use in future exercises. It also allows stakeholders to design and evaluate their own security exercises based on the unique needs of their specific transportation mode or method of operation. Utilizing and inputting information into EXIS is completely voluntary.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (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 valid OMB control number. The ICR documentation will be available at *http://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Consistent with the requirements of Executive Order (E.O.) 13771, Reducing Regulation and Controlling Regulatory Costs, and E.O. 13777, Enforcing the Regulatory Reform Agenda, TSA is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

Information Collection Requirement

Title: Exercise Information System (EXIS).

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0057.

Forms(s): NA.

Affected Public: Transportation System Sector.

Abstract: The Exercise Information System (EXIS) is a voluntary, online tool developed by TSA to support the mission of a program developed and implemented by TSA to fulfill requirements of the Implementing Recommendations of the 911

Commission Act of 2007 (9/11 Act).[1] These statutory programs led to the development of the Intermodal Security Training Exercise Program (I–STEP) for the Transportation Systems Sector (TSS). Within the I–STEP program, EXIS is an interactive resource for the TSS.

Number of Respondents: 9,551.

Estimated Annual Burden Hours: An estimated 4,804 hours annually.[2]

Dated: November 22, 2017.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2017–25669 Filed 11–27–17; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2017–N108; FXES11140200000–178–FF02ENEH00]

Notice of Availability; Draft Environmental Assessment for a Draft Amendment To Add the Northern Mexican Gartersnake to the Lower Colorado River Multi-Species Conservation Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of documents; request for public comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, as the lead Federal agency, along with the Bureau of Reclamation as a cooperating agency and the implementing agency for the Lower Colorado River Multi-Species Conservation Program (LCR MSCP), announce the availability of a draft environmental assessment (EA) under the National Environmental Policy Act. The draft EA evaluates the impacts of, and alternatives to, amendment of the existing Endangered Species Act permit for the LCR MSCP, in order to add the northern Mexican gartersnake as a covered species, and the impacts of implementation of the amended LCR MSCP.

DATES: To ensure consideration, written comments must be received or postmarked on or before December 28, 2017. Any comments we receive after the closing date or not postmarked by the closing date may not be considered in the final decision on this action.

ADDRESSES: *Obtaining Documents:*

- *Internet:* You may obtain copies of the draft EA, which includes the draft amendment to the LCR MSCP, on the U.S. Fish and Wildlife Service's Web site at *https://www.fws.gov/southwest/es/arizona/*.
- *U.S. Mail:* A limited number of CD–ROM and printed copies of the draft EA and associated draft amendment to the LCR MSCP are available, by request, from the Field Supervisor, Arizona Ecological Services Field Office, 9828 N. 31st Avenue #C3, Phoenix, AZ 85051; by phone at 602–242–0210; or by fax at 602–242–2513. Please note that your request is in reference to the draft amended LCR MSCP for northern Mexican gartersnake.
- *In-Person:* Copies of the draft EA and associated draft amendment to the LCR MSCP are also available for public inspection and review at the following locations, by appointment and written request only, 8 a.m. to 4:30 p.m.:
  - U.S. Fish and Wildlife Service, 500 Gold Avenue SW., Room 6034, Albuquerque, NM 87102.
  - Arizona Ecological Services Office (Phoenix; see information under *U.S. Mail,* above).

Submitting Comments: You may submit comments by one of the following methods.

- *U.S. Mail:* Arizona Ecological Services Office (Phoenix; see information under *U.S. Mail, Obtaining Documents,* above).
- *Electronically: incomingazcorr@fws.gov* or *fw2_hcp_permits@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor (see contact information for Arizona Ecological Services Field Office (Phoenix) in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), as the lead Federal agency, along with the Bureau of Reclamation (Reclamation) as a cooperating agency and the implementing agency for the Lower Colorado River Multi-Species Conservation Program (LCR MSCP), announce the availability of a draft environmental assessment (EA) under the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.;* NEPA). The draft EA evaluates the impacts of, and alternatives to, amendment of an existing permit for the LCR MSCP under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), in order to add the northern Mexican gartersnake (*Thamnophis eques*) as a covered species, as well as the impacts of implementation of the amended LCR MSCP.

Under the proposed amendment, there are no proposed changes to covered actions; no changes to the covered area; and no extension of the time period of permit coverage. Permittees with existing LCR MSCP certificates of inclusion are bound by the terms and conditions of their existing requirements. The amendment is not expected to trigger any new environmental consequences that were not identified in the LCR MSCP final programmatic environmental impact statement/environmental impact report (LCR MSCP EIS/EIR), which was prepared for the original LCR MSCP, or any new impacts to local economies or cultural resources. Nor are there any expected changes to direct, indirect, and cumulative effects, beyond those identified for biological resources.

Coverage for incidental take of the northern Mexican gartersnake will include the entire program area, as defined in the record of decision (ROD) for the LCR MSCP EIS/EIR, dated April 2005. This includes areas up to and including the full-pool elevation of Lakes Mead, Mohave, and Havasu and the historical floodplain of the Colorado River to the Southerly International Boundary with Mexico. The ROD also included off-site conservation areas for implementing the LCR MSCP. The LCR MSCP, with Reclamation as the implementing agency, will manage 512 acres of LCR MSCP-created marsh for the northern Mexican gartersnake. Of the 5,940 acres of LCR MSCP-created cottonwood-willow, 984 acres will be managed near marshes for the northern Mexican gartersnake.

Background

The original LCR MSCP permit was approved on April 4, 2005 (69 FR 75556), and extends through April 30, 2055. The LCR MSCP is a combined ESA section 10(a)(1)(B) and ESA section 7 approach to ESA compliance for implementation of covered activities for non-Federal (section 10) and Federal (section 7) participants.

The LCR MSCP is a habitat-based program that is responsible for the creation and management of land-cover types that benefit multiple covered species, including 5,940 acres of cottonwood-willow; 1,320 acres of honey mesquite; 512 acres of marsh; and 360 acres of backwater.

The LCR MSCP currently includes measures necessary to minimize and mitigate impacts to the 26 listed and unlisted species and their habitats covered by the plan. Take of covered species is incidental to covered activities associated with river operations and, water and power

[1] *See* 9/11 Act secs. 1407 (public transportation, codified at 6 U.S.C. 1136(a)), 1516 (railroads, codified at 6 U.S.C. 1166), and 1533 (over-the-road buses, codified at 6 U.S.C. 1183).

[2] TSA made an error in its calculations and reported the burden in the 60-day notice as 4,820 hours annually. The correct calculation is 4,804.

delivery to Arizona, California, and Nevada. The LCR MSCP provides incidental take coverage to the following listed species;

Razorback sucker (*Xyrauchen texanus*) Endangered

Bonytail chub (*Gila elegans*) Endangered

Humpback chub (*Gila cypha*) Endangered

Yuma Ridgway's (clapper) rail (*Rallus obsoletus [=longirostris] yumanensis*) Endangered

Southwestern willow flycatcher (*Empidonax traillii extimus*) Endangered

Yellow-billed cuckoo (*Coccyzus americanus*) Threatened

During the initial development of the LCR MSCP in 2005, the northern Mexican gartersnake was not considered for coverage, because the species was believed to be extirpated within the planning area. However, subsequently, the species was found to be present. On July 8, 2014, the Service listed the northern Mexican gartersnake as threatened under the ESA, and critical habitat was proposed, including portions of the Bill Williams River. In 2012, northern Mexican gartersnakes were detected in portions of the Bill Williams River, between Alamo Dam and the Colorado River. In 2015, the northern Mexican gartersnake was confirmed at the LCR MSCP's Beal Lake Conservation Area on Havasu National Wildlife Refuge, on the east side of the Colorado River, where it had been considered extirpated.

Public Availability of Comments

Written comments we receive become part of the public record associated with this action. 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. We will not consider anonymous comments. 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.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Amy Lueders,

Regional Director, Southwest Region, Albuquerque, New Mexico.

[FR Doc. 2017–25650 Filed 11–27–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GR17ND00GCT2800; OMB Control Number 1028—New]

Agency Information Collection Activities; Phragmites Adaptive Management Framework

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the USGS is proposing a new information collection (IC).

DATES: Interested persons are invited to submit comments on or before January 29, 2018.

ADDRESSES: You may submit comments on this information collection to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192 (mail); or *gs-info_collections@usgs.gov* (email). Please reference 'Information Collection 1028—NEW, Phragmites Adaptive Management Framework' in all correspondence.

FOR FURTHER INFORMATION CONTACT: Clint Moore, USGS Research Wildlife Biologist, at (706) 542–1166 or *cmoore@usgs.gov.*

SUPPLEMENTARY INFORMATION: We, the USGS, in accordance with the Paperwork Reduction Act of 1995, provide the general public and other Federal agencies with an opportunity to comment on 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 IC 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 USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS 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 IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The *Phragmites* Adaptive Management Framework (PAMF) is a collaborative effort to confront and reduce the spread of invasive *Phragmites* grass in the Great Lakes watershed. *Phragmites* is associated with reduced water quality, loss of biodiversity, reduced recreational opportunities, and increased fire hazards. Reducing or eliminating *Phragmites* throughout the region will reverse these deleterious effects and help achieve the comprehensive restoration goals for the Great Lakes basin (see the Great Lakes Restoration Initiative at *https://www.glri.us/*). The PAMF initiative uses the principles of adaptive management, a learning-based form of management in which data gathered following a treatment action are used to improve the predictive models that inform the decision-making process itself. Identified as a priority by the multi-national Great Lakes *Phragmites* Collaborative (*http://www.greatlakesphragmites.net/*), PAMF is a network of public and private cooperators who share a common desire to reduce or eradicate invasive *Phragmites* on lands that they manage. Membership in PAMF is voluntary and occurs after the cooperator has decided to treat *Phragmites.* A process is being developed to deliver site-specific guidance to participants that will both help them understand what treatment approach is most likely to achieve their management objectives and support regional adaptive learning through improvements and feedbacks to underlying scientific models. Cooperators will monitor and report vegetation characteristics on lands enrolled in the program, and they will report attributes about treatments

applied. The data will be used in analytical routines that will indicate a best treatment action to apply based on measured conditions and will update the set of predictive models that underlie the decision support tool. USGS is providing scientific leadership to the initiative through the development of models, monitoring design, data systems, and a workflow to process the collected data into management guidance.

Title: Phragmites Adaptive Management Framework.

OMB Control Number: 1028—NEW.

Type of Request: New information collection.

Affected Public: General public, private-sector business entities, NGOs, governmental entities (Federal, State, Local, Tribal, Provincial).

Frequency of Collection: Information is collected twice annually for each enrolled parcel, for as long as participant is enrolled in the program.

Estimated Annual Number of Respondents: 200.

Estimated Total Number of Annual Responses: 400.

Estimated Time per Response: An individual is expected to complete one response in about 4 hours, including review of training materials, traversing the property to observe conditions, and entering information into a web-based form.

Estimated Annual Burden Hours: 1,600.

Respondent's Obligation: Participation is voluntary but is required to obtain treatment guidance.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: None.

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authorities for this action are Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Russell Strach,

Center Director, USGS Great Lakes Science Center.

[FR Doc. 2017–25679 Filed 11–27–17; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau Of Land Management

[LLNMF00000.L13100000.PP0000 18X LXSSG0860000]

Notice of Public Meeting, Farmington District Resource Advisory Council, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) of 1976 and the Federal Advisory Committee Act (FACA) of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the Farmington District Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Farmington District RAC will hold a public meeting on Tuesday, January 30, 2018, from 8:00 a.m. to 4:00 p.m., and a field trip on Wednesday, January 31, 2018, from 8:00 a.m. to 12:00 p.m.

ADDRESSES: The Farmington District RAC will meet at the BLM Farmington District Office, 6251 College Blvd., Suite A, Farmington, NM 87402. The field trip participants will depart from the BLM Farmington District Office.

FOR FURTHER INFORMATION CONTACT: Zach Stone, Public Affairs Specialist, BLM Farmington District Office, 6251 College Blvd., Suite A, Farmington, NM 87402, (505) 564–7677, or *zstone@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with Mr. Stone. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Farmington District RAC consists of 10 members chartered and appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, conservation, and general interests. The RAC provides advice to BLM resource managers regarding management plans and proposed resource actions on public land in the BLM's Farmington District. Both the field trip and meeting are open to the public. However, the public is required to provide its own transportation for the field trip.

Agenda items for the meeting include an introduction of new RAC members; the election of a new RAC Chair; an updates on the Farmington Resources Management Plan Amendment and the land use planning in the Taos Field Office; updates on the Taos general recreation plan and the Farmington Glade Run recreation implementation plan; an overview of fire and fuel plan treatments for the Farmington District; an overview of Farmington District grazing permits; a presentation on Section 106 of the National Historic Preservation Act; and a presentation of BLM's role in the Four Corners Air Quality Group. Any other matters that may reasonably come before the Farmington District RAC may also be addressed.

On January 31, the RAC will participate in a field trip to Chockcherry Canyon in the Glade Run Recreation Area. More information is available at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/new-mexico/farmington-district-rac.*

Public Disclosure of Comments: The January 30, 2018, meeting will include a public comment period which will begin at 3:00 p.m. and continue to 3:30 p.m. Depending on the number of persons wishing to comment and time available, the amount of time for individual oral comments may be limited. The public may also submit written comments to Zach Stone, Farmington District, New Mexico, 6251 College Blvd., Suite A, Farmington, NM 87402; or by telephone (505) 564–7677, no later than January 29, 2018, to be made available to the RAC at the January 30, 2018, meeting. All written comments received prior to the meeting will be provided to the council members.

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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.

Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided above.

Authority: 43 CFR 1784.4–2.

David M. Herrell,

Acting Deputy State Director, Lands and Resources.

[FR Doc. 2017–25667 Filed 11–27–17; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNML00000 L12200000.DF0000 18XL1109AF]

Notice of Public Meeting, Las Cruces District Resource Advisory Council, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Las Cruces District Resource Advisory Council (RAC) will meet as indicated below.

DATES: The BLM Las Cruces District RAC will participate in a field trip on Tuesday, January 30, 2018, from 8:00 a.m. to 4:30 p.m., and hold a public meeting on Wednesday, January 31, 2018, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The Las Cruces District RAC will meet at the BLM Las Cruces District Office, 1800 Marquess Street, Las Cruces, NM 88001. The field trip participants will depart from the BLM Las Cruces District Office.

FOR FURTHER INFORMATION CONTACT: Deborah Stevens, BLM Las Cruces District, New Mexico, 1800 Marquess Street, Las Cruces, NM 88001, (575) 525–4421. Persons who use a telecommunications device for the deaf (TDD) may contact Ms. Stevens by calling the Federal Relay Service (FRS) at (800) 877–8339. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with Ms. Stevens. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 10-member RAC advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in New Mexico. The field trip on January 30, 2018, to the northern Potrillo Mountains will introduce the RAC members to the on-the-ground resources located and used by the public in the area. The public should provide their own transportation for the field trip. On January 31, 2018, the meeting agenda will include updates on current and proposed projects in the BLM Las Cruces District, including lands and realty, planning and energy projects; the Tri-County Supplemental Resource Management Plan (RMP); and, the land use planning process in the Las Cruces District. Additional agenda topics or changes to the agenda will be announced in local news releases. More information is available at *https://www.blm.gov/site-page/get-involved-rac-new-mexico-lcdo-rac.* RAC meetings are open to the public.

Public Disclosure of Comments: The meeting on January 31, 2018, will include a public comment period from 11:00 a.m. to 11:30 a.m. Depending on the number of persons wishing to comment and time available, the amount of time for individual oral comments may be limited. To allow for full consideration of information by the council members, written comments must be provided to Deborah Stevens, BLM Las Cruces District, New Mexico, 1800 Marquess Street, Las Cruces, NM 88001; or by telephone (575) 525–4421, no later than Monday, January 29, 2018. All written comments received will be provided to the council members.

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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.

Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided above.

Authority: 43 CFR 1784.4–2.

Melanie Barnes,

Deputy State Director, Lands and Resources.

[FR Doc. 2017–25665 Filed 11–27–17; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR03510000, XXXR0680R1, RR171260120019400]

Draft Environmental Impact Statement, Pure Water San Diego Program, North City Project; San Diego County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: The Bureau of Reclamation and the City of San Diego have completed a draft Environmental Impact Report/Environmental Impact Statement (EIR/EIS) to evaluate the effects of the North City Project, the first phase of the Pure Water San Diego Program (Pure Water Program). The Pure Water Program is a water and wastewater facilities plan to produce potable water from recycled water.

DATES: Please submit written comments no later than January 8, 2018.

ADDRESSES: Send written comments to Doug McPherson, Southern California Area Office, Bureau of Reclamation, 27708 Jefferson Avenue, Suite 202, Temecula, CA 92590; or email to *dmcpherson@usbr.gov.*

FOR FURTHER INFORMATION CONTACT: Doug McPherson, Environmental Protection Specialist, Bureau of Reclamation, Southern California Area Office, 27708 Jefferson Avenue, Suite 202, Temecula, CA 92590; telephone: (951) 695–5310; facsimile: (951) 695–5319; or email: *dmcpherson@usbr.gov.*

SUPPLEMENTARY INFORMATION: The Pure Water Program consists of the design and construction of new advanced water treatment facilities, wastewater treatment facilities, pump stations, and pipelines.

The proposed project will expand the existing North City Water Reclamation Plant and construct an adjacent North City Pure Water Facility with a purified water pipeline to Miramar Reservoir. A project alternative would install a longer pipeline to deliver product water to the San Vicente Reservoir.

Other project components include: A new pump station and forcemain to deliver additional wastewater to the North City Water Reclamation Plant, a brine discharge pipeline, and upgrades to the existing Metropolitan Biosolids Center to accommodate additional biosolids from the increased treatment capacity at the North City Water Reclamation Plant.

A new North City Renewable Energy Facility is proposed and would be constructed at the North City Water Reclamation Plant to receive landfill gas from the City's Miramar Landfill gas collection system via a new gas pipeline, providing power to some of the North City Project components. The landfill gas line would cross Marine Corps Air Station Miramar and the Miramar National Cemetery.

The Bureau of Reclamation issued a Notice of Intent on August 5, 2016 (81 FR 51937). The United States Marine Corps, the Veterans Administration, and the Environmental Protection Agency have each accepted cooperating agency status.

The draft EIR/EIS and technical appendices are available on the City of San Diego Web site at: *https://*

www.sandiego.gov/water/purewater/purewatersd/reports.

Public Disclosure

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.

Dated: November 20, 2017.

Jacklynn Gould,

Acting Regional Director, Lower Colorado Region.

[FR Doc. 2017–25662 Filed 11–27–17; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1087]

Certain Batteries and Electrochemical Devices Containing Composite Separators, Components Thereof, and Products Containing Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 25, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of LG Chem, Ltd. of South Korea; LG Chem Michigan Inc. of Holland Michigan; LG Chem Power Inc. of Troy, Michigan; and Toray Industries, Inc. of Japan. A supplement was filed on November 15, 2017. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain batteries and electrochemical devices containing composite separators, components thereof, and products containing same by reason of infringement of one or more of U.S. Patent No. 7,662,517 (''the '517 patent''); U.S. Patent No. 7,638,241 (''the '241 patent''); and U.S. Patent No. 7,709,152 (''the '152 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Docket Services, U.S. International Trade Commission, Katherine M. Hiner, Docket Services, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 21, 2017, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain batteries and electrochemical devices containing composite separators, components thereof, and products containing same by reason of infringement of one or more of claims 1, 2, 5–15, and 18 of the '517 patent; claims 1–5, 9–12, 14–31, and 33–36 of the '241 patent; and claims 1–13 and 16–20 of the '152 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

LG Chem, Ltd. LG, Twin Towers, 128 Yeoui-daero, Yeongdeungpo-gu, Seoul 07336, South Korea

LG Chem Michigan Inc., 1 LG Way, Holland, MI 49423

LG Chem Power Inc., 1857 Technology Drive, Troy, MI 48083

Toray Industries, Inc., Nihonbashi Mitsui Tower, 1–1, Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo, Japan

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:

Amperex Technology Limited, 3503 Wharf Cable TV Tower, 9 Hoi Shing Road, Tsuen Wan N.T., Hong Kong

DJI Technology Co., Ltd., 14th Floor, West Wing, Skyworth, Semiconductor Design Building, No. 18, Gaoxin South 4th Ave, Nanshan District, 518057 Shenzhen, China

DJI Technology, Inc., 201 S Victory Boulevard, Burbank, CA 91502

Guangdong OPPO Mobile, Telecommunications Corp., Ltd., 18 Haibin Road, Wusha, Chang'An Town, Dongguan, 523850, Guangdong, China

OPPO Digital, Inc., 162 Constitution Drive, Menlo Park, CA 94025

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge. The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to

the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 21, 2017.

Katherine M. Hiner,

Supervisory Attorney.

[FR Doc. 2017–25624 Filed 11–27–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1086]

Certain Mounting Apparatuses for Holding Portable Electronic Devices and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on October 24, 2017, under section 337 of the Tariff Act of 1930, as amended, on behalf of National Products Inc. of Seattle, Washington. A supplement to the complaint was filed on November 3, 2017. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mounting apparatuses for holding portable electronic devices and components thereof by reason of infringement of U.S. Patent No. 8,544,161 (''the '161 Patent''); U.S. Patent No. D703,657 (''the '657 Patent''); U.S. Patent No. 8,186,636 (''the '636 Patent''); U.S. Patent No. D571,278 (''the '278 Patent''); U.S. Patent No. D574,204 (''the '204 Patent''); U.S. Patent No. 9,568,148 (''the '148 Patent''); and U.S. Trademark Registration No. 4,254,086 (''the '086 Trademark''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION: *Authority:* The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2017).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 21, 2017, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) Whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain mounting apparatuses for holding portable electronic devices and components thereof by reason of infringement of one or more of claims 1–18 of the '161 patent; claim 1 of the '657 patent; claims 1–20 of the '636 patent; claim 1 of the '278 patent; claims 1 of the '204 patent; claims 1–13 of the '148 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(c) whether there is a violation of subsection (a)(1)(C) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain mounting apparatuses for holding portable electronic devices and components thereof by reason of infringement of the '086 trademark; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are: National Products Inc., 8410 Dallas Ave S., Seattle, WA 98108.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:

Shenzhen Chengshuo Technology Co., Ltd., d/b/a WUPP, Building A, No. 18, Zhongbuqiao, Qixianqiao Village, Dalu Ind. Zone, Liangzhu Town, Yuhang Dist., Hangzhou, Zhejiang, China

Foshan City Qishi Sporting Goods, Technology Co., Ltd. d/b/a N-Star, Guangfo Road No. 71, Nanhai District, Foshan City, Guangdong, China 258200

Chengdu MWUPP Technology Co., Ltd, Building 1, Third Floor, Door 15, 10 Jinkang Road; Wuhou District, Chengdu City, Sichuan Province, China 610045

Shenzhen Yingxue Technology Co., Ltd., d/b/a Yingxue Tech, Room 14H, Haojingmingyuan Phase II, No. 28 Zhengqing Road, Buji Town, Longgang District, Shenzhen, China 518112

Shenzhen Shunsihang Technology Co., Ltd., d/b/a BlueFire, Room 16D, Yonghuafu, Building No. 1, Longcheng Huafu, Longcheng St., Longgang, District, Shenzhen, China 518172

Guangzhou Kean Products Co., Ltd., Room 216–218, No. 275, D District, Zeng Cha Road, Baiyun District, Guangzhou, Guangdong, China

Prolech Electronics Limited, Building 2, Floor 2, Ba Fang Yuan Industrial, Gui Shan Road Number 9, Xixiang Town, Baoan District, Shenzhen, China

Gangzhou Kaicheng Metal Produce Co., Ltd. d/b/a ZJMOTO No. 17, Xijiu Street, Jinshazhou, Baiyun Dist., Guangzhou, Guangdong, China 510165

Shenzhen Smilin Electronic Technology, Co., Ltd., 40 Building, Niulanqian Village, Minzhi Street, Baoan District, Shenzhen, Guangdong, China 518131

Shenzhen New Dream Intelligent Plastic, Co., Ltd., B511, Lanshang Innovation Park, No. 7, Xinfeng Road, Longcheng Street, Longgang District, Shenzhen, Guangdong, China 518172

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge,

U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: November 21, 2017.

Katherine M. Hiner,

Supervisory Attorney.

[FR Doc. 2017–25623 Filed 11–27–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–709 (Fourth Review)]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Germany—Scheduling of an Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on seamless carbon and alloy steel standard, line, and pressure pipe from Germany would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: November 20, 2017.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones ((202) 205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On November 6, 2017, the Commission determined that the domestic interested party group response to its notice of institution (82 FR 35821, August 1, 2017) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on January 10, 2018, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before January 16, 2018 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by January 16, 2018. However, should the Department of Commerce extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules with respect to filing were revised effective July 25, 2014. *See* 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 22, 2017.

Katherine M. Hiner,

Supervisory Attorney.

[FR Doc. 2017–25639 Filed 11–27–17; 8:45 am]

BILLING CODE 7020–02–P

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements is available from the Office of the Secretary and at the Commission's Web site.

[2] The Commission has found the responses submitted by Benteler Steel/Tube GmbH to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1001]

Certain Digital Video Receivers and Hardware and Software Components Thereof Notice of the Commission's Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Denial of Petition Requesting Reconsideration of Commission Determination Finding Petition of Certain Issues To Be Waived; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the ''Commission'') has found a violation of section 337 in this investigation and has issued a limited exclusion order (''LEO'') prohibiting importation of certain digital video receivers and hardware and software components thereof, and has issued cease and desist orders (''CDOs'') directed to the Comcast respondents. This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3427. 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's TDD terminal, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 26, 2016, based on a complaint filed on behalf of Rovi Corporation and Rovi Guides, Inc. (collectively, ''Rovi''), both of San Carlos, California. 81 FR 33547–48 (May 26, 2016). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), by reason of infringement of certain claims of U.S. Patent Nos. 8,006,263 (''the '263 patent''); 8,578,413 (''the '413 patent''); 8,046,801 (''the '801 patent''); 8,621,512 (''the '512 patent''); 8,768,147 (''the '147 patent''); 8,566,871 (''the '871 patent''); and 6,418,556 (''the '556 patent''). The complaint further alleges that a domestic industry exists. *Id.* at 33548.

The Commission's notice of investigation named sixteen respondents (collectively, ''Respondents''). The respondents are Comcast Corporation of Philadelphia, PA; Comcast Cable Communications, LLC of Philadelphia, PA; Comcast Cable Communications Management, LLC of Philadelphia, PA; Comcast Business Communications, LLC of Philadelphia, PA; Comcast Holdings Corporation of Philadelphia, PA; Comcast Shared Services, LLC of Chicago, IL (collectively, ''Comcast''); Technicolor SA of Issy-les-Moulineaux, France; Technicolor USA, Inc. of Indianapolis, IN; Technicolor Connected Home USA LLC of Indianapolis, IN (collectively, ''Technicolor''); Pace Ltd. of Saltaire, England (now ARRIS Global Ltd.); Pace Americas, LLC of Boca Raton, FL; ARRIS International plc of Suwanee, GA; ARRIS Group Inc. of Suwanee, GA; ARRIS Technology, Inc. of Horsham, PA; ARRIS Enterprises Inc. of Suwanee, GA (now ARRIS Enterprises LLC); and ARRIS Solutions, Inc. of Suwanee, GA (collectively, ''ARRIS''). 81 FR at 33548; *see also* 82 FR 38934 (Aug. 16, 2017). The Office of Unfair Import Investigations is not a party to this investigation. 81 FR at 33548.

Prior to the evidentiary hearing, Rovi withdrew its allegations as to certain patent claims. *See* Order No. 17 (Sept. 23, 2016), *unreviewed,* Comm'n Notice (Oct. 21, 2016); Order No. 25 (Nov. 14, 2016), *unreviewed,* Comm'n Notice (Dec. 2, 2016); Order No. 27 (Dec. 5, 2016), *unreviewed,* Comm'n Notice (Dec. 28, 2016). Rovi proceeded at the evidentiary hearing on the following patents and claims: Claims 7, 18, and 40 of the '556 patent; claims 1, 2, 14, and 17 of the '263 patent; claims 1, 5, 10, and 15 of the '801 patent; claims 12, 17, and 18 of the '871 patent; claims 1, 3, 5, 9, 10, 14, and 18 of the '413 patent; and claims 1, 10, 13, and 22 of the '512 patent.

On May 26, 2017, the administrative law judge (the ''ALJ'') issued the final initial determination (the ''Final ID''), which finds a violation of section 337 by Respondents in connection with the asserted claims of the '263 and '413 patents. The Final ID finds no violation of section 337 in connection with the asserted claims of the '556, '801, '871, and '512 patents. The ALJ recommended that, subject to any public interest determinations of the Commission, the Commission should issue an LEO directed to certain accused products, that CDOs issue to Respondents, and that the Commission should not require any bond during the Presidential review period (*see* 19 U.S.C. 1337(j)).

On June 12, 2017, Rovi and Respondents filed with the Commission petitions for review of the Final ID. Respondents petitioned thirty-two of the Final ID's conclusions, and Rovi petitioned seven of the Final ID's conclusions. On June 20, 2017, the parties filed responsive submissions. On July 11, 2017, Rovi and Respondents filed statements on the public interest. The Commission also received and considered numerous comments on the public interest from non-parties. On July 5, 2017, Rovi and the ARRIS respondents filed a Joint Unopposed Motion for, and Memorandum in Support of, Leave to Amend the Complaint and Notice of Investigation to Correct Corporate Names of Two ARRIS Respondents. The motion indicated that ARRIS Enterprises, Inc. has changed its name to ARRIS Enterprises LLC and that Pace Ltd. has changed its name to ARRIS Global Ltd. And, on July 25, 2017, Comcast submitted with the Office of the Secretary a letter including supplemental disclosure and representations. On July 31, 2017, Rovi submitted with the Office of the Secretary a response thereto. On August 9, 2017, Comcast filed a response to Rovi's submission.

On August 10, 2017, and after having reviewed the record, including the petitions and responses thereto, the Commission determined to review the Final ID in part. 82 FR 38934–36 (Aug. 16, 2017) (the ''Notice of Review''). In particular, the Commission determined to review the following:

(1) The Final ID's determination that Comcast is an importer of the accused products (Issue 1 in Respondents' Petition for Review).

(2) The Final ID's determination that Comcast has not sold accused products in the United States after the importation of those products into the United States (the issue discussed in section III of Rovi's Petition for Review).

(3) The Final ID's determination that the accused Legacy products are ''articles that infringe'' (Issue 2 in Respondents' Petition for Review).

(4) The issue of whether the X1 products are ''articles that infringe'' (Issue 3 in Respondents' Petition for Review), the issue of direct infringement of the '263 and '413 patents by the X1 accused products (Issue 5 in Respondents' Petition for Review), and the issue of ''the nature and scope of the violation found'' (the issue discussed in

section X of Respondents' Petition for Review).

(5) The issue of whether Comcast's two alternative designs infringe the '263 and '413 patents (Issue 4 in Respondents' Petition for Review).

(6) The Final ID's claim construction of ''cancel a function of the second tuner to permit the second tuner to perform the requested tuning operation'' in the '512 patent, and the Final ID's infringement determinations as to that patent (Issue 26 in Respondents' Petition for Review).

(7) The Final ID's conclusion that the asserted claims of the '512 patent are invalid as obvious (the issue discussed in section VI.B.4 of Rovi's Petition for Review).

(8) The issue of whether the ARRIS-Rovi Agreement provides a defense to the allegations against the ARRIS respondents (the issue discussed in section XI of Respondents' Petition for Review).

(9) The Final ID's conclusion that Rovi did not establish the economic prong of the domestic industry requirement based on patent licensing (the issue discussed in section IV of Rovi's Petition for Review).

Id. at 38935. The Commission determined to not review the remainder of the Final ID. *Id.* The Commission additionally concluded that Respondents' petition of certain issues decided in the Final ID was improper, and therefore, those assignments of error were waived. *Id.* In the Notice of Review, the Commission also granted the motion to correct the corporate names of two of the respondents and determined to reopen the evidentiary record and accept the supplemental disclosure, response thereto, and reply to the response. *Id.* at 38934–35. The Commission requested briefing on some of the issues under review and also on remedy, the public interest, and bonding. *Id.* at 38935–36.

On August 23, 2017, Respondents filed a Petition for Reconsideration of the Commission's Determination of Waiver as to Certain Issues Specified in Respondents' Petition for Review or, Alternatively, Application of Waiver to Issues Raised in Rovi's Petition for Review. On August 30, 2017, Rovi filed a response thereto. The Commission has determined to deny that petition.

On August 24, 2017, Rovi and Respondents filed their written submissions on the issues under review and on remedy, public interest, and bonding, and on August 31, 2017, the parties filed their reply submissions.

Having examined the record in this investigation, the Commission has determined to affirm the Final ID's conclusion that Comcast has violated section 337 in connection with the asserted claims of the '263 and '413 patents.

The Commission has determined to affirm the Final ID in part, affirm the Final ID with modifications in part, reverse the Final ID in part, vacate the Final ID in part, and take no position as to certain issues under review. More particularly, the Commission affirms the Final ID's determination that Comcast imports the accused X1 set-top boxes (''STBs''), and takes no position as to whether Comcast is an importer of the Legacy STBs. The Commission also takes no position on as to whether Comcast sells the accused products after importation.

The Commission concludes that there is no section 337 violation as to the Legacy STBs. Regarding the X1 STBs, the Commission affirms the Final ID's conclusion that Comcast's customers directly infringe the '263 and '413 patents. Thus, the Commission affirms the Final ID's conclusion that complainant Rovi has established a violation by Comcast as to those patents and the X1 STBs.

The Commission also takes the following actions. The Commission vacates the Final ID's conclusion that Comcast's two alternative designs infringe the '263 and '413 patents and instead concludes that those designs are too hypothetical to adjudicate at this time. The Commission modifies and affirms the Final ID's claim construction of the claim term ''cancel a function of the second tuner to permit the second tuner to perform the requested tuning operation'' in the '512 patent and affirms the Final ID's infringement determinations as to that patent. The Commission modifies and affirms the Final ID's conclusion that the asserted claims of the '512 patent are invalid as obvious. The Commission takes no position as to whether the ARRIS-Rovi Agreement provides a defense to the allegations against ARRIS, and as to whether Rovi established the economic prong of the domestic industry requirement based on patent licensing. The Commission adopts the remainder of the Final ID to the extent that it does not conflict with the Commission's opinion or to the extent it is not expressly addressed in the Commission's opinion.

Having found a violation of section 337 in this investigation by Comcast with respect to the '263 and '413 patents, the Commission has determined that the appropriate form of relief is (1) a LEO, that subject to certain exceptions provided therein, prohibits the unlicensed entry of certain digital video receivers and hardware and software components thereof that infringe one or more of claims 1, 2, 14, and 17 of the '263 patent and claims 1, 3, 5, 9, 10, 14, and 18 of the '413 patent that are manufactured by, or on behalf of, or are imported by or on behalf of Comcast or any of its affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns; and (2) CDOs that, subject to certain exceptions provided therein, prohibit Comcast from conducting any of the following activities in the United States: importing, selling, offering for sale, leasing, offering for lease, renting, offering for rent, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for imported covered products; and aiding or abetting other entities in the importation, sale for importation, sale after importation, lease after importation, rent after importation, transfer, or distribution of covered products.

The Commission has also determined that the public interest factors enumerated in section 337(d) and (f) (19 U.S.C. 1337(d) and (f)) do not preclude issuance of the LEO or CDOs. Finally, the Commission has determined that the excluded digital video receivers and hardware and software components thereof may be imported and sold in the United States during the period of Presidential review with the posting of a bond in the amount of zero percent of the entered value of the infringing goods (*i.e.,* no bond). The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

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: November 21, 2017.

Katherine M. Hiner,

Supervisory Attorney.

[FR Doc. 2017–25625 Filed 11–27–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Stipulation and Order Under the Comprehensive Environmental Response, Compensation, and Liability Act

On November 20, 2017, the Department of Justice lodged a proposed Stipulation and Order with the United States Bankruptcy Court for the Southern District of New York in the bankruptcy proceedings entitled *In re*

Hawker Beechcraft, Inc., et al., No. 12–11873 (SMB) (lead case).

The United States filed a proof of claim in the Chapter 11 bankruptcy case of Hawker Beechcraft Corporation, seeking, *inter alia,* the recovery of past costs under the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA''), incurred by the United States responding to contamination at the Tri-County Public Airport site (''TCPA Site'') in Morris County, Kansas. Under the proposed Stipulation and Order, Hawker Beechcraft Corporation and related and successor entities (the ''Hawker Parties'') agree that the United States will have an allowed general unsecured claim of $738,336.62 for response costs incurred prior to the petition date, to be paid at the rate provided in the confirmed Chapter 11 plan of reorganization, and further agree that any claim for costs incurred on or after the petition date at the TCPA Site and three other Kansas sites (the Raytheon Aircraft Company Main Facility in Wichita, Kansas; Hangar 1 at Newton City-County Municipal Airport near Newton, Kansas; and Liberal Mid-America Regional Airport in Liberal, Kansas) is not discharged or impaired. Additionally, the Hawker Parties agree that they will comply with CERCLA administrative orders relating to the TCPA Site. In return, the United States covenants not to sue the Hawker Parties under CERCLA for any pre-petition response costs at the four sites.

The publication of this notice opens a period for public comment on the Stipulation and Order. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *In re Hawker Beechcraft, Inc.,* D.J. Ref. No. 90–11–3–10751. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Stipulation and Order may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Stipulation and Order upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $6.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Assistant Section Chief, Environment and Natural Resources Division.

[FR Doc. 2017–25636 Filed 11–27–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2007–0039]

Intertek Testing Services NA, Inc.: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces its final decision to expand the scope of recognition for Intertek Testing Services NA, Inc., as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of the scope of recognition becomes effective on November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov*.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov*. OSHA's Web page includes information about the NRTL Program (see *http://www.osha.gov/dts/otpca/nrtl/index.html*).

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of Intertek Testing Services NA, Inc. (ITSNA), as a NRTL. ITSNA's expansion covers the addition of seven test standards to its scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified by 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products properly approved by the NRTL to meet OSHA standards that require testing and certification of the products.

The Agency processes applications by a NRTL for initial recognition, or for expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational Web page for each NRTL that details its scope of recognition. These pages are available from the Agency's Web site at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

ITSNA submitted an application, dated April 21, 2015, (OSHA–2007–0039–0026) to expand its recognition to include seven additional test standards. OSHA staff conducted a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing ITSNA's expansion application in the **Federal Register** on August 30, 2017 (82 FR 41292). The Agency requested comments by September 15, 2017, but it received no comments in response to this notice. OSHA now is proceeding with this final notice to grant expansion of ITSNA's scope of recognition.

To obtain or review copies of all public documents pertaining to ITSNA's application, go to *www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of

Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210. Docket No. OSHA–2007–0039 contains all materials in the record concerning ITSNA's recognition.

II. Final Decision and Order

OSHA staff examined ITSNA's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that ITSNA meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the specified limitation and conditions listed below. OSHA, therefore, is proceeding with this final notice to grant ITSNA's scope of recognition. OSHA limits the expansion of ITSNA's recognition to testing and certification of products for demonstration of conformance to the test standards listed in Table 1 below.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN ITSNA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 109	Tube Fittings for Flammable and Combustible Fluids, Refrigeration Service and Marine Use.
UL 979	Water Treatment Appliances.
UL 1429	Pullout Switches.
UL 1441	Coated Electrical Sleeving.
UL 2420	Belowground Reinforced Thermosetting Resin Conduit (RTRC) and Fittings.
UL 2515	Aboveground Reinforced Thermosetting Resin Conduit (RTRC) and Fittings.
UL 60950–21	Information Technology Equipment—Safety—Part 21: Remote Power Feeding.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, a NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 1–0.3, Appendix C, paragraph XIV), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

In addition to those conditions already required by 29 CFR 1910.7, ITSNA must abide by the following conditions of the recognition:

1. ITSNA must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as a NRTL, and provide details of the change(s);

2. ITSNA must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. ITSNA must continue to meet the requirements for recognition, including all previously published conditions on ITSNA's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of ITSNA, subject to the limitation and conditions specified above.

III. Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on November 21, 2017.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2017–25570 Filed 11–27–17; 8:45 am]

BILLING CODE 4510–26–P

OFFICE OF MANAGEMENT AND BUDGET

Standard Occupational Classification (SOC) System—Revision for 2018

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of 2018 Standard Occupational Classification final decisions.

SUMMARY: The Office of Management and Budget (OMB) announces its final decision for the 2018 revision of Statistical Policy Directive No. 10, *Standard Occupational Classification* (SOC). More details on these revisions are presented in the **SUPPLEMENTARY INFORMATION** section below and on *https://www.bls.gov/SOC/.*

DATES: *Effective date:* Federal statistical agencies will begin using the 2018 SOC for occupational data they publish for reference years beginning on or after January 1, 2018. Electronic publication of the *2018 Standard Occupational Classification Manual* is planned following the publication of this notice.

The 2018 SOC was designed and developed solely for statistical purposes. Readers interested in the effective dates for the use of the 2018 SOC for non-statistical purposes should contact the relevant agency to determine the agency's plans, if any, for a transition from the 2010 SOC to the 2018 SOC.

ADDRESSES: Correspondence about the adoption and implementation of the SOC as described in this **Federal Register** notice should be sent to: Nancy A. Potok, U.S. Chief Statistician, New Executive Office Building, Washington, DC 20503, email *soc@omb.eop.gov.* Inquiries about the definitions for particular occupations that cannot be satisfied by use of the Web site should be addressed to Standard Occupational Classification Policy Committee, U.S. Bureau of Labor Statistics, Room 2135, Washington, DC 20212; email: *soc@bls.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Park, Senior Statistician, New Executive Office Building, Washington, DC 20503, *email address: soc@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Under 31 U.S.C. 1104(d) and 44 U.S.C. 3504(e), the Office of Management and Budget (OMB) announces its final decision for the 2018 revision of Statistical Policy

Directive No. 10, *Standard Occupational Classification* (SOC).

The SOC classifies all occupations for which work is performed for pay or profit. It covers all jobs in the national economy, including occupations in the public, private, and military sectors. In this way, the SOC is designed to reflect the current occupational composition of the United States.

The SOC supports efficiency and effectiveness of the Federal statistical system by providing a standard for occupation-based statistical data classification and thereby ensuring comparability of these data across Federal statistical agencies. Accordingly, all Federal agencies that publish occupational data for statistical purposes are required to use the SOC; State and local government agencies are strongly encouraged to use this national system to promote a common language for categorizing and analyzing occupations.

Consistent with good statistical practice, these classifications are reviewed and revised periodically to ensure relevance and accuracy. Prior **Federal Register** notices requested public comment regarding the 2018 revision to the SOC (May 22, 2014, 79 FR 29620–29624; and July 22, 2016, 81 FR 48306–&48310). The Standard Occupational Classification Policy Committee (SOCPC, a Federal interagency technical working group) carefully reviewed comments received in preparing its recommendations. OMB carefully considered these recommendations when making the decisions presented in this notice. OMB has requested that the SOCPC prepare the 2018 Standard Occupational Classification Manual for publication online reflecting these final decisions. The 2018 SOC Manual, a complete crosswalk between the 2010 and 2018 SOC, and other supporting materials will be available online at *https://www.bls.gov/SOC/* following publication of this notice.

Future activities: To ensure that the SOC continues to reflect the structure of the changing workforce in a timely and accurate manner, the SOCPC will serve as a standing committee. The SOCPC will meet periodically to monitor and maintain the implementation of the 2018 SOC, such as recommending, as needed, clarification of SOC occupational definitions, placement of new occupations within the existing structure, and updating title files.

Electronic Availability: This document is available at *https://www.bls.gov/SOC/*. The Web page contains links to previous SOC **Federal Register** notices and related documents, the full 2018 SOC structure and definitions, principles and guidelines, and other supporting materials, including the full 2018 SOC Manual.

Purpose and History of the SOC

The U.S. Federal statistical system is highly decentralized, with 13 principal Federal statistical agencies that have statistical activities as their primary mission and approximately 115 other agencies that carry out statistical activities in conjunction with other missions such as providing services, conducting research, or implementing laws and regulations. OMB coordinates the Federal statistical system by developing and overseeing the implementation of Government-wide principles, policies, standards, and guidelines concerning the presentation and dissemination of statistical information. These coordination efforts promote the efficiency and effectiveness of the Federal statistical system. One such standard for statistical data classification established by OMB is Statistical Policy Directive No. 10, *Standard Occupational Classification* (SOC), which ensures consistency of occupation-based statistical data classification across Federal statistical activities.

The SOC system classifies all occupations in the economy, including private, public, and military occupations, to facilitate comparability across occupational data produced for statistical purposes by Federal agencies. The SOC is designed to reflect the current occupational composition in the U.S. and to cover all occupations in which work is performed for pay or profit. Information about occupations—such as employment levels and projections, pay and benefits, skills required, and demographic characteristics of job holders—is widely used by individuals, businesses, researchers, educators, and public policy-makers.

The SOC is designed exclusively for statistical purposes. Although the SOC may also be used for various non-statistical purposes (*e.g.,* for administrative, regulatory, or taxation functions), the requirements of government agencies, businesses, or private users that choose to use the SOC for non-statistical purposes play no role in the development or revision of the SOC. The appropriateness of using the SOC for non-statistical purposes must be evaluated on a case-by-case basis.

The SOC was first issued in 1977. To reflect changes in the economy and in the nature of work, the SOC must be revised periodically. Prior to the 2000 SOC, the SOC was not widely used across Federal data collections. With the implementation of the 2000 SOC, all major occupational data collections in the Federal statistical system provided comparable data, greatly improving the utility of the data. The SOC has been revised four times since its inception: 1980, 2000, 2010, and this 2018 revision.

A new feature was introduced in the 2010 SOC: The Direct Match Title File. This feature lists job titles associated with detailed SOC occupations. Each of these titles directly matches to a single SOC detailed occupation (*i.e.,* one-to-one mappings, where all workers with the job title listed in the Direct Match Title File are classified into exactly one detailed SOC occupation code). The Direct Match Title File has been updated for 2018.

2018 Revision for the SOC—Overview of the Revision Process

The formal 2018 SOC revision process was initiated by OMB and the SOCPC through a request for public comment in a May 22, 2014, **Federal Register** notice (79 FR 29620). The 2018 revision process included two requests for public comment, review of the public comments by the SOCPC following each request, and the SOCPC making recommendations to OMB on the suite of 2018 revisions. The SOCPC created eight workgroups to carry out the bulk of the revision effort and examine occupations by groups of Major Groups. These workgroups were charged with reviewing the public comments received in response to each of the **Federal Register** notices and providing recommendations for addressing these comments to the SOCPC. The workgroups and the SOCPC made recommendations guided by the SOC Classification Principles and Coding Guidelines (available at *https://www.bls.gov/SOC/*). Following each review of public comments, the workgroups made recommendations by consensus to the SOCPC, the SOCPC reviewed the workgroup recommendations and made their own recommendations by consensus. The SOCPC sent their recommendations to OMB after reviewing both sets of public comments. These recommendations led to the creation of new occupations, revised occupational titles and definitions, and changes to the structure and placement of individual occupations.

The May 22, 2014, **Federal Register** notice requested public comments on (1) the proposed new Classification Principle to the 2010 SOC Classification Principles emphasizing the importance of maintaining time series continuity:

''To maximize the comparability of data, time series continuity is maintained to the extent possible;'' (2) the intention to retain the 2010 SOC Coding Guidelines; (3) the intention to retain the 2010 SOC Major Group structure; (4) proposals for the correction, change, or combination of 2010 SOC detailed occupations; and (5) proposals for new detailed occupations. The comment period for the May 22, 2014, **Federal Register** notice closed on July 21, 2014. Approximately 300 public comments were received in response to this May 22, 2014, notice.

OMB published the SOCPC interim recommendations in the July 22, 2016, **Federal Register** (81 FR 48306) requesting public comment on: (1) The 2018 SOC Classification Principles and Coding Guidelines recommended by the SOCPC; (2) the proposed hierarchical structure of the 2018 SOC, including changes to the major, minor, broad, and detailed occupation groups; (3) the titles, placement, and codes of new occupations that the SOCPC recommended be added in the revised 2018 SOC; and (4) preliminary definitions for revised and proposed 2018 SOC occupations. In conjunction with the publication of the July 22, 2016, **Federal Register** notice, rationales for the recommended changes in response to specific comments from the May 22, 2014, **Federal Register** notice were made available on the SOC Web site at *https://www.bls.gov/SOC/.* More than 6,300 public comments were received in response to the July 22, 2016, **Federal Register** notice.

The SOCPC's final recommendations of additional changes to the SOC structures and definitions were shared with OMB in a report; this report will be available at *https://www.bls.gov/SOC/.*

Public Comments

Each of the more than 6,300 individual public comments in response to the July 22, 2016, **Federal Register** notice received a unique docket number when received and similar dockets were reviewed simultaneously by the workgroups and the SOCPC. In total, approximately 223 unique issues were identified in commenters' correspondence. The SOCPC's full set of responses to the comments received in response to the July 22, 2016, **Federal Register** notice will be available at *https://www.bls.gov/SOC/.*

In some cases, the SOCPC recommended changes to the 2018 SOC based on input from member agencies and workgroups, separate from the public comment process. Changes to titles and definitions that resulted do not necessarily alter occupational coverage, but rather refine how occupations are described. For example, the SOCPC recommended accepting the internal suggestion for a different title, ''Radiologic Technologists and Technicians'' (29–2034) in place of the former 2010 SOC title, ''Radiologic Technologists.''

Many proposed new occupations were found to be already covered in the definition of an existing SOC occupation, resulting in no SOCPC recommended change or a SOCPC recommended change for clarification to the title or definition.

2018 Revision for the SOC—OMB Decision

The SOCPC's final recommendations for the 2018 revision to the SOC included a number of significant changes, including new occupations. Many recommended changes modified occupations' titles and definitions to appropriately reflect technological advancements within the occupations. Significant recommended updates were recommended in the management, business, finance, information technology, engineering, social science, education, media, healthcare, personal care, extraction, and transportation occupations.

Through this notice, OMB announces its final decisions regarding the 2018 revision to the SOC. OMB's final decision is to adopt all of the SOCPC's final recommendations with the exception of one. The SOCPC recommended no change to the title of the 2010 SOC occupation 43–5031 Police, Fire, and Ambulance Dispatchers for the 2018 revision. OMB has decided not to accept the SOCPC's recommendation in this case and to change the title of the 2010 SOC occupation 43–5031 Police, Fire, and Ambulance Dispatchers to 43–5031 Public Safety Telecommunicators for the 2018 revision to the SOC. OMB made this decision to reflect better the full scope of occupations organized under this title. All other SOCPC recommendations are adopted as part of OMB's final decision on the 2018 revision to the SOC and are outlined on the SOC Web site at *https://www.bls.gov/SOC/;* the final 2018 SOC will be published in the online 2018 SOC Manual following publication of this notice.

Compared to the 2010 SOC, the 2018 SOC realized a net gain of 27 detailed occupations and 1 minor group. The net number of broad occupations fell by 2 and the number of major groups remained unchanged. The 2018 SOC system contains 867 detailed occupations, aggregated into 459 broad occupations. In turn, the SOC combines these 459 broad occupations into 98 minor groups and 23 major groups. Of the 867 detailed occupations in the 2018 structure, 472 remained unchanged from 2010. Seventy detailed occupations are new to the 2018 SOC. Additional details describing the 2018 revisions are available on the SOC Web site at *https://www.bls.gov/SOC/.*

Next Steps

Implementation: Federal statistical agencies will implement the 2018 SOC as soon as is practical after its publication with the earliest implementations corresponding to collections with reference timeframes on or after January 1, 2018.

Maintaining currency. The SOCPC will continue to meet periodically following publication of the 2018 SOC Manual, particularly to consider new and emerging occupations and additional titles for the Direct Match Title File.

SOC users are reminded that the SOC coding system is designed to allow for delineation of occupations below the detailed occupation level for parties wishing to collect additional levels of detail, as stated in Coding Guideline 3, available at *https://www.bls.gov/SOC/.* OMB recommends that those needing extra detail consider using the structure of the Department of Labor's Employment and Training Administration's Occupational Information Network (O*NET), which adds a decimal point and additional digit (s) after the sixth digit of SOC codes.

Richard P. Theroux,

Acting Deputy Administrator, Office of Information and Regulatory Affairs.

[FR Doc. 2017–25622 Filed 11–27–17; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2018–006]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records

schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when agencies no longer need them for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives of the United States and to destroy, after a specified period, records lacking administrative, legal, research, or other value. NARA publishes notice in the **Federal Register** for records schedules in which agencies propose to destroy records they no longer need to conduct agency business. NARA invites public comments on such records schedules.

DATES: NARA must receive requests for copies in writing by December 28, 2017. Once NARA finishes appraising the records, we will send you a copy of the schedule you requested. We usually prepare appraisal memoranda that contain additional information concerning the records covered by a proposed schedule. You may also request these. If you do, we will also provide them once we have completed the appraisal. You have 30 days after we send to you these requested documents in which to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Appraisal and Agency Assistance (ACRA) using one of the following means:

Mail: NARA (ACRA); 8601 Adelphi Road; College Park, MD 20740–6001.

Email: request.schedule@nara.gov.

Fax: 301–837–3698.

You must cite the control number, which appears in parentheses after the name of the agency that submitted the schedule, and a mailing address. If you would like an appraisal report, please include that in your request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, by mail at Records Appraisal and Agency Assistance (ACRA); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, by phone at 301–837–1799, or by email at *request.schedule@nara.gov.*

SUPPLEMENTARY INFORMATION: NARA publishes notice in the **Federal Register** for records schedules they no longer need to conduct agency business. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

Each year, Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing records retention periods and submit these schedules for NARA's approval. These schedules provide for timely transfer into the National Archives of historically valuable records and authorize the agency to dispose of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless otherwise specified. An item in a schedule is media neutral when an agency may apply the disposition instructions to records regardless of the medium in which it creates or maintains the records. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is expressly limited to a specific medium. (See 36 CFR 1225.12(e).)

Agencies may not destroy Federal records without Archivist of the United States' approval. The Archivist approves destruction only after thoroughly considering the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value.

In addition to identifying the Federal agencies and any subdivisions requesting disposition authority, this notice lists the organizational unit(s) accumulating the records (or notes that the schedule has agency-wide applicability when schedules cover records that may be accumulated throughout an agency); provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction); and includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it also includes information about the records. You may request additional information about the disposition process at the addresses above.

Schedules Pending

1. Department of Agriculture, Rural Development (DAA–0572–2017–0005, 13 items, 13 temporary items). Records documenting the Water and Environmental Loan programs, including routine correspondence at both the national and state level, and loan and borrower information. Also included is information on rural community loans used for wastewater management assistance.

2. Department of the Army, Agency-wide (DAA–AU–2016–0053, 1 item, 1 temporary item). Master files of an electronic information system that contains records related to cases of absence without leave.

3. Department of the Army, Agency-wide (DAA–AU–2016–0055, 1 item, 1 temporary item). Master files of an electronic information system that contains records related to soldier and family fitness.

4. Department of Energy, Office of Fossil Energy (DAA–0434–2017–0001, 1 item, 1 temporary item). Records regarding applications for approval to import or export natural gas.

5. Department of Justice, Criminal Division (DAA–0060–2017–0030, 3 items, 2 temporary items). Project-related administrative records and training materials of the International Criminal Investigative Training Assistance Program. Proposed for permanent retention are records related to training projects in various countries.

6. Department of Justice, Criminal Division (DAA–0060–2017–0033, 3 items, 2 temporary items). Project-related administrative records and training materials of the Office of Overseas Prosecutorial Development, Assistance and Training. Proposed for permanent retention are records related to training projects in various countries.

7. Department of the Treasury, Internal Revenue Service (DAA–0058–2016–0019, 1 item, 1 temporary item). Information returns submitted by companies and businesses reporting on employees' health insurance coverage and associated filing data.

8. Federal Communications Commission, Wireline Competition Bureau (DAA–0173–2017–0001, 8 items, 8 temporary items). Records related to the management and oversight of the Universal Service Program administered by the Universal Service Administration Company (USAC). Includes applications, forms, audits, correspondence, and appeals made directly to USAC by consumers and telecommunications carriers.

9. National Science Foundation, Office of the General Counsel (DAA–0307–2017–0001, 10 items, 10 temporary items). Administrative records relating to routine litigation. Included are legal advice files, tracking logs, and copies of subpoenas served to an NSF office or facility.

10. Securities and Exchange Commission, Agency-wide (DAA–0266–2018–0001, 2 items, 2 temporary items). Records documenting delegations of authority.

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2017–25628 Filed 11–27–17; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Notice of Proposed Information Collection Requests: 2019–2021 IMLS Collections Assessment for Preservation Program

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice, request for comments on this collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments concerning the Collections Assessment for Preservation (CAP) Program designed to support collections assessments for small and medium-sized museums throughout the nation.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before January 24, 2018.

IMLS is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques, or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

ADDRESSES: Send comments to: Dr. Sandra Webb, Senior Advisor, Office of the Director, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718 Fax: 202–653–4608, or by email at *swebb@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of federal support for the nation's approximately 120,000 libraries and 35,000 museums and related organizations. Our mission is to inspire libraries and museums to advance innovation, lifelong learning, and cultural and civic engagement. Our grant making, policy development, and research help libraries and museums deliver valuable services that make it possible for communities and individuals to thrive. To learn more, visit *www.imls.gov.*

II. Current Actions

The Collections Assessment for Preservation Program (CAP) is designed to support collections assessments for small and medium-sized museums throughout the nation. The collections assessment is a study of all of the institution's collections, buildings and building systems, as well as its policies and procedures relating to collections care. Participants who complete the program receive an assessment report with prioritized recommendations to improve collections care.

Agency: Institute of Museum and Library Services.

Title: Collection Assessment for Preservation Program Forms.

OMB Number: 3137–0103.

Frequency: Once per application.

Affected Public: Museum applicants.

Number of Respondents: 775.

Estimated Average Burden per Response: 4 hours.

Estimated Total Annual Burden: 392 hours.

Total Annualized Capital/Startup Costs: n/a.

Total Annual Costs: $10,732.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Dr. Sandra Webb, Senior Advisor, Office of the Director, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718 Fax: 202–653–4608, or by email at *swebb@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

Dated: November 21, 2017.

Kim Miller,

Grants Management Specialist, Office of Chief Information Officer.

[FR Doc. 2017–25594 Filed 11–27–17; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Federal Council on the Arts and the Humanities; Arts and Artifacts Indemnity Panel Advisory Committee

AGENCY: National Endowment for the Humanities.

ACTION: Notice of Charter Renewal for Arts and Artifacts Indemnity Panel Advisory Committee.

SUMMARY: Pursuant to section 9(a)(2) of the Federal Advisory Committee Act and its implementing regulations, the Federal Council on the Arts and the Humanities (the Council) gives notice that the Charter for the Arts and Artifacts Indemnity Panel advisory committee will be renewed for an additional two-year period on November 24, 2017. The Council determined that renewing the advisory committee is necessary and in the public interest in connection with the duties imposed on the Council by the Arts and Artifacts Indemnity Act, as amended.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 Seventh Street SW., Washington, DC 20506. Telephone: (202) 606–8322, facsimile (202) 606–8600, or email at *gencounsel@neh.gov.* Hearing-impaired individuals are

advised that information on this matter may be obtained by contacting the National Endowment for the Humanities' TDD terminal at (202) 606–8282.

Dated: November 22, 2017.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2017–25712 Filed 11–27–17; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel Advisory Committee; Charter Renewal

AGENCY: National Endowment for the Humanities.

ACTION: Notice of Charter Renewal for Humanities Panel advisory committee.

SUMMARY: Pursuant to section 9(a)(2) of the Federal Advisory Committee Act and its implementing regulations, the National Endowment for the Humanities (NEH) gives notice that the Charter for the Humanities Panel advisory committee will be renewed for an additional two-year period on November 24, 2017. The Chairman of NEH determined that the renewal of the Humanities Panel is necessary and in the public interest in connection with the performance of duties imposed upon the Chairperson of NEH by the National Foundation on the Arts and the Humanities Act of 1965, as amended.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 Seventh Street SW., Washington, DC 20506. Telephone: (202) 606–8322, facsimile (202) 606–8600, or email at *gencounsel@neh.gov*. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the National Endowment for the Humanities' TDD terminal at (202) 606–8282.

Dated: November 22, 2017.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2017–25711 Filed 11–27–17; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–609; NRC–2013–0235]

Northwest Medical Isotopes, LLC; Notice of Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; notice of hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) will convene an evidentiary session to receive testimony and exhibits in the uncontested proceeding regarding the application from Northwest Medical Isotopes, LLC (NWMI), for a construction permit (CP) to construct a medical radioisotope production facility in Columbia, Missouri. This mandatory hearing will consider safety and environmental matters relating to the requested CP.

DATES: The hearing will be held on January 23, 2018, beginning at 9:00 a.m. Eastern Time. For the schedule for submitting pre-filed documents and deadlines affecting Interested Government Participants, see Section VI of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID 50–609 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *NRC's Electronic Hearing Docket:* You may obtain publicly available documents related to this hearing on line at *http://www.nrc.gov/about-nrc/regulatory/adjudicatory.html.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents,*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Denise McGovern, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0681; email: *Denise.McGovern@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Commission hereby gives notice that, pursuant to Section 189a of the Atomic Energy Act (AEA) of 1954, as amended (the Act), it will convene an evidentiary session to receive testimony and exhibits in the proceeding regarding the NWMI application for a CP under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), to construct a medical radioisotope production facility in Columbia, Missouri.

Part one of NWMI's two-part application was submitted by letter dated February 5, 2015 (ADAMS Accession No. ML15086A261), and by letter dated July 20, 2015 (ADAMS Accession No. ML15210A182), NWMI submitted the second part of its application. Revision 3 of the application may be viewed at ADAMS Accession No. ML17257A019.

The NRC staff's Environmental Impact Statement and Safety Evaluation Report may be viewed at ADAMS Accession Nos. ML17130A862 and ML17310A365, respectively. This mandatory hearing will concern safety and environmental matters relating to the requested construction permit application, as more fully described below.

II. Evidentiary Uncontested Hearing

The Commission will conduct this hearing beginning at 9:00 a.m., Eastern Time on January 23, 2018, at the Commission's headquarters in Rockville, Maryland. The hearing will continue on subsequent days, if necessary.

III. Presiding Officer

The Commission is the presiding officer for this proceeding.

IV. Matters To Be Considered

The matter at issue in this proceeding is whether the review of the NWMI CP application by the Commission's staff has been adequate to support the findings found in 10 CFR 50.35, 50.40, 50.50, and 10 CFR 51.105. Those findings are as follows:

Issues Pursuant to the Atomic Energy Act of 1954, as Amended

With respect to the CP: (1) Whether the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public; (2) whether such further technical or design information as may be required to complete the safety analysis, and which can reasonably be

left for later consideration, will be supplied in the final safety analysis report (3) whether safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; (4) whether on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public; (5) whether there is reasonable assurance (i) that the construction of the facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations; (6) whether the applicant is technically and financially qualified to engage in the proposed activities in accordance with the Commission's regulations in chapter I of title 10 of the CFR; (7) whether the issuance of a permit for the construction of the facility to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public; and (8) whether the application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

Issues Pursuant to the National Environmental Policy Act (NEPA) of 1969

With respect to the CP: (1) Determine whether the requirements of Sections 102(2)(A), (C), and (E) of NEPA and the applicable regulations in 10 CFR part 51 have been met; (2) independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; (3) determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values; and (4) determine whether the NEPA review conducted by the NRC staff has been adequate.

V. Schedule for Submittal of Pre-Filed Documents

No later than January 2, 2018, unless the Commission directs otherwise, the NRC staff and the applicant shall submit a list of its anticipated witnesses for the hearing.

No later than January 2, 2018, unless the Commission directs otherwise, the applicant shall submit its pre-filed written testimony. The NRC staff submitted its pre-filed testimony on November 16, 2017.

The Commission may issue written questions to the applicant or the NRC staff before the hearing. If such questions are issued, an order containing such questions will be issued no later than December 20, 2017. Responses to such questions are due January 2, 2018, unless the Commission directs otherwise.

VI. Interested Government Participants

No later than December 18, 2017, any interested State, local government body, or Federally-recognized Indian Tribe may file with the Commission a statement of any issues or questions that the State, local government body, or Indian Tribe wishes the Commission to give particular attention as part of the uncontested hearing process. Such statement may be accompanied by any supporting documentation that the State, local government body, or Indian Tribe sees fit to provide. Any statements and supporting documentation (if any) received by the Commission using the agency's E-filing system [1] by the deadline indicated above will be made part of the record of the proceeding. The Commission will use such statements and documents as appropriate to inform its pre-hearing questions to the NRC staff and applicant, its inquiries at the oral hearing, and its decision following the hearing. The Commission may also request, no later than December 20, 2017, that one or more particular States, local government bodies, or Indian Tribes send one representative each to the evidentiary hearing to answer Commission questions and/or make a statement for the purpose of assisting the Commission's exploration of one or more of the issues raised by the State, local government body, or Indian Tribe, in the pre-hearing filings described above. The decision whether to request the presence of a representative of a State, local government body, or Indian Tribe at the evidentiary hearing to make a statement and/or answer Commission questions is solely at the Commission's discretion. The Commission's request will specify the issue or issues that each representative should be prepared to address.

Many of the procedures and rights applicable to the inherently adversarial nature of NRC's contested hearing process are not available in this uncontested hearing. Participation in the NRC's contested hearing process is governed by 10 CFR 2.309 (for persons or entities, including a State, local government, or Indian Tribe seeking to file contentions of their own) and 10 CFR 2.315(c) (for an interested State, local government, or Federally-recognized Indian Tribe seeking to participate with respect to contentions filed by others). Participation in this uncontested hearing does not affect the right of a State, a local government, or an Indian Tribe to participate in the separate contested hearing process.

Dated at Rockville, Maryland, this 21st day of November 2017.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2017–25577 Filed 11–27–17; 8:45 am]

BILLING CODE 7590–01–P

[1] The process for accessing and using the agency's E-filing system is described in the May 24, 2016, notice of hearing (81 FR 32793) that was issued by the Commission for this proceeding. Participants who are unable to use the electronic information exchange (EIE), or who will have difficulty complying with EIE requirements in the time frame provided for submission of written statements, may provide their statements by electronic mail to *hearingdocket@nrc.gov.*

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0001]

Sunshine Act Meeting Notice

DATE: Weeks of November 27, December 4, 11, 18, 25, 2017, January 1, 2018.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of November 27, 2017

Tuesday, November 28, 2017

10:00 a.m. Briefing on Security Issues (Closed—Ex. 1)

Thursday, November 30, 2017

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public) (Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 4, 2017—Tentative

There are no meetings scheduled for the week of December 4, 2017.

Week of December 11, 2017—Tentative

Tuesday, December 12, 2017

9:00 a.m. Hearing on Combined Licenses for Turkey Point, Units 6 and 7: Section 189a. of the Atomic Energy Act Proceeding (Public Meeting) (Contact: Manny Comar: 301–415–3863)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 18, 2017—Tentative

There are no meetings scheduled for the week of December 18, 2017.

Week of December 25, 2017—Tentative

There are no meetings scheduled for the week of December 25, 2017.

Week of January 1, 2018—Tentative

There are no meetings scheduled for the week of January 1, 2018.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Patricia.Jimenez@nrc.gov* or *Jennifer.BorgesRoman@nrc.gov.*

Dated: November 24, 2017.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2017–25752 Filed 11–24–17; 11:15 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

[OPIC–252, OMB 3420–0036]

Submission for OMB Review; Comments Request

AGENCY: Overseas Private Investment Corporation (OPIC).

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act, agencies are required to publish a Notice in the **Federal Register** notifying the public that the agency is modifying an existing information collection for OMB review and approval and requests public review and comment on the submission. OPIC received one set of comments in response to the sixty (60) day notice. The purpose of this notice is to allow an additional thirty (30) days for public comments to be submitted. Comments are being solicited on the need for the information; the accuracy of OPIC's burden estimate; the quality, practical utility, and clarity of the information to be collected; and ways to minimize reporting the burden, including automated collected techniques and uses of other forms of technology.

DATES: Comments must be received within thirty (30) calendar days of publication of this Notice.

ADDRESSES: Mail all comments and requests for copies of the subject form to OPIC's Agency Submitting Officer: James Bobbitt, Overseas Private Investment Corporation, 1100 New York Avenue NW., Washington, DC 20527. See **SUPPLEMENTARY INFORMATION** for other information about filing.

FOR FURTHER INFORMATION CONTACT: OPIC Agency Submitting Officer: James Bobbitt, (202) 336–8558.

SUPPLEMENTARY INFORMATION: OPIC originally published a sixty (60) notice informing the public that it was renewing an existing collection. This notice was published in **Federal Register** volume 82 page 44220 on September 21, 2017. OPIC received one set of comments in response to the sixty (60) day notice and has made changes to the collection in response. OPIC has edited Question 6 to prompt affirmative answers to provide more information and also corrected an abbreviation in Question 7.

These are the only proposed changes to the OPIC–252.

All mailed comments and requests for copies of the subject form should include form number OPIC–252 on both the envelope and in the subject line of the letter. Electronic comments and requests for copies of the subject form may be sent to *James.Bobbitt@opic.gov,* subject line OPIC–252.

Summary Form Under Review

Type of Request: Extension without change of a currently approved information collection.

Title: U.S. Effects Screening Questionnaire.

Form Number: OPIC–252.

Frequency of Use: One per investor per project per year (as needed) and OPIC-supported financial intermediaries (as required by finance agreement or insurance contract).

Type of Respondents: Business or other institutions; individuals.

Standard Industrial Classification Codes: All.

Description of Affected Public: U.S. companies or citizens investing overseas.

Reporting Hours: 212.5 (2.125 hours per form).

Number of Responses: 100 per year.

Federal Cost: $16,104.

Authority for Information Collection: Sections 231(k)–(m) of the Foreign Assistance Act of 1961, as amended.

Abstract (Needs and Uses): The U.S. Effects Screening Questionnaire (OPIC–252) is a pre-screener used to identify an investment's potential negative impacts on the U.S. economy and employment. Title VI of the Foreign Assistance Act of 1961, as amended, prohibits OPIC from supporting investments that are likely to cause the loss of U.S. jobs, or that have performance requirements that may reduce substantially the positive trade benefits likely to accrue to the U.S. from the investment. OPIC–252 is used as a low-burden pre-screener which is submitted prior to a formal OPIC application or as required by OPIC-supported financial intermediaries. Pre-screening reduces the likelihood that an applicant will only be told after completing the application process that the project is barred for policy reasons. Projects which proceed to a full application will fill out the more detailed OPIC–248 to ensure full compliance with OPIC's policies.

Dated: November 21, 2017.

Nichole Skoyles,

Administrative Counsel, Department of Legal Affairs.

[FR Doc. 2017–25696 Filed 11–27–17; 8:45 am]

BILLING CODE 3210–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2017–278; MC2018–30 and CP2018–60]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 30, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2017–278; *Filing Title:* USPS Notice of Change in Prices Pursuant to Amendment to Priority Mail Express, Priority Mail & First-Class Package Service Contract 22; *Filing Acceptance Date:* November 20, 2017; *Filing Authority:* 39 CFR 3015.5; *Public Representative:* Timothy J. Schwuchow; *Comments Due:* November 30, 2017.

2. *Docket No(s).:* MC2018–30 and CP2018–60; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 28 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 20, 2017; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Timothy J. Schwuchow; *Comments Due:* November 30, 2017.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2017–25595 Filed 11–27–17; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2018–31 and CP2018–61]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing recent Postal Service filings for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 30, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's Web site (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment

deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2018–31 and CP2018–61; *Filing Title:* USPS Request to Add First-Class Package Service Contract 85 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 21, 2017; *Filing Authority:* 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.; Public Representative:* Timothy J. Schwuchow; *Comments Due:* November 30, 2017.

This notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2017–25666 Filed 11–27–17; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of notice required under 39 U.S.C. 3642(d)(1):* November 28, 2017.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 21, 2017, it filed with the Postal Regulatory Commission a *USPS Request to Add First-Class Package Service Contract 85 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2018–31, CP2018–61.

Ruth B. Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2017–25585 Filed 11–27–17; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82146; File No. 4–715]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing of Proposed Minor Rule Violation Plan

November 22, 2017.

Pursuant to Section 19(d)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19d–1(c)(2) thereunder,[2] notice is hereby given that on November 16, 2017, MIAX PEARL, LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed minor rule violation plan (''MRVP'') with sanctions not exceeding $2,500 which would not be subject to the provisions of Rule 19d–1(c)(1) of the Act [3] requiring that a self-regulatory organization (''SRO'') promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[4] In accordance with Rule 19d–1(c)(2) under the Act,[5] the Exchange proposed to designate certain specified rule violations as minor rule violations, and requested that it be relieved of the prompt reporting requirements regarding such violations, provided it gives notice of such violations to the Commission on a quarterly basis.

The Exchange proposes to include in its MRVP the procedures and violations currently included in Exchange Rule 1014 (''Imposition of Fines for Minor Rule Violations'').[6] According to the Exchange's MRVP, under Rule 1014, the Exchange may impose a fine (not to exceed $2,500) on any Member, or person associated with or employed by a Member, for any rule listed in Rule 1014(d).[7] The Exchange shall serve the person against whom a fine is imposed with a written statement setting forth the rule or rules violated, the act or omission constituting each such violation, the fine imposed, and the date by which such determination becomes final or by which such determination must be contested. If the person against whom the fine is imposed pays the fine, such payment shall be deemed to be a waiver of such person's right to a disciplinary proceeding and any review of the matter under the Exchange rules. Any person against whom a fine is imposed may contest the Exchange's determination by filing with the Exchange a written answer, at which point the matter shall become a disciplinary proceeding.

The Exchange proposes that, as set forth in Exchange Rule 1014(d), violations of the following rules would be appropriate for disposition under the MRVP: Rule 307 (Position Limits); Rule 803 (Focus Reports); Rule 804 (Requests for Trade Data); Rule 520 (Order Entry); Rule 605 (Execution of Orders in Appointed Options); Rule 314 (Mandatory Systems Testing); Rule 700 (Exercise of Option Contracts); Rule 309 (Exercise Limits); Rule 310 (Reports Related to Position Limits); Rule 403 (Trading in Restricted Classes); Rule 605 (Market Maker Quotations); and Rules 1301, 1302, and 1303 (Failure to Timely File Amendments to Form U4, Form U5, and Form BD). The Exchange notes that it is specifically excluding Rule 1014(d)(4), Conduct and Decorum Policies, from this filing.

Upon the Commission's declaration of effectiveness of the MRVP, the Exchange will provide to the Commission a quarterly report for any actions taken on minor rule violations under the MRVP. The quarterly report will include: The disposition date, the name of the firm/individual, the Exchange's internal enforcement number, the review period, the nature of the violation type, the number of the rule that was violated, the number of instances the violation occurred, and the sanction imposed.

The Exchange also proposes that, going forward, to the extent that there are any changes to the rules applicable to the Exchange's MRVP, the Exchange requests that the Commission deem such changes to be modifications to the Exchange's MRVP.

I. Solicitation of Comments

Interested persons are invited to submit written data, views, and

[1] 15 U.S.C. 78s(d)(1).

[2] 17 CFR 240.19d–1(c)(2).

[3] 17 CFR 240.19d–1(c)(1).

[4] The Commission adopted amendments to paragraph (c) of Rule 19d–1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Securities Exchange Act Release No. 21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to such a plan filed with and declared effective by the Commission shall not be considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[5] 17 CFR 240.19d–1(c)(2).

[6] The Exchange received its grant of registration on December 13, 2016, which included approving the rules that govern the Exchange. *See* Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016).

[7] While Rule 1014 allows the Exchange to administer fines up to $5,000, the Exchange is only seeking relief from the reporting requirements of paragraph (c)(1) of Rule 19d–1 for fines administered under Rule 1014(d) that do not exceed $2,500.

arguments concerning the Exchange's proposed MRVP, including whether the proposed MRVP 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. 4–715 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. 4–715. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed MRVP that are filed with the Commission, and all written communications relating to the proposed MRVP 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 Web site 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 proposed MRVP 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. 4–715 and should be submitted on or before December 19, 2017.

II. Date of Effectiveness of the Proposed Minor Rule Violation Plan and Timing for Commission Action

Pursuant to Section 19(d)(1) of the Act and Rule 19d–1(c)(2) thereunder,[8] after December 19, 2017, the Commission may, by order, declare the Exchange's proposed MRVP effective if the plan is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act. The Commission in its order may restrict the categories of violations to be designated as minor rule violations and may impose any other terms or conditions to the proposed MRVP, File No. 4–715, and to the period of its effectiveness, which the Commission deems necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Brent J. Fields,

Secretary.

[FR Doc. 2017–25648 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–657, OMB Control No. 3235–0705]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 30b1–8 and Form N–CR

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''Paperwork Reduction Act'') (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 30b1–8 under the Act [17 CFR 270.30b1–8], entitled ''Current Report for Money Market Funds,'' provides that every registered open-end management investment company, or series thereof, that is regulated as a money market fund under rule 2a–7 [17 CFR 270.2a–7], that experiences any of the events specified on Form N–CR [17 CFR 274.222], must file with the Commission a current report on Form N–CR within the time period specified in that form. The information collection requirements for rule 30b1–8 and Form N–CR are designed to assist Commission staff in its oversight of money market funds and its ability to respond to market events. It also provides investors with better and timelier disclosure of potentially important events. Finally, the Commission is able to use the information provided on Form N–CR in its regulatory, disclosure review, inspection, and policymaking roles. The rule imposes a burden per report of approximately 8.5 hours and $840, so that the total annual burden for the estimated 37 reports filed per year on Form N–CR is 315 hours and $31,080.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. The estimate is based on communications with industry representatives, and is not derived from a comprehensive or even a representative survey or study.

The collection of information on Form N–CR is mandatory for any fund that holds itself out as a money market fund in reliance on rule 2a–7. Responses will not be kept confidential. 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 public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

November 21, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25601 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(d)(1); 17 CFR 240.19d–1(c)(2).

[9] 17 CFR 200.30–3(a)(44).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82139; File No. SR–NYSEAMER–2017–33]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.35E Relating to Auction Collars and To Add Temporary Rules

November 21, 2017.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 17, 2017, NYSE American LLC (''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) amend Rule 7.35E(a)(10) to allow auctions to be conducted at a price equal to the Auction Collars and to change the rounding methodology for determining Auction Collars; (2) add Commentary .02 to Rule 7.35E to describe rules that would be in effect on a temporary basis pending the implementation of the auction logic changes; and (3) make clarifying amendments to Rules 7.35E(c)(1) and (d)(1). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.35E(a)(10) to allow auctions to be conducted at a price equal to the Auction Collars and to change the rounding methodology for determining Auction Collars.[4] The Exchange also proposes Commentary .02 to Rule 7.35E to provide that until the Exchange implements the amendments to Rule 7.35E(a)(10) (but no later than February 26, 2018): (1) The Re-Opening Time for a Trading Halt Auction will be extended if the unadjusted Indicative Match Price is equal to the Auction Collars; and (2) the Trading Halt Auction processing described in Rules 7.35E(e)(5), (6), (7)(C), (8), and (10) would not be applicable to a Trading Halt Auction following a trading halt due to extraordinary market volatility under Rule 7.12–E (''MWCB Halt'') or a regulatory halt (together, ''Temporary Rules''). Finally, the Exchange proposes clarifying amendments to Rules 7.35E(c)(1) and (d)(1).

The Exchange proposes that the Temporary Rules would become operative on the same date the Exchange implements recent amendments to Rule 7.35E, which the Exchange anticipates implementing at the same time that the changes described in the twelfth amendment to the Regulation NMS Plan to Address Extraordinary Market Volatility (''Plan'') are implemented.[5] As described in greater detail in the Reopening Filing, the Exchange amended its rules relating to the reopening of trading in conjunction with LULD Amendment 12. The Exchange and the participants to the Plan have announced that the changes described in the Reopening Filing and LULD Amendment 12 will be implemented on November 20, 2017.[6]

Proposed Amendment to Rule 7.35E(a)(10)

Rule 7.35E(a)(10)(B) provides that an Indicative Match Price that is *equal to or* higher (lower) than the upper (lower) boundary of the Auction Collar will be adjusted to one minimum price variation below (above) the upper (lower) boundary of the Auction Collar. In other words, the Exchange does not conduct an auction at the Auction Collar price.

By contrast, Rule 7.35E(e)(5) currently defines the term ''Impermissible Price,'' *i.e.,* when a Trading Halt Auction would not be conducted, to mean when the Indicative Match Price, before being adjusted based on Auction Collars, is below (above) the Lower (Upper) Auction Collar or if there is a sell (buy) Market Imbalance. In other words, the Exchange extends the Re-Opening Time for a Trading Halt Auction only if the unadjusted Indicative Match Price is outside the Auction Collar price.

As currently approved, because the Exchange does not operate an auction at the Auction Collar price, but also does not extend an auction if the unadjusted Indicative Match Price is at the Auction Collar Price, these two rules together would allow for a Trading Halt Auction where not all auction interest (including Market Orders) would be satisfied. For example, if the lower Auction Collar is 10.10 for a security, and at 10.10 there are 200 shares to buy, at 10.11 there are 100 shares to buy, and the Exchange receives a sell Limit Order for 300 shares priced at 10.10, the Indicative Match Price, before being adjusted for Auction Collars, would be 10.10, which would be equal to the lower Auction Collar. Pursuant to Rule 7.35E(e)(5), an unadjusted Indicative Match Price of 10.10 would not be an Impermissible Price and therefore the auction would be conducted and would not be extended. However, pursuant to Rule 7.35E(a)(10)(B), the collared Indicative Match Price for that security would be 10.11, which would be where the auction would be priced. Because the auction would be conducted at 10.11, the buy Limit Order priced at 10.10 would not participate. Accordingly, in this scenario, 200 shares of the sell order would not be executed and would be available to participate in continuous trading after the auction. Similarly, if the sell order were a 300 share Market Order, in this scenario, only 100 shares

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Capitalized terms used in this rule filing have the same meaning as the capitalized terms in Rule 7.35E.

[5] *See* Securities Exchange Act Release No. 81968 (October 27, 2017), 82 FR 50898 (November 2, 2017) (SR–NYSEAmer–2017–30) (Notice of filing and immediate effectiveness of proposed rule change) (''Reopening Filing''). *See also* Securities Exchange Act Release Nos. 79107 (October 18, 2016), 81 FR 73159 (October 24, 2016) (Notice) and 79846 (January 19, 2017), 82 FR 8548 (January 26, 2017) (Approval Order) (SR–NYSEArca–2016–130) (the ''NYSE Arca Reopening Filing''), *and* Securities Exchange Act Release No. 79845 (January 19, 2017), 82 FR 8551 (January 26, 2017) (File No. 4–631) (Order approving twelfth amendment to the Plan) (''LULD Amendment 12'').

[6] *See* Trader Update available here: *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Group_LULD_12_testing.pdf.*

of the Market Order would be executed, leaving 200 shares of the sell Market Order unexecuted.

The Exchange proposes to resolve the conflict between these two rules by adjusting the price at which its auctions would be eligible to trade. As proposed, the Exchange would permit auctions to be conducted at prices equal to the Auction Collar price threshold. This proposed rule change to allow for auctions to be priced equal to the Auction Collar price thresholds is consistent with how another exchange prices its auctions.[7] To effect this change, the Exchange proposes to amend Rule 7.35E(a)(10)(B) as follows (deletions in brackets):

(B) An Indicative Match Price that is [equal to or] higher (lower) than the upper (lower) boundary of the Auction Collar will be adjusted to [one MPV below (above)] the upper (lower) boundary of the Auction Collar and orders eligible to participate in the applicable auction will trade at the collared Indicative Match Price.

The Exchange similarly proposes to amend Rule 7.35E(a)(10)(C) to delete the phrase ''at or'' so that Limit Orders priced equal to the Auction Collars would be eligible to participate in the Auction without being collared, as follows (deletions in brackets):

(C) Limit Orders to buy (sell) with a limit price [at or] above (below) the upper (lower) Auction Collar will be included in the Auction Imbalance Information at the collared Indicative Match Price and will be eligible to trade at the Indicative Match Price.

Rule 7.35E(a)(10)(A) provides that the Auction Collar for the Core Open Auction and the Closing Auction (except as provided for in Rule 7.35E(e)(10)(B)) will be based on a price that is the greater of $0.50 or 10% away from the Auction Reference Price for the applicable Auction. The rule further provides that the upper (lower) boundary of the Auction Collar is the Auction Reference Price increased (decreased) by either $0.50 or 10%, as applicable, rounded down to the MPV. Finally, the rule provides that the Auction Collar for the Trading Halt Auction is specified in Rule 7.35E(e)(7). Rule 7.35E(e)(7)(B)(i) and (ii) similarly provide that Auction Collars for Trading Halt Auctions are rounded down to the nearest MPV.

The Exchange proposes to change its rounding methodology for determining Auction Collars for all auctions. To effect this change, the Exchange proposes to move the last sentence of Rule 7.35E(a)(10)(A) to after the first sentence of that paragraph and make a non-substantive amendment to change ''Rule 7.35E(e)(7)'' to ''paragraph (e)(7) of this Rule.'' Next, the Exchange proposes to amend what was formerly the second sentence of this paragraph, and what would now be the last sentence, to replace the term ''10%'' with the term ''specified percentage,'' so that this sentence, which addresses how Auction Collars are determined, would include how Auction Collars are determined for Trading Halt Auctions. Finally, the Exchange proposes to amend Rule 7.35E(a)(10)(A) to provide that the upper (lower) boundary of the Auction Collar is the Auction Reference Price increased (decreased) by either $0.50 or the specified percentage, as applicable, rounded to the nearest MPV.[8] The Exchange proposes to similarly amend Rule 7.35–E(e)(7)(B)(i) and (ii) to provide that Auction Collars would be rounded to the nearest MPV. Both Nasdaq Stock Market LLC (''Nasdaq'') and BZX Equities use this rounding methodology when determining auction collar prices for reopenings following a Trading Pause.[9] The Exchange would apply this same rounding methodology when determining the Auction Collars for all auctions on the Exchange.

The Exchange further proposes to amend Rules 7.35E(a)(10)(A) and (e)(7)(B)(i) and (ii) to provide that the lowest Auction Collar would be one MPV above $0.00. For example, if the Reference Price for a security is $0.10, subtracting $0.15 from this Reference Price would equal a negative number. In such case, the lower boundary of the Auction Collar would be $0.0001. Because, as described above, the Exchange would allow an auction to run at a price equal to an Auction Collar, this proposed rule change would make clear that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00.

Because of technology changes associated with the proposed changes to Rules 7.35E(a)(10)(A), (B), and (C), the Exchange proposes to announce the implementation date of these changes by Trader Update, which will be no later than February 26, 2018. Between the effective date of these proposed rule changes and the implementation date, the Exchange proposes to keep the deleted rule text in its rule book, but will keep the deleted text in brackets and new text underlined to indicate that the Exchange has an effective proposed rule change amending that text. To reduce confusion and promote transparency, the Exchange proposes to describe how the text will be marked in proposed paragraph (c) to new Commentary .02 as follows:

Paragraphs (a)(10)(A), (B), and (C) of this Rule will have text in brackets indicating which text will be deleted and underlined text indicating which text will be new when the Exchange implements the amendments to those paragraphs.

Temporary Rule for Extending an Auction When Indicative Match Price Is Equal to Auction Collar

Pending the implementation of the technology changes described above, the Exchange proposes a temporary rule that would provide that the Exchange would extend the Re-Opening Time for a Trading Halt Auction if the unadjusted Indicative Match Price is equal to an Auction Collar. As proposed, for the period beginning November 20, 2017, when the changes described in the Reopening Filing are implemented, and ending when the Exchange's technology changes are implemented or February 26, 2018, whichever is earlier, an Impermissible Price would include a price equal to the Auction Collar and thus a Trading Halt Auction would be extended when the unadjusted Indicative Match Price is equal to the Upper or Lower Auction Collar. This temporary rule would align the extension of an auction under Rule 7.35E(e)(5) with the price at which an auction would be conducted pursuant to Rule 7.35E(a)(10)(B). The Exchange believes that amending its rules on a temporary basis would be consistent with the purpose of the extension logic for Trading Halt Auctions, which is, in part, to ensure that all interest (including Market Orders) eligible to participate in the Trading Halt Auction is satisfied and not carried over to continuous trading.[10]

To effect this temporary change, the Exchange proposes to add Commentary .02 to Rule 7.35E that would describe the Temporary Rules that would be in effect until the earlier of February 26, 2018 or when the Exchange implements amendments to Rules 7.35E(a)(10)(A), (B), and (C), described above, which would be announced by Trader Update.

[7] *See* Cboe BZX Exchange, Inc. (''BZX Equities'') Rule 11.23(a)(6) and (d)(2)(C).

[8] If adding or subtracting the specified percentage of the Auction Reference price to the Auction Collar would result in a tenth of a penny, the Exchange would round down to the nearest penny when the calculation results in one to four tenths of a penny and the Exchange would round up to the nearest penny when the calculation results in five to nine tenths of a penny.

[9] *See* Nasdaq Rule 4120(c)(10)(A)(ii)a. and b. and BZX Equities Rule 11.23(d)(2)(C)(i) and (ii). The Nasdaq and BZX Equities rules are silent on the rounding methodology they use when applying percentages to auction collars for opening or closing auctions.

[10] *See* Reopening Filing, *supra* note 5.

Proposed paragraph (a) to new Commentary .02 to Rule 7.35E would describe the Temporary Rule relating to determining when a Trading Halt Auction would be extended and would provide that Rule 7.35E(e)(5) would not be in effect and a Trading Halt Auction would not be conducted if the Indicative Match Price, before being adjusted based on Auction Collars, would be equal to or below (above) the Lower (Upper) Auction Collar or if there is a sell (buy) Market Imbalance (an ''Impermissible Price'').

The Exchange believes that including temporary rule text that describes how the Exchange will be determining the Impermissible Price beginning on November 20, 2017 will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule. Once the temporary rule is no longer in effect, the Exchange will file a proposed rule change to delete the proposed Commentary .02(a) to Rule 7.35E.

Temporary Rule for MWCB and Regulatory Halts

In the Reopening Filing, the Exchange amended Rule 7.35E(e) to provide for a standardized methodology regarding how a primary listing exchange that conducts automated reopenings following a Trading Pause would reopen if Market Orders cannot be satisfied in the Trading Halt Auction. The amendments provide for a standardized Auction Reference Price and Auction Collar values, as well as for a standardized process for extending the Trading Pause if there is an Impermissible Price at the Re-Opening Time. The rule also implements the requirement set forth in LULD Amendment 12 that if an NMS Stock is in a Trading Pause during the last ten minutes of trading before the end of Regular Trading Hours, the Primary Listing Exchange shall not reopen trading and shall attempt to execute a closing transaction using its established closing procedures.[11]

As described in the Reopening Filing, the Exchange chose to make the changes described in the Reopening Filing available for Trading Halt Auctions following a MWCB Halt or regulatory halt.[12] However, because of the different technology supporting Trading Halt Auctions following MWCB Halts and regulatory halts, the changes described in the Reopening Filing as applicable for a Trading Halt Auction following a MWCB Halt or regulatory halt will not be available on the implementation date for the LULD Amendment 12 changes.[13]

The Exchange will adjust its technology to align the treatment of Trading Halt Auctions following a MWCB Halt or regulatory halt with current Rules 7.35E(e)(5)–(8) and (e)(10). However, because these technology changes will not be ready by November 20, 2017, which is when the rules described in the Reopening Filing will be implemented, the Exchange proposes paragraph (b) to Commentary .02 to Rule 7.35E to provide for the Temporary Rule that the Trading Halt Auction processing described in Rules 7.35E(e)(5), (6), (7)(C), (8) and (10) would not be applicable to a Trading Halt Auction following a MWCB Halt or a regulatory halt. Rule 7.35E(e)(7) and sub-paragraphs (A) and (B) of that Rule, which specify the Auction Collar Reference Price and Auction Collars for Trading Halt Auctions, including for Trading Halt Auctions following a MWCB Halt or regulatory halt, would be applicable beginning November 20, 2017 for all Trading Halt Auctions. The Exchange intends to make the technology changes relating to Trading Halt Auctions following a MWCB Halt or regulatory halt at the same time that it implements the technology changes relating to the amendments to Rules 7.35E(a)(10)(A), (B), and (C), described above.

The Exchange believes that including temporary rule text that describes how the Exchange will be processing Trading Halt Auctions following a MWCB Halt or regulatory halt beginning on November 20, 2017 will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule. Once the temporary rule is no longer in effect, the Exchange will file a proposed rule change to delete proposed Commentary .02(b) to Rule 7.35E.[14]

Clarifying Amendments to Rule 7.35E(c)(1) and (d)(1)

Rules 7.35E(c)(1) provides that the Exchange will begin publishing Core Open Auction Imbalance Information at 8:00 a.m. Eastern Time. Rule 7.35E(d)(1) provides that the Exchange will begin publishing Closing Auction Imbalance Information one hour before the scheduled time for the Closing Auction. Because regularly scheduled auctions are not overlapping, the Exchange does not publish auction imbalance information for more than one auction at a time. However, if there is a Trading Halt Auction during the period when the Exchange would otherwise be publishing either Core Open or Closing Auction Imbalance Information, the Exchange stops publishing the Core Open or Closing Auction information and begins publishing Trading Halt Auction Imbalance Information. The proprietary data feeds that carry the Auction Imbalance Information specify for which auction the auction imbalance information is for (*e.g.,* Trading Halt Auction or Core Open Auction).

The Exchange proposes to amend Rules 7.35E(c)(1) and (d)(1) to clarify what auction information is published if there is a halt (or pause) in the period when either Core Open Auction or Closing Auction Imbalance Information would otherwise be published.[15]

As proposed, Rule 7.35E(c)(1) would be amended to add that ''unless a security is halted,'' the Exchange will begin publishing Core Open Auction Imbalance Information at 8:00 a.m. Eastern Time. The Exchange further proposes to add two new sentences to the rule that would provide:

> If a security is halted after 8:00 a.m. Eastern Time but before the Core Open Auction, the Exchange will stop publishing Core Open Auction Imbalance Information and will begin publishing Trading Halt Auction Imbalance Information. The Exchange will resume publishing Core Open Auction Imbalance Information if the security reopens trading before Core Trading Hours begin.

Similarly, as proposed, Rule 7.35E(d)(1) would be amended to add that ''unless a security is halted or paused,'' the Exchange will begin publishing Closing Auction Imbalance Information one hour before the

[11] *See* LULD Amendment 12, *supra* note 5.

[12] *See* Reopening Filing, *supra* note 5.

[13] The changes described in the Reopening Filing as applicable for Trading Halt Auctions following a Trading Pause will be implemented at the same time as the LULD Amendment 12 changes.

[14] The Exchange also proposes to amend Rule 7.35E(e)(10) to add the phrase ''halted or'' to the second sentence of that rule so that it would provide: ''Instead, the Exchange will remain halted or paused and will conduct a Closing Auction in such security as provided for in paragraph (d) of this Rule.'' The Exchange believes that because current Rule 7.35E(e)(10) applies to both halts and pauses, this proposed rule change clarifies the existing rule text. This proposed rule change would be in effect once the Temporary Rule described in Commentary .02(b) to Rule 7.35E has ended.

[15] A halt before Core Trading Hours would be a regulatory halt because a Trading Pause will occur only during Core Trading Hours, and therefore a security would not be paused before the Core Open Auction, and a MWCB Halt can be triggered only during Core Trading Hours.

scheduled time for the Closing Auction. The Exchange further proposes to add two new sentences to that rule that would provide:

> If a security is halted or paused less than one hour before the scheduled time for the Closing Auction, the Exchange will stop publishing Closing Auction Imbalance Information and will begin publishing Trading Halt Auction Imbalance Information. The Exchange will resume publishing Closing Auction Imbalance Information the earlier of when the security reopens trading or ten minutes before the scheduled time for the Closing Auction.[16]

Because the proposed amendments to Rules 7.35E(c)(1) and (d)(1) describe current functionality, the Exchange proposes that these rule changes would be implemented on the operative date of this filing.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[17] in general, and with Section 6(b)(5),[18] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed amendment to Rules 7.35E(a)(10)(B) and (C) to allow auctions to be conducted at a price equal to the Auction Collars would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align how auctions are priced with the rules of another exchange.[19] Specifically, the application of auction collars on BZX Equities allow for an auction to be priced equal to the auction collars on that market. The proposed amendments to Rule 7.35E(a)(10) would similarly allow for the Exchange to price auctions equal to the Auction Collar. More specifically, for Trading Halt Auctions, the Exchange believes that this proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align how reopening auctions are priced, which is consistent with the goal of the Reopening Filing to have standardized processes for re-opening a security following a Trading Pause across the primary listing exchange.

The Exchange believes that the proposed amendment to Rules 7.35E(a)(10)(A) and 7.35–E(e)(7)(B)(i) and (ii) to apply the same rounding methodology as Nasdaq and BZX Equities when determining the Auction Collars following a Trading Halt Auction would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align the Exchange's rules regarding how Auction Collars would be determined for a Trading Halt Auction with the rules of Nasdaq and BZX Equities. The Exchange further believes that it would remove impediments to and perfect the mechanism of a free and open market to apply the proposed rounding methodology to determining Auction Collars for all auctions on the Exchange because it would promote consistency in the application of rounding when determining Auction Collars, thereby promoting consistency across Exchange rules and reducing potential confusion. The Exchange further believes that amending Exchange rules to provide that the lowest Auction Collar would be one MPV above $0.00 would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would clarify that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00, thereby promoting transparency in Exchange rules.

The Exchange believes that the Temporary Rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because these proposed rule changes would provide transparency regarding how the Exchange will function when the changes described in LULD Amendment 12 and the Reopening Filing are implemented, which is scheduled for November 20, 2017. The Exchange fully intends to implement the rules as approved in the Reopening Filing. However, the Exchange will not be able to implement Rule 7.35E(e)(5), as described in the Exchange's current rules, or apply the processing describing in Rules 7.35E(e)(5), (6), (7)(C), (8), and (10) to Trading Halt Auctions following a MWCB Halt or regulatory halt, until the changes described for the proposed amendments to Rule 7.35E(a)(10) are implemented. The Exchange believes that adding the Temporary Rules for the interim period pending such implementation will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule.

Finally, the Exchange believes that the proposed amendments to Rules 7.35E(c)(1) and (d)(1) will remove impediments to and perfect the mechanism of a free and open market and a national market system because these proposed amendments would clarify in Exchange rules which imbalance information would be published if there is a trading halt or pause during a period when either Core Open Auction or Closing Auction Imbalance Information is being published. The Exchange believes that the proposed clarifications will promote the protection of investors and the public interest because they will provide transparency regarding which imbalance information would be published at specific times prior to the Core Open and Closing Auctions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change to Rules 7.35E(a)(10) and (e)(7) would remove a potential burden on competition by aligning the Exchange's rules regarding how auctions would be priced and Auction Collars would be determined with the rules of other exchanges. The proposed Temporary Rules and clarifying amendment to Rules 7.35E(c)(1) and (d)(1) are not designed to address any competitive issues but rather to promote transparency in Exchange rules regarding how the Exchange will function.

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.

[16] The reference in this proposed rule to resuming publishing Closing Auction Imbalance Information ten minutes before the scheduled time for the Closing Auction refers to Rule 7.35–E(e)(10), which will be implemented for Trading Pauses on November 20, 2017, and will be implemented for MWCB Halts and regulatory halts the earlier of February 26, 2018 or when the technology changes described above are implemented.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] *See supra* note 7.

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, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [22] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [23] permits the Commission to 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 immediately upon filing. According to the Exchange, the implementation date of November 20, 2017 for the changes described in the Reopening Filing and LULD Amendment 12 is an industry-wide implementation date. The Exchange states that it fully intends to implement the rules as approved in the Reopening Filing, but it will not be able to implement Rule 7.35E(e)(5) or apply the processing described in Rules 7.35E(e)(5), (6), (7)(C), (8), and (10) to Trading Halt Auctions following a MWCB Halt or regulatory halt until the proposed amendments to Rule 7.35E(a)(10) are implemented.[24] According to the Exchange, until it makes the changes in the proposed amendments to Rule 7.35E(a)(10), it will have functionality in production that does not match its current rules.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission believes that implementing the Temporary Rules without delay will promote transparency in the Exchange's rules regarding how the Exchange will function during this interim period.[25] The Commission notes that the Temporary Rules will be in effect until the Exchange implements its technology changes or until February 26, 2018, whichever is earlier. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[26]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that 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 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–NYSEAMER–2017–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2017–33. 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 Web site (*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 Web site 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–NYSEAMER–2017–33 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25607 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] According to the Exchange, the proposed amendments to Rules 7.35E(a)(10) and (e)(7) are consistent with the goal of having standardized processes across primary listing exchanges for re-opening a security following a Trading Pause, will promote consistency when determining Auction Collars across the Exchange's auctions, and will make clear that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00.

[25] In addition, according to the Exchange, the proposed amendments to Rule 7.35E(c)(1) and (d)(1) will provide transparency regarding which imbalance information would be published at specific times prior to the Core Open and Closing Auctions.

[26] 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).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82135; File Nos. SR–BatsBZX–2017–37; SR–BatsEDGX–2017–23; SR–BOX–2017–17; SR–C2–2017–018; SR–CBOE–2017–041; SR–FINRA–2017–013; SR–ISE–2017–46; SR–IEX–2017–18; SR–MIAX–2017–20; SR–PEARL–2017–23; SR–NASDAQ–2017–055; SR–BX–2017–027; SR–Phlx–2017–43; SR–NYSE–2017–23; SR–NYSEArca–2017–57; SR–NYSEArca–2017–59; SR–NYSEMKT–2017–29; SR–NYSEMKT–2017–30]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Bats EDGX Exchange, Inc.; BOX Options Exchange LLC; C2 Options Exchange, Incorporated; Chicago Board Options Exchange, Incorporated; Financial Industry Regulatory Authority, Inc.; International Securities Exchange, LLC; Investors Exchange LLC; Miami International Securities Exchange LLC; MIAX PEARL, LLC; The NASDAQ Stock Market LLC; NASDAQ BX, Inc.; NASDAQ PHLX LLC; New York Stock Exchange LLC; NYSE Arca, Inc.; NYSE MKT LLC; Notice of Designation of Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Changes, as Modified by Amendments Thereto, To Eliminate Requirements That Will Be Duplicative of CAT

November 21, 2017.

On May 15, 2017, Bats BZX Exchange, Inc. (''Bats BZX'') (n/k/a Cboe BZX Exchange, Inc.);[1] Bats EDGX Exchange, Inc. (''Bats EDGX'') (n/k/a Cboe EDGX Exchange, Inc.);[2] BOX Options Exchange LLC (''BOX''); C2 Options Exchange, Incorporated (''C2'') (n/k/a Cboe C2 Exchange, Inc.);[3] Chicago Board Options Exchange, Incorporated (''CBOE'') (n/k/a Cboe Exchange, Inc.);[4] Financial Industry Regulatory Authority, Inc. (''FINRA''); International Securities Exchange, LLC (''ISE''); Investors Exchange LLC (''IEX''); Miami International Securities Exchange LLC (''MIAX''); MIAX PEARL, LLC (''PEARL''); NYSE Arca, Inc. (''NYSE Arca''); and NYSE MKT LLC (''NYSE MKT'') (n/k/a NYSE American LLC)[5] filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[6] and Rule 19b–4 thereunder,[7] proposed rule changes to eliminate or modify certain rules that require the collection or reporting of information that is duplicative of the information that will be collected by the Consolidated Audit Trail (''CAT'') established pursuant to the National Market System Plan contemplated by Rule 613 of Regulation NMS.[8] On May 22, 2017, the New York Stock Exchange LLC (''NYSE'') filed with the Commission a proposed rule change for the same purpose, and each of NYSE Arca and NYSE MKT filed an additional proposed rule change for the same purpose. On May 26, 2017, the NASDAQ Stock Market LLC (''NASDAQ'') and NASDAQ PHLX LLC (''Phlx'') filed with the Commission proposed rule changes for the same purpose.[9] On May 30, 2017, NASDAQ BX, Inc. (''BX'') filed with the Commission a proposed rule change for the same purpose.[10] In this notice, all of these proposed rule changes are referred to collectively as the ''Systems Retirement Proposals.''

On June 1, 2017, the proposed rule changes submitted by Bats BZX, Bats EDGX, BOX, C2, CBOE, FINRA, IEX, ISE, MIAX, and PEARL; both proposed rule changes submitted by NYSE MKT; and one of the proposed rule changes submitted by NYSE Arca were published for comment in the **Federal Register**.[11] On June 2, 2017, the proposed rule change submitted by NYSE and the other proposed rule change submitted by NYSE Arca were published for comment in the **Federal Register**.[12] On June 5, 2017, the proposed rule changes submitted by NASDAQ, BX, and Phlx were published for comment in the **Federal Register**.[13]

Four comments were submitted to File Number SR–FINRA–2017–013.[14]

On June 22, 2017, each of NASDAQ, BX, ISE, and Phlx filed an amendment to its proposed rule change. On July 14, 2017, the Commission extended the time period for Commission action on all of the Systems Retirement Proposals to August 30, 2017.[15]

On August 24, 2017, BOX submitted Amendment No. 1 to its proposed rule change, IEX submitted Amendment No. 1 to its proposed rule change, PEARL submitted Amendment No. 2 to its proposed rule change,[16] and MIAX submitted Amendment No. 3 to its proposed rule change.[17] On August 25, 2017, Bats BZX submitted Amendment No. 1 to its proposed rule change, Bats EDGX submitted Amendment No. 1 to its proposed rule change, BX submitted Amendment No. 2 to its proposed rule

[1] *See* Securities Exchange Act Release No. 81962 (October 26, 2017), 82 FR 50711 (November 1, 2017) (SR–BatsBZX–2017–70). The name change was not yet effective when Bats BZX filed SR–BatsBZX–2017–37.

[2] *See* Securities Exchange Act Release No. 81963 (October 26, 2017), 82 FR 50697 (November 1, 2017) (SR–BatsEDGX–2017–41). The name change was not yet effective when Bats EDGX filed SR–BatsEDGX–2017–23.

[3] *See* Securities Exchange Act Release No. 81979 (October 30, 2017), 82 FR 51317 (November 3, 2017) (SR–C2–2017–028). The name change was not yet effective when C2 filed SR–C2–2017–018.

[4] *See* Securities Exchange Act Release No. 81981 (October 30, 2017), 82 FR 51309 (November 3, 2017) (SR–CBOE–2017–066). The name change was not yet effective when CBOE filed SR–CBOE–2017–041.

[5] *See* Securities Exchange Act Release No. 80283 (March 21, 2017), 82 FR 15244 (March 27, 2017) (SR–NYSEMKT–2017–14). The name change was not yet effective when NYSE MKT filed SR–NYSEMKT–2017–29 and SR–NYSEMKT–2017–30.

[6] 15 U.S.C. 78s(b)(1).

[7] 17 CFR 240.19b–4.

[8] 17 CFR 242.613.

[9] NASDAQ and Phlx initially filed proposed rule changes on May 15, 2017 (SR–NASDAQ–2017–050 and SR–PHLX–2017–38). On May 26, 2017, NASDAQ and Phlx withdrew these filings and submitted new proposed rule changes (SR–NASDAQ–2017–055 and SR–PHLX–2017–43).

[10] BX initially filed a proposed rule change on May 15, 2017 (SR–BX–2017–025). On May 30, 2017, BX withdrew that initial filing and submitted a new proposed rule change (SR–BX–2017–027).

[11] *See* Securities Exchange Act Release No. 80796 (May 26, 2017), 82 FR 25374 (SR–BatsBZX–2017–37); Securities Exchange Act Release No. 80795 (May 26, 2017), 82 FR 25358 (SR–BatsEDGX–2017–23); Securities Exchange Act Release No. 80789 (May 26, 2017), 82 FR 25492 (SR–BOX–2017–17); Securities Exchange Act Release No. 80798 (May 26, 2017), 82 FR 25385 (SR–C2–2017–018); Securities Exchange Act Release No. 80797 (May 26, 2017), 82 FR 25429 (SR–CBOE–2017–041); Securities Exchange Act Release No. 80783 (May 26, 2017), 82 FR 25423 (SR–FINRA–2017–013); Securities Exchange Act Release No. 80788 (May 26, 2017), 82 FR 25400 (SR–IEX–2017–18); Securities Exchange Act Release No. 80787 (May 26, 2017), 82 FR 25469 (SR–ISE–2017–46); Securities Exchange Act Release No. 80790 (May 26, 2017), 82 FR 25366 (SR–MIAX–2017–20); Securities Exchange Act Release No. 80792 (May 26, 2017), 82 FR 25436 (SR–PEARL–2017–23); Securities Exchange Act Release No. 80791 (May 26, 2017), 82 FR 25362 (SR–NYSEArca–2017–59); Securities Exchange Act Release No. 80793 (May 26, 2017), 82 FR 25443 (SR–NYSEMKT–2017–29); Securities Exchange Act Release No. 80794 (May 26, 2017), 82 FR 25439 (SR–NYSEMKT–2017–30).

[12] *See* Securities Exchange Act Release No. 80799 (May 26, 2017), 82 FR 25635 (SR–NYSE–2017–23); Securities Exchange Act Release No. 80800 (May 26, 2017), 82 FR 25639 (SR–NYSEArca–2017–57).

[13] *See* Securities Exchange Act Release No. 80813 (May 30, 2017), 82 FR 25820 (SR–NASDAQ–2017–055); Securities Exchange Act Release No. 80814 (May 30, 2017), 82 FR 25872 (SR–BX–2017–027); Securities Exchange Act Release No. 80811 (May 30, 2017), 82 FR 25863 (SR–Phlx–2017–43).

[14] *See* letters from William H. Herbert, Managing Director, Financial Information Forum (''FIF''), dated June 22, 2017; Manisha Kimmel, Chief Regulatory Officer, Wealth Management, Thomson Reuters, dated June 22, 2017; Marc R. Bryant, Senior Vice President, Deputy General Counsel, Fidelity Investments, dated June 22, 2017; and Ellen Greene, Managing Director and Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association (''SIFMA''), dated June 23, 2017.

[15] *See* Securities Exchange Act Release No. 81145, 82 FR 33533 (July 20, 2017).

[16] PEARL filed Amendment No. 1 to its proposed rule change on August 22, 2017. On August 24, 2017, PEARL withdrew Amendment No. 1 and replaced it with Amendment No. 2.

[17] MIAX filed Amendment No. 1 to its proposed rule change on August 22, 2017 and withdrew and replaced it with Amendment No. 2 on the same day. On August 24, 2017, MIAX withdrew Amendment No. 2 and replaced it with Amendment No. 3.

change, C2 submitted Amendment No. 1 to its proposed rule change, CBOE submitted Amendment No. 1 to its proposed rule change, FINRA submitted Amendment No. 1 to its proposed rule change, ISE submitted Amendment No. 2 to its proposed rule change, NASDAQ submitted Amendment No. 2 to its proposed rule change, NYSE submitted Amendment No. 1 to its proposed rule change, NYSE Arca submitted Amendment No. 1 to each of its proposed rule changes, NYSE MKT submitted Amendment No. 1 to each of its proposed rule changes, and Phlx submitted Amendment No. 2 to its proposed rule change.

On August 30, 2017, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act [18] to determine whether to approve or disapprove the proposed rule changes, as modified by the respective amendments thereto.[19] Since then, the Commission has received eight additional comment letters on the proposed rule changes, including a response from FINRA and a response from the CAT NMS Plan Operating Committee Chair on behalf of Bats BZX, Bats EDGX, BOX, C2, CBOE, IEX, ISE, MIAX, NASDAQ, BX, Phlx, NYSE, NYSE Arca, NYSE MKT, and PEARL.[20]

Section 19(b)(2) of the Act [21] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving a proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may, however, extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule changes submitted by Bats BZX, Bats EDGX, BOX, C2, CBOE, FINRA, IEX, ISE, MIAX, and PEARL; both proposed rule changes submitted by NYSE MKT; and one of the proposed rule changes submitted by NYSE Arca were published for comment in the **Federal Register** on June 1, 2017. November 28, 2017, is 180 days from that date, and January 27, 2018, is 240 days from that date. The proposed rule change submitted by NYSE and the other proposed rule change submitted by NYSE Arca were published for comment in the **Federal Register** on June 2, 2017. November 29, 2017, is 180 days from that date, and January 28, 2018, is 240 days from that date. The proposed rule changes submitted by NASDAQ, BX, and Phlx were published for comment in the **Federal Register** on June 5, 2017. December 2, 2017, is 180 days from that date, and January 31, 2018, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the Systems Retirement Proposals so that it has sufficient time to consider the Systems Retirement Proposals, as modified by the respective amendments thereto, the issues raised in the comment letters that have been submitted in connection therewith, and FINRA's response to the comments. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[1] designates January 27, 2018, as the date by which the Commission should either approve or disapprove the proposed rule changes, as modified by the respective amendments thereto (File Numbers SR–BatsBZX–2017–37; SR–BatsEDGX–2017–23; SR–BOX–2017–17; SR–C2–2017–018; SR–CBOE–2017–041; SR–FINRA–2017–013; SR–ISE–2017–46; SR–IEX–2017–18; SR–MIAX–2017–20; SR–PEARL–2017–23; SR–NASDAQ–2017–055; SR–BX–2017–027; SR–PHLX–2017–43; SR–NYSE–2017–23; SR–NYSEArca–017–57; SR–NYSEArca–2017–59; SR–NYSEMKT–2017–29; and SR–NYSEMKT–2017–30).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25604 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(2)(B).

[19] *See* Securities Exchange Act Release No. 81499, 82 FR 42168 (September 6, 2017) (''OIP'').

[20] Six substantive comment letters were submitted in response to the OIP. *See* letters from Manisha Kimmel, Chief Regulatory Officer, Wealth Management, Thomson Reuters, dated September 27, 2017; William H. Herbert, Managing Director, FIF, dated September 29, 2017; Ellen Greene, Managing Director and Theodore R. Lazo, Managing Director and Associate General Counsel, SIFMA, dated September 29, 2017; Brant K. Brown, Associate General Counsel, FINRA, dated October 11, 2017; William H. Herbert, Managing Director, FIF, dated November 2, 2017; and Michael Simon, CAT NMS Plan Operating Committee Chair, dated November 2, 2017. A seventh letter in response to the OIP requested additional time to submit comments on the proposed rule changes. *See* letter from William H. Herbert, Managing Director, FIF, dated September 27, 2017. The eighth comment letter was submitted solely to File Number SR–Phlx–2017–43. *See* letter from Michael Kitlas, dated November 14, 2017.

[21] 15 U.S.C. 78s(b)(2).

[22] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82134; File No. SR–MRX–2017–25]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Remove Directed Order Functionality

November 21, 2017.

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 November 16, 2017, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the 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 remove Directed Order [3] functionality on MRX.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqmrx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Last year the Exchange filed to delay the implementation of the Directed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Directed Order'' is an order routed from an Electronic Access Member to an Exchange market maker through the Exchange's System.

Order functionality in conjunction with a replatform to INET.[4] INET is the proprietary core technology utilized across Nasdaq's global markets and utilized on The Nasdaq Options Market LLC (''NOM''), Nasdaq PHLX LLC (''Phlx'') and Nasdaq BX, Inc. (''BX'') (collectively, ''Nasdaq Exchanges''). MRX was migrated to INET technology in 2017. With the migration, MRX delayed the implementation of the Directed Order functionality to stage the re-platform to provide maximum benefit to its Members while also ensuring a successful rollout. At that time, the Exchange noted that the Exchange will introduce the Directed Order functionality within one year from the date of this filing, otherwise the Exchange will file a rule proposal with the Commission to remove these rules. The Exchange filed the initial rule change on May 17, 2017.[5] The Exchange has determined at this time not to offer Directed Order functionality. If the Exchange determines to offer this functionality at a later date a rule proposal will be filed at that time.

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 because the Exchange will remove rule text related to functionality which will not be offered on MRX. The current rule text indicates the functionality is not offered today. The Exchange believes that removing Rule 811 from the Rulebook will avoid confusion as to whether this functionality will be enabled in the future.

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 does not believe that the proposed rule change will impose any burden on intra-market competition because the Exchange is not offering this functionality today and believes there is no interest among Members for this functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[8] and subparagraph (f)(6) of Rule 19b–4 thereunder.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2017–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2017–25. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2017–25 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25603 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[4] *See* Securities Exchange Act Release No. 81204 (July 25, 2017), 82 FR 35557 (July 31, 2017) (SR–MRX–2017–02).

[5] *Id.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A)(iii).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82149; File No. SR–NYSEArca–2017–132]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 5.1–E(c) Regarding the Requirements for the Listing of Securities That Are Issued by the Exchange or Any of Its Affiliates

November 22, 2017.

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 November 17, 2017, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 5.1–E(c) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 5.1–E(c) (Listing of an Affiliate or Entity that Operates and/or Owns a Trading System or Facility of the Exchange) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates.

Paragraph (c) of 5.1–E(c) sets forth certain monitoring requirements that must be met throughout the continued listing and trading of securities issued by the Exchange's ultimate parent, Intercontinental Exchange, Inc. (''ICE''), or its affiliates. More specifically, paragraph (c)(1) and (2) of Rule 5.1–E(c) provide that, throughout the continued listing and trading of an Affiliate Security [4] on the Exchange:

- The Exchange will prepare a quarterly report on the Affiliate Security (''Quarterly Report'') for the Exchange's Regulatory Oversight Committee (''ROC''), and a copy of the Quarterly Report will be forwarded promptly to the Securities and Exchange Commission (''Commission''); and
- once a year, an independent accounting firm shall review the listing standards for the Affiliate Security to insure that the issuer is in compliance with the listing requirements (''Annual Report''), and a copy of the Annual Report shall be forwarded promptly to the ROC and the Commission.

The Exchange proposes to amend paragraph (c) of Rule 5.1–E(c) to remove the requirement that copies of the Quarterly and Annual Reports be forwarded to the Commission, by deleting the final sentence of Rule 5.1–E(c)(c)(1) and the text ''and the Commission'' from the end of Rule 5.1–E(c)(c)(2). In addition, because the proposed deletions would remove the definition of ''Commission'' currently in Rule 5.1–E(c)(c)(1), the Exchange proposes to add the definition to Rule 5.1–E(c)(c)(3).

No other changes would be made to paragraph (c) of Rule 5.1–E(c), which would continue to require that the Quarterly Report be prepared for the ROC and the Annual Report be forwarded promptly to the ROC.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act [5] in general, and Section 6(b)(5) [6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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, because the proposed changes would reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission. In discussions with the Commission Staff regarding Rule 5.1–E(c), it was determined that the Exchange no longer needed to provide copies of the Quarterly and Annual Reports to the Commission. The Quarterly and Annual Reports would continue to be available to the Commission, as they are subject to Section 17A of the Act [7] and Rule 17a–1 thereunder,[8] pursuant to which the Exchange is required to keep and preserve copies of the Quarterly and Annual Reports, and to promptly furnish to the Commission copies of such Reports upon request of any representative of the Commission.

The Exchange believes that the proposed non-substantive change adding the definition of ''Commission'' to Rule 5.1–E(c)(c)(3) would promote just and equitable principles of trade

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Pursuant to Rule 5.1–E(c)(a), ''Affiliate Security'' means any security issued by an ICE Affiliate or any Exchange-listed option on any such security, and ''ICE Affiliate'' means ICE and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with ICE, where ''control'' means that one entity possesses, directly or indirectly, voting control of the other entity either through ownership of capital stock or other equity securities or through majority representation on the board of directors or other management body of such entity.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78q.

[8] 17 CFR 240.17a–1.

and remove impediments to a free and open market by providing greater clarity in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather to reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

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) [12] 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–NYSEArca–2017–132 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2017–132. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2017–132 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25691 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82145; File No. 4–714]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing of Proposed Minor Rule Violation Plan

November 22, 2017.

Pursuant to Section 19(d)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19d–1(c)(2) thereunder,[2] notice is hereby given that on November 16, 2017, Miami International Securities Exchange, LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed minor rule violation plan (''MRVP'') with sanctions not exceeding $2,500 which would not be subject to the provisions of Rule 19d–1(c)(1) of the Act [3] requiring that a self-regulatory organization (''SRO'') promptly file notice with the Commission of any final disciplinary action taken with respect to any person or organization.[4] In accordance with Rule 19d–1(c)(2) under the Act,[5] the Exchange proposed to designate certain specified rule violations as minor rule violations, and requested that it be relieved of the prompt reporting requirements regarding such violations, provided it gives notice of such violations to the Commission on a quarterly basis.

The Exchange proposes to include in its MRVP the procedures and violations

[1] 15 U.S.C. 78s(d)(1).

[2] 17 CFR 240.19d–1(c)(2).

[3] 17 CFR 240.19d–1(c)(1).

[4] The Commission adopted amendments to paragraph (c) of Rule 19d–1 to allow SROs to submit for Commission approval plans for the abbreviated reporting of minor disciplinary infractions. *See* Securities Exchange Act Release No. 21013 (June 1, 1984), 49 FR 23828 (June 8, 1984). Any disciplinary action taken by an SRO against any person for violation of a rule of the SRO which has been designated as a minor rule violation pursuant to such a plan filed with and declared effective by the Commission shall not be considered ''final'' for purposes of Section 19(d)(1) of the Act if the sanction imposed consists of a fine not exceeding $2,500 and the sanctioned person has not sought an adjudication, including a hearing, or otherwise exhausted his administrative remedies.

[5] 17 CFR 240.19d–1(c)(2).

currently included in Exchange Rule 1014 (''Imposition of Fines for Minor Rule Violations'').[6] According to the Exchange's MRVP, under Rule 1014, the Exchange may impose a fine (not to exceed $2,500) on any Member, or person associated with or employed by a Member, for any rule listed in Rule 1014(d).[7] The Exchange shall serve the person against whom a fine is imposed with a written statement setting forth the rule or rules violated, the act or omission constituting each such violation, the fine imposed, and the date by which such determination becomes final or by which such determination must be contested. If the person against whom the fine is imposed pays the fine, such payment shall be deemed to be a waiver of such person's right to a disciplinary proceeding and any review of the matter under the Exchange rules. Any person against whom a fine is imposed may contest the Exchange's determination by filing with the Exchange a written answer, at which point the matter shall become a disciplinary proceeding.

The Exchange proposes that, as set forth in Exchange Rule 1014(d), violations of the following rules would be appropriate for disposition under the MRVP: Rule 307 (Position Limits); Rule 803 (Focus Reports); Rule 804 (Requests for Trade Data); Rule 520 (Order Entry); Rule 603 (Quotation Parameters); Rule 605 (Execution of Orders in Appointed Options); Rule 314 (Mandatory Systems Testing); Rule 700 (Exercise of Option Contracts); Rule 309 (Exercise Limits); Rule 310 (Reports Related to Position Limits); Rule 403 (Trading in Restricted Classes); Rule 604 (Market Maker Quotations); and Rules 1301, 1302, and 1303 (Failure to Timely File Amendments to Form U4, Form U5, and Form BD). The Exchange notes that it is specifically excluding Rule 1014(d)(4), Conduct and Decorum Policies, from this filing.

Upon the Commission's declaration of effectiveness of the MRVP, the Exchange will provide to the Commission a quarterly report for any actions taken on minor rule violations under the MRVP. The quarterly report will include: The disposition date, the name of the firm/individual, the Exchange's internal enforcement number, the review period, the nature of the violation type, the number of the rule that was violated, the number of instances the violation occurred, and the sanction imposed.

The Exchange also proposes that, going forward, to the extent that there are any changes to the rules applicable to the Exchange's MRVP, the Exchange requests that the Commission deem such changes to be modifications to the Exchange's MRVP.

I. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the Exchange's proposed MRVP, including whether the proposed MRVP 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. 4–714 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. 4–714. 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 Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed MRVP that are filed with the Commission, and all written communications relating to the proposed MRVP 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 Web site 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 proposed MRVP 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. 4–714 and should be submitted on or before December 19, 2017.

II. Date of Effectiveness of the Proposed Minor Rule Violation Plan and Timing for Commission Action

Pursuant to Section 19(d)(1) of the Act and Rule 19d–1(c)(2) thereunder,[8] after December 19, 2017, the Commission may, by order, declare the Exchange's proposed MRVP effective if the plan is consistent with the public interest, the protection of investors, or otherwise in furtherance of the purposes of the Act. The Commission in its order may restrict the categories of violations to be designated as minor rule violations and may impose any other terms or conditions to the proposed MRVP, File No. 4–714, and to the period of its effectiveness, which the Commission deems necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Brent J. Fields,

Secretary.

[FR Doc. 2017–25647 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[6] The Exchange received its grant of registration on December 3, 2012, which included approving the rules that govern the Exchange. *See* Securities Exchange Act Release No. 68341 (December 3, 2012), 77 FR 73065 (December 7, 2012). *See also* Securities Exchange Act Release No. 70357 (September 10, 2013), 78 FR 56960 (September 16, 2013) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Exchange Rule 1014).

[7] While Rule 1014 allows the Exchange to administer fines up to $5,000, the Exchange is only seeking relief from the reporting requirements of paragraph (c)(1) of Rule 19d–1 for fines administered under Rule 1014(d) that do not exceed $2,500.

[8] 15 U.S.C. 78s(d)(1); 17 CFR 240.19d–1(c)(2).

[9] 17 CFR 200.30–3(a)(44).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–422, OMB Control No. 3235–0471]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:
Rule 15c1–5

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15c1–5 (17 CFR 240.15c1–5) under

the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 15c1–5 states that any broker-dealer controlled by, controlling, or under common control with the issuer of a security that the broker-dealer is trying to sell to or buy from a customer must give the customer written notification disclosing the control relationship at or before completion of the transaction. The Commission estimates that 197 respondents collect information annually under Rule 15c1–5 and that each respondent would spend approximately 10 hours per year collecting this information (1,970 hours in aggregate). There is no retention period requirement under Rule 15c1–5. This Rule does not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 21, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25599 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82142; File No. SR–NASDAQ–2017–087]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Modify the Listing Requirements Related to Special Purpose Acquisition Companies To Reduce Round Lot Holders on Nasdaq Capital Market for Initial Listing From 300 to 150 and Eliminate Public Holders for Continued Listing From 300 to Zero, Require $5 Million in Net Tangible Assets for Initial and Continued Listing on Nasdaq Capital Market, and Impose a Deadline To Demonstrate Compliance With Initial Listing Requirements on All Nasdaq Markets Within 30 Days Following Each Business Combination

November 22, 2017.

On September 20, 2017, The NASDAQ Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to modify the listing requirements related to Special Purpose Acquisition Companies (''SPAC'') to reduce round lot holders on Nasdaq Capital Market for initial listing from 300 to 150 and eliminate the public holders required for continued listing from 300 to zero, require $5 million net tangible assets for initial and continued listing on Nasdaq Capital Market, and impose a deadline to demonstrate compliance with initial listing requirements on all Nasdaq Markets to within 30 days following each business combination. The proposed rule change was published for comment in the **Federal Register** on October 11, 2017.[3] The Commission received six comments on the proposal.[4]

Section 19(b)(2) of the Act [5] provides that within 45 days of the notice publication of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 25, 2017. The Commission is extending this 45-day time period. The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposal and the comment letters. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates January 9, 2018, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2017–087).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25687 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 17a–19 and Form X–17A–19; SEC File No. 270–148, OMB Control No. 3235–0133

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–19 (17 CFR 240.17a–19) and Form X–17A–19 under the Securities Exchange Act of 1934 (15

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 81816 (October 4, 2017), 82 FR 47269 (October 11, 2017) (''Notice'').

[4] *See* Letters to Brent J. Fields, Secretary, Commission, from Jeffrey M. Solomon, Chief Executive Officer, Cowen and Company, LLC, dated October 19, 2017; Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors, dated October 25, 2017; Sean Davy, Managing Director, Capital Markets Division, SIFMA, dated October 31, 2017; Akin Gump Strauss Hauer & Feld LLP, dated November 1, 2017; Steven Levine, Chief Executive Officer, EarlyBirdCapital, Inc., dated November 3, 2017; and Christian O. Nagler and David A. Curtiss, Kirkland & Ellis LLP, dated November 9, 2017.

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–19 requires every national securities exchange and registered national securities association to file a Form X–17A–19 with the Commission and the Securities Investor Protection Corporation (''SIPC'') within 5 business days of the initiation, suspension, or termination of any member and, when terminating the membership interest of any member, to notify that member of its obligation to file financial reports as required by Exchange Act Rule 17a–5(b) (17 CFR 240.17a–5(b)).

Commission staff anticipates that the national securities exchanges and registered national securities associations collectively will make 800 total filings annually pursuant to Rule 17a-19 and that each filing will take approximately 15 minutes. The total reporting burden is estimated to be approximately 200 total annual hours.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: November 22, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25708 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–305, OMB Control No. 3235–0346]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:
Rule 34b–1

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 34b–1 under the Investment Company Act (17 CFR 270.34b–1) governs sales material that accompanies or follows the delivery of a statutory prospectus (''sales literature''). Rule 34b-1 deems to be materially misleading any investment company (''fund'') sales literature required to be filed with the Securities and Exchange Commission (''Commission'') by Section 24(b) of the Investment Company Act (15 U.S.C. 80a–24(b)) that includes performance data, unless the sales literature also includes the appropriate uniformly computed data and the legend disclosure required in investment company advertisements by rule 482 under the Securities Act of 1933 (17 CFR 230.482). Requiring the inclusion of such standardized performance data in sales literature is designed to prevent misleading performance claims by funds and to enable investors to make meaningful comparisons among funds.

The Commission estimates that on average approximately 208 respondents file 13,004 [1] responses that include the information required by rule 34b–1 each year. The burden resulting from the collection of information requirements of rule 34b–1 is estimated to be 2 hours per response. The total hourly burden for rule 34b–1 is approximately 26,008 hours per year in the aggregate.[2]

The collection of information under rule 34b–1 is mandatory. The information provided under rule 34b–1 is not kept confidential. The Commission may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

November 22, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25710 Filed 11–27–17; 8:45 am]

BILLING CODE P

[1] The estimated number of responses to rule 34b–1 is composed of 12,772 responses filed with FINRA and 232 responses filed with the Commission in 2016.

[2] 13,004 responses × 2 hours per response = 26,008 hours.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82137; File No. SR–MIAX–2017–46]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Order Feed (''MOR'')

November 21, 2017.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 17, 2017, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend a proprietary options market data product.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/rule-filings/* at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the MIAX Order Feed (''MOR'') to reflect the addition of a new feature. The Exchange is proposing to indicate the Priority Customer [3] volume represented by derived orders, in connection with the Exchange's upcoming launch of derived orders.[4]

Background

The Exchange established MOR in 2015.[5] MOR is a real-time full order book data feed that provides information regarding all orders on the Exchange's order book, including both simple and complex orders, to enable users to keep track of the entire order book for all symbols listed on MIAX Options. MOR provides the following information regarding each order: Product ID, order price, order original volume, remaining volume open, and origin code (which specifies the order origin type as Priority Customer, Firm, Broker/Dealer, Market Maker,[6] non-MIAX Market Maker, or non-Priority Customer). The Exchange amended the MOR in 2016 in connection with the launch of complex orders on the Exchange, in order to include such complex orders in MOR.[7] The Exchange updates MOR upon receipt of each order or change in status to any order resting on the book (*e.g.,* routing, trading, or cancelling of the order). The Exchange makes MOR available, for the applicable fee, to any user that requests this data feed product.

Proposal

With the introduction of derived orders on the Exchange, the Exchange now proposes to add a new feature to MOR to indicate the Priority Customer volume represented by a derived order. A derived order [8] is an Exchange-generated limit order on the simple order book that represents either the bid or offer of one component of a complex order resting on the Strategy Book.[9] Derived orders are not routed outside of the Exchange regardless of the price(s) disseminated by away markets. The Exchange determines, on a class-by-class basis, whether to make available derived orders, and communicates such determination to Members [10] via a Regulatory Circular. Derived orders are firm orders (*i.e.,* if executed, firm for the disseminated price and size) that are included in the MBBO.[11]

Currently, for both simple orders and complex orders, MOR identifies the origin type of the order, as well as the order's original volume and the remaining volume open. As discussed above, one example of an existing origin type is Priority Customer. Also as discussed above, MOR currently displays the volume associated with any such Priority Customer order. However, with the introduction of derived orders on the Exchange and the inclusion of derived orders within MOR, the origin type of a derived order, for purposes of display on MOR, will simply be 'derived.' However, a derived order can be created for and represent an order for any permissible origin type on the Exchange. And for purposes of display on MOR, a single derived order can represent multiple orders for multiple permissible origin codes on the Exchange (provided all such derived orders are for the same product ID and at the same price). For example, for purposes of display on MOR, a single derived order could consist of two orders (one with an origin code of Priority Customer and one with an origin code of Firm). The Exchange believes that recipients of MOR would be interested in seeing the Priority Customer volume associated with a derived order (as they are accustomed to seeing the volume associated with non-derived Priority Customer orders in MOR), and thus proposes to include, as a separate feature associated with derived orders displayed in MOR, the Priority Customer volume associated with such derived orders.

The proposed new feature to MOR—including Priority Customer volume represented by derived orders in MOR—while a new feature, is not completely novel and does not raise any new regulatory issues, as the Exchange currently makes available Priority Customer origin code information and Priority Customer volume information with respect to all (i) simple, non-derived Priority Customer orders on the Exchange, and (ii) complex Priority Customer orders from which the derived orders are created. Thus, the Exchange believes that this new feature is not completely novel and is non-controversial. The Exchange believes that this new feature will make information that could otherwise already be discerned by recipients of MOR through looking at complex order information more easily accessible for users. Without this new feature, for a derived order displayed on MOR, users would only be able to identify the simple order as a derived order, and would not know how much volume of the simple order was represented by Priority Customer volume. To obtain that information, a user could identify the complex order in MOR from which

[3] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The term ''Priority Customer Order'' means an order for the account of a Priority Customer. *See* Exchange Rule 100.

[4] *See* Exchange Act Release No. 79072 (October 7, 2016), 81 FR 71131 (October 14, 2016) (SR–MIAX–2016–26); *see also* Exchange Act Release No. 81967 (October 27, 2017), 82 FR 50916 (November 2, 2017) (SR–MIAX–2017–44).

[5] *See* Securities Exchange Act Release No. 74759 (April 17, 2015), 80 FR 22749 (April 23, 2015) (SR–MIAX–2015–28) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Establish the MIAX Order Feed (''MOR'') Data Product).

[6] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* Exchange Rule 100.

[7] *See* Securities Exchange Act Release No. 79146 (October 24, 2016), 81 FR 75171 (October 28, 2016) (SR–MIAX–2016–36).

[8] *See* Exchange Rule 518(a)(9).

[9] The ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(17).

[10] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] The term ''MBBO'' means the best bid or offer on the Simple Order Book (as defined below) on the Exchange. *See* Exchange Rule 518(a)(13).

that derived order was created, and discern the origin type and volume of that complex order, thus determining the origin type (*e.g.,* Priority Customer) and volume associated with the simple order. The new proposed feature simply makes information that could otherwise already be discerned by recipients of MOR through looking at complex order information more easily accessible for users.

The Exchange believes that the proposed new feature of MOR will enhance subscribers' ability to make decisions on trading strategy, and provide data that should help bring about such decisions in a timely manner, which will benefit investors and the public interest. The Exchange also believes that the enhanced feature of MOR will assist market participants in making routing decisions concerning their options orders.

The Exchange makes MOR equally available to any market participant that wishes to subscribe to it. MOR is designed to enhance a user's ability to analyze market conditions, and to create and test trading models and analytical strategies. The Exchange believes that MOR is a valuable tool that subscribers can use to gain comprehensive insight into the limit order book in a particular option. The inclusion of total Priority Customer volume included in a given derived order will allow subscribers to obtain more insight into order flow and permit them to make targeted trading decisions.

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act [12] in general, and furthers the objectives of Section 6(b)(5) of the Act [13] in particular, in that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

MOR is designed to promote just and equitable principles of trade by providing all subscribers with limit order book data that should enable them to make informed decisions on trading strategy on the Exchange by using MOR to assess current market conditions that directly affect such decisions The proposed new feature to MOR facilitates transactions in securities, removes impediments to and perfects the mechanisms of a free and open market and a national market system by enhancing subscribers' ability to make decisions on trading strategy, and by providing data that should help bring about such decisions in a timely manner, all for the benefit of investors and the public interest. The proposed new feature to MOR removes impediments to, and is designed to further perfect, the mechanisms of a free and open market and a national market system by making the MIAX Options market more transparent and accessible to market participants making routing decisions concerning their options orders. Additionally, the proposed new feature to MOR is also designed to protect investors and the public interest by making information that could otherwise already be discerned by recipients of MOR through looking at complex order information more easily accessible for users. Furthermore, the Exchange believes that the proposed new feature to MOR is designed to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest, by enhancing a user's ability to analyze market conditions, and to create and test trading models and analytical strategies. It also enables MIAX Options to compete with such other exchanges, thereby offering market participants with additional data in order to seek the market center with the best price and the most liquidity on which to execute their transactions, all to the benefit of investors and the public interest, and to the marketplace as a whole.

B. Self-Regulatory Organization's Statement on Burden on Competition

MIAX Options 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. On the contrary, the Exchange believes that the proposed new feature to MOR will enhance competition in the U.S. options markets by providing subscribers on MIAX Options a market data product with an enhanced feature thereby making it more competitive with comparable products offered by other exchanges.

Additionally, respecting intra-market competition, the enhanced feature in MOR will be available to all subscribers at no additional cost, thus providing all subscribers to MOR with an even playing field with respect to information and access to trading on MIAX Options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

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 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–MIAX–2017–46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2017–46. This file

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2017–46 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25605 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82141; File No. SR–ISE–2017–98]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees for Regular Orders in Select Symbols

November 22, 2017.

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 November 13, 2017, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Schedule of Fees for regular orders in Select Symbols to: (1) Adjust rebates and tier thresholds for the Market Maker Plus program, and (2) increase taker fees for certain Firm-Proprietary, Broker-Dealer, and Priority Customer orders.

The text of the proposed rule change is available on the Exchange's Web site at *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Schedule of Fees for regular orders in Select Symbols to: (1) Adjust rebates and tier thresholds for the Market Maker Plus program, and (2) increase taker fees for certain Firm-Proprietary,[3] Broker-Dealer,[4] and Priority Customer[5] orders.

The Exchange initially filed the proposed pricing changes on November 1, 2017 (SR–ISE–2017–97). On November 13, 2017, the Exchange withdrew that filing and submitted this filing.

Market Maker Plus

The Exchange proposes to increase Market Maker Plus rebates in SPY and QQQ, and modify the associated tier thresholds to make it easier for Market Makers[6] to qualify for higher Market Maker Plus tiers in these symbols. The Market Maker Plus program is designed to attract additional liquidity from Market Makers and encourage Market Makers to maintain tight markets on ISE. The Exchange believes that the proposed fee changes will further these objectives.

A Market Maker Plus is a Market Maker who is on the National Best Bid or National Best Offer (''NBBO'') a specified percentage of the time for series trading between $0.03 and $3.00 (for options whose underlying stock's previous trading day's last sale price was less than or equal to $100) and between $0.10 and $3.00 (for options whose underlying stock's previous trading day's last sale price was greater than $100) in premium in each of the front two expiration months. Currently, the specified percentage for time at the NBBO for all symbols is at least 80% but lower than 85% of the time for Tier 1, at least 85% but lower than 95% of the time for Tier 2 and at least 95% of the time for Tier 3.[7] The Exchange proposes to modify the tier thresholds for SPY and QQQ only by adding a new Tier 1 and adjusting the other Market Maker Plus tiers such that: (1) Tier 1 rebates are provided to Market Makers that are on the NBBO at least 70% but lower than 80% of the time; (2) Tier 2 rebates are provided to market Makers that are on the NBBO at least 80% but lower than 85% of the time; (3) Tier 3 rebates are provided to Market Makers that are on the NBBO at least 85% but lower than 90% of the time; and (4) Tier 4 and

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account.

[4] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account.

[5] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Rule 100(a)(37A).

[6] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* Rule 100(a)(25).

[7] A Market Maker's single best and single worst quoting days each month based on the front two expiration months, on a per symbol basis, will be excluded in calculating whether a Market Maker qualifies for this rebate, if doing so will qualify a Market Maker for the rebate. Other than days where the Exchange closes early for holiday observance, any day that the market is not open for the entire trading day or the Exchange instructs members in writing to route their orders to other markets may be excluded from the Market Maker Plus tier calculation; provided that the Exchange will only remove the day for members that would have a lower time at the NBBO for the specified series with the day included.

rebates are provided to Market Makers that are on the NBBO at least 90% of the time.

The Exchange is not proposing any changes to the tier thresholds for Select Symbols other than SPY and QQQ. However, in connection with the changes described above for SPY and QQQ, the Exchange proposes to reformat the Schedule of Fees so that all Market Maker Plus tier thresholds and rebate amounts, including those for SPY and QQQ, and those for other Select Symbols, are clearly described in footnote 5 under Regular Order Fees and Rebates. With the proposed changes, this footnote will state that Market Makers that qualify for Market Maker Plus will receive rebates based on a table contained therein that separately identifies tier thresholds and rebate amounts for SPY and QQQ, and for Select Symbols other than SPY and QQQ. While tier thresholds and rebate amounts for Select Symbols other than SPY and QQQ are being moved to this section of the Schedule of Fees, the Exchange is not proposing any changes to those values. Therefore, the Market Maker Plus program will continue to operate in the same way that it does today for all symbols other than SPY and QQQ.

Currently, Market Makers that qualify for Market Maker Plus are provided a rebate for regular orders in Select Symbols of $0.15 per contract for Tier 1, $0.18 per contract for Tier 2, and $0.22 per contract for Tier 3.[8] For SPY and QQQ only, this rebate is $0.16 per contract for Tier 2 and $0.20 per contract for Tier 3.[9] A Market Maker that achieves a higher tier of Market Maker Plus in either SPY or QQQ receives the higher rebate in both SPY and QQQ. Market Makers that do not qualify for Market Maker Plus are not eligible for rebates and are instead charged a fee of $0.10 per contract. With the introduction of a new Tier 1 and adjustment of other tier thresholds for SPY and QQQ, the Exchange proposes to provide an increased Market Maker Plus rebate in SPY and QQQ that is: (1) $0.00 Per contract (*i.e.,* no fee or rebate) for new Tier 1; (2) $0.18 per contract for new Tier 2, (3) $0.22 per contract for new Tier 3, and (3) $0.26 per contract for new Tier 4. Each of these regular maker rebates is increased from current Market Maker Plus rebates provided to Market Makers that are at the NBBO for the same percentage of time today—or in the case of Tier 1, represents the elimination of a fee that would have been charged to Market Makers that are on the NBBO for the same percentage of the time. In addition, the Exchange proposes to adopt a ''linked maker rebate'' for proposed Tiers 2–4 that applies to executions in SPY or QQQ if the Market Maker does not achieve the applicable tier in that symbol but achieves the tier (*i.e.,* proposed Tiers 2–4) in the other symbol. Once the applicable tier—any of proposed Tiers 2, 3 or 4—is achieved for one symbol, the Market Maker will be eligible for the linked maker rebate in the other symbol, regardless of time at the NBBO in that symbol (*i.e.,* there is no minimum tier threshold to be met in that symbol for the proposed linked maker rebate). This linked maker rebate would be $0.16 per contract for Tier 2, $0.20 per contract for Tier 3, and $0.24 per contract for Tier 4. The regular maker rebate will be provided in the symbol that qualifies the Market Maker for the tier based on percentage of time at the NBBO. Thus, for example, if a Market Maker achieves Tier 3 in SPY and Tier 1 in QQQ, the Market Maker would receive the Tier 3 regular maker rebate in SPY (*i.e.,* $0.22 per contract) and the Tier 3 linked maker rebate in QQQ (*i.e.,* $0.20 per contract). This linked maker rebate is similar to how Market Maker Plus rebates are currently provided in SPY and QQQ—*i.e.,* a Market Maker that qualifies for a tier in one qualifies for both—but is more beneficial to the Market Maker because the Market Maker may earn the higher regular maker rebate in the symbol for which they qualify for that tier normally.

Taker Fees

Currently, the Exchange charges a taker fee for regular orders in Select Symbols that is $0.44 per contract for Market Maker and Priority Customer orders (other than Priority Customer orders in SPY, QQQ, IWM, and VXX) and $0.45 per contract for Non-Nasdaq ISE Market Maker,[10] Firm Proprietary, Broker-Dealer, and Professional Customer [11] orders. The taker fee for Priority Customer orders is $0.34 per contract in SPY, and $0.35 per contract in QQQ, IWM, and VXX. The Exchange proposes to: (1) Increase the taker fee for Firm Proprietary and Broker-Dealer orders in Select Symbols to $0.46 per contract; and (2) increase the taker fee for Priority Customer orders in SPY, QQQ, IWM, and VXX to $0.37 per contract.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Market Maker Plus

The Exchange believes that the proposed changes to the Market Maker Plus program in SPY and QQQ are reasonable and equitable as these changes would increase rebates for Market Makers that qualify for Market Maker Plus in these symbols, including linked maker rebates that will now be provided in a manner more beneficial to members—*i.e.,* by providing the higher maker rebate in the symbol where a member qualifies normally. Furthermore, the proposed rule change would also introduce a new tier that eliminates maker fees for Market Makers that do not meet the current requirements for time at the NBBO in SPY and QQQ, and ease the requirements needed to qualify for higher tiers of Market Maker Plus in these symbols. The Market Maker Plus program is designed to attract liquidity from Market Makers on ISE and provide incentives for those Market Makers to maintain tight markets, measured by time spent quoting at the NBBO. The Exchange believes the proposed rule change will further encourage Market Makers to maintain quality markets in SPY and QQQ, which are two of the most actively traded symbols on ISE, to the benefit of all market participants that trade on the Exchange.[14]

The Exchange also believes that these changes are not unfairly discriminatory as all Market Makers can qualify for Market Maker Plus in these symbols by meeting program requirements that are designed to incentivize Market Markets

[8] For all tiers, a $0.10 per contract fee applies when trading against Priority Customer complex orders that leg into the regular order book. There will be no fee charged or rebate provided when trading against non-Priority Customer complex orders that leg into the regular order book.

[9] As with other rebates provided under the Market Maker Plus program, this rebate does not apply when trading against complex orders that leg into the regular book.

[10] A ''Non-Nasdaq ISE Market Maker'' is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

[11] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

[14] The proposed rule change also reformats the way that Market Maker Plus rebates and tier thresholds are displayed, which will make the program easier to understand.

to maintain quality markets. As noted above, SPY and QQQ have been targeted by the Exchange as these are highly active symbols on the Exchange. The proposed rule change will allow Market Makers that would not qualify for Market Maker Plus in SPY or QQQ today to qualify for free maker executions based on a time at the NBBO of at least 70% of the time pursuant to proposed Tier 1. And, as is the case today, Market Makers that show commitment to market quality by maintaining quotes that qualify them for a higher tier in these symbols will earn higher rebates, including more favorably applied linked rebates. Furthermore, the Exchange continues to believe that it is not unfairly discriminatory to offer these rebates only to Market Makers as Market Makers, and, in particular, those Market Makers that achieve Market Maker Plus status, are subject to additional requirements and obligations (such as quoting requirements) that other market participants are not.

Taker Fees

The Exchange believes that the proposed changes to taker fees are reasonable and equitable as the proposed increases are modest and reflect reasonable charges to access liquidity on the Exchange. The Exchange believes that the increased taker fee for Firm Proprietary and Broker-Dealer orders in Select Symbols and the taker fee for Priority Customer orders in SPY, QQQ, IWM, and VXX will continue to be attractive to market participants. Furthermore, Priority Customers will continue to receive reduced taker fees in SPY, QQQ, IWM, and VXX, which represent some of the most heavily traded symbols on the Exchange. In particular, the proposed taker fees are lower than taker fees charged to Priority Customer orders in other Select Symbols as well as taker fees charged to other market participants. As such, the Exchange believes that the proposed taker fees will continue to attract order flow to the benefit of all market participants that trade on the Exchange. In addition, the Exchange believes that it is equitable and not unfairly discriminatory to increase the taker fees described above, as well as to only offer reduced taker fees in SPY, QQQ, IWM, and VXX to Priority Customer orders. The proposed taker fee increases apply equally to members based on a market participants' type. Furthermore, a Priority Customer is by definition not a broker or dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). This limitation does not apply to participants on the Exchange whose behavior is substantially similar to that of market professionals, including Professional Customers, who will generally submit a higher number of orders than Priority Customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes to the Market Maker Plus program in SPY and QQQ are designed to increase competition by encouraging Market Makers to provide liquidity and maintain tight markets in these symbols. Furthermore, the proposed increases to taker fees are modest and the Exchange does not expect that such minor increases will have any significant impact on competition. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[15] and Rule 19b–4(f)(2)[16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2017–98 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2017–98. 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 Web site (*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 Web site 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–ISE–2017–98 and should be submitted on or before December 19, 2017.

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25686 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82153; File No. SR–FINRA–2017–035]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Tier Size Pilot of Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities)

November 22, 2017.

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 November 20, 2017, 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 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 this 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 amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) to extend the Tier Size Pilot, which currently is scheduled to expire on December 8, 2017, until June 7, 2018.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, 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

FINRA proposes to amend FINRA Rule 6433 (Minimum Quotation Size Requirements for OTC Equity Securities) (the ''Rule'') to extend, until June 7, 2018, the amendments set forth in File No. SR–FINRA–2011–058 (''Tier Size Pilot'' or ''Pilot''), which currently are scheduled to expire on December 8, 2017.[4]

The Tier Size Pilot was filed with the SEC on October 6, 2011,[5] to amend the minimum quotation sizes (or ''tier sizes'') for OTC Equity Securities.[6] The goals of the Pilot were to simplify the tier structure, facilitate the display of customer limit orders, and expand the scope of the Rule to apply to additional quoting participants. During the course of the Pilot, FINRA collected and provided to the SEC specified data with which to assess the impact of the Pilot tiers on market quality and limit order display.[7] On September 13, 2013, FINRA provided to the Commission an assessment on the operation of the Tier Size Pilot utilizing data covering the period from November 12, 2012 through June 30, 2013.[8] As noted in the 2013 Assessment, FINRA believed that the analysis of the data generally showed that the Tier Size Pilot had a neutral to positive impact on OTC market quality for the majority of OTC Equity Securities and tiers; and that there was an overall increase of 13% in the number of customer limit orders that met the minimum quotation sizes to be eligible for display under the Pilot tiers. In the 2013 Assessment, FINRA recommended adopting the tiers as permanent, but extended the Pilot period to allow more time to gather and analyze data after the November 12, 2012 through June 30, 2013 assessment period.[9] The purpose of this filing is to further extend the operation of the Tier Size Pilot until June 7, 2018, to provide additional time to finalize a permanent proposal with regard to the Tier Size Pilot.[10]

FINRA has filed the proposed rule change for immediate effectiveness. The operative date of the proposed rule change will be December 8, 2017.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[11] 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 also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(11) of the Act.[12] Section 15A(b)(11) requires that FINRA rules include provisions governing the form and content of quotations relating to securities sold otherwise than on a national securities exchange which may be distributed or published by any member or person associated with a member, and the persons to whom such quotations may be supplied.

FINRA believes that the extension of the Tier Size Pilot until June 7, 2018, is consistent with the Act in that it would provide the Commission and FINRA with additional time to finalize a proposal with regard to the Tier Size Pilot.

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 80727 (May 18, 2017), 82 FR 23953 (May 24, 2017) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2017–014).

[5] *See* Securities Exchange Act Release No. 65568 (October 14, 2011), 76 FR 65307 (October 20, 2011) (Notice of Filing of File No. SR–FINRA–2011–058).

[6] ''OTC Equity Security'' means any equity security that is not an ''NMS stock'' as that term is defined in Rule 600(b)(47) of SEC Regulation NMS; provided, however, that the term OTC Equity Security shall not include any Restricted Equity Security. *See* FINRA Rule 6420.

[7] FINRA ceased collecting Pilot data for submission to the Commission on February 13, 2015.

[8] The assessment is part of the SEC's comment file for SR–FINRA–2011–058 and also is available on FINRA's Web site at: *http://www.finra.org/Industry/Regulation/RuleFilings/2011/P124615* (''Pilot Assessment'').

[9] *See* Securities Exchange Act Release No. 70839 (November 8, 2013), 78 FR 68893 (November 15, 2013) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2013–049).

[10] FINRA reviewed the post-June 30, 2013 data, and stated that the impact described in the 2013 Assessment continued to hold (and improved in certain areas). *See* June 2016 Extension.

[11] 15 U.S.C. 78*o*–3(b)(6).

[12] 15 U.S.C. 78*o*–3(b)(11).

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 of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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[13] and Rule 19b–4(f)(6) thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6)[15] normally does not become operative prior to 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii),[16] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Commission is waiving the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because such waiver will allow the pilot program to continue without interruption. Therefore, the Commission designates the proposal operative upon filing.[17]

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–FINRA–2017–035 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2017–035. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*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 Web site 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–2017–035 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25694 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 489 and Form F–N, SEC File No. 270–361, OMB Control No. 3235–0411

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 489 (17 CFR 230.489) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires foreign banks and foreign insurance companies and holding companies and finance subsidiaries of foreign banks and foreign insurance companies that are exempted from the definition of ''investment company'' by virtue of rules 3a–1 (17 CFR 270.3a–1), 3a–5 (17 CFR 270.3a–5), and 3a–6 (17 CFR 270.3a–6) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) to file Form F–N (17 CFR 239.43) to appoint an agent for service of process when making a public offering of securities in the United States. The information is collected so that the Commission and private plaintiffs may serve process on foreign entities in actions and administrative proceedings arising out of or based on the offer or sales of securities in the United States by such foreign entities.

The Commission received an average of 30 Form F–N filings from 22 unique filers each year for the last three years (2014–2016). The Commission has previously estimated that the total annual burden associated with information collection and Form F–N preparation and submission is one hour per filing. Based on the Commission's experience with disclosure documents generally, the Commission continues to

believe that this estimate is appropriate. Thus the estimated total annual burden for rule 489 and Form F–N is 30 hours.[1]

Estimates of the average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of rule 489 and Form F–N is mandatory to obtain the benefit of the exemption. Responses to the collection of information will not be kept confidential. 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 public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 22, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25643 Filed 11–27–17; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82148; File No. SR–NYSEAMER–2017–32]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 497—Equities (c) Regarding the Requirements for the Listing of Securities That Are Issued by the Exchange or Any of Its Affiliates

November 22, 2017.

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 November 17, 2017, 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 Rule 497—Equities (c) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 497—Equities (c) (Additional Requirements for Listed Securities Issued by ICE or its Affiliates) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates.

Rule 497—Equities (c) sets forth certain monitoring requirements that must be met throughout the continued listing and trading of securities issued by the Exchange's ultimate parent, Intercontinental Exchange, Inc. (''ICE''), or its affiliates. More specifically, Rule 497—Equities (c)(1) and (2) provide that, throughout the continued listing and trading of an Affiliate Security[4] on the Exchange:

- the Exchange will prepare a quarterly report on the Affiliate Security (''Quarterly Report'') for the Exchange's Regulatory Oversight Committee (''ROC''), and a copy of the Quarterly Report will be forwarded promptly to the Securities and Exchange Commission (''Commission''); and
- once a year, an independent accounting firm shall review the listing standards for the Affiliate Security to insure that the issuer is in compliance with the listing requirements (''Annual Report''), and a copy of the Annual Report shall be forwarded promptly to the ROC and the Commission.

The Exchange proposes to amend Rule 497—Equities (c) to remove the requirement that copies of the Quarterly and Annual Reports be forwarded to the Commission, by deleting the final sentence of Rule 497—Equities (c)(1) and the text ''and the Commission'' from the end of Rule 497—Equities (c)(2). In addition, because the proposed deletions would remove the definition of ''Commission'' currently in Rule 497—Equities (c)(1), the Exchange proposes to add the definition to Rule 497—Equities (c)(3).

No other changes would be made to Rule 497—Equities (c), which would continue to require that the Quarterly Report be prepared for the ROC and the Annual Report be forwarded promptly to the ROC.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act[5] in general, and Section 6(b)(5)[6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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

[1] 30 responses per year × 1 hour per response = 30 hours per year.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Pursuant to Rule 497—Equities (a), ''Affiliate Security'' means any security issued by an ICE Affiliate or any Exchange-listed option on any such security, and ''ICE Affiliate'' means ICE and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with ICE, where ''control'' means that one entity possesses, directly or indirectly, voting control of the other entity either through ownership of capital stock or other equity securities or through majority representation on the board of directors or other management body of such entity.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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, because the proposed changes would reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission. In discussions with the Commission Staff regarding Rule 497—Equities, it was determined that the Exchange no longer needed to provide copies of the Quarterly and Annual Reports to the Commission. The Quarterly and Annual Reports would continue to be available to the Commission, as they are subject to Section 17A of the Act[7] and Rule 17a–1 thereunder,[8] pursuant to which the Exchange is required to keep and preserve copies of the Quarterly and Annual Reports, and to promptly furnish to the Commission copies of such Reports upon request of any representative of the Commission.

The Exchange believes that the proposed non-substantive change adding the definition of ''Commission'' to Rule 497—Equities (c)(3) would promote just and equitable principles of trade and remove impediments to a free and open market by providing greater clarity in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather to reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission.

[7] 15 U.S.C. 78q.

[8] 17 CFR 240.17a–1.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

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)[12] 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–NYSEAMER–2017–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2017–32. 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 Web site (*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 Web site 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–NYSEAMER–2017–32 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25690 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82140; File No. SR–NYSEArca–2017–133]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.35–E Relating to Auction Collars and To Add Temporary Rules

November 21, 2017.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 17, 2017, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) amend Rule 7.35–E(a)(10) to allow auctions to be conducted at a price equal to the Auction Collars and to change the rounding methodology for determining Auction Collars; (2) add Commentary .02 to Rule 7.35–E to describe rules that would be in effect on a temporary basis pending the implementation of the auction logic changes; and (3) make clarifying amendments to Rules 7.35–E(c)(1) and (d)(1). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.35–E(a)(10) to allow auctions to be conducted at a price equal to the Auction Collars and to change the rounding methodology for determining Auction Collars.[4] The Exchange also proposes Commentary .02 to Rule 7.35–E to provide that until the Exchange implements the amendments to Rule 7.35–E(a)(10) (but no later than February 26, 2018): (1) The Re-Opening Time for a Trading Halt Auction will be extended if the unadjusted Indicative Match Price is equal to the Auction Collars; and (2) the Trading Halt Auction processing described in Rules 7.35–E(e)(5), (6), (7)(C), (8), and (10) would not be applicable to a Trading Halt Auction following a trading halt due to extraordinary market volatility under Rule 7.12–E (''MWCB Halt'') or a regulatory halt (together, ''Temporary Rules''). Finally, the Exchange proposes clarifying amendments to Rules 7.35–E(c)(1) and (d)(1).

The Exchange proposes that the Temporary Rules would become operative on the same date the Exchange implements previously-approved amendments to Rule 7.35–E, which the Exchange anticipates implementing at the same time that the changes described in the twelfth amendment to the Regulation NMS Plan to Address Extraordinary Market Volatility (''Plan'') are implemented.[5] As described in greater detail in the Reopening Filing, the Exchange amended its rules relating to the reopening of trading in conjunction with LULD Amendment 12. The Exchange and the participants to the Plan have announced that the changes described in the Reopening Filing and LULD Amendment 12 will be implemented on November 20, 2017.[6]

Proposed Amendment to Rule 7.35–E(a)(10)

Rule 7.35–E(a)(10)(B) provides that an Indicative Match Price that is *equal to or* higher (lower) than the upper (lower) boundary of the Auction Collar will be adjusted to one minimum price variation below (above) the upper (lower) boundary of the Auction Collar. In other words, the Exchange does not conduct an auction at the Auction Collar price.

By contrast, Rule 7.35–E(e)(5) currently defines the term ''Impermissible Price,'' *i.e.,* when a Trading Halt Auction would not be conducted, to mean when the Indicative Match Price, before being adjusted based on Auction Collars, is below (above) the Lower (Upper) Auction Collar or if there is a sell (buy) Market Imbalance. In other words, the Exchange extends the Re-Opening Time for a Trading Halt Auction only if the unadjusted Indicative Match Price is outside the Auction Collar price.

As currently approved, because the Exchange does not operate an auction at the Auction Collar price, but also does not extend an auction if the unadjusted Indicative Match Price is at the Auction Collar Price, these two rules together would allow for a Trading Halt Auction where not all auction interest (including Market Orders) would be satisfied. For example, if the lower Auction Collar is 10.10 for a security, and at 10.10 there are 200 shares to buy, at 10.11 there are 100 shares to buy, and the Exchange receives a sell Limit Order for 300 shares priced at 10.10, the Indicative Match Price, before being adjusted for Auction Collars, would be 10.10, which would be equal to the lower Auction Collar. Pursuant to Rule 7.35–E(e)(5), an unadjusted Indicative Match Price of 10.10 would not be an Impermissible Price and therefore the auction would be conducted and would not be extended. However, pursuant to Rule 7.35–E(a)(10)(B), the collared Indicative Match Price for that security would be 10.11, which would be where the auction would be priced. Because the auction would be conducted at 10.11, the buy Limit Order priced at 10.10 would not participate. Accordingly, in this scenario, 200 shares of the sell order would not be executed and would be available to participate in continuous trading after the auction. Similarly, if the sell order were a 300 share Market Order, in this scenario, only 100 shares of the Market Order would be executed, leaving 200 shares of the sell Market Order unexecuted.

The Exchange proposes to resolve the conflict between these two rules by

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Capitalized terms used in this rule filing have the same meaning as the capitalized terms in Rule 7.35–E.

[5] *See* Securities Exchange Act Release No. 81603 (September 13, 2017), 82 FR 43609 (September 18, 2017) (SR–NYSEArca–2017–102) (Notice of filing). *See also* Securities Exchange Act Release Nos. 79107 (October 18, 2016), 81 FR 73159 (October 24, 2016) (Notice) and 79846 (January 19, 2017), 82 FR 8548 (January 26, 2017) (Approval Order) (SR–NYSEArca–2016–130) (the ''Reopening Filing''), *and* Securities Exchange Act Release No. 79845 (January 19, 2017), 82 FR 8551 (January 26, 2017) (File No. 4–631) (Order approving twelfth amendment to the Plan) (''LULD Amendment 12'').

[6] *See* Trader Update available here: *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Group_LULD_12_testing.pdf.*

adjusting the price at which its auctions would be eligible to trade. As proposed, the Exchange would permit auctions to be conducted at prices equal to the Auction Collar price threshold. This proposed rule change to allow for auctions to be priced equal to the Auction Collar price thresholds is consistent with how another exchange prices its auctions.[7] To effect this change, the Exchange proposes to amend Rule 7.35–E(a)(10)(B) as follows (deletions in brackets):

(B) An Indicative Match Price that is [equal to or] higher (lower) than the upper (lower) boundary of the Auction Collar will be adjusted to [one MPV below (above)] the upper (lower) boundary of the Auction Collar and orders eligible to participate in the applicable auction will trade at the collared Indicative Match Price.

The Exchange similarly proposes to amend Rule 7.35–E(a)(10)(C) to delete the phrase ''at or'' so that Limit Orders priced equal to the Auction Collars would be eligible to participate in the Auction without being collared, as follows (deletions in brackets):

(C) Limit Orders to buy (sell) with a limit price [at or] above (below) the upper (lower) Auction Collar will be included in the Auction Imbalance Information at the collared Indicative Match Price and will be eligible to trade at the Indicative Match Price.

Rule 7.35–E(a)(10)(A) provides that the Auction Collar will be based on a price that is the greater of $0.15 or a specified percentage away from the Auction Reference Price for the applicable auction. The rule further provides that the upper (lower) boundary of the Auction Collar is the Auction Reference Price increased (decreased) by the greater of $0.15 or the specified percentage, rounded down to the MPV. Rule 7.35–E(e)(7)(B)(i) and (ii) similarly provide that Auction Collars for Trading Halt Auctions are rounded down to the nearest MPV. Rule 7.35–E(a)(10)(A) includes a chart with the specified percentages for the Core Open and Closing Auctions and the Exchange proposes a clarifying amendment to add a sentence to this Rule that would provide that the Auction Collar for the Trading Halt Auction is specified in Rule 7.35–E(e)(7).

The Exchange proposes to change its rounding methodology for determining Auction Collars for all auctions and, accordingly, to amend Rule 7.35–E(a)(10)(A) to provide that the upper (lower) boundary of the Auction Collar is the Auction Reference Price increased (decreased) by the greater of $0.15 or the specified percentage, rounded to the nearest MPV.[8] The Exchange proposes to similarly amend Rule 7.35–E(e)(7)(B)(i) and (ii) to provide that Auction Collars would be rounded to the nearest MPV. Both Nasdaq Stock Market LLC (''Nasdaq'') and BZX Equities use this rounding methodology when determining auction collar prices for reopenings following a Trading Pause.[9] The Exchange would apply this same rounding methodology when determining the Auction Collars for all auctions on the Exchange.

The Exchange further proposes to amend Rules 7.35–E(a)(10)(A) and (e)(7)(B)(i) and (ii) to provide that the lowest Auction Collar would be one MPV above $0.00. For example, if the Reference Price for a security is $0.10, subtracting $0.15 from this Reference Price would equal a negative number. In such case, the lower boundary of the Auction Collar would be $0.0001. Because, as described above, the Exchange would allow an auction to run at a price equal to an Auction Collar, this proposed rule change would make clear that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00.

Because of technology changes associated with the proposed changes to Rules 7.35–E(a)(10)(A), (B), and (C), the Exchange proposes to announce the implementation date of these changes by Trader Update, which will be no later than February 26, 2018. Between the effective date of these proposed rule changes and the implementation date, the Exchange proposes to keep the deleted rule text in its rule book, but will keep the deleted text in brackets and new text underlined to indicate that the Exchange has an effective proposed rule change amending that text. To reduce confusion and promote transparency, the Exchange proposes to describe how the text will be marked in proposed paragraph (c) to new Commentary .02 as follows:

Paragraphs (a)(10)(A), (B), and (C) of this Rule will have text in brackets indicating which text will be deleted and underlined text indicating which text will be new when the Exchange implements the amendments to those paragraphs.

Temporary Rule for Extending an Auction When Indicative Match Price Is Equal to Auction Collar

Pending the implementation of the technology changes described above, the Exchange proposes a temporary rule that would provide that the Exchange would extend the Re-Opening Time for a Trading Halt Auction if the unadjusted Indicative Match Price is equal to an Auction Collar. As proposed, for the period beginning November 20, 2017, when the changes described in the Reopening Filing are implemented, and ending when the Exchange's technology changes are implemented or February 26, 2018, whichever is earlier, an Impermissible Price would include a price equal to the Auction Collar and thus a Trading Halt Auction would be extended when the unadjusted Indicative Match Price is equal to the Upper or Lower Auction Collar. This temporary rule would align the extension of an auction under Rule 7.35–E(e)(5) with the price at which an auction would be conducted pursuant to Rule 7.35–E(a)(10)(B). The Exchange believes that amending its rules on a temporary basis would be consistent with the purpose of the extension logic for Trading Halt Auctions, which is, in part, to ensure that all interest (including all Market Orders) eligible to participate in the Trading Halt Auction is satisfied and not carried over to continuous trading.[10]

To effect this temporary change, the Exchange proposes to add Commentary .02 to Rule 7.35–E that would describe the Temporary Rules that would be in effect until the earlier of February 26, 2018 or when the Exchange implements amendments to Rules 7.35–E(a)(10)(A), (B), and (C), described above, which would be announced by Trader Update. Proposed paragraph (a) to new Commentary .02 to Rule 7.35–E would describe the Temporary Rule relating to determining when a Trading Halt Auction would be extended and would provide that Rule 7.35–E(e)(5) would not be in effect and a Trading Halt Auction would not be conducted if the Indicative Match Price, before being adjusted based on Auction Collars, would be equal to or below (above) the Lower (Upper) Auction Collar or if there is a sell (buy) Market Imbalance (an ''Impermissible Price'').

The Exchange believes that including temporary rule text that describes how

[7] *See* Cboe BZX Exchange, Inc. (''BZX Equities'') Rule 11.23(a)(6) and (d)(2)(C).

[8] If adding or subtracting the specified percentage of the Auction Reference price to the Auction Collar would result in a tenth of a penny, the Exchange would round down to the nearest penny when the calculation results in one to four tenths of a penny and the Exchange would round up to the nearest penny when the calculation results in five to nine tenths of a penny.

[9] *See* Nasdaq Rule 4120(c)(10)(A)(ii)a. and b. and BZX Equities Rule 11.23(d)(2)(C)(i) and (ii). The Nasdaq and BZX Equities rules are silent on the rounding methodology they use when applying percentages to auction collars for opening or closing auctions.

[10] *See* Reopening Filing, *supra* note 5.

the Exchange will be determining the Impermissible Price beginning on November 20, 2017 will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule. Once the temporary rule is no longer in effect, the Exchange will file a proposed rule change to delete the proposed Commentary .02(a) to Rule 7.35–E.

Temporary Rule for MWCB and Regulatory Halts

In the Reopening Filing, the Exchange amended Rule 7.35–E(e) to provide for a standardized methodology regarding how a primary listing exchange that conducts automated reopenings following a Trading Pause would reopen if Market Orders cannot be satisfied in the Trading Halt Auction. The amendments provide for a standardized Auction Reference Price and Auction Collar values, as well as for a standardized process for extending the Trading Pause if there is an Impermissible Price at the Re-Opening Time. The rule also implements the requirement set forth in LULD Amendment 12 that if an NMS Stock is in a Trading Pause during the last ten minutes of trading before the end of Regular Trading Hours, the Primary Listing Exchange shall not reopen trading and shall attempt to execute a closing transaction using its established closing procedures.[11]

As described in the Notice to the Reopening Filing, the Exchange chose to make the changes described in the Reopening Filing available for Trading Halt Auctions following a MWCB Halt or regulatory halt.[12] However, because of the different technology supporting Trading Halt Auctions following MWCB Halts and regulatory halts, the changes described in the Reopening Filing as applicable for a Trading Halt Auction following a MWCB Halt or regulatory halt will not be available on the implementation date for the LULD Amendment 12 changes.[13]

The Exchange will adjust its technology to align the treatment of Trading Halt Auctions following a MWCB Halt or regulatory halt with current Rules 7.35–E(e)(5)–(8) and (e)(10). However, because these technology changes will not be ready by November 20, 2017, which is when the rules described in the Reopening Filing will be implemented, the Exchange proposes paragraph (b) to Commentary .02 to Rule 7.35–E to provide for the Temporary Rule that the Trading Halt Auction processing described in Rules 7.35–E(e)(5), (6), (7)(C), (8), and (10) would not be applicable to a Trading Halt Auction following a MWCB Halt or a regulatory halt. Rule 7.35–E(e)(7) and sub-paragraphs (A) and (B) of that Rule, which specify the Auction Collar Reference Price and Auction Collars for Trading Halt Auctions, including for Trading Halt Auctions following a MWCB Halt or regulatory halt, would be applicable beginning November 20, 2017 for all Trading Halt Auctions. The Exchange intends to make the technology changes relating to Trading Halt Auctions following a MWCB Halt or regulatory halt at the same time that it implements the technology changes relating to the amendments to Rules 7.35–E(a)(10)(A), (B), and (C), described above.

The Exchange believes that including temporary rule text that describes how the Exchange will be processing Trading Halt Auctions following a MWCB Halt or regulatory halt beginning on November 20, 2017 will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule. Once the temporary rule is no longer in effect, the Exchange will file a proposed rule change to delete proposed Commentary .02(b) to Rule 7.35–E.[14]

Clarifying Amendments to Rule 7.35–E(c)(1) and (d)(1)

Rule 7.35–E(c)(1) provides that the NYSE Arca Marketplace will begin publishing Core Open Auction Imbalance Information at 8:00 a.m. Eastern Time. Rule 7.35–E(d)(1) provides that the NYSE Arca Marketplace will begin publishing Closing Auction Imbalance Information one hour before the scheduled time for the Closing Auction. Because regularly scheduled auctions are not overlapping, the Exchange does not publish auction imbalance information for more than one auction at a time. However, if there is a Trading Halt Auction during the period when the Exchange would otherwise be publishing either Core Open or Closing Auction Imbalance Information, the Exchange stops publishing the Core Open or Closing Auction information and begins publishing Trading Halt Auction Imbalance Information. The proprietary data feeds that carry the Auction Imbalance Information specify for which auction the auction imbalance information is for (*e.g.,* Trading Halt Auction or Core Open Auction).

The Exchange proposes to amend Rules 7.35–E(c)(1) and (d)(1) to clarify what auction information is published if there is a halt (or pause) in the period when either Core Open Auction or Closing Auction Imbalance Information would otherwise be published.[15]

As proposed, Rule 7.35–E(c)(1) would be amended to add that ''unless a security is halted,'' the NYSE Arca Marketplace will begin publishing Core Open Auction Imbalance Information at 8:00 a.m. Eastern Time. The Exchange further proposes to add two new sentences to the rule that would provide:

If a security is halted after 8:00 a.m. Eastern Time but before the Core Open Auction, the Exchange will stop publishing Core Open Auction Imbalance Information and will begin publishing Trading Halt Auction Imbalance Information. The Exchange will resume publishing Core Open Auction Imbalance Information if the security reopens trading before Core Trading Hours begin.

Similarly, as proposed, Rule 7.35–E(d)(1) would be amended to add that ''unless a security is halted or paused,'' the NYSE Arca Marketplace will begin publishing Closing Auction Imbalance Information one hour before the scheduled time for the Closing Auction. The Exchange further proposes to add two new sentences to that rule that would provide:

If a security is halted or paused less than one hour before the scheduled time for the Closing Auction, the Exchange will stop publishing Closing Auction Imbalance Information and will begin publishing Trading Halt Auction Imbalance Information. The Exchange

[11] *See* LULD Amendment 12, *supra* note 5.

[12] *See* Reopening Filing Notice, *supra* note 5.

[13] The changes described in the Reopening Filing as applicable for Trading Halt Auctions following a Trading Pause will be implemented at the same time as the LULD Amendment 12 changes.

[14] The Exchange also proposes to amend Rule 7.35–E(e)(10) to add the phrase ''halted or'' to the second sentence of that rule so that it would provide: ''Instead, the Exchange will remain halted or paused and will conduct a Closing Auction in such security as provided for in paragraph (d) of this Rule.'' The Exchange believes that because current Rule 7.35–E(e)(10) applies to both halts and pauses, this proposed rule change clarifies the existing rule text. This proposed rule change would be in effect once the Temporary Rule described in Commentary .02(b) to Rule 7.35–E has ended.

[15] A halt before Core Trading Hours would be a regulatory halt because a Trading Pause will occur only during Core Trading Hours, and therefore a security would not be paused before the Core Open Auction, and a MWCB Halt can be triggered only during Core Trading Hours.

will resume publishing Closing Auction Imbalance Information the earlier of when the security reopens trading or ten minutes before the scheduled time for the Closing Auction.[16]

Because the proposed amendments to Rules 7.35–E(c)(1) and (d)(1) describe current functionality, the Exchange proposes that these rule changes would be implemented on the operative date of this filing.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act,[17] in general, and with Section 6(b)(5),[18] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed amendment to Rules 7.35–E(a)(10)(B) and (C) to allow auctions to be conducted at a price equal to the Auction Collars would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align how auctions are priced with the rules of another exchange.[19] Specifically, the application of auction collars on BZX Equities allow for an auction to be priced equal to the auction collars on that market. The proposed amendments to Rule 7.35–E(a)(10) would similarly allow for the Exchange to price auctions equal to the Auction Collar. More specifically, for Trading Halt Auctions, the Exchange believes that this proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align how reopening auctions are priced, which is consistent with the goal of the Reopening Filing to have standardized processes for re-opening a security following a Trading Pause across the primary listing exchange.

The Exchange believes that the proposed amendment to Rules 7.35–E(a)(10)(A) and 7.35–E(e)(7)(B)(i) and (ii) to apply the same rounding methodology as Nasdaq and BZX Equities when determining the Auction Collars following a Trading Halt Auction would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would align the Exchange's rules regarding how Auction Collars would be determined for a Trading Halt Auction with the rules of Nasdaq and BZX Equities. The Exchange further believes that it would remove impediments to and perfect the mechanism of a free and open market to apply the proposed rounding methodology to determining Auction Collars for all auctions on the Exchange because it would promote consistency in the application of rounding when determining Auction Collars, thereby promoting consistency across Exchange rules and reducing potential confusion. The Exchange further believes that amending Exchange rules to provide that the lowest Auction Collar would be one MPV above $0.00 would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would clarify that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00, thereby promoting transparency in Exchange rules.

The Exchange believes that the Temporary Rules would remove impediments to and perfect the mechanism of a free and open market and a national market system because these proposed rule changes would provide transparency regarding how the Exchange will function when the changes described in LULD Amendment 12 and the Reopening Filing are implemented, which is scheduled for November 20, 2017. The Exchange fully intends to implement the rules as approved in the Reopening Filing. However, the Exchange will not be able to implement Rule 7.35–E(e)(5), as described in the Exchange's current rules, or apply the processing describing in Rules 7.35–E(e)(5), (6), (7)(C), (8), and (10) to Trading Halt Auctions following a MWCB Halt or regulatory halt, until the changes described for the proposed amendments to Rule 7.35–E(a)(10) are implemented. The Exchange believes that adding the Temporary Rules for the interim period pending such implementation will promote the protection of investors and the public interest because it will provide transparency in Exchange rules regarding how the Exchange is operating. The proposed amendment would further promote transparency by including the end date for the temporary rule.

Finally, the Exchange believes that the proposed amendments to Rules 7.35–E(c)(1) and (d)(1) will remove impediments to and perfect the mechanism of a free and open market and a national market system because these proposed amendments would clarify in Exchange rules which imbalance information would be published if there is a trading halt or pause during a period when either Core Open Auction or Closing Auction Imbalance Information is being published. The Exchange believes that the proposed clarifications will promote the protection of investors and the public interest because they will provide transparency regarding which imbalance information would be published at specific times prior to the Core Open and Closing Auctions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change to Rules 7.35–E(a)(10) and (e)(7) would remove a potential burden on competition by aligning the Exchange's rules regarding how auctions would be priced and Auction Collars would be determined with the rules of other exchanges. The proposed Temporary Rules and clarifying amendment to Rules 7.35–E(c)(1) and (d)(1) are not designed to address any competitive issues but rather to promote transparency in Exchange rules regarding how the Exchange will function.

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

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, the

[16] The reference in this proposed rule to resuming publishing Closing Auction Imbalance Information ten minutes before the scheduled time for the Closing Auction refers to Rule 7.35–E(e)(10), which will be implemented for Trading Pauses on November 20, 2017, and will be implemented for MWCB Halts and regulatory halts the earlier of February 26, 2018 or when the technology changes described above are implemented.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] *See supra* note 7.

proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [22] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [23] permits the Commission to 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 immediately upon filing. According to the Exchange, the implementation date of November 20, 2017 for the changes described in the Reopening Filing and LULD Amendment 12 is an industry-wide implementation date. The Exchange states that it fully intends to implement the rules as approved in the Reopening Filing, but it will not be able to implement Rule 7.35–E(e)(5) or apply the processing described in Rules 7.35–E(e)(5), (6), (7)(C), (8), and (10) to Trading Halt Auctions following a MWCB Halt or regulatory halt until the proposed amendments to Rule 7.35–E(a)(10) are implemented.[24] According to the Exchange, until it makes the changes in the proposed amendments to Rule 7.35–E(a)(10), it will have functionality in production that does not match its current rules.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission believes that implementing the Temporary Rules without delay will promote transparency in the Exchange's rules regarding how the Exchange will function during this interim period.[25] The Commission notes that the Temporary Rules will be in effect until the Exchange implements its technology changes or until February 26, 2018, whichever is earlier. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[26]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that 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 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–NYSEArca–2017–133 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2017–133. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2017–133 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25608 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] According to the Exchange, the proposed amendments to Rules 7.35–E(a)(10) and (e)(7) are consistent with the goal of having standardized processes across primary listing exchanges for re-opening a security following a Trading Pause, will promote consistency when determining Auction Collars across the Exchange's auctions, and will make clear that an auction could run even if the Auction Collar would mathematically be equal to or below $0.00.

[25] In addition, according to the Exchange, the proposed amendments to Rule 7.35–E(c)(1) and (d)(1) will provide transparency regarding which imbalance information would be published at specific times prior to the Core Open and Closing Auctions.

[26] 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).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:

Rule 30b2–1, SEC File No. 270–213, OMB Control No. 3235–0220

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 30b2–1 (17 CFR 270.30b2–1) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (the ''Investment Company Act'') requires a registered management investment company (''fund'') to (1) file a report with the Commission on Form N–CSR (17 CFR 249.331 and 274.128) not later than 10 days after the transmission of any report required to be transmitted to

shareholders under rule 30e–1 under the Investment Company Act, and (2) file with the Commission a copy of every periodic or interim report or similar communication containing financial statements that is transmitted by or on behalf of such fund to any class of such fund's security holders and that is not required to be filed with the Commission under (1), not later than 10 days after the transmission to security holders. The purpose of the collection of information required by rule 30b2–1 is to meet the disclosure requirements of the Investment Company Act and certification requirements of the Sarbanes-Oxley Act of 2002 (Pub. L. 107–204, 116 Stat. 745 (2002)) and to provide investors with information necessary to evaluate an interest in the fund.

The Commission estimates that there are 2,401 funds, with a total of approximately 11,555 portfolios, that are governed by the rule. For purposes of this analysis, the burden associated with the requirements of rule 30b2–1 has been included in the collection of information requirements of rule 30e–1 and Form N–CSR, rather than the rule. The Commission has, however, requested a one hour burden for administrative purposes.

The collection of information under rule 30b2–1 is mandatory. The information provided under rule 30b2–1 is not kept confidential. 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 public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 22, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25642 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82144; File No. S7–04–09]

Order Extending Conditional Temporary Exemption for Nationally Recognized Statistical Rating Organizations From Requirements of Rule 17g–5(A)(3) Under the Securities Exchange Act of 1934

November 22, 2017.

I. Introduction

On May 19, 2010, the Securities and Exchange Commission (''Commission'') conditionally exempted, with respect to certain credit ratings and until December 2, 2010, nationally recognized statistical rating organizations (''NRSROs'') from certain requirements in Rule 17g–5(a)(3) [1] under the Securities Exchange Act of 1934 (''Exchange Act''), which had a compliance date of June 2, 2010.[2] Pursuant to the Order, an NRSRO is not required to comply with Rule 17g–5(a)(3) until December 2, 2010 with respect to credit ratings where: (1) The issuer of the structured finance product is a non-U.S. person; and (2) the NRSRO has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the U.S. (''covered transactions'').[3] The conditional temporary exemption was extended until December 2, 2011, and subsequently further extended until December 2, 2017.[4] The Commission is extending the conditional temporary exemption exempting NRSROs from complying with Rule 17g–5(a)(3) with respect to rating covered transactions until the earlier of (i) December 2, 2019, or (ii) the compliance date set forth in any final rule that may be adopted by the Commission that provides for a similar exemption.

[1] *See* 17 CFR 240.17g–5(a)(3).

[2] *See* Exchange Act Release No. 62120 (May 19, 2010), 75 FR 28825 (May 24, 2010) (''Order'').

[3] *See id.* at 28827–28 (setting forth conditions of relief).

[4] *See* Exchange Act Release No. 34–76183 (Oct. 16, 2015), 80 FR 64031 (Oct. 22, 2015); *see also* Exchange Act Release No. 34–73649 (Nov. 19, 2014), 79 FR 70261 (Nov. 25, 2014), Exchange Act Release No. 34–70919 (Nov. 22, 2013), 78 FR 70984 (Nov. 27, 2013), Exchange Act Release No. 34–68286 (Nov. 26, 2012), 77 FR 71201(Nov. 29, 2012), Exchange Act Release No. 65765 (Nov. 16, 2011), 76 FR 72227 (Nov. 22, 2011), and Exchange Act Release No. 63363 (Nov. 23, 2010), 75 FR 73137 (Nov. 29, 2010) (collectively, the ''Extension Orders'').

II. Background

Rule 17g–5 identifies, in paragraphs (b) and (c) of the rule, a series of conflicts of interest arising from the business of determining credit ratings.[5] Paragraph (a) of Rule 17g–5 [6] prohibits an NRSRO from issuing or maintaining a credit rating if it is subject to the conflicts of interest identified in paragraph (b) of Rule 17g–5 unless the NRSRO has taken the steps prescribed in paragraph (a)(1) (*i.e.,* disclosed the type of conflict of interest in Exhibit 6 to Form NRSRO in accordance with Section 15E(a)(1)(B)(vi) of the Exchange Act [7] and Rule 17g–1 [8]) and paragraph (a)(2) (*i.e.,* established and is maintaining and enforcing written policies and procedures to address and manage conflicts of interest in accordance with Section 15E(h) of the Exchange Act [9]). Paragraph (c) of Rule 17g–5 specifically prohibits eight types of conflicts of interest. Consequently, an NRSRO is prohibited from issuing or maintaining a credit rating when it is subject to these conflicts regardless of whether it had disclosed them and established procedures reasonably designed to address them.

In November 2009, the Commission adopted paragraph (a)(3) of Rule 17g–5. This provision requires an NRSRO that is hired by an arranger to determine an initial credit rating for a structured finance product to take certain steps designed to allow an NRSRO that is not hired by the arranger to nonetheless determine an initial credit rating—and subsequently monitor that credit rating—for the structured finance product.[10] In particular, under Rule 17g–5(a)(3), an NRSRO is prohibited from issuing or maintaining a credit rating when it is subject to the conflict of interest identified in paragraph (b)(9) of Rule 17g–5 (*i.e.,* being hired by an arranger to determine a credit rating for a structured finance product) [11] unless it has taken the steps prescribed in paragraphs (a)(1) and (2) of Rule 17g–5 (discussed above) and the steps prescribed in paragraph (a)(3) of Rule

[5] 17 CFR 240.17g–5(b) and (c).

[6] 17 CFR 240.17g–5(a).

[7] 15 U.S.C. 78o–7(a)(1)(B)(vi).

[8] 17 CFR 240.17g–1.

[9] 15 U.S.C. 78o–7(h).

[10] *See* 17 CFR 240.17g–5(a)(3); *see also* Exchange Act Release No. 61050 (Nov. 23, 2009), 74 FR 63832 (Dec. 4, 2009) (''Adopting Release'') at 63844–45.

[11] Paragraph (b)(9) of Rule 17g–5 identifies the following conflict of interest: Issuing or maintaining a credit rating for a security or money market instrument issued by an asset pool or as part of any asset-backed securities transaction that was paid for by the issuer, sponsor, or underwriter of the security or money market instrument. 17 CFR 240.17g–5(b)(9).

17g–5.[12] Rule 17g–5(a)(3), among other things, requires that the NRSRO must:

- Maintain on a password-protected Internet Web site a list of each structured finance product for which it currently is in the process of determining an initial credit rating in chronological order and identifying the type of structured finance product, the name of the issuer, the date the rating process was initiated, and the Internet Web site address where the arranger represents the information provided to the hired NRSRO can be accessed by other NRSROs;
- Provide free and unlimited access to such password-protected Internet Web site during the applicable calendar year to any NRSRO that provides it with a copy of the certification described in paragraph (e) of Rule 17g–5 that covers that calendar year; [13] and
- Obtain from the arranger a written representation that can reasonably be relied upon that the arranger will, among other things, disclose on a password-protected Internet Web site the information it provides to the hired NRSRO to determine the initial credit rating (and monitor that credit rating) and provide access to the Web site to an NRSRO that provides it with a copy of the certification described in paragraph (e) of Rule 17g–5.[14]

The Commission stated in the Adopting Release that Rule 17g–5(a)(3) is designed to address conflicts of interest and improve the quality of credit ratings for structured finance products by making it possible for more NRSROs to rate structured finance products.[15] For example, the Commission noted that when an NRSRO is hired to rate a structured finance product, some of the information it relies on to determine the rating is generally not made public.[16] As a result, structured finance products frequently are issued with ratings from only the one or two NRSROs that have been hired by the arranger, with the attendant conflict of interest that creates.[17] The Commission stated that Rule 17g–5(a)(3) was designed to increase the number of credit ratings extant for a given structured finance product and, in particular, to promote the issuance of credit ratings by NRSROs that are not hired by arrangers.[18] The Commission's goal in adopting the rule was to provide users of credit ratings with more views on the creditworthiness of structured finance products.[19] In addition, the Commission stated that Rule 17g–5(a)(3) was designed to reduce the ability of arrangers to obtain better than warranted ratings by exerting influence over NRSROs hired to determine credit ratings for structured finance products.[20] Specifically, by opening up the rating process to more NRSROs, the Commission intended to make it easier for the hired NRSRO to resist such pressure by increasing the likelihood that any steps taken to inappropriately favor the arranger could be exposed to the market through the credit ratings issued by other NRSROs.[21]

Rule 17g–5(a)(3) became effective on February 2, 2010, and the compliance date for Rule 17g–5(a)(3) was June 2, 2010.

III. Extension of Conditional Temporary Exemption

In the Order, the Commission requested comment generally, but also on a number of specific issues.[22] The Commission received seven comment letters in response to this solicitation of comment.[23] The commenters expressed concern that the application of Rule 17g–5(a)(3) to transactions outside the United States could, in the commenters' view, among other things, disrupt local securitization markets,[24] inhibit the ability of local firms to raise capital,[25] and conflict with local laws.[26] Several commenters also requested that the

[12] 17 CFR 240.17g–5(a)(3).

[13] Paragraph (e) of Rule 17g–5 requires that an NRSRO seeking to access the hired NRSRO's Internet Web site during the applicable calendar year must furnish the Commission with the following certification:

The undersigned hereby certifies that it will access the Internet Web sites described in 17 CFR 240.17g–5(a)(3) solely for the purpose of determining or monitoring credit ratings. Further, the undersigned certifies that it will keep the information it accesses pursuant to 17 CFR 240.17g–5(a)(3) confidential and treat it as material nonpublic information subject to its written policies and procedures established, maintained, and enforced pursuant to Section 15E(g)(1) of the Act (15 U.S.C. 78o–7(g)(1)) and 17 CFR 240.17g–4. Further, the undersigned certifies that it will determine and maintain credit ratings for at least 10% of the issued securities and money market instruments for which it accesses information pursuant to 17 CFR 240.17g–5(a)(3)(iii), if it accesses such information for 10 or more issued securities or money market instruments in the calendar year covered by the certification. Further, the undersigned certifies one of the following as applicable: (1) In the most recent calendar year during which it accessed information pursuant to § 17 CFR 240.17g–5(a)(3), the undersigned accessed information for [Insert Number] issued securities and money market instruments through Internet Web sites described in 17 CFR 240.17g–5(a)(3) and determined and maintained credit ratings for [Insert Number] of such securities and money market instruments; or (2) The undersigned previously has not accessed information pursuant to 17 CFR 240.17g–5(a)(3) 10 or more times during the most recently ended calendar year.

[14] In particular, under paragraph (a)(3)(iii) of Rule 17g–5, the arranger must represent to the hired NRSRO that it will:

(1) Maintain the information described in paragraphs (a)(3)(iii)(C), (a)(3)(iii)(D), and (a)(3)(iii)(E) of Rule 17g–5 available at an identified password-protected Internet Web site that presents the information in a manner indicating which information currently should be relied on to determine or monitor the credit rating; (2) provide access to such password-protected Internet Web site during the applicable calendar year to any NRSRO that provides it with a copy of the certification described in paragraph (e) of Rule 17g–5 that covers that calendar year, provided that such certification indicates that the nationally recognized statistical rating organization providing the certification either: (i) Determined and maintained credit ratings for at least 10% of the issued securities and money market instruments for which it accessed information pursuant to paragraph (a)(3)(iii) of Rule 17g–5 in the calendar year prior to the year covered by the certification, if it accessed such information for 10 or more issued securities or money market instruments; or (ii) has not accessed information pursuant to paragraph (a)(3) of Rule 17g–5 10 or more times during the most recently ended calendar year; (3) post on such password-protected Internet Web site all information the arranger provides to the NRSRO, or contracts with a third party to provide to the NRSRO, for the purpose of determining the initial credit rating for the security or money market instrument, including information about the characteristics of the assets underlying or referenced by the security or money market instrument, and the legal structure of the security or money market instrument, at the same time such information is provided to the NRSRO; (4) post on such password-protected Internet Web site all information the arranger provides to the NRSRO, or contracts with a third party to provide to the NRSRO, for the purpose of undertaking credit rating surveillance on the security or money market instrument, including information about the characteristics and performance of the assets underlying or referenced by the security or money market instrument at the same time such information is provided to the NRSRO; and (5) post on such password-protected Internet Web site, promptly after receipt, any executed Form ABS Due Diligence—15E containing information about the security or money market instrument delivered by a person employed to provide third-party due diligence services with respect to the security or money market instrument.

[15] Adopting Release at 63844.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *See* Order at 28828.

[23] Letter from Masamichi Kono, Vice Commissioner for International Affairs, Financial Services Agency, Japan, dated Nov. 12, 2010 (''*Japan FSA Letter*''); Letter from Masaru Ono, Executive Director, Securitization Forum of Japan, dated Nov. 12, 2010 (''*SFJ Letter*''); Letter from Rick Watson, Managing Director, Association for Financial Markets in Europe/European Securitisation Forum, dated Nov. 11, 2010 (''*AFME Letter*''); Letter from Tom Deutsch, Executive Director, American Securitization Forum, and Chris Dalton, Chief Executive Officer, Australian Securitisation Forum, dated Oct. 27, 2010 (''*ASF/AuSF Letter*''); Letter from Jack Rando, Director, Capital Markets, Investment Industry Association of Canada, dated Sep. 22, 2010 (''*IIAC Letter*''); Letter from Chris Dalton, Chief Executive Officer, Australian Securitisation Forum, dated Jun. 27, 2010 (''*AuSF Letter*''); Letter from Takefumi Emori, Managing Director, Japan Credit Rating Agency, Ltd. (''JCR''), dated Jun. 25, 2010 (''*JCR Letter*'').

[24] *See Japan FSA Letter; SFJ Letter; AFME Letter; JCR Letter; AuSF Letter.*

[25] *See AFME Letter; JCR Letter; AuSF Letter.*

[26] *See Japan FSA Letter; AFME Letter; JCR Letter; AuSF Letter; IIAC Letter.*

conditional temporary exemption be extended or made permanent.[27] The Commission's Extension Orders again solicited public comment on issues raised in connection with the application of Rule 17g–5(a)(3) outside the United States. Commenters generally supported the exemption regarding such application of the rule, with some commenters requesting that the exemption be made permanent.[28]

Given the continued concerns about potential disruptions of local securitization markets, the staff of the Commission is considering recommending that the Commission propose an amendment to Rule 17g–5(a)(3) that would provide for a permanent exemption with respect to credit ratings satisfying the conditions of the exemption. In order to provide time for the Commission to consider any such a recommendation and to avoid any disruption if the exemption were allowed to expire, the Commission believes that it is necessary and appropriate in the public interest, and consistent with the protection of investors, to extend the conditional temporary exemption until the earlier of (i) December 2, 2019, or (ii) the compliance date set forth in any final rule that may be adopted by the Commission that provides for a similar exemption.

IV. Conclusion

Accordingly,

It is hereby ordered, pursuant to Section 36 of the Exchange Act, that a nationally recognized statistical rating organization is exempt from the requirements in Rule 17g–5(a)(3) (17 CFR 240.17g–5(a)(3)) for credit ratings where:

(1) The issuer of the security or money market instrument is not a U.S. person (as defined under Securities Act Rule 902(k)); and

(2) The nationally recognized statistical rating organization has a reasonable basis to conclude that the structured finance product will be offered and sold upon issuance, and that any arranger linked to the structured finance product will effect transactions of the structured finance product after issuance, only in transactions that occur outside the U.S.,

Until the earlier of (i) December 2, 2019, or (ii) the compliance date set forth in any final rule that may be adopted by the Commission that provides for a similar exemption.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2017–25646 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[27] *See Japan FSA Letter; SFJ Letter; AFME Letter; JCR Letter; ASF/AuSF Letter.*

[28] Comment letters received in response to the requests for comment regarding the application of Rule 17g–5(a)(3) to transactions outside the United States are available at *https://www.sec.gov/comments/s7-04-09/s70409.shtml. See, e.g.,* Letter from Richard Hopkin, Managing Director & Head of Fixed Income, Association for Financial Markets in Europe, dated Nov. 1, 2017; Letter from Richard Johns, Executive Director, Structured Finance Industry Group, and Chris Dalton, Chief Executive Officer, Australian Securitisation Forum, dated Jul. 19, 2017.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82138; File No. SR–NYSEArca–2017–88]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the U.S. Equity Cumulative Dividends Fund—Series 2027 and the U.S. Equity Ex-Dividend Fund—Series 2027 Under NYSE Arca Rule 8.200–E, Commentary .02

November 21, 2017.

I. Introduction

On August 8, 2017, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the U.S. Equity Cumulative Dividends Fund—Series 2027 (''Dividend Fund'') and the U.S. Equity Ex-Dividend Fund—Series 2027 (''Ex-Dividend Fund,'' each a ''Fund,'' and collectively the ''Funds'') under NYSE Arca Equities Rule 8.200, Commentary .02.[3] The proposed rule change was published for comment in the **Federal Register** on August 28, 2017.[4] On November 14, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.[5] On November 16, 2017, the Exchange filed Amendment No. 2 to the proposed rule change.[6] The Commission has not received any comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendments No.1 and 2 thereto.

II. The Exchange's Description of the Proposal[7]

The Exchange proposes to list and trade the Shares under NYSE Arca Rule 8.200–E, Commentary .02, which governs the listing and trading of Trust Issued Receipts.[8] Each Fund will be a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission notes that, on August 17, 2017, the Commission approved a proposed rule change that, among other things, created a single rulebook of the Exchange. *See* Securities Exchange Act Release No. 81419, 82 FR 40044 (Aug. 23, 2017) (SR–NYSEArca–2017–40). As a result, NYSE Arca Equities Rule 8.200 became NYSE Arca Rule 8.200–E.

[4] *See* Securities Exchange Act Release No. 81453 (Aug. 22, 2017), 82 FR 40816.

[5] In Amendment No. 1 (''Amendment No. 1''), which amended and replaced the proposed rule change in its entirety, the Exchange: (1) Changed the custodian of the Funds; (2) stated that the Dividend Fund will seek investment results that, before fees and expenses, correspond to the performance of the Solactive U.S. Cumulative Dividends Index Series 2027 over each calendar year; (3) clarified that the value of the Dividend Fund's Shares will be affected by the ordinary cash dividends that have been paid to date and general expectations in the market regarding the future levels of such dividends; (4) clarified that the Dividend Fund's exposure to dividend payments made by S&P 500 constituent companies will be based exclusively on its investments in annual S&P 500 dividend futures contracts; (5) clarified that pricing may be an example of a market factor pursuant to which the Dividend Fund may invest in quarterly S&P 500 dividend futures contracts; (6) clarified that the Ex-Dividend Fund will seek investment results that, before fees and expenses, correspond to the performance of the Solactive U.S. Equity Ex-Dividends Index—Series 2027 so as to provide shareholders with returns that are equivalent to the performance of 0.5 shares of SPDR® S&P 500® ETF less the value of current and future expected ordinary cash dividends to be paid on the S&P 500 constituent companies over the term of the Ex-Dividend Fund; (7) stated that the quarterly S&P 500 Index futures contracts are traded on the Chicago Mercantile Exchange (''CME''); (8) clarified that the Ex-Dividend Fund intends to track the performance of the Solactive Ex-Dividend Index by selling annual S&P dividend futures contracts; (9) represented that the Trust (defined herein) will issue and sell Shares of a Fund in one or more block size aggregations of 50,000 shares; (10) represented that an updated indicative fund value'' (''IFV'') will be calculated and disseminated by a third party service provider in accordance with the rules of the Exchange, and the IFV will be calculated by using the prior day's closing net asset value (''NAV'') per Share of a Fund as a base and updating that value throughout the trading day to reflect changes in the most recently reported trade prices for instruments traded by a Fund; and (11) made other technical changes. Because Amendment No. 1 made the clarifying changes and representations summarized above and does not raise unique or novel regulatory issues. Amendment No. 1 is not subject to notice and comment.

[6] In Amendment No. 2, which is a partial amendment, the Exchange updated the proposed rule change to reflect that the Registration Statement has been filed with the Commission. Because Amendment No. 2 simply deletes information regarding the draft registration statement and provides information related to the filed Registration Statement and does not raise unique or novel regulatory issues, Amendment No. 2 is not subject to notice and comment.

[7] Additional information regarding the Funds, the Trust, and the Shares can be found in Amendments No. 1 and 2 and the Registration Statement. *See supra* notes 5 and 6 and *infra* note 9.

[8] Commentary .02 to NYSE Arca Rule 8.200–E applies to Trust Issued Receipts that invest in ''Financial Instruments.'' The term ''Financial

Continued

series of Metaurus Equity Component Trust (''Trust''), a Delaware statutory trust.[9] Metaurus Advisors LLC (''Metaurus'' or ''Sponsor'') will be the sponsor, commodity pool operator and commodity trading advisor of each Fund. The Funds' administrator will be SEI Investments Global Fund Services, (''Administrator''), who will be responsible for the day-to-day administration of the Trust and the Funds, including valuing all of the portfolio holdings of the Funds and calculating the NAV of the Funds. The Bank of New York Mellon will serve as registrar and transfer agent for the Funds as well as custodian for the Funds. Each Fund is a commodity pool as defined in the Commodity Exchange Act[10] and the applicable regulations of the Commodity Futures Trading Commission (''CFTC'').

A. U.S. Equity Cumulative Dividends Fund—Series 2027

The Dividend Fund will seek investment results that, before fees and expenses, correspond to the performance of the Solactive U.S. Cumulative Dividends Index—Series 2027 (''Solactive Dividend Index'') over each calendar year. The Dividend Fund will be a term fund that will terminate on or prior to December 31, 2027. The Dividend Fund will seek to provide shareholders of the Dividend Fund with returns designed to replicate the dividends on constituent companies of the S&P 500 Index (''S&P 500''), without exposure to the underlying securities.

The Dividend Fund intends primarily to invest its assets in the component instruments of the Solactive Dividend Index, as well as cash and cash equivalents.[11] The component instruments of the Solactive Dividend Index consist of U.S. Treasury Securities (''Treasury Securities'') and long positions in annual futures contracts listed on the CME[12] that provide exposure to dividends paid on the S&P 500 constituent companies (''Annual S&P 500 Dividend Futures Contracts'')[13] *pro rata* for each year of the life of the Dividend Fund.[14] The value of the Annual S&P 500 Dividend Futures Contracts, on which the value of the Dividend Fund will be based, will tend to increase if the actual dividends paid or expected to be paid by S&P 500 constituent companies in the periods tracked by the Annual S&P 500 Dividend Futures Contracts increase; the value of the Annual S&P 500 Dividend Futures Contracts will tend to decrease if the actual dividends paid or expected to be paid by S&P 500 constituent companies (as measured in the current year by the Dividend Points Index) decrease in the periods tracked by the Annual S&P 500 Dividend Futures Contracts. While the Dividend Fund will invest primarily in the component instruments of the Solactive Dividend Index, cash and cash equivalents, in certain instances, the Dividend Fund may invest in quarterly S&P 500 dividend futures contracts[15] (''Quarterly S&P 500 Dividend Futures Contracts, and, together with the Annual S&P 500 Dividend Futures Contracts, the ''Dividend Futures Contracts''), rather than the Annual S&P 500 Dividend Futures Contracts if, in the judgment of Metaurus, utilizing such alternative maturity instruments would be in the best interest of the Dividend Fund (*e.g.,* due to liquidity or similar market factors).

The Dividend Fund expects to pay monthly cash distributions to its shareholders throughout each calendar year. Such distributions will, on an annual basis, before fees and expenses, equal all or a substantial portion of the Dividend Fund's NAV attributable to the ordinary cash dividends accumulated by the S&P 500 Dividend Points Index (Annual) (''Dividend Points Index'') for the year (as reflected in the current year's Annual S&P 500 Dividend Futures Contracts held by the Dividend Fund).[16] The Dividend Fund's exposure to dividend payments made by S&P 500 constituent companies will be based exclusively on its investments in the Annual S&P 500 Dividend Futures Contracts.

The Dividend Fund will not employ leverage[17] to implement its investment strategy. The Dividend Fund may, however, enter into short-term loans and reverse repurchase agreements for liquidity purposes, including to fund distributions.

Solactive Dividend Index. The Solactive Dividend Index is an index that is owned, maintained, calculated and distributed by Solactive AG, an independent index sponsor and data provider (''Solactive'').[18] The index aims to represent the discounted present value of all listed Annual S&P 500 Dividend Futures Contracts out to and including the December 2027 Annual S&P 500 Dividend Futures Contract.

To accomplish this, each Annual S&P 500 Dividend Futures Contract market price will be discounted by using the computed yield of a specified Treasury Security with a similar or prior maturity date as the corresponding Annual S&P 500 Dividend Futures Contract expiry. After annual expiry of an Annual S&P 500 Dividend Futures Contract, such futures contract and its corresponding Treasury Security will be removed from the Solactive Dividend Index during the annual rebalancing of the Solactive Dividend Index. All specifications and information relevant for calculating the Solactive Dividend Index are made available at *http://www.solactive.de.*

The Solactive Dividend Index is calculated and published in United States dollars (''USD'') based on the prices of the components on the

Instruments,'' as defined in Commentary .02(b)(4) to NYSE Arca Rule 8.200–E, means any combination of investments, including cash; securities; options on securities and indices; futures contracts; options on futures contracts; forward contracts; equity caps, collars, and floors; and swap agreements.

[9] On November 15, 2017, the Trust filed with the Commission a registration statement on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a) relating to the Funds (File No. 333–221591) (''Registration Statement''). The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement.

[10] 7 U.S.C. 1a(10).

[11] Cash equivalents are short-term instruments with maturities of less than three months and shall include the following: (i) Certificates of deposit issued against funds deposited in a bank or savings and loan association; (ii) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (iii) repurchase agreements and reverse repurchase agreements; (iv) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (v) commercial paper, which are short-term unsecured promissory notes; (vi) Treasury Securities, and (vii) money market funds, including exchange-traded funds (''ETFs''). The ETFs in which a Fund may invest will be ETFs that invest principally in money market instruments, and all ETF shares will be listed and traded on national securities exchanges.

[12] CME Group, Inc. is a member of the Intermarket Surveillance Group (''ISG''). *See* note 8, *infra.*

[13] The Dividend Fund will hold the following Annual S&P 500 Dividend Futures Contracts: S&P 500 Annual Dividend Index Futures with annual expiry of 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, and 2027.

[14] As a result, in addition to the Treasury Securities, cash and/or cash equivalents, the Dividend Fund is initially expected to hold each of the Annual S&P 500 Dividend Futures Contracts that are traded and expire during its ten-year term. Each year thereafter, until December 2027 when the Dividend Fund will terminate, the Dividend Fund will hold one less Annual S&P 500 Dividend Futures Contract due to expiry of the prior year's contract.

[15] The Dividend Fund will hold the following Quarterly S&P 500 Dividend Futures Contracts: S&P 500 Quarterly Dividend Index Futures with quarterly expiry of 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, and 2027. These contracts trade on the CME.

[16] The Dividend Points Index resets to zero on the third Friday of each December contemporaneously with the expiration of the applicable Annual S&P 500 Dividend Futures Contract.

[17] Leverage means the use of loans, borrowings and extensions of credit from third parties for the purchase of investments.

[18] The Sponsor developed the algorithm on which the Solactive Dividend Index is based and licensed it to Solactive. Solactive is not affiliated with the Sponsor and is solely responsible for calculating the Solactive Dividend Index.

applicable listing exchanges posted by quotation services or otherwise as determined by Solactive. The Solactive Dividend Index does not weigh the values of the index components. The value of the Solactive Dividend Index is widely disseminated every 15 seconds on each ''Business Day'' [19] by major market data vendors during the NYSE Arca's Core Trading Session.

The Exchange represents that a committee composed of staff from Solactive is responsible for decisions regarding the composition of the Solactive Dividend Index as well as any amendments to the index calculation methodology. Members of the committee can recommend changes to the index calculation methodology for calculating the Solactive Dividend Index and submit them to the committee for approval. Members of the committee are subject to procedures designed to prevent the use and dissemination of material non-public information regarding changes to the Solactive Dividend Index.

B. U.S. Equity Ex-Dividend Fund—Series 2027

The Ex-Dividend Fund will be a term fund that will terminate on or prior to December 31, 2027. The Ex-Dividend Fund will seek investment results that, before fees and expenses, correspond to the performance of the Solactive U.S. Equity Ex-Dividends Index—Series 2027 (''Solactive Ex-Dividend Index'', and together with the Solactive Dividend Index, the ''Underlying Indexes'') so as to provide shareholders with returns that are equivalent to the performance of 0.5 shares of SPDR® S&P 500® ETF (''SPDRs'') [20] less the value of current and future expected ordinary cash dividends to be paid on the S&P 500 constituent companies over the term of the Ex-Dividend Fund.

In seeking to track the Solactive Ex-Dividend Index, the Ex-Dividend Fund intends to replicate the returns of SPDRs through: (1) Owning long positions in quarterly S&P 500 Index futures contracts traded on the CME (''Quarterly S&P 500 Index Futures Contracts'') rather than shares of SPDRs; [21] and (2) selling Annual S&P 500 Dividend Futures Contracts. The Ex-Dividend Fund may also hold Treasury Securities, cash, and cash equivalents. If in the best interest of the Ex-Dividend Fund, the Ex-Dividend Fund also may invest in annual S&P 500 Index futures contracts [22] (''Annual S&P 500 Index Futures Contracts,'' and, together with the Quarterly S&P 500 Index Futures Contracts, the ''Index Futures Contracts'') and Quarterly S&P 500 Dividend Futures Contracts.

The Ex-Dividend Fund will not employ leverage [23] to implement its investment strategy. The Ex-Dividend Fund may, however, enter into short-term loans and reverse repurchase agreements for liquidity purposes.

Solactive Ex-Dividend Index

The Solactive Ex-Dividend Index tracks the performance of SPDRs together with the performance of short positions in the Annual S&P 500 Dividend Futures Contracts for each year from the Ex-Dividend Fund's launch date through December 2027. The index is owned, maintained, calculated, and distributed by Solactive.[24]

The Solactive Ex-Dividend Index aims to represent the current value of 0.5 shares of SPDRs, less the current value of ordinary cash dividends expected to be paid on the S&P 500, until the Ex-Dividend Fund's maturity. The current value of such dividends is represented by the Solactive Dividend Index. The Solactive Dividend Index aims to represent the discounted present value of all listed Annual S&P 500 Dividend Futures Contracts out to and including the December 2027 Annual S&P 500 Dividend Futures Contracts expiry. The Solactive Ex-Dividend Index includes shares of SPDRs and short positions in Annual S&P 500 Dividend Futures Contracts for each year from the Ex-Dividend Fund's launch date through December 2027. The Solactive Ex-Dividend Index, which is calculated and published in USD, is based on the most recent prices of the index components on the applicable listing exchanges posted by quotation services or otherwise as determined by Solactive. In calculating the index value, no weighting is applied to the components. All specifications and information relevant for calculating the Solactive Ex-Dividend Index are made available at *http://www.solactive.de.*

The Solactive Ex-Dividend Index is widely disseminated every 15 seconds on each Business Day by major market data vendors during the NYSE Arca's Core Trading Session.

A committee composed of staff from Solactive is responsible for decisions regarding the composition of the Solactive Ex-Dividend Index as well as any amendments to the index calculation methodology. Members of the committee can recommend changes to the index calculation methodology for calculating the Solactive Ex-Dividend Index and submit them to the committee for approval. Members of the committee are subject to procedures designed to prevent the use and dissemination of material non-public information regarding changes to the Solactive Ex-Dividend Index.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[25] In particular, the Commission finds that the proposed rule change, as modified by Amendments No. 1 and 2, is consistent with Section 6(b)(5) of the Act,[26] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Act,[27] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities.

The Commission believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately. According to the Exchange, quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association

[19] A ''Business Day'' means any day on which the NYSE Arca is open for business, including any partial-day opening.

[20] Shares of SPDRs are listed and traded on the Exchange pursuant to NYSE Arca Equities Rule 8.100 (Portfolio Depositary Receipts).

[21] The Quarterly S&P 500 Index Futures Contracts include: (i) S&P 500 Futures and (ii) E-mini S&P 500 Futures. These contracts trade on the CME.

[22] These contracts trade on the CME.

[23] *See supra* note 7.

[24] The Sponsor developed the algorithm on which the Solactive Ex-Dividend Index is based and licensed it to Solactive. Solactive is not affiliated with the Sponsor and is solely responsible for calculating the Solactive Ex-Dividend Index.

[25] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78k–1(a)(1)(C)(iii).

(''CTA''). The Funds' Web site, *www.metaurus.com,* will display the applicable end of day closing NAV. The daily holdings of each Fund will be available on the Funds' Web site before 9:30 a.m. E.T. each day. The Funds' Web site disclosure of portfolio holdings will be made daily and will include, as applicable: The composite value of the total portfolio; the quantity and type of each holding (including the ticker symbol, maturity date or other identifier, if any) and other descriptive information; the value of each Treasury Security and cash equivalent; and the amount of cash held in each Fund's portfolio. Accordingly, each investor will have access to the current daily holdings of each Fund through the Funds' Web site, which will be publicly accessible at no charge. This Web site disclosure of each Fund's daily holdings will occur at the same time as the disclosure by the Trust of the daily holdings to authorized participants so that all market participants are provided daily holdings information at the same time. The intraday, closing prices, and settlement prices of the S&P 500 Futures Contracts will be readily available from the CME Web site, automated quotation systems, published or other public sources, or major market data vendors. Pricing information for cash equivalents is available from major market data vendors. In addition, price information for the underlying money market ETFs is available from the applicable exchange. Quotation information from brokers and dealers or pricing services is available for Treasury Securities. Complete real-time data for the S&P 500 Futures Contracts is available by subscription through online information services. CME also provides delayed futures information on current and past trading sessions and market news free of charge on its Web site.

Additionally, the Commission believes that the proposal to list and trade the Shares is reasonably designed to prevent trading when a reasonable degree of transparency cannot be assured. If the Exchange becomes aware that the NAV with respect to the Shares is not disseminated to all market participants at the same time, it will halt trading in the Shares until such time as the NAV is available to all market participants. Further, the Exchange may halt trading during the day in which an interruption to the dissemination of the Indicative Fund Value (''IFV'') or the value of an Underlying Index occurs. If the interruption to the dissemination of the IFV, or the value of an Underlying Index, persists past the trading day in which it occurred, the Exchange will halt trading no later than the beginning of the trading day following the interruption. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Rule 7.12–E have been reached or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

The Commission believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because the Exchange has a general policy prohibiting the distribution of material, non-public information by its employees. Moreover, trading of the Shares will be subject to NYSE Arca Rule 8.200–E, Commentary .02(e), which sets forth certain restrictions on Equity Trading Permit (''ETP'') Holders acting as registered market makers in Trust Issued Receipts to facilitate surveillance. The Commission notes that the Exchange or the Financial Industry Regulatory Authority (''FINRA''), on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares and S&P 500 Futures Contracts with other markets and other entities that are members of the ISG, and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares and S&P 500 Futures Contracts from such markets and other entities. In addition, all S&P 500 Futures Contracts are traded on CME, an ISG member and the Exchange may obtain information regarding trading in the Shares and S&P 500 Futures Contracts from markets and other entities that are members of ISG.[28]

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange represented that:

(1) The Shares will conform to the initial and continued listing criteria under NYSE Arca Rule 8.200–E.[29]

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.[30]

(3) Trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.[31]

(4) Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a)The risks involved in trading the Shares during the Early and Late Trading Sessions when an updated IFV will not be calculated or publicly disseminated; (b) the procedures for purchases and redemptions of Shares in Baskets (and that Shares are not individually redeemable); (c) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (d) how information regarding the IFV is disseminated; (e) how information regarding portfolio holdings is disseminated; (f) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (g) trading information.[32]

(5) For initial and continued listing, each Fund will be in compliance with Rule 10A–3 under the Act,[33] as provided by NYSE Arca Rule 5.3–E.[34]

(6) A minimum of 50,000 Shares of a Fund will be outstanding at the commencement of trading on the Exchange.[35]

(7) All statements and representations made in this filing regarding (a) the description of the portfolios, indexes and reference assets, (b) limitations on portfolio holdings, indexes and reference assets, or (c) applicability of Exchange listing rules specified in this filing shall constitute continued listing requirements for listing the Shares on the Exchange.[36]

(8) The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Funds to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements.[37] If a Fund is not in

[28] For a list of the current members of ISG, *see www.isgportal.org.*

[29] *See* Amendment No. 1, *supra* note 5.

[30] *See id.*

[31] *See id.*

[32] *See* Amendment 1, *supra* note 5.

[33] 17 CFR 240.10A–3.

[34] *See* Amendment 1, *supra* note 5.

[35] *See id.*

[36] *See id.*

[37] *See id.* The Commission notes that certain other proposals for the listing and trading of Managed Fund Shares include a representation that

compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

This approval order is based on all of the Exchange's representations and description of the Funds, including those set forth above and in Amendments No. 1 and 2. The Commission notes that the Shares must comply with the requirements of NYS Arca Rule 8.200–E, Commentary .02 thereto to be listed and traded in the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendments No.1 and 2, is consistent with Section 6(b)(5) of the Act [38] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[39] that the proposed rule change (SR–NYSEArca–2017–88), as modified by Amendments No. 1 and 2, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25606 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82152; File No. SR–NASDAQ–2017–122]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 4702

November 22, 2017.

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 November 9, 2017, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4702(b)(5) to provide that Midpoint Peg Post-Only Orders may not participate in the Nasdaq Closing Cross, and to make other technical changes with respect to Order Types flagged for the Nasdaq Closing Cross pursuant to Rule 4702(b)(12).

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 4702(b)(5) to provide that Midpoint Peg Post-Only Orders (''MPPOs'') may not participate in the Nasdaq Closing Cross, and to make other technical changes with respect to Order Types flagged for the Nasdaq Closing Cross pursuant to Rule 4702(b)(12).

An ''MPPO'' is defined in Rule 4702(b)(5) as an Order Type with a Non-Display Order Attribute that is priced at the midpoint between the national best bid and offer, and that will execute upon entry only in circumstances where economically beneficial to the party entering the Order. Today, MPPOs are available during Market Hours only, and MPPOs remaining on the Nasdaq Book at 4:00 p.m. ET are cancelled by the System. Due to how the Exchange currently processes these cancel messages, however, Rule 4702(b)(5)(C) also provides that an MPPO may participate in the Nasdaq Closing Cross if the Nasdaq Closing Cross occurs prior to the cancellation message being fully processed. The Exchange believes that it would be beneficial to members and investors to completely prevent MPPOs from executing in the Nasdaq Closing Cross rather than having their participation determined by whether the cancel message is processed prior to the Nasdaq Closing Cross. The Exchange therefore proposes to eliminate language indicating that MPPOs may participate in the Nasdaq Closing Cross if the Nasdaq Closing Cross for the security occurs prior to the cancellation message being fully processed, and instead provide that MPPOs may not participate in the Nasdaq Closing Cross. In connection with this change, the Exchange also proposes to remove language indicating that the trading system ''attempts to'' cancel MPPOs prior to the commencement of the Nasdaq Closing Cross as the ''attempts to'' language is no longer necessary with the elimination of the race condition described above. With this change members will have more certainty with respect to MPPO handling for the Nasdaq Closing Cross since no MPPOs will be allowed to participate, which is consistent with how the Exchange believes members want these order treated. In addition, since the Exchange is explicitly addressing MPPO availability for the Nasdaq Closing Cross in this rule, the Exchange also proposes to add language indicating that MPPOs may not participate in the Nasdaq Opening Cross. MPPOs are excluded from the Nasdaq Opening Cross today as they can only be entered during Market Hours and are cancelled at the end of the trading day. Furthermore, Rule 4703(l) provides that Order Types except Supplemental Orders participate in the Nasdaq Opening Cross and/or the Nasdaq Closing Cross if the Order has a Time-in-Force that would cause the Order to be in effect at the time of the Nasdaq Opening Cross and/or Nasdaq Closing Cross. Since MPPOs will not be permitted to participate in the Nasdaq Opening Cross or Nasdaq Closing Cross under any circumstances, the Exchange proposes to amend Rule 4703(l) to state

---

the exchange will ''surveil'' for compliance with the continued listing requirements. *See, e.g.,* Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428 (April 7, 2016), available at: *http://www.sec.gov/rules/sro/bats/2016/34-77499.pdf.* In the context of this representation, it is the Commission's view that ''monitor'' and ''surveil'' both mean ongoing oversight of each Fund's compliance with the continued listing requirements. Therefore, the Commission does not view ''monitor'' as a more or less stringent obligation than ''surveil'' with respect to the continued listing requirements.

[38] 15 U.S.C. 78f(b)(5).

[39] 15 U.S.C. 78s(b)(2).

[40] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

that MPPOs do not participate in these crosses.

Furthermore, Rule 4702(b)(12) contains language explaining which Order Types are not available to be flagged for the Nasdaq Closing Cross, including orders entered with a time-in-force of IOC, or orders entered with a time-in-force that continues after the time of the Nasdaq Closing Cross, *i.e.,* Closing Cross/Extended Hours Orders. MPPOs cannot be flagged for the Nasdaq Closing Cross today as closing cross participation is not permitted for this Order Type, with the one exception being remedied above. The same is also true of Supplemental Orders. A ''Supplemental Order'' is an Order Type with a Non-Display Order Attribute that is held on the Nasdaq Book in order to provide liquidity at the NBBO through a special execution process described in Rule 4757(a)(1)(D). Pursuant to Rule 4702(b)(6)(B), Supplemental Orders are not permitted to participate in the Nasdaq Closing Cross. In connection with the other changes described above, the Exchange therefore proposes to amend Rule 4702(b)(12) to state that MPPOs and Supplemental Orders may not be flagged to solely participate in the Nasdaq Closing Cross. Rule 4702(b)(12) already contains language indicating that these order types are not permitted to be entered as Closing Cross/Extended Hours Orders. The Exchange believes that adding this additional detail to the rule will make the operation of the Exchange more transparent to members and other market participants.

Implementation

The Exchange proposes to introduce the MPPO changes described in this proposed rule change in Q4 2017 or Q1 2018. The Exchange will announce the implementation date of this functionality in an Equity Trader Alert issued to members prior to the launch date.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Section 6(b)(5) of the Act,[4] 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. As indicated in the Exchange's current rules, MPPOs are designed for Market Hours trading and are therefore cancelled at 4:00 p.m. ET each day when the Exchange begins processing the Nasdaq Closing Cross pursuant to Rule 4754. Nevertheless, MPPOs may trade in the Nasdaq Closing Cross in the race condition described above where the cancellation of the MPPO is not processed by the trading system prior to the Nasdaq Closing Cross. The Exchange believes that it is consistent with the protection of investors and the public interest to eliminate this race condition and ensure that no MPPOs participate in the Nasdaq Closing Cross. This change will perfect the mechanism of a free and open market by eliminating the possibility that MPPOs can inadvertently make it into the Nasdaq Closing Cross due to the sequence of messages received by the trading system. The Exchange believes that members prefer not to have their MPPOs executed in the Nasdaq Closing Cross, and therefore cancels these orders immediately prior to the closing auction today. The proposed changes would further enhance MPPO handling by ensuring that no MPPOs are permitted to trade in the Nasdaq Closing Cross. Furthermore, the proposed rule change would increase transparency surrounding the operation of the Exchange, and, in particular, the availability of MPPOs and Supplemental orders to be flagged for the Nasdaq Closing Cross. The Exchange believes that the proposed changes will benefit members and other market participants by specifying with additional clarity that these Order Types cannot be flagged for participation in the Nasdaq Closing Cross, as closing cross participation is not available for either MPPOs or Supplemental Orders.

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. Currently, MPPOs can participate in the Nasdaq Closing Cross if the cancel message is not fully processed prior to the closing auction. The Exchange is now enhancing MPPO handling to prevent all MPPOs from participating in the Nasdaq Closing Cross. The Exchange does not believe this change will have any significant impact on competition as no members will have their MPPOs participate in the Nasdaq Closing Cross, which is how the Exchange believes members want these orders treated. Furthermore, the other proposed change with respect to handling of MPPOs and Supplemental Orders that are flagged for the Nasdaq Closing Cross is a non-substantive clarifying change and will therefore have no impact on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were 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 [5] and Rule 19b–4(f)(6) thereunder.[6]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2017–122 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2017–122. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2017–122 and should be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25693 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82150; File No. SR–NYSE–2017–61]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 497(c) Regarding the Requirements for the Listing of Securities That Are Issued by the Exchange or Any of Its Affiliates

November 22, 2017.

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 November 17, 2017, 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, 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 Rule 497(c) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates. The proposed rule change is available on the Exchange's Web site 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 497(c) (Additional Requirements for Listed Securities Issued by Intercontinental Exchange, Inc. or its Affiliates) regarding the requirements for the listing of securities that are issued by the Exchange or any of its affiliates.

Rule 497(c) sets forth certain monitoring requirements that must be met throughout the continued listing and trading of securities issued by the Exchange's ultimate parent, Intercontinental Exchange, Inc. (''ICE''), or its affiliates. More specifically, Rule 497(c)(1) and (2) provide that, throughout the continued listing and trading of an Affiliate Security [4] on the Exchange:

- The Exchange will prepare a quarterly report on the Affiliate Security (''Quarterly Report'') for the Exchange's Regulatory Oversight Committee (''ROC''), and a copy of the Quarterly Report will be forwarded promptly to the Securities and Exchange Commission (''Commission''); and
- once a year, an independent accounting firm shall review the listing standards for the Affiliate Security to insure that the issuer is in compliance with the listing requirements (''Annual Report''), and a copy of the Annual Report shall be forwarded promptly to the ROC and the Commission.

The Exchange proposes to amend Rule 497(c) to remove the requirement that copies of the Quarterly and Annual Reports be forwarded to the Commission, by deleting the final sentence of Rule 497(c)(1) and the text ''and the Commission'' from the end of Rule 497(c)(2). In addition, because the proposed deletions would remove the definition of ''Commission'' currently in Rule 497(c)(1), the Exchange proposes to add the definition to Rule 497(c)(3).

No other changes would be made to Rule 497(c), which would continue to require that the Quarterly Report be

[4] Pursuant to Rule 497(a), ''Affiliate Security'' means any security issued by an ICE Affiliate or any Exchange-listed option on any such security, with the exception of Investment Company Units as defined in Para. 703.16 of the Listed Company Manual, and ''ICE Affiliate'' means ICE and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with ICE, where ''control'' means that one entity possesses, directly or indirectly, voting control of the other entity either through ownership of capital stock or other equity securities or through majority representation on the board of directors or other management body of such entity.

prepared for the ROC and the Annual Report be forwarded promptly to the ROC.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act [5] in general, and Section 6(b)(5) [6] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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, because the proposed changes would reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission. In discussions with the Commission Staff regarding Rule 497, it was determined that the Exchange no longer needed to provide copies of the Quarterly and Annual Reports to the Commission. The Quarterly and Annual Reports would continue to be available to the Commission, as they are subject to Section 17A of the Act [7] and Rule 17a–1 thereunder,[8] pursuant to which the Exchange is required to keep and preserve copies of the Quarterly and Annual Reports, and to promptly furnish to the Commission copies of such Reports upon request of any representative of the Commission.

The Exchange believes that the proposed non-substantive change adding the definition of ''Commission'' to Rule 497(c)(3) would promote just and equitable principles of trade and remove impediments to a free and open market by providing greater clarity in the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed rule change is not intended to address competitive issues but rather to reduce the paperwork received by the Commission and ease the burden of submitting the Quarterly and Annual Reports, without changing the information available to the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

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) [12] 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–2017–61 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–2017–61. 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 Web site (*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 Web site 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–2017–61 and should

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78q.

[8] 17 CFR 240.17a–1.

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[12] 15 U.S.C. 78s(b)(2)(B).

be submitted on or before December 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25692 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–516, OMB Control No. 3235–0574]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:
Rule 3a–8

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit the existing collection of information to the Office of Management and Budget for extension and approval.

Rule 3a–8 (17 CFR 270.3a–8) of the Investment Company Act of 1940 (15 U.S.C. 80a) (the ''Act''), serves as a nonexclusive safe harbor from investment company status for certain research and development companies (''R&D companies'').

The rule requires that the board of directors of an R&D company seeking to rely on the safe harbor adopt an appropriate resolution evidencing that the company is primarily engaged in a non-investment business and record that resolution contemporaneously in its minute books or comparable documents.[1] An R&D company seeking to rely on the safe harbor must retain these records only as long as such records must be maintained in accordance with state law.

Rule 3a–8 contains an additional requirement that is also a collection of information within the meaning of the PRA. The board of directors of a company that relies on the safe harbor under rule 3a–8 must adopt a written policy with respect to the company's capital preservation investments. We expect that the board of directors will base its decision to adopt the resolution discussed above, in part, on investment guidelines that the company will follow to ensure its investment portfolio is in compliance with the rule's requirements.

The collection of information imposed by rule 3a–8 is voluntary because the rule is an exemptive safe harbor, and therefore, R&D companies may choose whether or not to rely on it. The purposes of the information collection requirements in rule 3a–8 are to ensure that: (i) The board of directors of an R&D company is involved in determining whether the company should be considered an investment company and subject to regulation under the Act, and (ii) adequate records are available for Commission review, if necessary. Rule 3a–8 would not require the reporting of any information or the filing of any documents with the Commission.

Commission staff estimates that there is no annual recordkeeping burden associated with the rule's requirements. Nevertheless, the Commission requests authorization to maintain an inventory of one burden hour for administrative purposes.

Commission staff estimates that approximately 65,139 R&D companies may take advantage of rule 3a–8.[2] Given that the board resolutions and investment guidelines will generally need to be adopted only once (unless relevant circumstances change),[3] the Commission believes that all the R&D companies that existed prior to the adoption of rule 3a–8 adopted their board resolutions and established written investment guidelines in 2003 when the rule was adopted. We expect that R&D companies formed subsequent to the adoption of rule 3a–8 would adopt the board resolution and investment guidelines simultaneously with their formation documents in the ordinary course of business.[4] Therefore, we estimate that rule 3a–8 does not impose additional burdens.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov*.

November 22, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25709 Filed 11–27–17; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–035, OMB Control No. 3235–0029]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736

Extension:
Rule 17Ad–2(c), (d), and (h)

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad–2(c), (d), and (h), (17 CFR 240.17Ad–2(c), (d), and (h)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17f–2(c) allows persons required to be fingerprinted pursuant to Section 17(f)(2) of the Act to submit their fingerprints to the Attorney General of the United States or its designee (*i.e.,* the Federal Bureau of Investigation (''FBI'')) through a registered national securities exchange or a registered national securities association

[13] 17 CFR 200.30–3(a)(12).

[1] Rule 3a–8(a)(6) (17 CFR 270.3a–8(6)).

[2] *See* National Science Foundation/Division of Science Resources Statistics, Business Research and Development and Innovation Survey: 2013 (results published August 2, 2016).

[3] In the event of changed circumstances, the Commission believes that the board resolution and investment guidelines will be amended and recorded in the ordinary course of business and would not create additional time burdens.

[4] In order for these companies to raise sufficient capital to fund their product development stage, Commission staff believes that they will need to present potential investors with investment guidelines. Investors generally want to be assured that the company's funds are invested consistent with the goals of capital preservation and liquidity.

(collectively, also known as ''self-regulatory organizations'' or ''SROs'') pursuant to a fingerprint plan filed with, and declared effective by, the Commission. Fingerprint plans have been approved for the American, Boston, Chicago, New York, and Philadelphia stock exchanges and for the Financial Industry Regulatory Authority (''FINRA'') and the Chicago Board Options Exchange. Currently, the bulk of the fingerprints are submitted through FINRA.

It is estimated that 4,200 respondents submit approximately 285,600 sets of fingerprints (consisting of approximately 243,600 electronic sets and 42,000 hard copy sets) to SROs on an annual basis. The Commission estimates that it would take approximately 15 minutes to create and submit each fingerprint card. The total reporting burden is therefore estimated to be approximately 71,400 hours, or approximately 15 hours per respondent, annually.

In addition, the SROs charge an estimated $25.00 fee for processing fingerprint cards submitted electronically, resulting in a total annual cost to all 4,200 respondents of $6,090,000, or $1,450 per respondent per year. The SROs charge an estimated $40.00 fee for processing fingerprint cards submitted in hard copy, resulting in a total annual cost to all 4,200 respondents of approximately $1,680,000, or $400 per respondent per year. The combined annual cost to all respondents is thus $7,770,000.

Because the FBI will not accept fingerprint cards directly from submitting organizations, Commission approval of fingerprint plans from certain SROs is essential to carry out the Congressional goal to fingerprint securities industry personnel. Filing these plans for review assures users and their personnel that fingerprint cards will be handled responsibly and with due care for confidentiality.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

Dated: November 21, 2017.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25600 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–82147; File No. SR–Phlx–2017–75]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Amend Rule 1009 To Modify the Criteria for Listing an Option on an Underlying Covered Security

November 22, 2017.

On September 27, 2017, Nasdaq PHLX LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the criteria for listing an option on an underlying covered security in Rule 1009, Commentary .01. The proposed rule change was published for comment in the **Federal Register** on October 11, 2017.[3]

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is November 25, 2017. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates January 9, 2018 as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–Phlx–2017–75).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–25689 Filed 11–27–17; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 81814 (Oct. 4, 2017), 82 FR 47254.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SMALL BUSINESS ADMINISTRATION

Committee Member Nominations Sought Notice; Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open nominations for veteran small business owners and veteran service organization representatives for the Advisory Committee on Veterans Business Affairs and the Interagency Task Force on Veterans Small Business Development.

SUMMARY: The U.S. Small Business Administration seeks member nominations from veteran owned small businesses and veteran service organizations to serve on the Advisory Committee on Veterans Business Affairs and member nominations from veteran service organizations and military service organizations to serve on the Interagency Task Force for Veterans Small Business Development.

DATES: Nomination applications due by 11:59 p.m. (EST), December 15, 2017.

ADDRESSES: Send nominations to *veteransbusiness@sba.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Small Business Administration (SBA) seeks member nominations from veteran owned small businesses and veteran service organizations (VSO) to serve on the Advisory Committee on Veterans Business Affairs (ACVBA). The SBA also seeks member nominations from two VSO or Military Service Organizations (MSO) to serve on the Interagency Task Force for Veterans Small Business Development (IATF).

Additional Information: Nominations of eligible representatives must be sent

via email to *veteransbusiness@sba.gov.* The submission deadline for nominations is December 15, 2017. Submissions should include the following information:

- Name and contact information of the individual
- Name and contact information of represented organization
- Federal Committee that nominee is interested in serving on, stated clearly
- If VSO or MSO nomination, include a description of how the organization supports veteran and service-disabled owned small business issues
- If nominee is a member of a local chapter of VSO, a national-level endorsement letter from the VSO is required

The SBA Administrator will appoint individuals who will serve on the ACVBA for a period of three years and, on the IATF, for a period of two years.

The Veterans Entrepreneurship and Small Business Development Act of 1999—Public Law 106–50—established the ACVBA to serve as an independent source of advice and policy recommendations on veteran owned small business opportunities. Through an annual report, the ACVBA reports to the SBA Administrator, SBA's Associate Administrator for Veterans Business Development, the Congress, the President, and other U.S. policy makers. The ACVBA is comprised of 15 members—eight members represent veteran owned small business and seven members represent veteran service or military organizations.

The Interagency Task Force for Small Business Development (Task Force) was established February 14, 2008 by Public Law 110–186 and executed by Executive Order. The Task Force is chaired by the SBA and is comprised of representatives appointed by SBA's Administrator from: SBA's Office of Veterans Business Development (OVBD), the Department of Defense (DoD), the Department of Labor (DOL), the Department of Treasury (Treasury), the Department of Veterans Affairs (DVA), the General Services Administration (GSA), the Office of Management and Budget (OMB), and four representatives from veterans service organizations and/or military service organizations.

Additional information for the ACVBA and IATF and SBA resources for veteran owned small business is located at *www.sba.gov/ovbd.* On Aug. 13, 2014, the Office of Management and Budget (OMB) published revised guidance, in the **Federal Register**, on individuals who are not eligible to serve on federal advisory committees. In accordance with OMB guidance, the President directed agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions.

Dated: November 21, 2017.

Richard W. Kingan,

SBA Committee Management Officer.

[FR Doc. 2017–25629 Filed 11–27–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice: 10215]

Notice of Preparation and Request for Input for the United States-Chile Environmental Cooperation Agreement Work Program

ACTION: Notice of preparation of the 2018–2020 United States-Chile Environmental Cooperation Agreement Work Program and request for comments.

SUMMARY: The U.S. Department of State is providing notice that the United States and Chile intend to establish a 2018–2020 Work Program pursuant to the United States-Chile Environmental Cooperation Agreement (ECA). The Department of State invites the public, including nongovernmental organizations, academic institutions, private sector enterprises, and other interested persons to submit written comments or suggestions regarding items for inclusion in a new Work Program for implementing the United States-Chile ECA, which entered into force in 2004.

DATES: To be assured of timely consideration, all comments or questions are requested by December 6, 2017.

ADDRESSES: If you have access to the Internet, you can view and comment on this notice by going to *http://www.regulations.gov* and entering [DOS–2017–0043] or the title of this Notice into the search field and following the prompts.

FOR FURTHER INFORMATION CONTACT: All comments or inputs should be directed to Keri Holland, U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Environmental Quality and Transboundary Issues by email at *HollandKJ@state.gov* with the subject line ''UNITED STATES-CHILE Work Program'' or by fax to (202) 647–5947 or by phone at (202) 647–6777.

SUPPLEMENTARY INFORMATION: The United States and Chile negotiated the United States-Chile FTA and United States-Chile ECA in concert, signing the FTA on June 6, 2003 in Miami, U.S.A. and the ECA on June 17, 2003 in Santiago, Chile. Article 19.3 of the FTA establishes an Environment Affairs Council (Council). The Joint Commission on Environmental Cooperation (Commission) was established in Article II of the ECA. The Council and Commission last met in August 2015 in Washington, DC. The Council reviewed the implementation of the Environment Chapter of the FTA. The Commission signed the 2015–2017 Work Program, which built on previous successes and identified activities to achieve the long-term goals of: (1) Strengthening effective implementation and enforcement of environmental laws and regulations; (2) encouraging development and adoption of sound environmental practices and technologies, particularly in business enterprises; (3) promoting sustainable development and management of environmental resources, including wild fauna and flora, protected wild areas, and other ecologically important ecosystems; and (4) encouraging civil society participation in the environmental decision-making process and environmental education.

We encourage submitters to refer to: (1) The United States-Chile Free Trade Agreement (FTA) Environment Chapter; (2) the United States-Chile ECA; and (3) the United States-Chile 2015–2017 ECA Work Program. Documents are available at:

- Chapter 19 of the United States-Chile FTA, *https://ustr.gov/sites/default/files/uploads/agreements/fta/chile/asset_upload_file482_4013.pdf.*
- United States-Chile ECA and the 2015–2017 Work Program, *https://www.state.gov/e/oes/eqt/trade/chile/index.htm.*

These and other useful documents are available at: *https://ustr.gov/trade-agreements/free-trade-agreements/chile-fta* and at *https://www.state.gov/e/oes/eqt/trade/chile/index.htm.*

Carol Volk,

Acting Director, Office of Environmental Quality and Transboundary Issues, Department of State.

[FR Doc. 2017–25681 Filed 11–27–17; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 10213]

Notice of Meeting of Advisory Committee on International Law

A meeting of the Department of State's Advisory Committee on International Law will take place on Thursday, December 14, 2017, from 9:30 a.m. to 5:00 p.m. at the George Washington University Law School, Michael K. Young Faculty Conference Center, 716 20th St. NW., 5th Floor, Washington, DC. It is anticipated that Acting Legal Adviser Richard C. Visek will chair the meeting, which will be open to the public up to the capacity of the meeting room. It is anticipated that the meeting will include discussions on international law and cyberspace, lethal autonomous weapons systems, and self-determination under international law.

Members of the public who wish to attend should contact the Office of the Legal Adviser by December 10 at *heathjb@state.gov* or 202–776–8315 and provide their name, professional affiliation, address, and phone number. A valid photo ID is required for admission to the meeting. Attendees who require reasonable accommodation should make their requests by December 7. Requests received after that date will be considered but might not be possible to accommodate.

J. Benton Heath,

Attorney-Adviser, Office of the Legal Adviser, Executive Director, Advisory Committee on International Law, Department of State.

[FR Doc. 2017–25641 Filed 11–27–17; 8:45 am]

BILLING CODE 4710–08–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1259X]

Chesapeake and Indiana Railroad Company—Discontinuance of Service Exemption—in Starke County, Indiana

Chesapeake and Indiana Railroad Company, Inc. (CKIN), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR. 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 5.45-mile line of railroad extending between milepost CI 212.55, at or near North Judson, Ind., and milepost CI 218.0, at or near English Lake, Ind., in Starke County, Ind. (the Line). The Line, which traverses United States Postal Service Zip Code 46366, is owned by the Town of North Judson, Ind. (Town), which acquired it through an offer of financial assistance. *CSX Transp., Inc.—Aban. Exemption—in LaPorte, Porter, & Starke Ctys., Ind.,* AB 55 (Sub-No. 643X) (STB served May 14, 2004).[1]

CKIN has certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line; (3) no formal complaint filed by a user of a rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line is either pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will be effective on December 28, 2017, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[2] must be filed by December 8, 2017.[3] Petitions for reconsideration must be filed by December 18, 2017, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with Board should be sent to CKIN's representative, John D. Heffner, Strasburger & Price, LLP, 1025 Connecticut Avenue NW., Suite 717, Washington, DC 20036.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available on our Web site at ''*WWW.STB.GOV*.''

Decided: November 21, 2017.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2017–25531 Filed 11–27–17; 8:45 am]

BILLING CODE 4915–01–P

[1] According to CKIN, the Town will continue to own the Line, which will host excursion passenger services operated by the Hoosier Valley Railroad Museum. CKIN also states that it is willing to consider providing freight service over the Line as a ''private carrier'' pursuant to contracts with individual shippers should a demand arise for service that is economical.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,800. *See Regulations Governing Fees for Servs. Performed in Connection with Licensing & Related Servs.—2017 Update,* EP 542 (Sub-No. 25), slip op. App. C at 20 (STB served July 28, 2017).

[3] Because this is a discontinuance proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons and vessels 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 and these vessels 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 Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; 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 and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On November 21, 2017, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons and the following vessels subject to U.S. jurisdiction are blocked pursuant to the relevant sanctions authorities listed below. Dealings in property subject to U.S. jurisdiction in which a person identified as Government of North Korea has an interest are prohibited effective as of the date of that status, which may be earlier than the date of OFAC's determination.

Individuals

1. SUN, Sidong, Liaoning, China; DOB 11 May 1976; POB Dandong, China; Gender Male; Passport G55296890 (China) issued 15 Sep 2011 expires 14 Sep 2021; National ID No. 210623197605112215 (individual) [DPRK4].

Designated pursuant to Section 1(a)(vi) of Executive Order 13810 of September 20, 2017, ''Imposing Additional Sanctions With Respect to North Korea'' (Executive Order 13810) for being owned, or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, DANDONG DONGYUAN INDUSTRIAL CO, LTD., an entity whose property and interests in property are blocked pursuant to E.O. 13810.

Entities

1. KOREA SOUTH–SOUTH COOPERATION CORPORATION (a.k.a. NAM NAM GENERAL CORPORATION; a.k.a. NAM–NAM (SOUTH–SOUTH) COOPERATIVE GENERAL COMPANY), Central District, Pyongyang, Korea, North; China; Russia; Poland [DPRK3].

Designated pursuant to Section 2(a)(iv) of Executive Order 13722 of March 15, 2008, ''Blocking Property of the Government of North Korea and the Workers' Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea'' (Executive Order 13722) for having engaged in, facilitated, or been responsible for the exportation of workers from North Korea, including exportation to generate revenue for the Government of North Korea or the Worker's Party of Korea.

2. MARITIME ADMINISTRATION OF THE DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA (a.k.a. MARITIME ADMINISTRATION BUREAU), Pyongyang, Korea, North [DPRK3].

Identified as meeting the definition of the Government of North Korea as set forth in Section 9(d) of Executive Order 13722 because it is an agency, instrumentality, or controlled entity of the Government of North Korea.

3. MINISTRY OF LAND AND MARITIME TRANSPORTATION OF THE DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA (a.k.a. MINISTRY OF LAND AND MARINE TRANSPORT), Korea, North [DPRK3].

Identified as meeting the definition of the Government of North Korea as set forth in Section 9(d) of Executive Order 13722 because it is an agency, instrumentality, or controlled entity of the Government of North Korea.

4. DANDONG DONGYUAN INDUSTRIAL CO., LTD. (a.k.a. DANDONG DONGYUAN INDUSTRIAL CO.; a.k.a. DANDONG DONGYUAN INDUSTRY CO., LTD.), No. 34–7, Zhenba Street, Zhenxing District, Dandong 118001, China; Rm 3002 No 99 3 1 Binjiang Middle Rd, Zhenxing District, Dandong, China; D–U–N–S Number 542957624 [DPRK4].

Designated pursuant to Section 1(a)(iii) of Executive Order 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

5. KOREA KUMBYOL TRADING COMPANY (a.k.a. KUMBYOL TRADING; a.k.a. KUMBYOL TRADING COMPANY OF NORTH KOREAN WORKERS' PARTY), Pyongyang, Korea, North [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

Also designated pursuant to Section 1(a)(iii) of Executive Order 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

6. YUSONG SHIPPING CO, Uiam-dong, Taedonggang-guyok, Pyongyang, Korea, North; Nationality of Registration Korea, North; Company Number 5146578 [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

7. DAWN MARINE MANAGEMENT CO LTD, Changgyong 2-dong, Sosong-guyok, Pyongyang, Korea, North; Nationality of Registration Korea, North; Company Number 5926921 [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

8. KOREA DAEBONG SHIPPING CO, Ansan 1-dong, Pyongchon-guyok, Pyongyang, Korea, North; Nationality of Registration Korea, North; Company Number 5145243 [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

9. KOREA RUNGRADO RYONGAK TRADING CO, Pulgunkori 2-dong, Potonggang-guyok, Pyongyang, Korea, North; Nationality of Registration Korea, North; Company Number 5787653 [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

10. KOREA RUNGRADO SHIPPING CO, Pulgunkori 1-dong, Potonggang-guyok, Pyongyang, Korea, North; Nationality of Registration Korea, North; Company Number 1414592 [DPRK4].

Designated pursuant to Section 1(a)(i) of Executive Order 13810 for operating in the transportation industry in North Korea.

11. DANDONG HONGDA TRADE CO. LTD., China; Room 301, No. 1 Building, Business & Tourist Section, Dandong, Liaoning, China [DPRK4].

Designated pursuant to Section 1(a)(iii) of Executive Order 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

12. DANDONG XIANGHE TRADING CO., LTD. (a.k.a. DANDONG XIANGHE TRADING CORPORATION; a.k.a. DANDONG XIANGHE TRADING LTD. CO; a.k.a. XIANGHE TRADE CO., LTD.), China; No. 603, 2F, Jiadi Square, Developing Zone, Dandong, Liaoning, China; Beida Rd., Pingxiang City, Chongzuo, Guangxi 532600, China; Room 703, No. 7 Building, Fangba, Yanjiang Development Zone, Dandong, China [DPRK4].

Designated pursuant to Section 1(a)(iii) of Executive Order 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

13. DANDONG KEHUA ECONOMY & TRADE CO., LTD. (a.k.a. DANDONG KEHUA ECONOMIC AND TRADE CO. LTD.), China; Room 102, 1/F, Antai Garden, Zhengxing District, Dandong, Liaoning 118000, China [DPRK4].

Designated pursuant to Section 1(a)(iii) of Executive Order 13810 for having engaged in at least one significant importation from or exportation to North Korea of any goods, services, or technology.

Vessels

1. KU BONG RYONG Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8983404 (vessel) [DPRK4] (Linked To: KOREA KUMBYOL TRADING COMPANY).

Identified pursuant to Executive Order 13810 of September 20, 2017, ''Imposing Additional Sanctions With Respect to North Korea'' (E.O. 13810) as property in which KOREA KUMBYOL TRADING COMPANY, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

2. SO BAEK SAN Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8658267 (vessel) [DPRK4] (Linked To: KOREA KUMBYOL TRADING COMPANY).

Identified pursuant to E.O. 13810E.O. 13810 as property in which KOREA KUMBYOL TRADING COMPANY, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

3. RYE SONG GANG 1 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 7389704 (vessel) [DPRK4] (Linked To: KOREA KUMBYOL TRADING COMPANY).

Identified pursuant to E.O. 13810 as property in which KOREA KUMBYOL TRADING COMPANY, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

4. KANG SONG 1 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 6908096 (vessel) [DPRK4] (Linked To: KOREA KUMBYOL TRADING COMPANY).

Identified pursuant to E.O. 13810 as property in which KOREA KUMBYOL TRADING COMPANY, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

5. ZA RYOK 2 Democratic People's Republic of Korea flag; Vessel Registration

Identification IMO 8898738 (vessel) [DPRK4] (Linked To: YUSONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which YUSONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

6. KUM SONG 5 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8661719 (vessel) [DPRK4] (Linked To: DAWN MARINE MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which DAWN MARINE MANAGEMENT CO LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

7. WON SAN 2 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 9159787 (vessel) [DPRK4] (Linked To: YUSONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which YUSONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

8. KUM SONG 3 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8661850 (vessel) [DPRK4] (Linked To: DAWN MARINE MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which DAWN MARINE MANAGEMENT CO LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

9. 7–28 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8898831 (vessel) [DPRK4] (Linked To: YUSONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which YUSONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

10. YU SONG 7 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8400854 (vessel) [DPRK4] (Linked To: YUSONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which YUSONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

11. JANG GYONG Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8203933 (vessel) [DPRK4] (Linked To: DAWN MARINE MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which DAWN MARINE MANAGEMENT CO LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

12. YU SONG 12 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 9096791 (vessel) [DPRK4] (Linked To: YUSONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which YUSONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

13. KUM UN SAN 3 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8705539 (vessel) [DPRK4] (Linked To: DAWN MARINE MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which DAWN MARINE MANAGEMENT CO LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

14. RAK RANG Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 7506118 (vessel) [DPRK4] (Linked To: KOREA DAEBONG SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which KOREA DAEBONG SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

15. PU HUNG 1 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8703933 (vessel) [DPRK4] (Linked To: KOREA RUNGRADO SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which KOREA RUNGRADO SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

16. RUNG RA DO Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8989795 (vessel) [DPRK4] (Linked To: KOREA RUNGRADO SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which KOREA RUNGRADO SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

17. YANG GAK DO Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 6401828 (vessel) [DPRK4] (Linked To: KOREA RUNGRADO SHIPPING CO).

Identified pursuant to E.O. 13810 as property in which KOREA RUNGRADO SHIPPING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

18. RUNG RA 1 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8713457 (vessel) [DPRK4] (Linked To: KOREA RUNGRADO RYONGAK TRADING CO).

Identified pursuant to E.O. 13810 as property in which KOREA RUNGRADO RYONGAK TRADING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

19. RUNG RA 2 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 9020534 (vessel) [DPRK4] (Linked To: KOREA RUNGRADO RYONGAK TRADING CO).

Identified pursuant to E.O. 13810 as property in which KOREA RUNGRADO RYONGAK TRADING CO, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

20. KUM SONG 7 Democratic People's Republic of Korea flag; Vessel Registration Identification IMO 8739396 (vessel) [DPRK4] (Linked To: DAWN MARINE MANAGEMENT CO LTD).

Identified pursuant to E.O. 13810 as property in which DAWN MARINE MANAGEMENT CO LTD, an entity whose property and interests in property are blocked pursuant to E.O. 13810, has an interest.

Dated: November 22, 2017.

John E. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2017–25637 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is removing the name of one individual whose property and interests in property have been blocked pursuant to an executive order issued on January 23, 1995, titled ''Prohibiting Transactions with Terrorists Who Threaten to Disrupt the Middle East Peace Process,'' from the list of Specially Designated Nationals and Blocked Persons (SDN List).

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; 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 SDN List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*).

Notice of OFAC Action

The following person is removed from the SDN List, effective as of November 21, 2017.

Individual

1. QASEM, Talat Fouad; DOB 02 Jun 1957; alt. DOB 03 Jun 1957; POB Al Mina, Egypt; Propaganda Leader of ISLAMIC GAMA'AT (individual) [SDT].

Dated: November 21, 2017.

John E. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2017–25602 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Departmental Offices Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before December 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Departmental Offices (DO)

Title: Monthly Consolidated Foreign Currency Report of Major Market Participants.

OMB Control Number: 1505–0010.

Type of Review: Revision of a currently approved collection.

Abstract: Collection of information on Form FC–2 is required by law. Form FC–2 is designed to collect timely information on foreign exchange contracts purchased and sold; foreign exchange futures purchased and sold; foreign currency options and net delta equivalent value; foreign currency denominated assets and liabilities; net reported dealing positions.

Form: FC–2.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,296.

Title: Weekly Consolidated Foreign Currency Report of Major Market Participants.

OMB Control Number: 1505–0012.

Type of Review: Revision of a currently approved collection.

Abstract: Collection of information on Form FC–1 is required by law. Form FC–1 is designed to collect timely information on foreign exchange spot, forward and futures purchased and sold; net options position, delta equivalent value long or short; net reported dealing position long or short.

Form: FC–1.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,248.

Title: Quarterly Consolidated Foreign Currency Report.

OMB Control Number: 1505–0014.

Type of Review: Revision of a currently approved collection.

Abstract: Collection of information on Form FC–3 is required by law. Form FC–3 is designed to collect timely information on foreign exchange contracts purchased and sold; foreign exchange futures purchased and sold; foreign currency denominated assets and liabilities; foreign currency options and net delta equivalent value.

Form: FC–3.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,664.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 21, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017–25611 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple FinCEN Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before December 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Financial Crimes Enforcement Network (FinCEN)

Title: FinCEN Suspicious Activity Report (SAR).

OMB Control Number: 1506–0065.

Type of Review: Revision of a currently approved collection.

Abstract: FinCEN and the bank regulators adopted the suspicious activity report (''SAR'') in 1996 to simplify the process through which depository institutions (''banks'') inform their regulators and law enforcement about suspected criminal activity, pursuant to the Bank Secrecy Act (31 U.S.C. 5318(g)). The SAR is also filed by money services businesses, broker dealers in securities, casinos, certain futures commission merchants, life insurance companies, mutual funds, non-bank residential mortgage lenders and originators, and Government Sponsored Enterprises's (GSE's). All reporting financial institutions are required to retain a copy of any SAR filed and supporting documentation for the filing of the SAR for five years. These documents are necessary for criminal investigations and prosecutions. The filing of a SAR is necessary to prevent and detect the laundering of money and other funds at the filing institutions.

Form: FinCEN 111.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 4,038,044.

Title: Additional Records to be Made and Retained by Banks.

OMB Control Number: 1506–0059.

Type of Review: Extension without change of a currently approved collection.

Abstract: The statute generally referred to as the ''Bank Secrecy Act,'' Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5332, authorizes the Secretary of the Treasury, inter alia, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities, to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures. A bank must retain an original or copy of certain documents, as specified in section 1020.410. The required records must be maintained for five years (31 CFR 1010.430).

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,290,000.

Title: Designation of Exempt Person.

OMB Control Number: 1506–0012.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Designation of Exempt Person report (DOEP) FinCEN Report 110 is filed by banks to exempt certain businesses from the requirement to report transactions in currency.

Form: FinCEN 110.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 27,040.

Title: Report of Cash Payment over $10,000 Received in a Trade or Business.

OMB Control Number: 1506–0018.

Type of Review: Extension without change of a currently approved collection.

Abstract: Anyone in a trade or business who, in the course of such trade or business, receives more than $10,000 in cash or foreign currency in one or more related transactions must report it to FinCEN and provide a statement to the payer. Any transaction which must be reported under Title 31 on FinCEN Form 112 (BCTR) is exempted from reporting the same transaction on Form 8300. The USA Patriot Act of 2001 (Pub. L. 107–56) authorized the Financial Crimes Enforcement Network to collect the information reported on Form 8300.

Form: FinCEN 8300.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 164,952.

Title: Administrative Rulings.

OMB Control Number: 1506–0050.

Type of Review: Extension without change of a currently approved collection.

Abstract: Under the Bank Secrecy Act, financial institutions may request administrative rulings from FinCEN. Administrative ruling requests are sent to FinCEN either by the U.S. Mail or electronically for consideration and determination.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 120.

Title: Special Rules for Casinos.

OMB Control Number: 1506–0051.

Type of Review: Extension without change of a currently approved collection.

Abstract: This section provides special rules for casinos, including the requirement that casinos maintain a written anti money laundering compliance program.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 92,500.

Title: Additional Records to be Made and Retained by Currency Dealers or Exchangers.

OMB Control Number: 1506–0052.

Type of Review: Extension without change of a currently approved collection.

Abstract: A currency dealer or exchanger must make and maintain a record of the taxpayer identification number of certain persons for whom a transaction account is opened or a line of credit is extended, and must maintain a list containing the names, addresses, and account or credit line numbers of those persons from whom it has been unable to secure such information. A currency dealer or exchanger must retain the original or a copy of certain documents, as specified in 31 CFR 1022.410. The required records must be maintained for five years.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 36,800.

Title: Additional Records to be Made and Retained by Brokers or Dealers in Securities.

OMB Control Number: 1506–0053.

Type of Review: Extension without change of a currently approved collection.

Abstract: A broker or dealer in securities must retain an original or copy of certain documents, as specified in section 1023.410. The required records must be maintained for five years (31 CFR 1010.430).

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 830,000.

Title: Additional Records to be Made and Retained by Casinos.

OMB Control Number: 1506–0054.

Type of Review: Extension without change of a currently approved collection.

Abstract: Casinos (and card clubs) must make and retain a record of the name, permanent address, and taxpayer identification number for each person who deposits funds with the casino, opens an account at the casino, or to whom the casino extends a line of credit (and maintain a list, available to the Secretary upon request, of the names and addresses of persons who do not furnish a taxpayer identification number), and must retain the original or a copy of certain documents, as specified in section 1021.410(a)&(b)(1)–(8). Casinos must also maintain a list of transactions with customers involving certain instruments (31 CFR 1021.410(b)(9)). Card clubs must maintain records of currency transactions by customers and records of activity at cages (31 CFR 1021.410(b)(11)). Casinos that input, store, or retain required records on computer disk, tape or other machine-readable media must maintain the records on such media (31 CFR 1021.410(c)). Required records must be maintained for five years (31 CFR 1010.430).

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 121,056.

Title: Reports of Transactions with Foreign Financial Agencies.

OMB Control Number: 1506–0055.

Type of Review: Revision of a currently approved collection.

Abstract: Treasury may, by regulation, require specified financial institutions to report transactions by persons with designated foreign financial agencies.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 1,000.

Title: Reports of Certain Domestic Coin and Currency Transactions.

OMB Control Number: 1506–0056.

Type of Review: Revision of a currently approved collection.

Abstract: Upon a finding that additional reporting or recordkeeping is necessary to carry out the purposes, or prevent the evasion, of the Bank Secrecy Act, Treasury may issue an order requiring financial institutions or groups of financial institutions in certain geographic locations to report certain transactions in prescribed amounts for a limited period of time (31 CFR 1010.360). Financial institutions subject to a geographic targeting order must maintain records for such period of time as the order requires but not more than 5 years (31 CFR 1010.410(d)). Although the burden is stated as an annual burden in accordance with the Paperwork Reduction Act, the estimated annual burden is not intended to indicate that there is a geographic targeting order in effect throughout a year or in each year.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 8,000.

Title: Purchases of Bank Checks and Drafts, Cashier's Checks, Money Orders and Traveler's Checks.

OMB Control Number: 1506–0057.

Type of Review: Extension without change of a currently approved collection.

Abstract: Financial institutions must maintain records of certain information related to the sale of bank checks and drafts, cashiers checks, money orders, or traveler's checks when the sale involves currency between $3,000–$10,000. The records must be maintained for a period of five years and be made available to Treasury upon request.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 456,750.

Title: Records to be Made and Retained by Financial Institutions.

OMB Control Number: 1506–0058.

Type of Review: Extension without change of a currently approved collection.

Abstract: Each financial institution must retain an original or copy of records related to extensions of credit in excess of $10,000 (other than those secured by real property), and records related to transfers of funds, currency, other monetary instruments, checks, investment securities, or credit of more than $10,000 to or from the United States (31 CFR 1010.410(a)–(d)). Banks and non-bank financial institutions must also maintain records related to, and include certain information as part of, funds transfers or transmittals of funds involving more than $3,000 (31 CFR 1010.410(e)–(f)–(g)). The required records must be maintained for five years (31 CFR 1010.430).

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,150,200.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 21, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017–25574 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before December 28, 2017 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov*..

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

Title: Application for an Industrial Alcohol User Permit.

OMB Control Number: 1513–0028.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 5271 authorizes the Secretary of the Treasury to prescribe regulations requiring persons using tax-free alcohol for certain nonbeverage purposes (hospitals, laboratories, research centers, etc.) and persons using or dealing in specially denatured spirits (alcohol and/or rum) to apply for and receive a permit to do so prior to commencing business. Under that authority, the TTB regulations prescribe the use of TTB F 5150.22 as the application form for dealers or users of specially denatured spirits (alcohol/rum) (see 27 CFR 20.41) and for users of tax-free alcohol (see 27 CFR 22.41). TTB uses the information reported on the form to, among other things, determine the eligibility of the applicant to engage in certain operations involving specially denatured or tax-free alcohol, the location of the business or entity, and whether the operations will be in conformance with Federal laws and regulations.

Form: TTB F 5150.22.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 357.

Title: Report—Manufacturer of Tobacco Products or Cigarette Papers and Tubes; Report—Manufacturer of Processed Tobacco.

OMB Control Number: 1513–0033.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Internal Revenue Code at 26 U.S.C. 5722 requires that every manufacturer of tobacco products, cigarette papers and tubes, or processed tobacco make reports containing such information, in such form, at such times, and for such periods as the Secretary of the Treasury shall by regulation prescribe. The TTB regulations at 27 CFR 40.202, 40.422, and 40.522 prescribe, as appropriate, the use of TTB F 5210.5 to report tobacco products and cigarette papers and tubes manufactured, received, and removed

per month, and the use of TTB F 5250.1 to report all processed tobacco manufactured, received, and removed per month. TTB uses the collected information to ensure that Federal excise taxes have been properly paid and that manufacturers are in compliance with applicable Federal law and regulations.

Form: TTB F 5210.5, TTB F 5250.1.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 2,820.

Title: Manufacturers of Nonbeverage Products—Records to Support Claims for Drawback.

OMB Control Number: 1513–0073.

Type of Review: Extension without change of a currently approved collection.

Abstract: The Internal Revenue Code (IRC) at 26 U.S.C. 5001 imposes a Federal excise tax of $13.50 per proof gallon on distilled spirits produced or imported into the United States. However, the IRC at 26 U.S.C. 5111–5114, allows manufacturers of certain nonbeverage products that are unfit for beverage use—medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume—to claim drawback (refund) of all but $1.00 per proof gallon of the excise tax paid on the distilled spirits used in the production of such products. Under these IRC authorities, TTB has issued regulations governing nonbeverage product drawback claims, contained in 27 CFR part 17, which includes a requirement to keep source records supporting such claims. The required source records include information about distilled spirits received, gauge records, evidence of taxes paid, the date spirits were used, the quantity and kind used in each product, receipt and usage of other ingredients (to validate formula compliance), inventory records, records of recovered alcohol, the quantity of intermediate products transferred to other plants, the disposition of each nonbeverage product produced, and the purchasers (except for retail sales). These records are necessary to protect the revenue; the required records help prevent fraudulent claims and the diversion to beverage use of spirits on which nonbeverage product drawback is claimed.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 11,130.

Title: Proprietors or Claimants Exporting Liquors.

OMB Control Number: 1513–0075.

Type of Review: Extension without change of a currently approved collection.

Abstract: Under the Internal Revenue Code at 26 U.S.C. 5053, 5214, and 5362, distilled spirits, wine, and beer may be exported without payment of Federal excise tax. In addition, under the IRC at 26 U.S.C. 5055 and 5062, taxpaid distilled spirits, wine, and beer may be exported and the exporter may claim drawback (refund) on the excise taxes paid. To protect the revenue, exporters must complete various TTB and customs forms to show that the products were in fact exported. Under the TTB alcohol beverage export regulations in 27 CFR part 28, proprietors and drawback claimants are required to maintain record copies of all pertinent forms and commercial records that document the exportation of non-taxpaid alcohol beverages and the exportation of taxpaid alcohol beverages for which drawback will be claimed, and such records must be maintained for not less than 3 years.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 750.

Title: Administrative Remedies—Requests for Closing Agreements.

OMB Control Number: 1513–0099.

Type of Review: Extension without change of a currently approved collection.

Abstract: The IRC, at 26 U.S.C. 7121, authorizes the Secretary of the Treasury to enter into a written agreement with any person relating to the liability of such person (or of the person or estate for whom he or she acts) in respect to any internal revenue tax for any taxable period. That IRC section also states that such agreements, once approved, are final and conclusive, unless it is shown that the taxpayer exhibited fraud or malfeasance, or misrepresented a material fact. Under its delegated authority, TTB has issued regulations at 27 CFR 70.485 pertaining to such ''closing agreements.'' Specific to this information collection, the regulation requires a taxpayer or their agent to submit a written request to TTB to enter into a closing agreement to resolve certain Federal excise tax matters. TTB uses the information collected in such a request and any attached supporting documentation to determine whether the Bureau should pursue a closing agreement with the taxpayer. Closing agreements allow TTB and a taxpayer to resolve tax liability matters prior to any adversarial legal or administrative proceedings.

Form: None.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 5.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 22, 2017.

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2017–25680 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Terrorism Risk Insurance Program 2018 Data Call

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Request for comments.

SUMMARY: Pursuant to the Terrorism Risk Insurance Act of 2002 (TRIA),[1] the Federal Insurance Office (FIO) requests public feedback on the proposed consolidation of the separate federal and state data calls regarding terrorism risk insurance, and the proposed data collection forms for use in the 2018 data call. Copies of these forms and associated explanatory materials (including a document identifying specific changes to the reporting templates and instructions as previously used by Treasury) are available for electronic review on the Treasury Web site at *https://www.treasury.gov/resource-center/fin-mkts/Pages/program.aspx.* State insurance regulators, through the National Association of Insurance Commissioners (NAIC), will also be separately seeking comment from stakeholders on the proposal.

DATES: Submit comments on or before January 29, 2018.

ADDRESSES: Submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov,* or by mail to the Federal Insurance Office, Attn: Richard Ifft, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. Because postal mail may be subject to processing delays, it is recommended that comments be submitted electronically. If submitting comments by mail, please submit an original version with two copies. Comments concerning the proposed data collection forms and

[1] Public Law 107–297, 116 Stat. 2322, codified at 15 U.S.C. 6701, note. Because the provisions of TRIA (as amended) appear in a note, instead of particular sections, of the United States Code, the provisions of TRIA are identified by the sections of the law.

collection process should be captioned with ''2018 TRIP Data Collection Comments.'' Please include your name, group affiliation, address, email address, and telephone number(s) in your comment. Where appropriate, a comment should include a short Executive Summary (no more than five single-spaced pages).

FOR FURTHER INFORMATION CONTACT: Richard Ifft, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, Room 1410 MT, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220, at (202) 622–2922 (not a toll-free number), Lindsey Baldwin, Senior Policy Analyst, Federal Insurance Office, at (202) 622–3220 (not a toll free number), or Kevin Meehan, Senior Insurance Regulatory Policy Analyst, Federal Insurance Office, at (202) 622–7009 (not a toll-free number). Persons who have difficulty hearing or speaking may access these numbers via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background and Proposed Consolidated Approach

TRIA created the Terrorism Risk Insurance Program (Program) within the U.S. Department of the Treasury (Treasury) to address disruptions in the market for terrorism risk insurance, to help ensure the continued availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for the private markets to stabilize and build insurance capacity to absorb any future losses for terrorism events. The Program has been reauthorized on a number of occasions, most recently in the Terrorism Risk Insurance Program Reauthorization Act of 2015 (2015 Reauthorization Act).[2] Section 111 of the 2015 Reauthorization Act [3] (Section 111) requires the Secretary of the Treasury (Secretary) to perform periodic analyses of certain matters concerning the Program. In order to assist the Secretary with this process, Section 111 requires insurers to submit on an annual basis certain insurance data and information regarding their participation in the Program. FIO is authorized to assist the Secretary in the administration of the Program.[4]

Treasury began collecting data from insurers in 2016 on a voluntary basis,[5] and on a mandatory basis in 2017.[6] Treasury also arranged in 2017 for workers' compensation rating bureaus to provide most of the workers' compensation insurance data elements.[7] 31 CFR 50.51 requires insurers to submit the specified data no later than May 15 of each calendar year. Treasury, through an insurance statistical aggregator, uses a web portal through which insurers must submit the requested data. All information submitted via the web portal is subject to the confidentiality and data protection provisions of applicable federal law.

State insurance regulators also began annually collecting data relating to terrorism risk insurance in 2016. The state insurance regulator data calls have sought information similar to that collected by Treasury, although in some cases on a more detailed, granular basis. Given the similarity of the information sought, and the burden presented to insurers by the existence of dual data calls on the same subject, Treasury and state insurance regulators have sought to create a consolidated data call for 2018 that will satisfy each of their respective objectives. For the 2018 data call, Treasury and state insurance regulators have agreed on joint reporting templates substantially similar to those used by Treasury in prior years, subject to minor changes based upon experience gained from the 2017 data call, coordination with state insurance regulators and the NAIC, and feedback from participating insurers. The most significant changes are identified below.

Insurers subject to the consolidated data call will report on a group basis, if part of a group, and otherwise will report on an individual company basis. Insurers with property exposures will also be required to submit to state insurance regulators, on an individual company basis, an additional supplement focusing on the property lines of insurance subject to the Program. This supplement calls for data with respect to geographic exposures by ZIP Code.

II. Changes to Data Collection Templates

Pursuant to Section 111 of the 2015 Reauthorization Act, Treasury has coordinated with publicly available sources to collect information for the 2018 data call. Information relating to workers' compensation exposures is available from the workers' compensation rating bureaus, and those entities have agreed to provide that information on behalf of participating insurers. Treasury has determined, however, that all other data components remain unavailable from other sources. Accordingly, Treasury will continue to request this remaining data and information directly from insurers. However, Treasury's analysis indicates that the proposed consolidated approach for the 2018 data call will result in a significant reduction in overall data collection burdens for participating insurers.

After coordinating with state insurance regulators, Treasury again proposes to use four different data collection templates (see 31 CFR 50.51(c)), depending upon the type of insurer involved. Insurers will fill out the template identified ''Insurer (Non-Small) Groups or Companies,'' unless the insurer meets the definition of a small insurer, captive insurer, or alien surplus lines insurer as set forth in 31 CFR 50.4. Such small insurers, captive insurers, and alien surplus lines insurers are required to complete separate tailored templates. Each template will be accompanied by separate instructions providing guidance on each data element.

There are four global changes to the proposed reporting templates for 2018. First, all reporting templates will now include a standalone cyber insurance worksheet. Second, the reinsurance worksheet that is required for non-small insurers, alien surplus lines insurers, and captive insurers will include a new modeled loss question.[8] Third, the exposures worksheet (required for all insurers) will request information concerning policyholder deductibles and retention amounts, in addition to insurer exposure under policies subject to the Program. Fourth, the reporting templates no longer seek premium information on terrorism risk insurance for years prior to the reporting period.[9] In addition to these four changes, the instructions for each reporting template will contain clarifications on how to report specific data elements.

There are also a number of changes for specific insurer categories. For the 2018 data call (requesting insurer data for calendar year 2017), an insurer will qualify as a small insurer if it had both *2016* policyholder surplus and *2016* direct earned premium in the TRIP-

[2] Public Law 114–1, 129 Stat. 3.

[3] TRIA sec. 104(h).

[4] 31 U.S.C. 313(c)(1)(D).

[5] 81 FR 11649 (March 4, 2016).

[6] A reporting exemption was extended to small insurers that wrote less than $10 million in TRIP-eligible lines premium in 2016. *See* 81 FR 95310 (December 27, 2016); 82 FR 20420 (May 1, 2017).

[7] 82 FR 20420 (May 1, 2017).

[8] Small insurers complete a separate reinsurance worksheet that does not contain a modeled loss question.

[9] For purposes of future reports, Treasury will use the information received during the 2017 data call, and continue to update this information over time as subsequent data calls are completed.

eligible lines of insurance of less than $700 million.[10] Small insurers that had TRIP-eligible direct earned premium of less than $10 million in 2017 will be exempt from the 2018 consolidated TRIP data call.[11] Neither captive insurers nor alien surplus lines insurers are eligible for this reporting exemption.

In addition to the global changes identified above, small insurers will be required to report additional information on standalone terrorism policies (in addition to the new standalone cyber insurance policy worksheet). In addition, small insurers will now report their largest estimated probable maximum loss at a single location, and the ZIP code of that location, on the reinsurance worksheet. Insurers defined as small insurers for the 2018 data call will report the same information to Treasury (on a group basis) and state insurance regulators (also on a group basis), except with respect to property coverages, for which insurers will also provide additional reporting on an individual company basis in the property supplement submitted solely to state insurance regulators. State insurance regulators will provide their own guidance regarding the submission of data for the state property supplement.

In addition to the global changes identified above, non-small insurers will no longer be required to complete a separate worksheet on package/multi-line policies. The non-small insurer template should be completed by insurance groups (or individual insurers not affiliated with a group) that had either a 2016 policyholder surplus or 2016 direct earned premium in the TRIP-eligible lines of insurance equal to or greater than $700 million, and are not otherwise captive insurers or alien surplus lines insurers. Insurers defined as non-small insurers for the 2018 data call will report the same information to Treasury (on a group basis) and state insurance regulators (also on a group basis), except with respect to property coverages. For property coverages, insurers will also provide additional reporting on an individual company basis in a property supplement submitted solely to state insurance regulators. As noted above, state insurance regulators will provide their own guidance regarding the submission of data for the state property supplement.

In addition to the global changes identified above, captive insurers will no longer be required to complete a separate worksheet for workers' compensation deductible policies, as this information will now be collected on the general premium worksheet. Captive insurers are defined in 31 CFR 50.4(g) as insurers licensed under the captive insurance laws or regulations of any state. As in 2017, captive insurers that write policies in TRIP-eligible lines of insurance are required to report in 2018, unless they do not provide their insureds with any terrorism risk insurance subject to the Program.

The reporting template for alien surplus lines insurers does not contain changes, other than the global changes identified above. Alien surplus lines insurers are defined in 31 CFR 50.4(o)(1)(i)(B) as insurers not licensed or admitted to engage in the business of providing primary or excess insurance in any state, but that are eligible surplus line insurers listed on the NAIC Quarterly Listing of Alien Insurers. Alien surplus lines insurers that are part of a larger group classified as a non-small insurer or a small insurer should report as part of the group, using the appropriate template. Therefore, the alien surplus lines insurer template should only be used by an alien surplus lines insurer that is not part of a larger group subject to the 2018 data call. Insurers defined as alien surplus lines insurers for the 2018 data call will report their information to Treasury and provide an identical copy to state insurance regulators.[12]

III. Submission of Data

Following registration with the data aggregator, all insurers will be provided with the appropriate reporting templates for completion. Insurers will be required to submit the completed reporting templates through a secure web portal provided by the data aggregator. All data must be provided no later than May 15, 2018, which will also be the reporting deadline for state insurance regulators. Treasury intends to provide training and provide additional resources throughout the data collection period to facilitate the proper completion of reporting templates.

To permit greater flexibility in the submission of data, Treasury will permit the submission of completed reporting templates in .csv file format, consistent with the format currently used by state insurance regulators. Treasury will provide further guidance on how this can be accomplished in a later notice or web posting. Responding companies may also continue to report using the templates (in Excel format) used in prior years.

Reporting under the 2018 data call will be mandatory for all commercial property and casualty insurers writing insurance in lines subject to TRIA, unless the insurer falls within the exceptions for certain small insurers and captive insurers identified above.

IV. Request for Comments

To ensure efficient and accurate completion of the forms, Treasury is requesting public feedback on the content of the 2018 data call reporting templates, and the consolidated approach to the separate federal and state reporting outlined in this Request for Comments. The proposed forms are available for review at *https://www.treasury.gov/resource-center/fin-mkts/Pages/program.aspx.*

V. Procedural Requirements

Paperwork Reduction Act. The collection of information contained in this notice will be submitted to the Office of Management and Budget (OMB) for review under the requirements of the Paperwork Reduction Act, 44 U.S.C. 3507(d). Comments should be sent to Treasury in the form discussed in the **ADDRESSES** section of this notice. Comments on the collection of information should be received by January 29, 2018.

Comments are being sought with respect to the collection of information in the proposed Terrorism Risk Insurance Program 2018 data call. *Treasury specifically invites comments on:* (a) Whether the proposed collection is responsive to the statutory requirement; (b) the accuracy of the estimate of the burden of the collections of information (*see below*); (c) ways to enhance the quality, utility, and clarity of the information collection; (d) ways to use automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to maintain the information.

[10] Small insurers are defined in 31 CFR 50.4(z) as insurers (or an affiliated group of insurers) whose policyholder surplus for the immediately preceding year is less than five times the Program Trigger for the current year, and whose TRIP-eligible lines direct earned premium for the previous year is also five times less than the Program Trigger. Accordingly, for the 2018 data call, an insurer qualifies as a small insurer if its 2016 policyholder surplus and 2016 direct earned premium are less than five times the 2017 Program Trigger of $140 million.

[11] To the extent an insurer with less than this level of TRIP-eligible lines direct earned premium is part of a larger group that is required to report, the insurer must report as part of the group as a whole, even if it is under the $10,000,000 direct earned premium threshold on an individual basis. Individual company information for such entities must also be reported to state insurance regulators.

[12] For 2017, state insurance regulators collected terrorism risk insurance data from alien surplus lines insurers through the NAIC's International Insurers Department (IID).

Treasury previously analyzed the potential burdens associated with the 2017 data call. See 81 FR 95310, 95312 (December 27, 2016). The information sought by Treasury comprises data elements that insurers currently collect or generate, although not necessarily grouped together the way in which insurers currently collect and evaluate the data. Based upon insurer submissions to the 2017 data call, Treasury estimates that for purposes of the 2018 data call, approximately 100 Program participants will be required to submit the ''Insurer (Non-Small) Groups or Companies'' data collection form, 200 Program participants will be required to submit the ''Small Insurer'' form, 400 Program participants will be required to submit the ''Captive Insurer'' form, and 25 Program participants will be required to submit the ''Alien Surplus Lines Insurers'' form.

Each set of reporting templates is expected to incur a different level of burden. The changes to the proposed data reporting elements in 2018 are not anticipated to have a material impact on Treasury's prior burden estimates. Treasury anticipates approximately 75 hours will be required to collect, process, and report the data for each non-small insurer, approximately 25 hours will be required to collect, process, and report data for each small insurer, and 50 hours will be required to collect, process, and report data for each captive insurer and alien surplus lines insurer. Due to the proposed consolidation of the separate federal and state data calls, however, the total burden upon reporting insurers overall (once state and federal obligations are accounted for) will be materially reduced for most insurers.

Assuming this breakdown, and when applied to the number of reporting insurers anticipated in light of the experience of the 2017 data call, the estimated annual burden would be 33,750 hours ((100 insurers × 75 hours) + (200 insurers × 25 hours) + (400 insurers × 50 hours) + (25 insurers × 50 hours)). At a blended, fully loaded hourly rate of $85, the cost would be $2,868,750 across the industry as a whole, or $6,375 per non-small insurer, $2,125 per small insurer, and $4,250 each per captive insurer or alien surplus lines insurer.

Steven E. Seitz,

Deputy Director, Federal Insurance Office.

[FR Doc. 2017–25402 Filed 11–27–17; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0658]

Agency Information Collection Activity Under OMB Review: Lender's Staff Appraisal Reviewer (SAR) Application

AGENCY: Loan Guaranty Service, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Loan Guaranty Service, 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 December 28, 2017.

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. 2900–0658'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Office of Quality, Privacy and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov*.

Please refer to ''OMB Control No. 2900–0658'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VA FORM 26–0785, Lender's Staff Appraisal Reviewer (SAR) Application.

OMB Control Number: 2900–0658.

Type of Review: Extension of a currently approved collection.

Abstract: Title 38 U.S.C. 3702(d) authorizes VA to establish standards for lenders making automatically guaranteed loans and 38 CFR 36.4344 establishes requirements and procedures for lenders in being approved to perform the functions under the Lender Appraisal Processing Program (LAPP).

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 82 FR 38759 on August 15, 2017, pages 38759–38760.

Affected Public: Individuals (employees of lenders making applications).

Estimated Annual Burden: 200 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 2,400 per year.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2017–25593 Filed 11–27–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee Charter Renewals

AGENCY: Department of Veterans Affairs.

ACTION: Notice of advisory committee charter renewals.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act (FACA) and after consultation with the General Services Administration, the Secretary of Veterans Affairs has renewed the charter for the following statutorily authorized Federal advisory committee for a two-year period, beginning on the date listed below:

Committee name	Committee description	Charter renewed on
Advisory Committee on Cemeteries and Memorials.	Provides advice to the Secretary on the administration of national cemeteries, Soldiers' lots and plots, the selection of cemetery sites, the erection of appropriate memorials, and the adequacy of Federal burial benefits.	August 16, 2017.

Committee name	Committee description	Charter renewed on
Veterans' Advisory Committee on Rehabilitation.	Provides advice to the Secretary on the rehabilitation needs of disabled Veterans and the administration of VA's rehabilitation programs.	September 25, 2017.
Advisory Committee on Women Veterans.	Provides advice to the Secretary on the needs of women Veterans regarding health care, rehabilitation benefits, compensation, outreach, and other programs administered by VA.	September 29, 2017.

FOR FURTHER INFORMATION CONTACT: Jeffrey Moragne, Committee Management Office, Department of Veterans Affairs, Advisory Committee Management Office (00AC), 810 Vermont Avenue NW., Washington, DC 20420; telephone (202) 266–4660; or email at *Jeffrey.Moragne@va.gov.* To view a copy of a VA Federal advisory committee charter, visit *http://www.va.gov/advisory.*

Dated: November 22, 2017.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2017–25630 Filed 11–27–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0776]

Agency Information Collection Activity Under OMB Review: Artery and Vein Conditions (Vascular Diseases Including Varicose Veins) Disability Benefits Questionnaire, Hypertension Disability Benefits Questionnaire, Non-Ischemic Heart Disease (Including Arrhythmias and Surgery) Disability Benefits Questionnaire, Diabetic Peripheral Neuropathy (Diabetic Sensory-Motor Peripheral Neuropathy) Disability Benefits Questionnaire, Diabetes Mellitus Disability Benefits Questionnaire, Scars/Disfigurement Disability Benefits Questionnaire, Skin Diseases Disability Benefits Questionnaire, Amputations Disability Benefits Questionnaire, Muscles Injuries Disability Benefits Questionnaire, Temporomandibular Joint (TMJ) Conditions Disability Benefits Questionnaire, Eye Conditions Disability Benefits 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, 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 December 28, 2017.

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. 2900–0776'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Enterprise Records Service (005R1B), Department of Veterans Affairs, 811 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0776'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Artery and Vein Conditions (Vascular Diseases Including Varicose Veins) Disability Benefits Questionnaire (VA Form 21–0960A–2), Hypertension Disability Benefits Questionnaire (VA Form 21–0960A–3), Non-Ischemic Heart Disease (Including Arrhythmias and Surgery) Disability Benefits Questionnaire (VA Form 21–0960A–4), Diabetic Peripheral Neuropathy (Diabetic Sensory-Motor Peripheral Neuropathy) Disability Benefits Questionnaire (VA Form 21–0960C–4), Diabetes Mellitus Disability Benefits Questionnaire (VA Form 21–0960E–1), Scars/Disfigurement Disability Benefits Questionnaire (VA Form 21–0960F–1), Skin Diseases Disability Benefits Questionnaire (VA Form 21–0960F–2), Amputations Disability Benefits Questionnaire (VA Form 21–0960M–1), Muscles Injuries Disability Benefits Questionnaire (VA Form 21–0960M–10), Temporomandibular Joint (TMJ) Conditions Disability Benefits Questionnaire (VA Form 21–0960M–15), Eye Conditions Disability Benefits Questionnaire (VA Form 21–0960N–2)

OMB Control Number: 2900–0776.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21–0960 series is used to gather necessary information from a claimant's treating physician regarding the results of medical examinations. VA gathers medical information related to the claimant that is necessary to adjudicate the claim for VA disability benefits. The Disability Benefit Questionnaire title will include the name of the specific disability for which it will gather information. VAF 21–0960A–2, Artery and Vein Conditions vascular diseases including varicose veins) Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of arteries, veins, and/or peripheral vascular disease; VAF 21–0960A–3, Hypertension, Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of hypertension; VAF 21–0960A–4, Non-ischemic Heart Disease (including Arrhythmias and Surgery) Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of any non-ischemic heart disease; VAF 21–0960C–4, Diabetic Peripheral Neuropathy (diabetic sensory-motor peripheral neuropathy) Disability Benefits Questionnaire will gather information related to the claimant's diagnosis of a diabetic sensory-motor peripheral neuropathy condition; VAF 21–0960E–1, Diabetes Mellitus Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of diabetes mellitus; VAF 21–0960F–1, Scars/Disfigurement Disability Benefits Questionnaire will gather information related to the claimant's diagnosis of any scars or disfigurement; VAF 21–0960F–2, Skin Diseases Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of any skin disease. VAF 21–0960M–1, Amputations Disability Benefits Questionnaire, will gather information related to the claimant's amputations; VAF 21–0960M–10, Muscle Injuries Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of a muscle injury disability. VAF 21–

0960M–15, Temporomandibular Joint (TMJ) Conditions Disability Benefits Questionnaire, will gather information related to the claimant's diagnosis of temporomandibular joint dysfunction or TMJ. VAF 21–0960N–2, Eye Conditions Disability Benefits Questionnaire will gather information related to the claimant's diagnosis of an eye condition.

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 82 FR 79 on April 26, 2017, pages 19311 and 19312.

Affected Public: Individuals or Households.

Estimated Annual Burden: 162,500.

Estimated Average Burden per Respondent: 25 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 400,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2017–25592 Filed 11–27–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0711]

Agency Information Collection Activity Under OMB Review: VBA Loan Guaranty Service Lender Satisfaction Survey

AGENCY: Loan Guaranty Service, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Loan Guaranty Service, 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 December 28, 2017.

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. 2900–0711'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor, Office of Quality, Privacy and Risk (OQPR), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–5870 or email *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0711'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VBA Loan Guaranty Service Lender Satisfaction Survey.

OMB Control Number: 2900–0711.

Type of Review: Extension of a currently approved collection.

Abstract: As part of the agency's continuing commitment to improve the services provided to veterans, VA will conduct the VBA Loan Guaranty Service Lender Satisfaction Survey. The proposed effort will measure lender satisfaction with the various aspects of the VA Home Loan Guaranty program.

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 82 FR 38760 on August 15, 2017, pages 38760–38761.

Affected Public: Private sector.

Estimated Annual Burden: 69 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 275.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2017–25591 Filed 11–27–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 82 Tuesday,

No. 227 November 28, 2017

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, et al.

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; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, and 498

[CMS–4182–P]

RIN 0938–AT08

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act; improve program quality, accessibility, and affordability; improve the CMS customer experience; address program integrity policies related to payments based on prescriber, provider and supplier status in Medicare Advantage, Medicare cost plan, Medicare Part D and the PACE programs; provide a proposed update to the official Medicare Part D electronic prescribing standards; and clarify program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 16, 2018.

ADDRESSES: In commenting, please refer to file code CMS–4182–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4182–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4182–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Theresa Wachter, (410) 786–1157, Part C Issues.

Marie Manteuffel, (410) 786–3447, Part D Issues.

Kristy Nishimoto, (206) 615–2367, Beneficiary Enrollment and Appeals Issues.

Raghav Aggarwal, (410) 786–0097, Part C and D Payment Issues.

Vernisha Robinson-Savoy, (267) 970–2395, Part C and D Compliance Issues.

Frank Whelan, (410) 786–1302, Preclusion List Issues.

Shelly Winston, (410) 786–3694, Part D E-Prescribing Program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

Acronyms

ACA Affordable Care Act
ACS American Community Survey
AEP Annual Election Period
ANDA Abbreviated New Drug Application
ANOC Annual Notice of Change
AMA American Medical Association
AO Accrediting Organization
ASPE Office of the Assistant Secretary for Planning and Evaluation
AWP Any Willing Pharmacy
CAI Categorical Adjustment Index
CARA Comprehensive Addiction and Recovery Act
CCIP Chronic Care Improvement Program
CMS Centers for Medicare & Medicaid Services
CPT Current Procedural Terminology
DAB Departmental Appeals Board
DE Dual Eligible
DIR Direct or Indirect Remuneration
DME Durable Medical Equipment
DSMO Designated Standards Maintenance Organization
D–SNP Dual-Eligible Special Needs Plan
EDM Enhanced Disease Management
EHR Electronic Health Record
EOC Evidence of Coverage
EP Eligible Professionals
FFS Fee-for-Service
ePA Electronic Prior Authorization
eRx Electronic Prescription (e-prescribing)
FDA Food and Drug Administration
FIDE Fully Integrated Dual Eligible
FMV Fair Market Value
FPL Federal Poverty Level
HPMS Health Plan Management System
ICD–10 ICD–10–CM
IRE Independent Review Entity
LIS Low Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MADP Medicare Advantage Disenrollment Period
MA–PD Medicare Advantage Prescription Drug
MAO Medicare Advantage Organizations
MIPPA Medicare Improvements for Patients and Providers Act
MLR Medical Loss Ratio
MOOP Maximum Out-of-Pocket
NCPDP National Council of Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDC National Drug Code
NSO National Standard Organization
OIG Office of Inspector General
OEP Open Enrollment Period
OMHA Office of Medicare Hearings and Appeals
OOPC Out-of-Pocket Cost
PA Prior Authorization
PBM Pharmacy Benefit Manager
PBP Plan Benefit Package
PDP Prescription Drug Plan
PHSA Public Health Service Act

PIP Physician Incentive Plan
PQA Pharmacy Quality Alliance
PSO Provider Sponsored Organization
PSP Provider Specific Plan
QBP Quality Bonus Payment
QI Quality Improvement
QIA Quality Improvement Activities
QIP Quality Improvement Project
REMS Risk Evaluation and Mitigation Strategies
RFI Request for Information
RHC Rural Health Center
RI Rewards and Incentives
RPPO Regional Preferred Provider Organization
RRB Railroad Retirement Board
SE Standard Error
SEP Special Enrollment/Election Period
SES Socio-Economic Status
SNP Special Needs Plan
SSA Social Security Administration
TMP Timeliness Monitoring Project

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to make revisions to 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 Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. The proposed changes are necessary to—(1) Support Innovative Approaches to Improving Quality, Accessibility, and Affordability; (2) Improve the CMS Customer Experience; and (3) Implement Other Changes. In addition, this rule proposes technical changes related to treatment of Part A and Part B premium adjustments and updates the Script standard used for Part D electronic prescribing. While the Part D program has high satisfaction among users, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies. Specifically, this regulation meets the Administration's priorities to reduce burden and provide the regulatory framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program.

B. Summary of the Major Provisions

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

This proposed regulatory provision would implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, which amended the Social Security Act and includes new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Through this provision, CMS proposes a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or ''at-risk beneficiaries.'' CMS proposes that, under such programs, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ''frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). CMS also proposes to limit the use of the special enrollment period (SEP) for dually- or other low income subsidy (LIS)-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. Finally, this provision proposes to codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating this current policy with our proposals for implementing the drug management program provisions. The current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Through the adoption of this policy, from 2011 through 2016, there was a 61 percent decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers.[1] Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications.

2. Updating the Part D E-Prescribing Standards (§ 423.160)

This provision proposes an update to the electronic standards to be used by Medicare Part D prescription drug plans. This includes the proposed adoption of the NDPDP SCRIPT Standard Version 2017071, and retirement of the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals. These changes would become effective January 1, 2019. The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans.

Although e-prescribing is optional for physicians and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit e-prescriptions and related communications electronically must utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and could provide a number of efficiencies which the industry and CMS supports.

In order to facilitate this change, we propose to update § 423.160, and also make a number of conforming technical changes to other sections of part 423. In addition, we are proposing to correct a typographical error that occurred in the regulatory text listing the applicability dates of the standards by changing the reference in § 423.160(b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii) to correctly cite to the present use of the currently adopted NCPDP SCRIPT Standard Version 10.

3. Revisions to Timing and Method of Disclosure Requirements

We are proposing to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC). Additionally, we are proposing to change the timeframe for delivery of the EOC in particular to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date. Allowing plans to provide the EOC electronically would alleviate plan burden related to printing and mailing, and simultaneously would reduce the number of paper documents that beneficiaries receive from plans. This would allow beneficiaries to focus on materials, like the Annual Notice of Change (ANOC), that drive decision making. Changing the date by which plans must provide the EOC to members would allow plans more time to finalize the formatting and ensure the accuracy of the information, as well as further distance it from the ANOC, which must still be delivered 15 days prior to the AEP. We see this proposed change as an overall reduction of impact that our regulations have on plans and beneficiaries. In aggregate, we estimate a savings (to plans for not producing

[1] CY 2018 Final Parts C&D Call Letter, April 3, 2017.

and mailing hard-copy EOCs) of approximately $51 million.

4. Preclusion List

a. Part D

This proposed rule would rescind the current provisions in § 423.120(c)(6) that require physicians and eligible professionals (as defined in section 1848(k)(3)(B) of the Act) to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional to be covered. As a replacement, we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the ''preclusion list,'' which would be defined in § 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. We recognize, however, the need to minimize interruptions to Part D beneficiaries' access to needed medications. Therefore, we also propose to prohibit plan sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber's inclusion on the preclusion list, unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis.

b. Part C

This proposed rule would rescind the current provisions in § 422.222 stating that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act must be enrolled in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. As a replacement, we propose that an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the ''preclusion list.'' The preclusion list, which would be defined in § 422.2, would consist of certain individuals and entities that are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program.

C. Summary of Costs and Benefits

Provision	Savings
Implementation of the Comprehensive Addiction and Recovery Act of 2016.	Besides the benefits of preventing opioid dependency in beneficiaries we estimate a net savings in 2019 of $13 million to the Trust Fund because of reduced scripts, modestly increasing to a savings of $14 million in 2023. The cost to industry is estimated at about $2.8 million per year.
Revisions to Timing and Method of Disclosure Requirements.	We estimate 67% of the current 47.8 million beneficiaries will prefer use of the internet vs. hard copies. This will result in savings of $55 million in 2019 and growing due to inflation to $67 million in 2023.

II. Provisions of the Proposed Regulations

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

a. Medicare Part D Drug Management Programs

The Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, amended the Social Security Act and includes new authority for the establishment of drug management programs in Medicare Part D, effective on or after January 1, 2019. In accordance with section 704(g)(3) of CARA and revised section 1860D–4(c) of the Act, CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at-risk for prescription drug abuse, or ''at-risk beneficiaries.'' Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are ''frequently abused drugs'' to a selected prescriber(s) and/or network pharmacy(ies). While such programs, commonly referred to as ''lock-in programs,'' have been a feature of many state Medicaid programs for some time, prior to the enactment of CARA, there was no statutory authority to allow Part D plan sponsors to require beneficiaries to obtain controlled substances from a certain pharmacy or prescriber in the Medicare Part D program.

In summary, this proposed rule would implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) (''current policy''). As explained in more detail later in this section, this integration would mean that Part D sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of opioids beginning 2019 through a point-of-sale (POS) claim edit and/or by requiring the beneficiary to obtain opioids from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that the beneficiary is taking a high-risk dose of opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and multiple pharmacies. This proposed rule would also implement a limitation on the use of the special enrollment period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries.

b. Stakeholder Input Informing This Notice of Proposed Rulemaking

Section 704(g)(2) of CARA required us to convene stakeholders to provide input on specific topics so that we could take such input into account in promulgating regulations governing Part D drug management programs. Stakeholders include Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled

substances), retail pharmacies, Part D plan sponsors and their delegated entities (such as pharmacy benefit managers), and biopharmaceutical manufacturers.

We hosted a Listening Session on the CARA drug management program provisions via a public conference call on November 14, 2016 that was announced in the October 26, 2016 **Federal Register** (81 FR 74388). We sought stakeholder input on specific topics enumerated in sections 704(a)(1) and 704(g)(2)(B) of the CARA and other related topics of concern to the stakeholders.

In developing this proposed rule, we considered the stakeholders' comments provided during the Listening Session, as well as written comments submitted afterward, including those submitted in response to the Request for Information associated with the publication of the Plan Year 2018 Medicare Parts C&D Final Call Letter. We refer to this input in this preamble using the terms ''stakeholders,'' ''commenters'' and ''comments.''

c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS

As noted in section II.A.1. of this proposed rule previously, we are proposing to implement the CARA Part D drug management program provisions by integrating them with our current policy that is not currently codified, but would be under this proposal. In using the term ''current policy'', we refer to the aspect of our current Part D opioid overutilization policy that is based on retrospective DUR.[2] Specifically, we are proposing a regulatory framework for Part D plan sponsors to voluntarily adopt drug management programs through which they address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/criteria that identify potential at-risk beneficiaries and conduct case management which incorporates clinical contact and prescriber verification that a beneficiary is an at-risk beneficiary. If deemed necessary, a sponsor could limit at-risk beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit. Finally, sponsors would report to CMS the status and results of their case management to OMS and any beneficiary coverage limitations they have implemented to MARx, CMS' system for payment and enrollment transactions. While plan sponsors would have the option to implement a drug management program, our proposal codifies a framework that would place requirements upon such programs. We foresee that all plan sponsors will implement such drug management programs based on our experience that all plan sponsors' are complying with the current policy as laid out in guidance, the fact that our proposal largely incorporates the CARA drug management provisions into existing CMS and sponsor operations, and especially, in light of the national opioid epidemic and the declaration that the opioid crisis is a nationwide Public Health Emergency.

Because we propose to integrate the CARA Part D drug management program provisions with the current policy and codify them both, we describe the current policy in section II.A.1.c.(1) of this proposed rule, noting where our proposal incorporates changes to the current policy in order to comply with CARA and achieve operational consistency. Where we do not note a change, our intent is to codify the current policy, and we seek specific comment as to whether we have overlooked any feature of the current policy that should be codified. CMS communications regarding the current policy can be found at the CMS Web site, ''Improving Drug Utilization Review Controls in Part D'' at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html*.

Then we set forth our proposal for codification of the regulatory framework for drug management programs in section II.A.1.c.(2) of this proposed rule, which includes provisions specific to lock-in, which is not a feature of the current policy.

(1) Current Part D Opioid DUR Policy and OMS

CMS is actively engaged in addressing the opioid epidemic and committed to implementing effective tools in Medicare Part D. We will work across all stakeholder, beneficiary and advocacy groups, health plans, and other federal partners to help address this devastating epidemic. CMS has worked with plan sponsors and other stakeholders to implement Medicare Part D opioid overutilization policies with multiple initiatives to address opioid overutilization in Medicare Part D through a medication safety approach. These initiatives include better formulary and utilization management; real-time safety alerts at the pharmacy aimed at coordinated care; retrospective identification of high risk opioid overutilizers who may need case management; and regular actionable patient safety reports based on quality metrics to sponsors.

The goal of the current policy and OMS is to reduce opioid overutilization in Part D. In conjunction with related Part D opioid overutilization policies that address prospective opioid use, the current policy has played a key role in reducing high risk opioid overutilization in the Part D program by 61 percent (representing over 17,800 beneficiaries) from 2011 (pre-policy pilot) through 2016, even as the number of beneficiaries enrolled in Part D increased overall during this period from 31.5 million to 43.6 million enrollees, or a 38 percent increase.[3]

The purpose of the current policy is to provide Part D plan sponsors with specific guidance about compliance with § 423.153(b)(2) as to opioid overutilization, which requires a Part D plan sponsor to have a reasonable and appropriate drug utilization management program that maintains policies and systems to assist in preventing overutilization of prescribed medications. We adopted the current policy on January 1, 2013, and it has evolved over time in scope in several ways with stakeholder feedback and support, including through the addition of the OMS in July 2013, primarily via the annual Parts C&D Call Letter process.

The current policy has two aspects. First, in the CY 2013 final Call Letter and subsequent supplemental guidance, we provided guidance about our expectations for Part D plan sponsors to retrospectively identify beneficiaries who are at high risk for potential opioid overutilization and provide appropriate case management aimed at coordinated care.[4] More specifically, we currently expect Part D plan sponsors' Pharmacy and Therapeutics (P&T) committees to establish criteria consistent with CMS guidance to retrospectively identify potential opioid overutilizers at high risk for an adverse event enrolled in their plans who may warrant case management because they are receiving opioid prescriptions from multiple prescribers and pharmacies. Enrollees

[2] Please refer to the CMS Web site, ''Improving Drug Utilization Review Controls in Part D'' at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html* which contains CMS communications regarding the current policy.

[3] Final CY 2018 Parts C&D Call Letter, April 3, 2017.

[4] An excerpt from the Final 2013 Call Letter, the supplemental guidance, and additional information about the policy and OMS are available on the CMS Web page, ''Improving Drug Utilization Controls in Part D'' at *https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html*.

with cancer or in hospice are excluded from the current policy, because the benefit of their high opioid use may outweigh the risk associated with such use. This exclusion was supported by stakeholder feedback on the current policy.

Once such enrollees are identified through retrospective prescription drug claims review, we expect the Part D plan sponsors to diligently assess each case, and if warranted, have their clinical staff conduct case management with the beneficiary's opioid prescribers until the case is resolved. According to the supplemental guidance,[5] case management entails:

- The personnel communicating with prescribers have appropriate credentials.
- Written inquiries to the prescribers of the opioid medications about the appropriateness, medical necessity and safety of the apparent high dosage for their patient.
- Attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period from the issuance of the written inquiry notification, if necessary.
- The clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits the information necessary to identify any complicating factors in the beneficiary's treatment that are relevant to the case management effort.
- After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-specific opioid POS claim edit, as deemed appropriate by the prescribers, to prevent further Part D coverage of an unsafe level of drug.
- In cases of non-responsive prescribers, the sponsor may also implement a beneficiary-specific opioid POS claim edit to prevent further coverage of an unsafe level of drug and to encourage the prescribers to participate in case management.

Thus, we expect case management to confirm that the beneficiary's opioid use is medically necessary or resolve an overutilization issue.

As part of the current policy, and because the Food and Drug Administration (FDA)-approved labeling for opioids generally does not include maximum daily doses, CMS developed specific criteria to identify beneficiaries at high risk through retrospective review of their opioid use in order to assist Part D sponsors in identifying such beneficiaries. These criteria incorporate a morphine milligram equivalent (MME)[6] approach, which is a method to uniformly calculate the total daily dosage of opioids across all of a patient's opioid prescription drug claims. Beginning with plan year 2018, we adjusted these criteria to align with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline)[7] issued in March 2016 in terms of using 90 MME as a threshold to identify beneficiaries who appear to be at high risk due to their opioid use. In its guideline, after considering information from relevant studies and experts, the CDC identifies 50 MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Our criteria, which we will discuss more fully later in the preamble, also incorporate a multiple prescriber and pharmacy count to focus on beneficiaries who appear to be not only overutilizing opioids but who also are at increased risk due to potential coordination of care issues, such that the providers who are prescribing or dispensing opioids to these beneficiaries may not know that other providers are also doing so.

The second aspect of the current policy came into place in July 2013, when CMS launched the OMS as a tool to monitor Part D plan sponsors' effectiveness in complying with § 423.153(b)(2) to address opioid overutilization. Through the OMS, CMS sends sponsors quarterly reports about their Part D enrollees who meet the criteria for being at high risk of opioid overutilization. Then, we expect sponsors to address each case through the case management process previously described and respond to CMS through the OMS using standardized responses. In addition, we expect sponsors to provide information to their regional CMS representatives and the MARx system about beneficiary-specific opioid POS claim edits that they intend to or have implemented.[8]

Because case management is very resource intensive for sponsors and PBMs, we have limited the scope of the current policy in terms of the number of beneficiaries identified by OMS, and when expanding that number, we have made changes incrementally through annual Parts C&D Call Letter process.

(2) Proposed Requirements for Part D Drug Management Programs (§§ 423.100 and 423.153)

We first propose several definitions for terms we propose to use in establishing requirements for Part D drug management programs.

(i) Definitions (§ 423.100)

(A) Definition of ''Potential At-Risk Beneficiary'' and ''At-Risk Beneficiary'' (§ 423.100)

Section 1860D–4(c)(5)(C) of the Act contains a definition for ''at-risk beneficiary'' that we propose to codify at § 423.100. In addition, although the section 1860D–4(c)(5) of the Act does not explicitly define a ''potential at-risk beneficiary,'' it contemplates a beneficiary who is potentially at-risk. Accordingly, we propose to define these two terms at § 423.100 as follows: Potential at-risk beneficiary means a Part D eligible individual—(1) Who is identified using clinical guidelines (as defined in § 423.100); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. At-risk beneficiary means a Part D eligible individual—(1) who is—(i) Identified using clinical guidelines (as defined in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most

[5] September 6, 2012 HPMS memo, ''Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D.''

[6] Please note that CMS will use the term ''MME'' going forward instead of morphine equivalent dose (MED), which CMS has used to date. CMS used the term MED in a manner that was equivalent to MME. We will update CMS documents that currently refer to MED as soon as practicable.

[7] Please see *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[8] Please refer to the CMS Web site, ''Improving Drug Utilization Review Controls in Part D'' at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html* which contains CMS communications regarding the current policy.

recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. The distinction between a ''potential at-risk beneficiary'' and an ''at-risk beneficiary'' is important for a few reasons that we will explain later in this preamble. Also, we added the phrase, ''and the new plan has adopted the identification'' to both definitions for cases where a beneficiary has been identified as a potential at-risk or at-risk beneficiary by the immediately prior plan to indicate that the beneficiary's status in the subsequent plan is not automatic.

(B) Definition of ''Frequently Abused Drug'', ''Clinical Guidelines'', ''Program Size'', and ''Exempted Beneficiary'' (§ 423.100)

Because we use these terms in the proposed definitions of ''potential at-risk beneficiary'' and ''at-risk beneficiary,'' we propose to define ''frequently abused drug,'' ''clinical guidelines'', ''program size'', and ''exempted beneficiary'' at § 423.100 as follows:

- Frequently Abused Drug

Section 1860D–4(c)(5)(G) of the Act defines ''frequently abused drug'' as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted. Consistent with the statutory definition, we propose to define ''Frequently abused drug'' at § 423.100 to mean a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account the following factors: (1) The drug's schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused; and (3) An analysis of Medicare or other drug utilization or scientific data. This definition is intended to provide enough specificity for stakeholders to know how the Secretary will determine a frequently abused drug, while preserving flexibility to update which drugs CMS considers to be frequently abused drugs based on relevant factors, such as actions by the Drug Enforcement Administration and/or trends observed in Medicare or scientific data.

We plan to publish and update a list of frequently abused drugs for purposes of Part D drug management programs. We propose that future designations of frequently abused drugs by the Secretary primarily be included in the annual Parts C&D Call Letter or in similar guidance, which would be subject to public comment, if necessary to address midyear entries to the drug market or evolving government or professional guidelines. This approach would be consistent with our approach under the current policy and necessary for Part D drug management programs to be responsive to changing public health issues over time.

While this is the approach we propose for future designations of frequently abused drugs, we are including a discussion of the designation for plan year 2019 in this preamble. For plan year 2019, consistent with current policy, we propose that opioids are frequently abused drugs. Our proposal to designate opioids as frequently abused drugs illustrates how the proposed definition could work in practice:

First, the Secretary determines opioids are frequently abused or diverted, because they are controlled substances, and drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are so considered precisely because they have abuse potential. The Drug Enforcement Administration (DEA) divides controlled substances into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. Most prescription opioids are Schedule II, where the DEA places substances with a high potential for abuse with use potentially leading to severe psychological or physical dependence.[9] A few opioids are Schedule III or IV, where the DEA places substances that have a potential for abuse.

Second, on October 26, 2017, the President directed that executive agencies use all appropriate emergency authorities and other relevant authorities to address drug addiction and opioid abuse, and the Acting Secretary of Health and Human Services declared a nationwide Public Health Emergency to address the opioid crisis.[10] In addition, the CDC has declared opioid overuse a national epidemic, both of which are relevant factors.[11] More than 33,000 people died from opioid overuse in 2015, which is the highest number per year on record. From 2000 to 2015, more than half a million people died from drug overdoses, and 91 Americans die every day from an opioid overdose. Nearly half of all opioid overdose deaths involve a prescription opioid. Given that opioids, including prescription opioids, are the main driver of drug overdose deaths in the U.S., it is reasonable for the Secretary to conclude that opioids are frequently abused and misused.

Third, government or professional guidelines support determining that opioids are frequently abused or misused. Consistent with current policy, we propose to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. The CDC MME Conversion Factor file[12] does not include all formulations of buprenorphine for MAT so that access is not limited, and injectables are not included due to low claim volume. Therefore, CMS cannot determine the MME. CMS will consider revisions to the CDC MME Conversion Factor file when updating the list of opioids designated as frequently abused drugs in future guidance.

Fourth, an analysis of Medicare data supports designating opioids as ''frequently abused drugs,'' at least initially. Over 727,000 Part D beneficiaries had an average MME of at least 90 mg during the 6-month period from July 1, 2015 to December 31, 2015 (''90 mg MME + users''), a number which excludes beneficiaries with cancer or in hospice, whom we propose to exempt from drug management programs, as we discuss later. As noted earlier, the CDC recommends prescribers generally avoid increasing the daily opioid dosage to 90 MME. Given that so many beneficiaries have an average MME above this threshold, it is reasonable that the Secretary consider this data to be a relevant factor in determining that opioids are frequently abused or diverted.

Most stakeholders recommended designating opioids as frequently abused drugs. In this regard, we note

[9] The abuse rate is a determinate factor in the DEA's scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes— Schedule II, Schedule III, etc., so does the abuse potential— Schedule V drugs represents the least potential for abuse. See DEA Web site about Drug Scheduling: *https://www.dea.gov/druginfo/ds.shtml.*

[10] See White House Web site *https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive-departments-and-agencies, and* the HHS Web site *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[11] See CDC Web site *https://www.cdc.gov/drugoverdose/index.html for all statistics in this paragraph.*

[12] See *https://www.cdc.gov/drugoverdose/resources/data.html.*

that our current policy applies only to opioids and that we are integrating the drug management provisions of CARA with our current policy. Therefore, designating opioids as frequently abused drugs, at least in the initial implementation of drug management programs, would have the added benefit of allowing CMS and stakeholders to gain experience with the use of lock-in in the Part D program, before potentially designating other controlled substances as frequently abused drugs.

Some commenters expressed support for including other or all controlled substances, such as benzodiazepines, sedatives, and certain muscle relaxants as frequently abused drugs; however, we are not persuaded. Opioids are unique in that there is generally no maximum dose for them in the FDA labeling. Also, in the proposed Contract Year 2016 Parts C&D Call Letter, we solicited feedback on expanding the current policy to other drugs, and the comments were mixed. A few commenters suggested that we expand the current policy to benzodiazepines and muscle relaxants when used with opioids. In respond to the feedback, we did not expand the current policy beyond the opioid class but indicated that we would investigate. Subsequently, the CDC Guideline was published and it specifically recommends that clinicians avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible due to increased risk for overdose. Therefore, we added a concurrent benzodiazepine-opioid flag to OMS in October 2016 to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management, and we will continue to do so.[13]

Other than conveying the concurrent benzodiazepine use information to sponsors, we have not expanded the current policy to address non-opioid medications. However, we have stated that if a sponsor chooses to implement the current policy for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications.[14] We have taken this approach to the current policy so that we could focus on the opioid epidemic and also due to the difficulty in establishing overuse guidelines for non-opioid controlled substances. For this reason our proposal would not identify benzodiazepines as frequently abused drugs. However, we solicit additional comment on our proposed approach to frequently abused drugs. Also, we propose that, if finalized, this rule would supersede our current policy, and sponsors would no longer be allowed to implement the current policy for non-opioid medications. We seek feedback on allowing sponsors to continue to implement the current policy for non-opioid medications with respect to beneficiary-specific claim edits.

- Clinical Guidelines and Program Size

Section 1860D–4(c)(5)(C)(i)(I) of the Act requires at-risk beneficiaries to be identified using clinical guidelines that indicate misuse or abuse of frequently abused drugs and that are developed in consultation with stakeholders. We propose to include a definition of ''clinical guidelines'' that cross references standards that we are proposing at § 423.153(f) for how the guidelines would be established and updated. Specifically, we propose to define clinical guidelines for purposes of a Part D drug management program as criteria to identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs, and that are developed in accordance with the proposed standards in § 423.153(f)(16) and published in guidance annually.

We also propose to add § 423.153(f)(16) to state that potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that: (1) Are developed with stakeholder consultation; (2) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) Are derived from expert opinion and an analysis of Medicare data; and (4) Include a program size estimate. This proposed approach to developing and updating the clinical guidelines is intended to provide enough specificity for stakeholders to know how CMS would determine the guidelines by identifying the standards we would apply in determining them.

This proposed approach indicates that the program size would be determined as part of the process to develop the clinical guidelines—a process into which stakeholders would provide input. Section 1860D–4(c)(5)(C)(iii) of the Act states that the Secretary shall establish policies, including the guidelines and exemptions, to ensure that the population of enrollees in drug management programs could be effectively managed by plans. We propose to define ''program size'' in § 423.100 to mean the estimated population of potential at-risk beneficiaries in drug management programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

This proposed approach to developing and updating the clinical guidelines would also be flexible enough to allow for updates to the guidelines outside of the regulatory process to address trends in Medicare with respect to the misuse and/or diversion of frequently abused drugs. We have determined this approach is appropriate to enable CMS to assist Part D drug management programs in being responsive to public health issues over time. This approach would also be consistent with how the OMS criteria have been established over time through the annual Medicare Parts C&D Call Letter process, which we plan to continue except for 2019.

For plan year 2019, we propose the clinical guidelines in this preamble to be the OMS criteria established for plan year 2018, which meet the proposed standards for the clinical guidelines for the following reasons: First, as described earlier, the OMS criteria incorporate a 90 MME threshold cited in a CDC Guideline, which was developed by experts as the level that prescribers should avoid reaching with their patients. This threshold does not function as a prescribing limit for the Part D program; rather, it identifies potentially risky and dangerous levels of opioid prescribing in terms of misuse or abuse. Second, the OMS criteria also incorporate a multiple prescriber and pharmacy count. A high MED level combined with multiple prescribers and/or pharmacies may also indicate the abuse or misuse of opioids due to the possible lack of care coordination among the providers for the patient. Third, the OMS criteria have been revised over time based on analysis of Medicare data and with stakeholder input via the annual Parts C&D Call Letter process. Indeed, many stakeholders recommended the use of the CDC Guideline as part of the clinical guidelines the Secretary must develop, with some noting that they would need to be used in a way that accounts for use of multiple providers, which the OMS criteria do. Fourth, these criteria are familiar to Part D sponsors—they will already have experience with them by

[13] Please refer to the memo, ''Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid-Benzodiazepine Use Flag'' dated October 21, 2016.

[14] See ''Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,'' dated September 6, 2012.

2019, and they were established with an estimate of program size.

Several stakeholders in their comments referred to various criteria used in state Medicaid lock-in programs to identify beneficiaries appropriate for lock-in, without suggesting that any particular ones be adopted. Other commenters suggested CMS consider other guidelines, such as the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use and the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline on Opioid Therapy for Chronic Pain. However, these guidelines are similar to or moving toward an MME methodology which we currently use or address a more narrow population than persons who may be abusing or misusing frequently abused drugs, and they do not directly address situations involving multiple opioid providers. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain is similar to the scope of the CDC Guideline. The ASAM Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use was developed specifically for the evaluation and treatment of opioid use disorder and for the management of opioid overdose, which would not be applicable here because it serves a different purpose. Therefore, we do not see a reason to adopt these guidelines instead of the 2018 OMS criteria.

The clinical guidelines for use in drug management programs we are proposing for 2019 are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies *OR* 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. We note that we have described alternative clinical guidelines that we considered in the Regulatory Impact Analysis section of this rule. Stakeholders are invited to comment on those alternatives and any others which would involve identifying more or fewer potential at-risk beneficiaries.

We propose that under the proposed clinical guidelines, prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber. This is consistent with the current policy under which we have found that such prescribers are typically in the same group practice that is coordinating the care of the patients served by it. Thus, it is appropriate to count such prescribers as one, so as not to identify beneficiaries who are not at-risk.

In this regard, in applying the OMS criteria, CMS counts prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. For example, under the criteria we have proposed, a beneficiary who meets the 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 3 independent opioid prescribers (1 group practice + 3 prescribers = 4 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies, would still meet the criteria, which is appropriate. However, a beneficiary who meets that 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 1 independent opioid prescriber (1 group practice + 1 prescriber = 2 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies would not meet the criteria, which is also appropriate at this time given program size concerns.

Section 1860D–4(c)(5)(D) of the Act specifies that for purposes of limiting access to coverage of frequently abused drugs to those obtained from a selected pharmacy, if the pharmacy has multiple locations that share real-time electronic data, all such locations of the pharmacy collectively are treated as one pharmacy. Given this provision, as well as our proposal to treat multiple prescribers from the same group practice as one prescriber under the clinical guidelines, we propose that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.

Because not all Part D plans' data systems may be able to account for group practice prescribers as we described above, or chain pharmacies through data analysis alone, or may not be able to fully account for them, we request information on sponsors' systems capabilities in this regard. Also, if a plan sponsor does not have the systems capability to automatically determine when a prescriber is part of a group or a pharmacy is part of a chain, the plan sponsor would have to make these determinations during case management, as they do with respect to group practices under the current policy. If through such case management, the Part D plan finds that the multiple prescribers who prescribed frequently abused drugs for the beneficiary are members of the same group practice, the Part D plan would treat those prescribers as one prescriber for purposes of identification of the beneficiary as a potential at-risk beneficiary. Similarly, if through such case management, the Part D plan finds that multiple locations of a pharmacy used by the beneficiary share real-time electronic data, the Part D plan would treat those locations as one pharmacy for purposes of identification of the beneficiary as a potential at-risk beneficiary. Both of these scenarios may result in a Part D sponsor no longer conducting case management for a beneficiary because the beneficiary does not meet the clinical guidelines. We also note that group practices and chain pharmacies are important to consider for purposes of the selection of a prescriber(s) and pharmacy(ies) in cases when a Part D plan limits a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s), which we discuss in more detail later in this preamble.

Under the current policy, sponsors must use 90 MME as a ''floor'' for their own criteria to identify beneficiaries who may be overutilizing opioids, but they may vary the prescriber and pharmacy count. This means sponsors may review beneficiaries who do not meet the OMS criteria but meet the sponsors' internal criteria for review, or they may not review beneficiaries who meet the OMS criteria but do not meet the sponsors' internal criteria for review. However, under our proposal to adopt the 2018 OMS criteria as the 2019 clinical guidelines for Part D drug management programs, we also propose to mostly eliminate this feature of the current policy. Under our proposal, Part D plan sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except that we propose to continue to permit plan sponsors to apply the criteria more frequently than CMS would apply them through OMS in 2018, which can result in sponsors identifying beneficiaries earlier. This is because CMS evaluates enrollees quarterly using a 6-month look back period, whereas sponsors may evaluate enrollees more frequently (for example, monthly).

While several commenters stated that Part D plan sponsors should have flexibility in developing their own criteria for identifying at-risk beneficiaries in their plans, a more conservative and uniform approach is warranted for the initial implementation of Part D drug management programs. While we already have experience with how frequently Part D plan sponsors use beneficiary-specific opioid POS claim edits to prevent opioid overutilization, we wish to learn how sponsors will use

lock-in as a tool to address this issue before adopting clinical guidelines that might include parameters for permissible variations of the criteria. We plan to monitor compliance of drug management programs as we monitor compliance with the current policy through various CMS data sources, such as OMS, MARx, beneficiary complaints and appeals.

Also, we note that despite sponsors' additional identification of some beneficiaries currently, in practice, we have found that CMS identifies the vast majority of beneficiaries who are reviewed by Part D sponsors through OMS. CMS identifies over 80 percent of the cases reviewed through OMS, and about 20 percent are identified by sponsors based on their internal criteria. We understand that most of the beneficiaries representing the 20 percent were reported to OMS due to the sponsors averaging the MME calculations across all opioid prescriptions, which has subsequently been changed in the 2018 OMS criteria. The 2018 OMS criteria also have a lower MME threshold and account for additional beneficiaries who receive their opioids from many prescribers regardless of the number of pharmacies, which will result in the identification of more beneficiaries through OMS. Thus, our proposal would not substantially change the current practice.

Furthermore, in approximately 39 percent of current OMS cases, sponsors respond that the case does not meet the sponsor's internal criteria for review.[15] We found that the original OMS criteria generated false positives that some sponsors' internal criteria did not because these sponsors used a shorter look back period or were able to group prescribers within the same practice or chain pharmacies. These best practices have also been incorporated into the revised 2018 OMS criteria, which are the basis of the proposed 2019 clinical guidelines. Thus, while our proposal will prevent sponsors from voluntarily reviewing more potential at-risk beneficiaries than CMS identifies through OMS, it will likely require sponsors to review more beneficiaries than they currently do.

Table 1 shows that in 2015 approximately 33,000 beneficiaries would have met the proposed 2019 clinical guidelines, which is approximately 0.08 percent of the 42 million beneficiaries enrolled in Part D in 2015. We think this population would constitute a manageable program size because this is the estimated OMS population we finalized during the Plan Year 2018 Parts C&D Call Letter process. Moreover, we have no evidence to suggest that this program size will be problematic for sponsors.

In addition, current Medicaid lock-in programs support the notion that this program size would be manageable by Part D plan sponsors. In 2015, an average 0.37 percent of Medicaid recipients were locked-in and the percentage of recipient's locked-in by state programs ranged from 0.01 percent to 1.8 percent.[16]

To derive this estimated population of potential at-risk beneficiaries, we analyzed prescription drug event data (PDE) from 2015,[17] using the CDC opioid drug list and MME conversion factors, and applying the criteria we proposed earlier as the clinical guidelines. This estimate is over-inclusive because we did not exclude beneficiaries in long-term care (LTC) facilities who would be exempted from drug management programs, as we discuss later in this section. However, based on similar analyses we have conducted, this exclusion would not result in a noteworthy reduction to our estimate. Also, we were unable to count all locations of a pharmacy that has multiple locations that share real-time electronic data as one, which is a topic we discussed earlier and will return to later. Thus, there likely are beneficiaries counted in our estimate who would not be identified as potential at-risk beneficiaries because they are in an LTC facility or only use multiple locations of a retail chain pharmacy that share real-time electronic data.

TABLE 1—CLINICAL GUIDELINES OR IDENTIFYING POTENTIAL AT-RISK BENEFICIARIES

Criteria applied	Impact to Part D program
≥90 mg MED and either:	33,053 beneficiaries in 2015 (76.3% were LIS).
4+ opioid prescribers *AND* 4+ opioid dispensing pharmacies	Represents 0.08% of 41,835,016 Part D beneficiaries in 2015.
OR	LTC beneficiaries included in estimate but are exempt.
6+ opioid prescribers (regardless of the number of opioid dispensing pharmacies).	Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

We note that the alternatives for clinical guidelines that we considered, which are described in the Regulatory Impact Analysis (RIA) section of this rule, also include estimated population of potential at-risk beneficiaries for each alternative. Most of the options include a 90 MME threshold with varying prescriber and pharmacy counts and range from identifying 33,053 to 319,133 beneficiaries. Again, stakeholders are invited to comment on these alternatives. We are particularly interested in receiving comments on whether CMS should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified, and if more are identified, whether the additional number would result in a manageable program size for plan sponsors (or too few beneficiaries to be meaningful).

- Exempted Beneficiary

Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents

[15] We noted in the final CY Parts C&D Call Letter, for the January 2014 OMS reports, 67 percent of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria. We explained the reasons for this figure and the actions we took to reduce it.

[16] Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug-Fee-For-Service Programs (December 2016), pg. 26.

[17] Unique count of beneficiaries who met the criteria in any 6 month measurement period (January 2015–June 2015; April 2015–September 2015; or July 2015–December 2015).

through a contract with a single pharmacy; or (3) Has a cancer diagnosis.

While the first two exceptions are required under CARA, we propose to exercise the authority in section 1860D–4(c)(5)(C)(ii)(III) of the Act to treat a beneficiary who has a cancer diagnosis as an exempted individual for two reasons. First, many commenters recommended that the Secretary exempt beneficiaries who have a cancer diagnosis, because a Part D drug management program should not be able to interfere administratively with their pain control regimen in the form of additional notices from their prescription drug benefit plans and limitations on their access to coverage for frequently abused drugs. We agree with these commenters. Second, exempting beneficiaries with a cancer diagnosis would be consistent with current policy. Under the current policy, which has been developed through stakeholder feedback, beneficiaries with cancer are excluded because the benefit of their opioid use may outweigh the risk associated with their opioid use. Also, as noted previously, some commenters requested that implementation of the drug management program provisions of CARA be as consistent as possible with the current policy for operational ease. We also agree with these commenters.

Some commenters recommended against exempting beneficiaries with cancer diagnoses, stating that there is no standard clinical reason why a beneficiary with cancer should be receiving opioids from multiple prescribers and/or multiple pharmacies, and that such situations warrant further review. While we understand the concern of these commenters, we maintain that beneficiaries who have a cancer diagnosis should be exempted for the reasons stated just above. Moreover, our experience with this exemption under the current policy suggests that the exemption is workable and appropriate. We understand beneficiaries with cancer diagnoses are identifiable by Part D plan sponsors either through recorded diagnoses, their drug regimens or case management, and no major concerns have been expressed about this exemption under our current policy, including from standalone Part D plan sponsors who may not have access to their enrollees' medical records.

A few commenters suggested exempting beneficiaries who are receiving palliative and end-of-life care, since not all patients receiving this type of care are necessarily enrolled in hospice or reside in an LTC facility. Two commenters suggested exempting beneficiaries in assisted living. Other commenters suggested exempting beneficiaries in various other health care facilities, such as group homes and adult day care centers, where medication is supervised. Other commenters suggested exempting beneficiaries with debilitating disorders or receiving medication-assisted treatment for substance abuse disorders.

We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale. First, we have not exempted these other beneficiaries under the current policy, and we thus do not think it is necessary to exempt them from drug management programs. Second, unlike with cancer diagnoses, we are not able to determine administratively through CMS data who these beneficiaries are to exempt them from OMS reporting. Consequently, it could be burdensome for Part D sponsors to attempt to exempt these beneficiaries, by definition, from their drug management programs. Third, it is important to remember that the proposed clinical guidelines would only identify potential at-risk beneficiaries in the Part D program who are receiving potentially unsafe doses of opioids from multiple prescribers and/or multiple pharmacies who typically do not know about each other in terms of providing services to the beneficiary. Thus, it is likely that a plan would discover during case management that a potential at-risk beneficiary is receiving palliative and end-of-life care during case management. Absent a compelling reason, we would expect the plan not to seek to implement a limit on such beneficiary's access to coverage of opioids under the current policy nor a drug management program, as it would seem to outweigh the medication risk in such circumstances. Moreover, in cases where a prescriber is cooperating with case management, we would not expect the prescriber to agree to such a limitation, again, absent a compelling reason. With respect to beneficiaries receiving medication-assisted treatment for substance abuse for opioid use disorder, we decline to propose to treat these individuals as exempted individuals. It is these beneficiaries who are among the most likely to benefit from a drug management program.

(ii) Requirements of Drug Management Programs (§§ 423.153, 423.153(f))

As noted previously, we are proposing to codify a regulatory framework under which Part D plan sponsors may adopt drug management programs to address overutilization of frequently abused drugs. Therefore, we propose to amend § 423.153(a) by adding this sentence at the end: ''A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section,'' in accordance with our authority under revised section 1860D–4(c)(5)(A) of the Act.

We also propose to revise § 423.153 by adding a new paragraph (f) about drug management programs for which the introductory sentence would read: ''(f) Drug Management Programs. A drug management program must meet all the following requirements.'' Thus, the requirements that a Part D plan sponsor must meet to operate a drug management program would be codified in various provisions under subsection § 423.153(f).

(iii) Written Policies and Procedures (§ 423.153(f)(1))

We propose to require Part D sponsors document their programs in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate, which is consistent with the current policy. Also consistent with the current policy, we would require these policies and procedures to address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. We additionally propose to require sponsors to monitor information about incoming enrollees who would meet the definition of a potential at-risk and an at-risk beneficiary in proposed § 423.100 and respond to requests from other sponsors for information about potential at-risk and at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. We discuss potential at-risk and at-risk beneficiaries who are identified as such in their most recent Part D plan later in this preamble.

To codify these requirements, we propose that section § 423.153(f)(1) read as follows: (1) Written policies and procedures. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. The policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following: (i) The appropriate credentials of the personnel conducting case management required under

paragraph (f)(2); (ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2); and (iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in § 423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. Thus, Part D sponsors would have flexibility—as they do today under the current policy—to adopt specific policies and procedures for their drug management programs, as long as they are consistent with the requirements of § 423.153, as finalized.

(iv) Case Management/Clinical Contact/Prescriber Verification (§ 423.153(f)(2))

As discussed earlier, case management is a key feature of the current policy, under which we currently expect Part D plan sponsors' clinical staff to diligently engage in case management with the relevant opioid prescribers to coordinate care with respect to each beneficiary reported by OMS until the case is resolved (unless the beneficiary does not meet the sponsor's internal criteria). We propose that the second requirement for drug management programs in a new § 423.153(f)(2) reflect the current policy with some adjustment to the current policy to require all beneficiaries reported by OMS to be reviewed by sponsors.

Our proposal for a new § 423.153(f)(2) also meets the requirements of section 1860D–4I(5)(C) of the Act. This section of the Act requires that, with respect to each at-risk beneficiary, the sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions. Further, our proposal meets the requirements of Section 1860D–4(c)(5)(B)(i)(II) of the Act, which requires that a Part D sponsor first verify with the beneficiary's providers that the beneficiary is an at-risk beneficiary, if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs.

Specifically, we propose that a new § 423.153(f)(2) read as follows: Case Management/Clinical Contact/Prescriber Verification. (i) General Rule. The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Proposed § 423.153(f)(2)(i) would further state that, except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following: (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and (C) In cases where the prescribers have not responded to the inquiry described in (i)(B), make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.

Given the ''Except as provided in paragraph (f)(2)(ii) of this section'', we propose to add paragraph (ii) to § 423.153(f)(2) that would read: (ii) Exception for identification by prior plan. If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan, and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date. This proposal is to avoid unnecessary burden on health care providers when additional case management outreach is not necessary. This is consistent with the current policy under which sponsors are expected to enter information into MARx about pending, implemented and terminated beneficiary-specific POS claim edits, which is transferred to the next sponsor, if applicable. Pending and implemented POS claim edits are actions that sponsors enter into MARx after case management. We discuss potential at-risk and at-risk beneficiaries who change plans again later in this preamble.

The information that the plan sends to the prescribers and elicits from them is intended to assist a Part D sponsor to understand why the beneficiary meets the clinical guidelines and if a plan intervention is warranted for the safety of the beneficiary. Also, sponsors use this information to choose standardized responses in OMS and provide information to MARx about plan interventions that were referenced earlier. We will address required reporting to OMS and MARx by sponsors again later.

We note that, currently, OMS standardized responses generally fall into four categories: First, in approximately 18 percent of cases, the enrollee's opioid use is medically necessary. Second, approximately 38 percent of cases are resolved without a beneficiary-specific POS opioid claim edit, for example, when the sponsor takes a ''wait and see'' approach to observe if the prescribers adjust their management of, and the opioid prescriptions they are writing for, their patient due to the written information they received from the sponsor about their patient. Third, a small subset of cases—on average 1.3 percent—need a beneficiary-specific opioid POS claim edit to resolve the beneficiary's opioid overutilization issue. From 2013 through of July 4, 2017, CMS received 4,617 contract-beneficiary-level opioid POS claim edit notifications through MARx for 3,961 unique beneficiaries. Fourth, as previously mentioned, approximately 39 percent of cases do not meet the sponsor's internal criteria for review. We expect adjustment to these percentages under our proposal, particularly since we anticipate that plans will no longer be able to respond that a case does not meet its internal criteria for review. In addition, the revised 2018 OMS criteria which are the basis of the proposed 2019 clinical guidelines should reduce ''false positives'' which may have been reported through OMS but not identified through sponsors' internal criteria due to a shorter look back period and ability to group prescribers within the same practice.

We also note that under the current policy, sponsors are expected to make ''at least three (3) attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period (for example, a 10 business day period) from the issuance of the written inquiry notification.'' If the prescribers are unresponsive to case management, under our current policy, a sponsor may also implement a beneficiary-specific POS claim edit for opioids as a last resort to encourage prescriber engagement with case management.

By contrast, our proposed § 423.153(f)(2) uses the terms ''reasonable attempts'' and ''reasonable period'' rather than a specific number of attempts or a specific timeframe for plan to call prescribers. The reason for this proposed adjustment to our policy is because our current policy also states that ''[s]ponsors are not required to

automatically contact prescribers telephonically,'' but those that ''employ a wait-and-see approach'' should understand that ''we expect sponsors to address the most egregious cases of opioid overutilization without unreasonable delay, and that we do not believe that all such cases can be addressed through a prescriber letter campaign.'' Our guidance further states that, ''to the extent that some cases can be addressed through written communication to prescribers only, we would acknowledge the benefit of not aggravating prescribers with unnecessary telephonic communications.'' Finally, our guidance states that, ''[s]ponsors must determine for themselves the usefulness of attempting to call or contact all opioid prescribers when there are many, particularly when they are emergency room physicians.'' [18]

Given the competing priorities of sponsors' diligently addressing opioid overutilization in the Part D program through case management, which may necessitate telephone calls to the prescribers, while being cognizant of the need to be judicious in contacting prescribers telephonically in order to not unnecessarily disrupt their practices, we wish to leave flexibility in the regulation text for sponsors to balance these priorities on a case-by-case basis in their drug management programs, particularly since this flexibility exists under the current policy. We note however, that we propose a 3 attempts/10 business days requirement for sponsors to conclude that a prescriber is unresponsive to case management in § 423.153(f)(4) discussed later in this section.

(v) Limitations on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(3))

As described earlier, under the current policy, Part D sponsors may implement a beneficiary-specific opioid POS claim edit to prevent continued overutilization of opioids, with prescriber agreement or in the case of an unresponsive prescriber during case management. If a sponsor implements a POS claim edit, the sponsor thereafter does not cover opioids for the beneficiary in excess of the edit, absent a subsequent determination, including a successful appeal.

As noted earlier, revised section 1860D–4(c)(5)(A) of the Act provides additional tools commonly known as ''lock-in'', for Part D plans to limit an at-risk beneficiary's access to coverage for frequently abused drugs. Prescriber lock-in would limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers, and pharmacy lock-in would restrict an at-risk beneficiary's access to coverage for frequently abused drugs to those that are dispensed to the beneficiary by one or more network pharmacies.

If the sponsor uses a lock-in tool(s), the sponsor must generally cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), as applicable, absent a subsequent determination, including a successful appeal. Pursuant to section 1860D–4(c)(5)(D)(i)(II) of the Act, a sponsor would also have to cover frequently abused drugs from a non-selected pharmacy or prescriber, if such coverage were necessary in order to provide reasonable access. We discuss selection of pharmacies and prescribers and reasonable access later.

We propose to describe all the tools that would be available to sponsors to limit an at-risk beneficiary's access to coverage for frequently abused drugs through a drug management program in § 423.153(f)(3) as follows: Limitation on Access to Coverage for Frequently Abused Drugs. Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following: (i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary; or (ii) In accordance with paragraphs (f)(10) and (f)(11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are (A) Prescribed for the beneficiary by one or more prescribers; (B) Dispensed to the beneficiary by one or more network pharmacies; or (C) Specified in both paragraphs (3)(ii)(B)(1) and (2) of this paragraph. Paragraph (iii)(A) would state that if the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal. Paragraph (iii)(B) would state that if the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), or both, as applicable, (1) in accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal, and (2) except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(4))

We propose that before a Part D plan sponsor could limit the access of at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first take certain actions, consistent with current policy. We propose that a sponsor must first conduct the case management discussed earlier, which includes clinical contact to determine whether prescribed medications are appropriate for the potential at-risk beneficiary's medical conditions and prescriber verification that the beneficiary is an at-risk beneficiary. We also propose that the sponsor must first obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management, in light of the risk to the beneficiary's health. We further propose that the sponsor must first provide notice to the beneficiary in accordance with section 1860D–4(c)(5)(B)(i)(I) of the Act.

We propose to require the additional step of prescriber agreement, which is consistent with the current policy as discussed earlier, because a prescriber may verify that the beneficiary is an at-risk beneficiary but may not view a limitation on the beneficiary's access to coverage for frequently abused drugs as appropriate. Given the additional information the prescribers would have from the Part D sponsor through case management about the beneficiary's utilization of frequently abused drugs, the prescribers' professional opinion may be that an adjustment to their prescribing for, and care of, the beneficiary is all that is needed to safely manage the beneficiary's use of frequently abused drugs going forward. We invite stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in. We could foresee a case in which the prescriber is responsive, but does not agree with pharmacy lock-in.

We also propose language that would provide an exception to the case management requirement in § 423.153(f)(2) when an at-risk

[18] See ''Supplemental Guidance Relating to Improving Drug Utilization Review Controls in Part D'', September 6, 2012 (pp. 5, 19–20) at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html.*

beneficiary was identified as an at-risk beneficiary by the beneficiary's most recent prior prescription drug benefit plan. We discuss such cases more later in this section. Given the foregoing, we propose to add a paragraph (f)(4) to § 423.153 that reads: Requirements for Limiting Access to Coverage for Frequently Abused Drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following: (A) Conducted the case management required by paragraph (f)(2) of this section and updated it, if necessary; (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section. We would also state in subsection (ii) that if the sponsor complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section. Finally, we would state in a subsection (iii) that if the beneficiary meets paragraph (2) of the definition of a potential at-risk beneficiary or an at-risk beneficiary, and the sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate, the sponsor has met the case management requirement in paragraph (f)(2)(i).

(vii) Beneficiary Notices and Limitation of Special Enrollment Period (§§ 423.153(f)(5), 423.153(f)(6), 423.38)

(A) Initial Notice to Beneficiary and Sponsor Intent To Implement Limitation on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(5))

The notices referred to in proposed § 423.153(f)(4)(i)(C) are the initial and second notice that section 1860D–4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to send to potential at-risk and at-risk beneficiaries regarding their drug management programs. We remind Part D sponsors that under Section 504 of the Rehabilitation Act of 1973, effective communications requirements would apply to both these notices. We first discuss the initial notice.

We propose in § 423.153(f)(5) that if a Part D plan sponsor intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs, the sponsor would be required to provide an initial written notice to the potential at-risk beneficiary. We also propose that the language be approved by the Secretary and be in a readable and understandable form that contains the language required by section 1860D–4(c)(5)(B)(ii) of the Act to which we propose to add detail in the regulation text. Finally, we propose that the sponsor be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice.

We propose that § 423.153(f)(5)(i) read as follows: Initial Notice to Beneficiary. A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary. Paragraph (f)(5)(ii) would require that the notice use language approved by the Secretary and be in a readable and understandable form that provides the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary; (2) A description of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits); (3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at § 423.580 *et seq.;* (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under § 423.153(f)(3)(ii); (5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including an explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program, the timeframe for the sponsor's decision, and if applicable, any limitation on the availability of the special enrollment period described in § 423.38; (6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4); (7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program; and (8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

We propose to require at § 423.153(f)(5)(iii) that the Part D plan sponsor make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i).

The content of the initial notice we propose in § 423.153(f)(5) closely follows the content required by section 1860D–4(c)(5)(B)(ii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (f)(5)(ii)(C)(2)—which would require a description of public health resources that are designed to address prescription drug abuse—we propose to require that the notice contain information on how to access such services. We also included a reference in proposed paragraph (ii)(C)(4) to the fact that a beneficiary would have 30 days to provide information to the sponsor, which is a timeframe we discuss later in this preamble. We propose an additional requirement in paragraph (ii)(C)(5) that the sponsor include the limitation the sponsors intends to place on the beneficiary's access to coverage for frequently abused drugs, the timeframe for the sponsor's decision, and, if applicable, any limitation on the availability of the SEP. Finally, we proposed a requirement in paragraph (ii)(C)(8) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.

We note that our proposed implementation of the statutory requirements for the initial notice would permit the notice also to be used when the sponsor intends to implement a beneficiary-specific POS claim edit for frequently abused drugs. This is consistent with our current policy and would streamline beneficiary notices about opioids since we propose frequently abused drugs to consist of opioids for 2019.

Although section 1860D–4(c)(5) is silent as to the sequence of the steps of clinical contact, prescriber verification, and the initial notice, we propose to implement these requirements such that they would occur in the following order: First, the plan sponsor would conduct the case management which encompasses clinical contact and prescriber verification required by § 423.153(f)(2) and prescriber agreement required by § 423.153(f)(4), and second would, as applicable, indicate the sponsor's intent to limit the beneficiary's access to frequently abused drugs by providing the initial notice. In our view, a sponsor cannot reasonably intend to limit the beneficiary's access unless it has first undertaken case management to make clinical contact and obtain prescriber verification and agreement. Further, under our proposal, although the proposed regulatory text of (f)(4)(i) states that the sponsor must verify with the prescriber(s) that the beneficiary is an at-risk beneficiary in accordance with the applicable statutory language, the beneficiary would still be a potential at-risk beneficiary from the sponsor's perspective when the sponsor provides the beneficiary the initial notice. This is because the sponsor has yet to solicit information from the beneficiary about his or her use of frequently abused drugs, and such information may have a bearing on whether a sponsor identifies a potential at-risk beneficiary as an at-risk beneficiary.

Moreover, we believe that in general, a sponsor should not send a potential at-risk beneficiary an initial notice until after the sponsor has been in contact with the beneficiary's prescribers of frequently abused drugs, so as to avoid unnecessarily alarming the beneficiary, considering that a sponsor may learn from the prescribers that the beneficiary's use of the drugs is medically necessary, or that the beneficiary is an exempted beneficiary. This proposed approach is also consistent with our current policy and stakeholder comments. Therefore, under this approach, a sponsor would provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, and the sponsor would provide a second notice to an at-risk beneficiary when it actually limits the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor would provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. We discuss the second notice and alternate second notice later in this preamble.

We intend to develop language for the initial notice. Therefore, the proposed regulatory text states that the notice must use language approved by the Secretary.

(B) Limitation on the Special Enrollment Period for LIS Beneficiaries With an At-Risk Status (§ 423.38)

In addition to providing relevant information to a potential at-risk beneficiary, we propose that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries, that they will be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their at-risk status. (Hereafter, this SEP is referred to as the ''duals' SEP''). Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish a Part D SEP for full-benefit dually eligible (FBDE) beneficiaries. This SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries (*75 FR 19720*) so that all LIS-eligible beneficiaries were treated uniformly. The duals' SEP currently allows such individuals to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans) throughout the year, unlike other Part D enrollees who generally may make enrollment changes only during the annual election period (AEP). Individuals using this SEP can enroll in either a stand-alone Part D prescription drug plan (PDP) or a Medicare Advantage plan with prescription drug coverage.

Section 704(a)(3) of CARA gives the Secretary the discretion to limit the SEP for FBDE beneficiaries outlined in section 1860D–1(b)(3)(D) of the Act. This limitation is related to, but distinct from, other changes to the duals' SEP proposed in section III.A.11 of this proposed rule (as discussed later). A limitation under a sponsor's drug management program can only be effective as long as the individual is enrolled in that plan or another plan that also has a drug management program. Therefore, this proposed SEP limitation would be an important tool to reduce the opportunities for LIS-eligible beneficiaries designated as at-risk to switch plans. If an individual is determined to be an at-risk beneficiary, and is permitted to change plans using the duals' SEP, he or she could avoid the drug management program by leaving the plan before the program can be started or by enrolling in a PDP that does not have a drug management program. This would allow the beneficiary to circumvent the lock-in program and not receive the care coordination such a program provides. Even if an-risk beneficiary joined another plan that had a drug management program in place, there would be challenges in terms of preventing a gap managing their potential or actual overutilization of frequently abused drugs due to timing of information sharing between the plans and possible difference in provider networks.

Accordingly, we are proposing to revise § 423.38(c)(4), so that it is not available to potential at-risk beneficiaries or at-risk beneficiaries. Once an individual is identified as a potential at-risk beneficiary and the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, the sponsor would provide an initial notice to the beneficiary and the duals' SEP would no longer be available to the otherwise eligible individual. This means that he or she would be unable to use the duals' SEP to enroll in a different plan or disenroll from the current Part D plan. The limitation would be effective as of the date the Part D plan sponsor identifies an individual to be potentially at-risk. Limiting the duals' SEP concurrent with the plan's identification of a potential at-risk beneficiary would reduce the opportunities for such beneficiaries to use the interval between receipt of the initial notice and application of the limitation (for example, pharmacy or prescriber lock-in, beneficiary-specific POS claim edit) as an opportunity to change plans before the restriction takes effect.

Based on the 2015 data in CMS' OMS, more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS-eligible individuals. Based on this data, without an SEP limitation at the initial point of identification, the notification of a potential drug management program may prompt these individuals to switch plans immediately after receiving the initial notice. In effect, under the current regulations, if unchanged, the dually- or other LIS-eligible individual, could keep changing plans and avoid being subject to any drug management program.

We propose that, consistent with the timeframes discussed in proposed paragraph § 423.153(f)(7), if the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 90 days from the initial notice, the ''potentially at-risk'' designation and the duals' SEP limitation would expire. If the sponsor determines that the potential at-risk beneficiary is an at-risk beneficiary, the

duals' SEP would not be available to that beneficiary until the date the beneficiary's at-risk status is terminated based on a subsequent determination, including a successful appeal, or at the end of a 12-month period calculated from the effective date the sponsor provided the beneficiary in the second notice as proposed at § 423.153(f)(6) whichever is sooner.

As discussed in section III.A.11 of this proposed rule, we are also proposing to revise § 423.38(c)(4) to make the SEP for FBDE or other subsidy-eligible individuals available only in certain circumstances. As further explained in section III.A.11, we also are proposing to establish a new SEP at § 423.38(c)(9) to permit any beneficiary to make an enrollment change when he or she has a gain, loss, or change in Medicaid or LIS eligibility.

We propose not to limit the availability of this new SEP to potential at-risk and at-risk beneficiaries. In situations where an individual is designated as a potential at-risk beneficiary or an at-risk beneficiary and later determined to be dually-eligible for Medicaid or otherwise eligible for LIS, that beneficiary should be afforded the ability to receive the subsidy benefit to the fullest extent for which he or she qualifies and therefore should be able to change to a plan that is more affordable, or that is within the premium benchmark amount if desired. Likewise, if an individual with an ''at-risk'' designation loses dual-eligibility or LIS status, or has a change in the level of extra help, he or she would be afforded an opportunity to elect a different Part D plan, as discussed in section III.A.11 of this proposed rule. This is also a life changing event that may have a financial impact on the individual, and could necessitate an individual making a plan change in order to continue coverage.

We note that auto- and facilitated enrollment of LIS eligible individuals and plan annual reassignment processes would still apply to dual- and other LIS-eligible individuals who were identified as an at-risk beneficiary in their previous plan. This is consistent with CMS's obligation and general approach to ensure Part D coverage for LIS-eligible beneficiaries and to protect the individual's access to prescription drugs. Furthermore, we note that the proposed enrollment limitations for Medicaid or other LIS-eligible individuals designated as at-risk beneficiaries would not apply to other Part D enrollment periods, including the AEP or other SEPs. As discussed previously, we propose that the ability to use the duals' SEP, as outlined in section III.A.11. of this proposed rule, would not be permissible once the individual is enrolled in a plan that has identified him or her as a potential at-risk beneficiary or at-risk beneficiary, for a dual or other LIS-eligible who meets the definition of at-risk beneficiary or potential at-risk beneficiary under proposed § 423.100.

(C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs by Sponsor (§ 423.153(f)(6))

As previously noted, section 1860D–4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to provide a second written notice to at-risk beneficiaries when they limit their access to coverage for frequently abused drugs. Also, as with the initial notice, our proposed implementation of this statutory requirement for the second notice would permit the second notice to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs.

We propose to codify this requirement in § 423.153(f)(6)(i). Specifically, we propose to require the sponsor to provide the second notice when it determines that the beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs. We further propose to require the second notice to include the effective and end date of the limitation. Thus, this second notice would function as a written confirmation of the limitation the sponsor is implementing with respect to the beneficiary, and the timeframe of that limitation.

We also propose that the second notice, like the initial notice, contain language required by section 1860D–4(c)(5)(B)(iii) of the Act to which we propose to add detail in the regulation text. We also propose that the second notice, like the initial notice, be approved by the Secretary and be in a readable and understandable form, as well as contain other content that CMS determines is necessary for the beneficiary to understand the information required in this notice. Finally, in § 423.153(f)(6)(iii), we propose that the sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice, as we proposed with the initial notice.

Proposed § 423.153(f)(6)(i) would read as follows: Second notice. Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary. Paragraph (f)(6)(ii) would require that the second notice use language approved by the Secretary and be in a readable and understandable form that contains the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary; (2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including the limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and, if applicable, any limitation on the availability of the special enrollment period described in § 423.38 *et seq.;* (3) The prescriber(s) and/or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor; (4) An explanation of the beneficiary's right to a redetermination under § 423.580 *et seq.,* including a description of both the standard and expedited redetermination processes, with the beneficiary's right to, and conditions for, obtaining an expedited redetermination; (5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs; (6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section; and (7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

The content of the second notice we propose in § 423.153(f)(6) closely follows the content required by section 1860D–4(c)(5)(B)(iii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (2), we have proposed language that would require a sponsor to include the limitation the sponsors is placing on the beneficiary's access to coverage for frequently abused drugs, the effective and end date of the limitation, and if applicable, any limitation on the availability of the SEP. We propose an additional requirement in paragraph (6) that the sponsor include instructions how the beneficiary

may submit information to the sponsor in response to the request described in paragraph (4). Finally, we proposed a requirement in paragraph (7) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.

We note that under our current policy, plan sponsors send only one notice to the beneficiary if they intend to implement a beneficiary-specific POS opioid claim edit, which generally provides the beneficiary with a 30-day advance written notice and opportunity to provide additional information, as well as to request a coverage determination if the beneficiary disagrees with the edit. If our proposal is finalized, the implementation of a beneficiary-specific POS claim edit or a limitation on the at-risk beneficiary's coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) would be an at-risk determination (a type of initial determination that would confer appeal rights). Also, the sponsor would generally be required to send two notices—the first signaling the sponsor's intent to implement a POS claim edit or limitation (both referred to generally as a ''limitation''), and the second upon implementation of such limitation. Under our proposal, the requirement to send two notices would not apply in certain cases involving at-risk beneficiaries who are identified as such and provided a second notice by their immediately prior plan's drug management program.

(D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (§ 423.153(f)(7))

We propose that if a sponsor does not implement the limitation on the potential at-risk beneficiary's access to coverage of frequently abused drugs it described in the initial notice, then the sponsor would be required to provide the beneficiary with an alternate second notice. Although not explicitly required by the statute, we believe this notice is consistent with the intent of the statute and is necessary to avoid beneficiary confusion and minimize unnecessary appeals. We propose generally that in such an alternate notice, the sponsor must notify the beneficiary that the sponsor no longer considers the beneficiary to be a potential at-risk beneficiary upon making such determination; will not place the beneficiary in its drug management program; will not limit the beneficiary's access to coverage for frequently abused drugs; and if applicable, that the SEP limitation no longer applies.

Specifically, we propose that § 423.153(f)(7)(i) would read: Alternate second notice. (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary. Paragraph (f)(7)(ii) would require that the notice use language approved by the Secretary in a readable and understandable form containing the following information: (1) The sponsor has determined that the beneficiary is not an at-risk beneficiary; (2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs; (3) If applicable, the SEP limitation no longer applies; (4) Clear instructions that explain how the beneficiary may contact the sponsor; and (5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

Again, as with the initial and second notices, we propose in a paragraph (f)(7)(iii) that the Part D sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(7)(i). Also, as with the initial and second notices, we propose in paragraph (ii) that the notice use language approved by the Secretary and be in a readable and understandable form; in paragraph (ii)(C)(4) that the notice contain clear instructions that explain how the beneficiary may contact the sponsor; and in paragraph (ii)(C)(5), that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the notice.

(E) Timing of Notices (§ 423.153(f)(8))

Section 1860D–4(c)(5)(B)(iv) of the Act requires a Part D sponsor to provide the second notice to the beneficiary on a date that is not less than 30 days after the sponsor provided the initial notice to the beneficiary. We interpret the purpose of this requirement to be that the beneficiary should have ample time to provide information to the sponsor that may alter the sponsor's intended action that is contained in the initial notice to the beneficiary, or to provide the sponsor with the beneficiary's pharmacy and/or prescriber preferences, if the sponsor's intent is to limit the beneficiary's access to coverage for frequently abused drugs from selected a pharmacy(ies) and/or prescriber(s).

In addition, we propose to impose a deadline by when a sponsor must provide the second notice or alternate second notice to the beneficiary, although not specifically required by CARA. Such a requirement should provide the sponsor with sufficient time to complete the administrative steps necessary to execute the action the sponsor intends to take that was explained in the initial notice to the beneficiary, while acknowledging that the sponsor would have already met in the case management, clinical contact and prescriber verification requirement.

In the case of an alternate second notice, the timeframe should provide the beneficiary with definitive notice that the sponsor has not identified the beneficiary as an at-risk beneficiary and that there will be no limitation on his/her access to coverage for frequently abused drugs. Accordingly, we propose that the sponsor would be required to send either the second notice or the alternate second notice, as applicable, when it makes its determination or no later than 90 calendar days after the date on the initial notice, whichever comes sooner.

Specifically, we propose to include at § 423.153(f)(8) the following: Timing of Notices. (i) Subject to paragraph (ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section. We intend this proposed timeframe for the sponsor to provide either the second notice or the alternate second notice, as applicable, to be reasonable for both Part D sponsors and the relevant beneficiaries and important to ensuring clear, timely and reasonable communication between the parties.

Section 1860D–4(c)(5)(B)(iv)(II) of the Act explicitly provides for an exception to the required timeframe for issuing a second notice. Specifically, the statute permits the Secretary to identify through rulemaking concerns regarding the health or safety of a beneficiary or significant drug diversion activities that would necessitate that a Part D sponsor provide the second written notice to the beneficiary before the 30 day time period normally required has elapsed. For this reason, we included the language, ''subject to paragraph (ii),'' at the beginning of proposed § 423.153(f)(8)(i).

We note that the proposed definition of at-risk beneficiary would include beneficiaries for whom a gaining Part D plan sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon enrollment. This proposed definition is based on the language in section 1860–D–4(c)(5)(C)(i)(II) of the Act.

Given that this provision allows an at-risk identification to carry forward to the next plan, we believe it is appropriate to propose to permit a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most recent prior plan sooner than would otherwise be required. For the same reasons, we believe that it would be appropriate to permit the gaining plan to even send the beneficiary a combined initial and second notice, under certain circumstances. However, because the content of the initial notice would not be appropriate for an at-risk beneficiary, and because such beneficiary would have already received an initial notice from his or her immediately prior plan sponsor, the content of this combined notice should only consist of the required content for the second notice so as not to confuse the beneficiary. Thus, our interpretation of section 1860D–4(c)(5)(B)(iv)(II) of the Act in conjunction with section 1860D–4(c)(5)(C)(i)(II) of the Act is that a gaining Part D sponsor may send the second notice immediately to a beneficiary for whom the sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. This is consistent with our current policy under which a gaining sponsor may immediately implement a beneficiary-specific opioid POS claim edit, if the gaining sponsor is notified that the beneficiary was subject to such an edit in the immediately prior plan and such edit had not been terminated.[19]

We propose that sending a second notice to an at-risk beneficiary so identified in the most recent plan would be permissible only if the new sponsor is implementing a beneficiary-specific POS claim edit for a frequently abused drug, or if the sponsor is implementing a limitation on access to coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) and has the same location of pharmacy(ies) and/or the same prescriber(s) in its provider network, as applicable, that the beneficiary used to obtain frequently abused drugs in the most recent plan. Otherwise, we propose that the new sponsor would be required to provide the initial notice to the at-risk beneficiary, even though the initial notice is generally intended for potential at-risk beneficiaries, and could not provide the second notice until at least 30 days had passed. This is because even though there would also be a concern for the at-risk beneficiary's health and safety in this latter case as well, this concern would be outweighed by the fact that the beneficiary had not been afforded a chance to submit his or her preference for a pharmacy(ies) and/or prescriber(s), as applicable, from which he or she would have to obtain frequently abused drugs to obtain coverage under the new plan's drug management program.

We propose to codify this policy by adding a paragraph (ii) to § 423.153(f)(8), as noted earlier, to read as follows: Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may provide a second notice described in paragraph (f)(6) to a beneficiary for whom the gaining sponsor received notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan and such identification had not been terminated in accordance with § 423.153(f)(14), if the sponsor is implementing either of the following: (A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i); or (B) A limitation on access to coverage as described in paragraph(f)(3)(ii), if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under (f)(9).

Some stakeholders commented that sponsors should be allowed to expedite the second notice in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court. However, given the importance of a beneficiary having advance notice of a pending limit on his or her access to coverage for frequently abused drugs and sufficient time to respond and/or prepare, we believe exceptions to the timing of the notices should be very narrow. Therefore, we have only included a proposal for an exception to shorten the 30 day timeframe between the initial and second notice that is based on a beneficiary's status as an at-risk beneficiary in an immediately preceding plan. We note that is a status the drug management provisions of CARA explicitly requires to be shared with the next plan sponsor, if a beneficiary changes plans, which means there would be a concrete data point for this proposed exception to the timing of the notices. We discuss such sharing of information later in the preamble.

(viii) Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (§§ 423.153(f)(4), 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423,153(f)(13))

Some of the drug management program provisions in CARA are only relevant to ''lock-in''. We propose several regulatory provisions to implement these provisions, as follows:

(A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (§ 423.153(f)(4))

We believe prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abused drugs, meaning when a different approach has not been successful, whether that was a ''wait and see'' approach or the implementation of a beneficiary specific POS claim edit or a pharmacy lock-in. Limiting an at-risk beneficiary's access to coverage for frequently abused drugs from only selected prescribers impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs.

As a result, we propose that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. We propose that this date be the date of the first OMS report that identified the beneficiary, so long as the beneficiary was also reported in the most recent OMS report that the sponsor received. This is because limiting the beneficiary's access to coverage of frequently abused drugs from a selected prescriber would only be necessary if the beneficiary continues to meet the clinical guidelines despite any existing

[19] See ''Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014.

intervention or limitation. We discuss OMS reports in more detail later.

We expect that the 6-month waiting period will provide the sponsor additional time to assess whether case management or another tool, such as a beneficiary-specific POS claim edit or pharmacy lock-in has failed to resolve the beneficiary's overutilization of frequently abused drugs. Sponsors have indicated in comments on the current policy that the case management process can take 3 to 6 months. Also, sponsors would need time to determine whether the beneficiary still meets the clinical guidelines and is thus continuing to be reported by OMS. Therefore, the time period we propose was chosen to account for time needed for the case management process and to align with the 6 month measurement period of the proposed clinical guidelines.

We seek comment on whether this 6-month waiting period would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s). Comments should include the additional operational considerations for sponsors to implement this proposal.

Given our proposal, we propose adding a paragraph (iv) to § 423.153(f)(4) that would state: (f)(4)(iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under § 423.153(f)(3)(ii)(A) unless—(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and (B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.

We note that in conducting the case management required under § 423.153(f)(4)(i)(A) in anticipation of implementing a prescriber lock-in, the sponsor would be expected to update any case management it had already conducted. Also, even if a sponsor had already obtained the prescriber's agreement to implement a limitation on the beneficiary's coverage of frequently abused drugs to a selected pharmacy to comply with § 423.153(f)(4)(i)(B), for example, the sponsor would have to obtain the agreement of the prescriber who would be selected to implement a limitation on a beneficiary's coverage of frequently abused drugs to a selected prescriber. Finally, we note that even if a sponsor had already provided the beneficiary with the required notices to comply with § 423.153(f)(4)(i)(C), the sponsor would have to provide them again in order to remain compliant, because the beneficiary would not have been notified about the specific limitation on his or her access to coverage for frequently abused drugs to a selected prescriber(s) and has an opportunity to select the prescriber(s).

We foresee a scenario in which a sponsor may wish to implement a limitation on a beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) when the sponsor's first round of case management, clinical contact and prescriber verification resulted only in sending the prescribers of frequently abused drugs a written report about the beneficiary's utilization of frequently abused drugs and taking a ''wait and see'' approach, which did not result in the prescribers' adjusting their prescriptions for frequently abused drugs for their patient. In such a scenario, assuming the patient still meets the clinical guidelines and continues to be reported by OMS, the sponsor would need to try another intervention to address the opioid overuse. Another scenario could be that the sponsor implemented a pharmacy lock-in, but after 6-months, the beneficiary still meets the clinical guidelines due to receiving frequently abused drugs from additional prescribers.

(B) Selection of Pharmacies and Prescribers (§§ 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13))

(*1*) Beneficiary Preferences (§ 423.153(f)(9))

Section 1860D–4(c)(5)(D) of the Act provides that, if a sponsor intends to impose, or imposes, a limit on a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) or prescriber(s), and the potential at-risk beneficiary or at-risk beneficiary submits preferences for a pharmacy(ies) or prescriber(s), the sponsor must select the pharmacy(ies) and prescriber(s) for the beneficiary based on such preferences, unless an exception applies, which we will address later in the preamble. We further propose that such pharmacy(ies) or prescriber(s) must be in-network, except if the at-risk beneficiary's plan is a stand-alone prescription drug benefit plan and the beneficiary's preference involves a prescriber. Because stand-alone Part D plans (PDPs) do not have provider networks, and thus no prescriber would be in-network, the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. We discuss exceptions in the next section of this preamble. In our view, it is essential that an at-risk beneficiary must generally select in-network pharmacies and prescribers so that the plan is in the best possible position to coordinate the beneficiary's care going forward in light of the demonstrated concerns with the beneficiary's utilization of frequently abused drugs.

Accordingly, we propose § 423.153(f)(9) to read: Beneficiary preferences. Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following—(i) Review such preferences and (ii) If the beneficiary is—(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s) or (B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s). If the beneficiary submits preferences for a non-network pharmacy(ies), or in the case of a Medicare Advantage prescription drug benefit plan a non-network prescriber(s), or both, the sponsor does not have to select or change the selection for the beneficiary to a non-network pharmacy or prescriber except if necessary to provide reasonable access.

In a paragraph (iii), we propose that the sponsor must inform the beneficiary of the selection in the second notice, or if not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission. Thus, this section would require a Part D plan sponsor to honor an at-risk beneficiary's preferences for in-network prescribers and pharmacies from which to obtain frequently abused drugs, unless the plan was a stand-alone PDP and the selection involves a prescriber. In other words, a stand-alone PDP or MA–PD does not have to honor a beneficiary's selection of a non-network pharmacy, except as necessary

to provide reasonable access, which we discuss later in this section. Also, under our proposal, the beneficiary could submit preferences at any time. Finally, the sponsor would be required to confirm the selection in writing either in the second notice, if feasible, or within 14 days of receipt of the beneficiary's submission.

(*2*) Exception to Beneficiary Preferences (§ 423.153(f)(10))

Section 1860D–4(c)(5)(D)(iv) of the Act, provides for an exception to an at-risk beneficiary's preference of prescriber or pharmacy from which the beneficiary must obtain frequently abused drugs, if the beneficiary's allowable preference of prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary. Section 1860–D–4(c)(5)(D)(iv) of the Act requires the sponsor to provide the at-risk beneficiary with at least 30 days written notice and a rationale for not honoring his or her allowable preference for pharmacy or prescriber from which the beneficiary must obtain frequently abused drugs under the plan.

A few commenters asserted there should be limits to how many times beneficiaries can submit their preferences. Other commenters stated there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection.

We are not proposing to place a limit on how many times beneficiaries can submit their preferences, but we are open to additional comments on this topic. We agree with commenters who stated that there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection, but we note that because such a situation would often involve a network pharmacy or prescriber, we would expect that the sponsor would also take appropriate action with respect to the pharmacy or prescriber, such as termination from the network.

Given the foregoing, we propose to add the following: § 423.153(f)(10) Exception to Beneficiary Preferences. (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary. (ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with (A) At least 30 days advance written notice of the change; and (B) A rationale for the change.

(*3*) Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12))

If a potential at-risk beneficiary or at-risk beneficiary does not submit pharmacy or prescriber preferences, section 1860–D–4(c)(5)(D)(i) of the Act provides that the Part D sponsor shall make the selection. Section 1860–D–4(c)(5)(D)(ii) of the Act further provides that, in making the selection, the sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time.

We propose to add the following at § 423.153(f)(11): Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following: (i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, the beneficiary's predominant usage of a prescriber or pharmacy or both, impact on cost-sharing, and reasonable travel time; and (ii) reasonable access to frequently abused drugs in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

Since the statute explicitly allows the beneficiary to submit preferences, we interpret the additional reference to beneficiary preference in the context of reasonable access to mean that a beneficiary allowable preference should prevail over a sponsor's evaluation of geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy impact on cost-sharing and reasonable travel time. In the absence of a beneficiary preference for pharmacy and/or prescriber, however, a Part D plan sponsor must take into account geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy, impact on cost-sharing and reasonable time travel in selecting a pharmacy and/or prescriber, as applicable, from which the at-risk beneficiary will have to obtain frequently abused drugs under the plan. Thus, absent a beneficiary's allowable preference, or the beneficiary's selection would contribute to prescription drug abuse or drug diversion, the sponsor must ensure reasonable access by choosing the network pharmacy or prescriber that the beneficiary uses most frequently to obtain frequently abused drugs, unless the plan is a stand-alone PDP and the selection involves a prescriber(s). In the latter case, the prescriber will not be a network provider, because such plans do not have provider networks. In urgent circumstances, we propose that reasonable access means the sponsor must have reasonable policies and procedures in place to ensure beneficiary access to coverage of frequently abused drugs without a delay that may seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function.

Determining reasonable access may be complicated when an enrollee has multiple addresses or his or her health care necessitates obtaining frequently abused drugs from more than one prescriber and/or more than one pharmacy. Section 1860D–4(c)(5) addresses this issue by requiring the Part D plan sponsor to select more than one prescriber to prescribe frequently abused drugs and more than one pharmacy to dispense them, as applicable, when it reasonably determines it is necessary to do so to provide the at-risk beneficiary with reasonable access.

Given the foregoing, we propose the following at § 423.153(f)(12): Selection of Prescribers and Pharmacies. (i) A Part D plan sponsor must select, as applicable—(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and (B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.

We also propose to address chain pharmacies and group practices by adding a paragraph (ii) that states: (ii) (A) For purposes of this subsection (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy; and (B) For purposes of this subsection (f)(12), in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.

We would interpret these provisions to mean that a sponsor would be required to select more than one prescriber of frequently abused drugs, if more than one prescriber has asserted

during case management that multiple prescribers of frequently abused drugs are medically necessary for the at-risk beneficiary. We further propose that if no prescribers of frequently abused drugs were responsive during case management, and the beneficiary does not submit preferences, the sponsor would be required to select the pharmacy or prescriber that the beneficiary predominantly uses to obtain frequently abused drugs.

(*4*) Confirmation of Pharmacy and Prescriber Selection (§ 423.153(f)(13))

Section 1860D–4(c)(5)(D)(v) of the Act requires that, before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion in the drug management program which will limit the beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s) and that the prescriber and/or pharmacy has been selected as a designated prescriber and/or pharmacy for the at-risk beneficiary.

We propose that plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. However, the contract between the sponsor and the network provider would need to specify how the sponsor will notify the provider of its selection. Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/or pharmacy(ies) that the selection is accepted before conveying this information to the at-risk beneficiary. Otherwise, the plan would need to make another selection and seek confirmation.

We propose § 423.153(f)(13) to read: Confirmation of Selections(s). (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. (ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection.

(ix) Drug Management Program Appeals (§§ 423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, 423.638, 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126)

Section 1860D–4(c)(5)(E) of the Act specifies that the identification of an individual as an at-risk beneficiary for prescription drug abuse under a Part D drug management program, a coverage determination made under such a program, the selection of a prescriber or pharmacy, and information sharing for subsequent plan enrollments shall be subject to reconsideration and appeal under section 1860D–4(h) of the Act. This provision also permits the option of an automatic escalation to external review to the extent provided by the Secretary.

As discussed earlier in this preamble, we are proposing to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, proposed at § 423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an ''at-risk determination'' made under a drug management program. The at-risk determination includes prescriber and/or pharmacy selection for lock-in, beneficiary-specific POS claim edits for frequently abused drugs, and information sharing for subsequent plan enrollments. Given the concomitant nature of the at-risk determination and associated aspects of the drug management program applicable to an at-risk beneficiary, we expect that any dispute under a plan's drug management program will be adjudicated as a single case involving a review of all aspects of the drug management program for the at-risk beneficiary. While a beneficiary who is subject to a Part D plan sponsor's drug management program always retains the right to request a coverage determination under existing § 423.566 for any Part D drug that the beneficiary believes may be covered by their plan, we believe that appeals of an at-risk determination made under proposed § 423.153(f) should involve consideration of all relevant elements of that at-risk determination. For example, if a Part D plan determines that a beneficiary is at-risk, implements a beneficiary-specific claim edit on 2 drugs that beneficiary is taking and locks that beneficiary into a specific pharmacy, the affected beneficiary should not be expected to raise a dispute about the pharmacy selection and about one of the claim edits in distinct appeals.

We note that, while section 1860D–4(c)(5)(B)(ii)(III) of the Act requires the initial written notice to the beneficiary, which identifies him or her as *potentially* being at-risk, to include ''notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h),'' we interpret ''such identification'' to refer to any subsequent identification that the beneficiary is actually at-risk. Because CARA, at section 1860D–4(c)(5)(E) of the Act, specifically provides for appeal rights under subsection (h) but does not refer to identification as a potential at-risk beneficiary, we believe this interpretation is consistent with the statutory intent. Furthermore, when a beneficiary is identified as being potentially at-risk, but has not yet been identified as at-risk, the plan is not taking any action to limit such beneficiary's access to frequently abused drugs; therefore, the situation is not ripe for appeal. While an LIS SEP under § 423.38 would be restricted at the time the beneficiary is identified as potentially at-risk under proposed § 423.100, the loss of such SEP is not appealable under section 1860D–4(h) of the Act.

As noted previously, section 1860D–4(c)(5)(E) of the Act specifically refers to the Part D benefit appeals provisions in section 1860D–4(h) of the Act, which require Part D plan sponsors to meet the requirements of paragraphs (4) and (5) of section 1852(g) of the Act for benefits in a manner similar to the manner such requirements apply to MA organizations. Section 1852(g)(4) of the Act specifically provides for independent review of ''reconsiderations that *affirm denial* of coverage, in whole or in part (emphasis added).'' We believe section 1860D–4(c)(5)(E) of the Act broader reference to ''reconsideration and appeal'' should be interpreted to mean that individuals have a right to a plan level appeal, consistent with the reconsideration provisions under section 1860D–4(g) of the Act, followed by the right to independent review if the plan level affirms the initial adverse decision. In other words, we believe the reference to ''reconsideration'' means that a Part D plan sponsor should conduct the initial

level of appeal following an at-risk determination under the plan sponsor's drug management program, consistent with the existing Part D drug benefit appeals process, despite the absence of a specific reference to section 1860D–4(g) of the Act.

Part D enrollees, plan sponsors, and other stakeholders are already familiar with the Part D benefit appeals process. Resolving disputes that arise under a plan sponsor's drug management program within the existing Part D benefit appeals process would allow at-risk beneficiaries to be more familiar with, and more easily access, the appeals process instead of creating a new process specific to appeals related to a drug management program. Also, allowing a plan sponsor the opportunity to review information it used to make an at-risk determination under the drug management program (and any additional relevant information submitted as part of the appeal) would be efficient for both the individual and the Medicare program because it would potentially resolve the issues at a lower level of administrative review. Conversely, permitting review by the independent review entity (IRE) before a plan sponsor has an opportunity to review and resolve any errors or omissions that may have been made during the initial at-risk determination would likely result in an unnecessary increase in costs for plan sponsors as well as CMS' Part D IRE contract costs.

As noted previously, the Secretary has the discretion under CARA to provide for automatic escalation of drug management program appeals to external review. Under existing Part D benefit appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D IRE. Under the existing Part D benefit appeals process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe. During the stakeholder call and in subsequent written comments, most commenters opposed automatic escalation to the IRE, citing support for using the existing appeals process for reasons of administrative efficiency and better outcomes for at-risk beneficiaries. The majority of stakeholders supported following the existing Part D appeals process, and some commenters specifically supported permitting the plan to review its lock-in decision prior to the case being subject to IRE review. Stakeholders cited a variety of reasons for their opposition, including increased costs to plans, the IRE, and the Part D program. Stakeholders cited administrative efficiency in using the existing appeal process that is familiar to enrollees, plans, and the IRE, while other commenters expressed support for automatic escalation to the IRE as a beneficiary protection.

We are proposing that at-risk determinations made under the processes at § 423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in Subpart M. However, we are not proposing to revise the existing definition of a coverage determination. The types of decisions made under a drug management program align more closely with the regulatory provisions in Subpart D than with the provisions in Subpart M related to coverage or payment for a drug based on whether the drug is medically necessary for an enrollee. Therefore, we believe it is clearer to set forth the rules for at-risk determinations as part of § 423.153 and cross reference § 423.153(f) in relevant provisions in Subpart M and Subpart U. While a coverage determination made under a drug management program would be subject to the existing rules related to coverage determinations, the other types of initial determinations made under a drug management program (for example, a restriction on the at-risk beneficiary's access to coverage of frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers) would be subject to the processes set forth at proposed § 423.153(f). Consistent with existing rules for redeterminations at § 423.582, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the second written notice to make such request, unless the enrollee shows good cause for untimely filing under § 423.582(c). As previously discussed for proposed § 423.153(f)(6), the second written notice is sent to a beneficiary the plan has identified as an at-risk beneficiary and with respect to whom the sponsor limits his or her access to coverage of frequently abused drugs regarding the requirements of the sponsor's drug management programs.

Also consistent with the existing Part D benefit appeals process, we are proposing that at-risk beneficiaries (or an at-risk beneficiary's prescriber, on behalf of the at-risk beneficiary) must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. In other words, under this proposal, an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to meet the redetermination adjudication timeframe. We are also proposing to amend the existing Subpart M rules at § 423.584 and § 423.600 related to obtaining an expedited redetermination and IRE reconsideration, respectively, to apply them to appeals of a determination made under a drug management program. The right to an expedited appeal of such a determination, which must be adjudicated as expeditiously as the at-risk beneficiary's health condition requires, would ensure that the rights of at-risk beneficiaries are protected with respect to access to medically necessary drugs. While we are not proposing to adopt auto-escalation, we believe our proposed approach ensures that an at-risk beneficiary has the right to obtain IRE review and higher levels of appeal (ALJ/attorney adjudicator, Council, and judicial review). Accordingly, we also are proposing to add the reference to an ''at-risk determination'' to the following regulatory provisions that govern ALJ and Council processes: §§ 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126.

Finally, we are also proposing a change to § 423.1970(b) to address the calculation of the amount in controversy (AIC) for an ALJ hearing in cases involving at-risk determinations made under a drug management program in accordance with proposed § 423.153(f). Specifically, we propose that the projected value of the drugs subject to the drug management program be used to calculate the amount remaining in controversy. For example, if the beneficiary is disputing the lock-in to a specific pharmacy for frequently abused drugs and the beneficiary takes 3 medications that are subject to the plan's drug management program, the projected value of those 3 drugs would be used to calculate the AIC, including the value of any refills prescribed for the drug(s) in dispute during the plan year.

In addition to the proposed changes related to the implementation of drug management program appeals, we are also proposing to make technical changes to § 423.562(a)(1)(ii) to remove the comma after ''includes'' and replace the reference to ''§§ 423.128(b)(7) and (d)(1)(iii)'' with a reference to ''§§ 423.128(b)(7) and (d)(1)(iv).''

(x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (§ 423.153(f)(14))

Section 1860–D–4(c)(5)(F) of the Act provides that the Secretary shall develop standards for the termination of the identification of an individual as an at-risk beneficiary, which shall be the

earlier of the date the individual demonstrates that he or she is no longer likely to be an at-risk beneficiary in the absence of limitations, or the end of such maximum period as the Secretary may specify.

Most commenters recommended a maximum 12-month period for an at-risk beneficiary to be locked-in. We also note that a 12-month lock-in period is common in Medicaid lock-in programs.[20] A few commenters stated that a physician should be able to determine that a beneficiary is no longer an at-risk beneficiary. One commenter was opposed to an arbitrary termination based on a time period.

Given that most commenters recommended a 12-month period and such a period is common in Medicaid ''lock-in'' program, we propose a maximum 12-month period for both a lock-in period, and also for the duration of a beneficiary-specific POS claim edit for frequently abused drugs through the addition of the following language at § 423.153(f)(14): Termination of Identification as an At-Risk Beneficiary. The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following—

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary; or

(ii) The end of a 12 calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.

Thus, we note that if a beneficiary continues to meet the clinical guidelines and, if the sponsor implements an additional, overlapping limitation on the at-risk beneficiary's access to coverage for frequently abused drugs, the beneficiary may experience a coverage limitation beyond 12-months. The same is true for at-risk beneficiaries who were identified as such in the most recent prescription drug plan in which they were enrolled and the sponsor of his or her subsequent plan immediately implements a limitation on coverage of frequently abused drugs.

Section 1860–D–4(c)(5)(F)(ii) of the Act states that nothing in CARA shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary after such termination on the basis of additional information on drug use occurring after the date of notice of such termination. Accordingly, we note that our proposed approach to termination of an at-risk determination would not prevent an at-risk beneficiary from being subsequently identified as a potential at-risk beneficiary or at-risk beneficiary on the basis of new information on drug use occurring after the date of such termination that causes the beneficiary to once again meet the clinical guidelines.

(xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (§ 423.153(f)(15))

In order for Part D sponsors to conduct the case management/clinical contact/prescriber verification required by proposed § 423.153(f)(2), CMS must identify potential at-risk beneficiaries to sponsors who are in the sponsors' Part D prescription drug benefit plans. In addition, new sponsors must have information about potential at-risk beneficiaries and at-risk beneficiaries who were so identified by their immediately prior plan and enroll in the new sponsor's plan and such identification had not terminated before the beneficiary disenrolled from the immediately prior plan. Finally, as discussed earlier, sponsors may identify potential at-risk beneficiaries by their own application of the clinical guidelines on a more frequent basis. It is important that CMS be aware of which Part D beneficiaries sponsors identify on their own, as well as which ones have been subjected to limitations on their access to coverage for frequently abused drugs under sponsors' drug management programs for Part D program administration and other purposes. This data disclosure process would be consistent with current policy, as described earlier in this preamble.

As we also discussed earlier, under the current policy, CMS provides quarterly reports to sponsors about beneficiaries enrolled in their plans who meet the OMS criteria. In turn, Part D sponsors are expected to provide responses to CMS through the OMS for each case identified within 30 days of receiving a report that reflects the status or outcome of their case management.[21] At the same time, also within 30 days, sponsors are expected to report additional beneficiaries to OMS that they identify using their own opioid overutilization identification criteria.[22]

Regarding data disclosures, section 1860D–4(c)(5)(H) of the Act provides that, in the case of potential at-risk beneficiaries and at-risk beneficiaries, the Secretary shall establish rules and procedures to require the Part D plan sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

Sponsors also report information to CMS' MARx system about pending, implemented and terminated beneficiary-specific POS claim edit for opioids within 7 business days of the date on the applicable beneficiary notice or of the termination.[23] The MARx system transfers information about pending and implemented claim edits to the gaining sponsor with the beneficiary's enrollment record if the beneficiary disenrolls and enrolls in the gaining sponsor's plan. If a gaining sponsor requests case management information from the losing sponsor about the beneficiary, we expect the losing sponsor to transfer the information to the gaining sponsor as soon as possible, but no later than 2 weeks from the date of the gaining sponsor's request.[24]

Section 1860–D–4(c)(5)(I) of the Act requires that the Secretary establish procedures under which Part D sponsors must share information when at-risk beneficiaries or potential at-risk beneficiaries enrolled in one prescription drug plan subsequently disenroll and enroll in another prescription drug plan offered by the next sponsor (gaining sponsor). We plan to expand the scope of the reporting to MARx under the current policy to include the ability for sponsors to report similar information to MARx about all pending, implemented and terminated limitations on access to coverage of frequently abused drugs associated with their plans' drug management programs.

We propose to codify the data disclosure and information sharing process under the current policy, with the expansion just described, by adding the following requirement to § 423.153: (f)(15) Data Disclosure. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled. (ii) A Part D sponsor that operates a drug management program must disclose any

[20] Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug Fee-For Service Program (December 2016).

[21] See ''Medicare Part D Overutilization Monitoring System,'' July 5, 2013.

[22] See ''Medicare Part D Overutilization Monitoring System, January 17, 2014.

[23] Final Parts C&D 2017 Call Letter, April 4, 2016.

[24] See ''Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014.

data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner, specified by CMS. The data and information disclosures must do all of the following: (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS; (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries; (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs; and (D) Transfer case management information upon request of a gaining sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request when: (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(xii) Summary

Our proposal is intended to be responsive to stakeholder input that CMS focus on opioids; allow for flexibility to adjust the clinical guidelines and frequently abused drugs in the future; is reflective of the importance of the provider-patient relationship; protects beneficiary's rights and access, and allows for operational manageability and consistency with the current policy to the extent possible. This proposal, if finalized, should result in effective Part D drug management programs within a regulatory framework provided by CMS, and further reduce opioid overutilization in the Part D program.

2. Flexibility in the Medicare Advantage Uniformity Requirements

We have determined that providing access to services (or specific cost sharing for services or items) that is tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the Medicare Advantage (MA) regulations at § 422.100(d). This regulatory requirement is a means to implement both section 1852(d) of the Act, which requires that benefits under the MA plan be available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. We have determined that these statutory provisions and the regulation at § 422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. For example, reduced cost sharing flexibility would allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits. Similarly, with this flexibility, a MA plan may offer diabetic enrollees more frequent foot exams as a tailored, supplemental benefit. In addition, with this flexibility, a MA plan may offer diabetic enrollees a lower deductible. Under this example, non-diabetic enrollees would not have access to these diabetic-specific tailored cost-sharing or supplemental benefits; however, any enrollee that develops diabetes would then have access to these benefits.

Such flexibility under our new interpretation of the uniformity requirement is not without limits, however, as section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. MA regulations (for example, §§ 422.100(f)(2) and 422.110(a)) reiterate and implement this non-discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans consider this new flexibility in meeting the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.[25] MA plans that exercise this flexibility must ensure that the cost sharing reductions and targeted supplemental benefits are for health care services that are medically related to each disease condition. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. We will review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations.

For example, an MA plan could identify enrollees diagnosed with specific diseases, such as diabetes, chronic heart failure, and COPD, as medically vulnerable and in need of certain services, which could be offered to these enrollees in the form of tailored supplemental benefits. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider to assure equal application of the objective criteria necessary to provide equal treatment of similarly situated individuals.

For contract year 2019, we are considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees. A benefit package that offers differential access to enhanced services or benefits or reduced cost sharing or different deductibles based on objective criteria, and ensures equal treatment of similarly situated enrollees, for whom such services and benefits are useful, can be priced at a uniform premium consistent with the requirements for availability and accessibility throughout the service area for all enrollees in section 1852(d)(1)(A) of the Act and for uniform bids and premiums in section 1854(c) of the Act. We believe this flexibility will help MA plans better manage health care services for the most vulnerable enrollees. The benefit and cost sharing flexibility we have discussed here applies to Part C benefits but not Part D benefits. We are requesting comments and/or questions from stakeholders about the implementation of this flexibility. We note that CMS is currently testing value based insurance design (VBID) through the use of our demonstration authority under Section 1115A of the Act (42 U.S.C. 1315a, added by Section 3021 of the Affordable Care Act), which will include some of the elements we have discussed

[25] Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act.

previously. However, there are also features of the VBID demonstration that are unique to the demonstration test. We expect the VBID demonstration to provide CMS with insights into future VBID innovations for the MA program.

3. Segment Benefits Flexibility

In reviewing section 1854(h) of the Social Security Act and Medicare Advantage (MA) regulations governing plan segments, we have determined that the statute and existing regulations may be interpreted to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. Plans segments are county-level portions of a plan's overall service area which, under current CMS policy, are permitted to have different premiums and cost sharing amounts as long as these premiums and cost sharing amounts are uniform throughout the segment. We are proposing to revise our interpretation of the existing statute and regulations to allow MA plan segments to vary by benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at § 422.262(c)(2).

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)

As provided at § 422.100(f)(4) and (5) and § 422.101(d)(2) and (3), all Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)), must establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS. CMS added §§ 422.100(f)(4) and (f)(5), effective for coverage in 2011, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory) (75 FR 19709–11). Section 1858(b)(2) of the Act requires a limit on in-network out-of-pocket expenses for enrollees in Regional MA Plans. In addition, Local Preferred Provider Organization (LPPO) plans, under § 422.100(f)(5), and Regional PPO (RPPO) plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have a ''catastrophic'' limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the annual limit which is also established by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services, excluding plan premium, must be included in each plan's Maximum Out-of-Pocket (MOOP) amount subject to these limits.

As discussed in the 2010 rulemaking (75 FR 19709), CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7 percent in CY 2011 to 68.1 percent in CY 2017. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in CY 2011 to 21 percent in CY 2017.

As stated in the CY 2018 final Call Letter [26] and in the 2010 final rule (75 FR 19710), CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS) for local and regional MA plans. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance. The voluntary MOOP amount of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs. The Office of the Actuary conducts an annual analysis to help CMS determine the MOOP limits. Since the MOOP requirements for local and regional MA plans were finalized in regulation, a strict application of the 95th and 85th percentile would have resulted in MOOP limits for local and regional MA plans fluctuating from year-to-year. Therefore, CMS has exercised discretion in order to maintain stable MOOP limits from year-to-year, when the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages year over year, and does not discourage the adoption of the lower voluntary MOOP amount because of fluctuations in the amount. CMS expects to change MOOP limits if a consistent pattern of increasing or decreasing costs emerges over time.

As part of the annual Call Letter process, stakeholders have suggested changes to how CMS establishes MOOP limits. Some of the comments suggested CMS use Medicare FFS and MA encounter data to inform its decision-making. Other suggestions received have included increasing the voluntary MOOP limit, increasing the number of service categories that have higher cost sharing in return for a plan offering a lower MOOP limit, and considering three levels of MOOP and service category cost sharing to encourage plan offerings with lower MOOP limits.

CMS's goal is to establish future MOOP limits based on the most relevant and available data, or combination of data, that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. Medicare FFS data currently represents the most relevant and available data at this time. CMS may consider future rulemaking regarding the use of MA encounter cost data to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. Under this current proposal to revise the regulations controlling MOOP limits, CMS might change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. CMS expects to establish future limits by striking the appropriate balance between limiting MOOP costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages. While CMS intends to continue using the 85th and 95th percentiles of projected beneficiary out-of-pocket spending for the immediate future to set MA MOOP limits, CMS proposes to amend the regulation text in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (d)(3) to incorporate authority to balance factors discussed previously. The flexibility provided by these proposed changes will permit CMS to annually adjust mandatory and voluntary MOOP limits based on changes in market conditions and to ensure the sustainability of the MA program and benefit options.

The proposed new authority permitting changes in data and methodology related to establishing MOOP limits would be exercised by CMS in advance of each plan year; CMS would use the annual Call Letter and other guidance documents to explain its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid

[26] The CY 2018 final Call Letter may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

deadlines. This will provide MA organizations adequate time to comment and prepare for changes. In addition, CMS plans to transition any significant changes under this proposal over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.

CMS proposes to codify specific requirements because of the number of comments received in the past about MOOP changes. CMS proposes to amend §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits. In addition, CMS would have authority to increase the voluntary MOOP limit to another percentile level of Medicare FFS, increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, and implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits. This proposal includes authority to increase the number of service categories that have higher cost sharing in return for offering a lower (voluntary) MOOP amount and considering more than two levels of MOOP (with associated cost sharing limits) to encourage plan offerings with lower MOOP limits. Consistent with past practice, CMS will continue to publish annual limits and a description of how the regulation standard was applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with parameters that CMS has determined to meet the cost sharing limits requirements. CMS seeks comments and suggestions on the topics discussed in this section.

5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

As provided at §§ 417.454(e), 422.100(f)(6), and 422.100(j), MA plan cost sharing for Parts A and B services specified by CMS must not exceed certain levels. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS determines annually the level at which certain cost sharing becomes discriminatory. Sections 417.454(e) and 422.100(j), on the other hand, are based on how section 1852(a)(1)(B)(iii) and (iv) of the Act directs that cost sharing for certain services may not exceed cost sharing levels in Medicare Fee-for-Service (FFS); under the statute and the regulations, CMS may add to that list of services. CMS reviews cost sharing set by MA organizations using parameters based on Parts A and B services that are more likely to have a discriminatory impact on beneficiaries. The review parameters are currently based on Medicare FFS data and reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. CMS uses multiple utilization scenarios for some services (for example, inpatient care) to guard against MA organizations distributing benefit cost sharing amounts in a manner that is discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services.

CMS proposes here to amend § 422.100(f)(6) to clarify that it may use Medicare FFS data to establish appropriate cost sharing limits. In addition, CMS intends to use MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory; we solicit comment on whether to codify that use of MA encounter data for this purpose in § 422.100(f)(6). This proposal is not related to a statutory change.

This proposal aims to allow CMS to use the most relevant and appropriate information in determining whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. CMS intends to continue the practice of furnishing information to MA organizations about the methodology used to establish cost sharing limits and the thresholds CMS identifies as non-discriminatory through the annual Call Letter process or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory.

As specified in section 1852(a)(1)(B)(iv) of the Act, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has issued guidance that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability for the benefit in order for the cost sharing for such services to be considered non-discriminatory; CMS believes that cost sharing (service category deductibles, copayments or co-insurance) that fails to cover at least half the cost of a particular service or item acts to discriminate against those for whom those services and items are medically necessary and discourages enrollment by beneficiaries who need those services and items. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Medicare FFS service category cannot exceed 50 percent of the average contracted rate of that service under this guidance (Medicare Managed Care Manual, Chapter 4, Section 50.1). Some service categories may identify specific benefits for which a unique copayment would apply, while others include a variety of services with different levels of cost which may reasonably have a range of copayments based on groups of similar services, such as durable medical equipment or outpatient diagnostic and radiological services.

CMS affords MA plans that adopt a lower, voluntary MOOP limit greater flexibility in establishing Parts A and B cost sharing than is available to plans that adopt the higher, mandatory MOOP limit. As discussed in section III.A.5, CMS intends to continue to establish more than one set of Parts A and B service cost sharing thresholds for plans choosing to offer benefit designs with either a lower, voluntary MOOP limit or the higher, mandatory MOOP limit set under §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Medicare FFS data currently represents the most relevant and available data at this time and is used to evaluate cost sharing for specific services as well in applying the standard currently at § 422.100(f)(6) and in considering CMS's authority to add (by regulation) categories of services for which cost sharing may not exceed levels in Medicare FFS.

As noted with regard to setting MOOP limits under §§ 422.100 and 422.101, CMS expects that MA encounter data will be more accurate and complete in the future and may consider future rulemaking regarding the use of MA encounter to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. For reasons discussed in section III.A.5, CMS proposes to amend § 422.100(f)(6) to permit use of Medicare FFS to evaluate whether cost sharing for Part A and B services is discriminatory to set the evaluation limits announced each year in the Call Letter: in addition, we propose to use MA utilization encounter data as part of that evaluation process. As with the proposal to authorize use of this data for setting MOOP limits, CMS intends to use the Advance Notice/Call Letter process to communicate its

application of the regulation and to transition any significant changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.

This proposal will allow CMS to use the most relevant and appropriate information in determining cost sharing standards and thresholds. For example, analyses of MA utilization encounter data can be used with Medicare FFS data to establish the appropriate utilization scenarios to determine MA plan cost sharing standards and thresholds. CMS seeks comments and suggestions on this proposal, particularly whether additional regulation text is needed to achieve CMS's goal of setting and announcing each year presumptively discriminatory levels of cost sharing.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

As provided at §§ 422.254(a)(4) and 422.256(b)(4), CMS will only approve a bid submitted by a Medicare Advantage (MA) organization if its plan benefit package is substantially different from those of other plans offered by the organization in the area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. MA organizations may submit bids for multiple plans in the same area under the same contract only if those plans are substantially different from one another based on CMS's annual meaningful difference evaluation standards. CMS proposes to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019. Separate meaningful difference rules were concurrently adopted for MA and stand-alone prescription drug plans (PDPs), but this specific proposal is limited to the meaningful difference provision related to the MA program. This proposal is not related to a statutory change.

This proposal aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation. CMS will maintain requirements that prohibit plans from misleading beneficiaries in their communication materials, provide CMS the authority to disapprove a bid if a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and allow CMS to non-renew a plan that fails to attract a sufficient number of enrollees over a sustained period of time (§§ 422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects organizations to continue designing plan benefit packages that, within a service area, are different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized when comparing multiple plans offered by the organization. For example, beneficiaries may consider the following factors when they make their health care decisions: plan type, Part D coverage, differences in provider network, Part B and plan premiums, and unique populations served (for example, special needs plans, or SNPs). In addition, CMS intends to continue the practice of furnishing information to MA organizations about their bid evaluation methodology through the annual Call Letter process and/or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows CMS to articulate bid requirements and MA organizations to prepare bids that satisfy CMS requirements and standards prior to bid submission in June each year.

Research studies indicate that consumers, especially elderly consumers, may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth.[27] Beneficiaries indicate they want to make informed and effective decisions, but do not feel qualified. As a result, they seek help from Medicare Plan Finder (MPF), brokers or plan representatives, providers, and family members. Although challenged by choices, beneficiaries do not want their plan choices to be limited and understand key decision factors such as premiums, out-of-pocket cost sharing, Part D coverage, familiar providers, and company offering the plan.[28] CMS continues to explore enhancements to MPF that will improve the customer experience; some examples of recent updates are provided below.

As discussed later in this section, CMS believes that it is challenging to apply the current standardized meaningful difference evaluation (which is applied consistently to all plans) in a manner that accommodates and evaluates important considerations objectively. CMS is concerned that the current evaluation may create unintended consequences related to innovative benefit designs. In addition, CMS's efforts in implementing more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices. For example, in MPF, plan details have been expanded to include MA and Part D benefits and a new consumer friendly tool for the CY 2018 Medicare open enrollment period which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions.

Prior to implementing the meaningful difference evaluation for CY 2011 bid submissions, the beneficiary weighted average number of plans per county was about 30 in 2010 compared to 18 in 2017 (these numbers do not include SNPs or employer group plans which have additional criteria for enrollment). Private-fee-for-service (PFFS) plans represented 13 of the 30 plans in 2010 and less than 1 of the 18 plans in 2017. The Medicare Improvements for Patients and Providers Act of 2008 required PFFS plans to establish contracted provider networks by 2011 and many PFFS plans non-renewed. The weighted average number of plans has remained relatively stable since the decline of PFFS options. MA enrollment continued to grow from more than 11 million in July 2010 to 18.7 million in July 2017, fueled by the continued overall acceptance of managed care, the baby boom generation aging into Medicare beginning in 2011, and decreases in average plan premium during the time period.

As stated in the October 22, 2009, proposed rule (74 FR 54670 through 73) and April 15, 2010, final rule (75 FR 19736 through 40), CMS's goal for the meaningful difference evaluation was to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. The meaningful difference evaluation was initiated when cost sharing and benefits were relatively consistent within each plan and similar plans within the same contract could be readily compared by measuring estimated out-of-pocket costs and other factors currently integrated in the evaluation's methodology.

The current meaningful difference evaluation uses estimated enrollee out-of-pocket costs based on the CMS Out-of-Pocket Cost (OOPC) model. This model uses a nationally representative cohort of beneficiaries from the Medicare Beneficiary Surveys (MCBS)

[27] McWilliams JM, Afendulis CC, McGuire TG, Landon BE. Complex Medicare advantage choices may overwhelm seniors—especially those with impaired decision making. Health Aff (Millwood). 2011;30(9):1786–94.

[28] Jacobson, G. Swoope, C., Perry, M. Slosar, M. How are seniors choosing and changing health insurance plans? Kaiser Family Foundation. 2014.

and is intended to be objective and applied in a standardized and consistent manner across plans. MCBS data collected by CMS from beneficiaries are used to create the cohort of beneficiaries whose medical and prescription data are used to estimate out-of-pocket costs. The OOPC model generates estimated out-of-pocket costs based on utilization from the cohort of beneficiaries and each plan's benefit design entered into the Plan Benefit Package submitted to CMS as part of the bidding process. Detailed information about the meaningful difference evaluation is available in the CY 2018 Final Call Letter issued April 3, 2017 (pages 115–118) and information about the CMS OOPC model is available at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html*. Estimated enrollee cost sharing is determined by the cost sharing amounts for Part A, B, and D services and most mandatory supplemental benefits (for example, dental services). Benefit service categories within a plan may have a range of multiple and varying cost sharing amounts. For example, the outpatient procedures, tests, labs, and radiology services benefit category includes many services that may have a wide range of cost sharing amounts. The OOPC model uses the minimum or lowest cost sharing value placed in the Plan Benefit Package (PBP) for each service category to estimate out-of-pocket costs in these situations. As discussed in the CY 2018 Final Call Letter, the differences between similar plans must have at least a $20 per member per month estimated beneficiary out-of-pocket cost difference. Differences in plan type (for example, HMO, LPPO), SNP sub-type, and inclusion of Part D coverage are considered meaningful differences which aligns with beneficiary decision-making. Premiums, risk scores, actual plan utilization and enrollment are not included in the evaluation because these factors would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity.

Based on CMS's efforts to revisit MA standards and the implementation of the governing law to find flexibility for MA beneficiaries and plans, MA organizations are able to: (1) Tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data which was communicated in CY 2011 guidance; (2) establish Provider Specific Plans (PSPs) designed to offer enrollees benefits through a subset of the overall contracted network in a given service area, which are sometimes referred to as narrower networks, and which was collected in the PBP beginning in CY 2011; and (3) beginning in CY 2019, provide different cost sharing and/or additional supplemental benefits for enrollees based on defined health conditions within the same plan (Flexibility in the Medicare Advantage Uniformity Requirements). These flexibilities allow MA organizations to provide beneficiaries with access to health care benefits that are tailored to individual needs, but make it difficult for CMS to objectively measure meaningful differences between plans. Items 1 and 3 provide greater cost sharing flexibility to address individual beneficiary needs, but result in a much broader range of cost sharing values being entered into PBP. As discussed in the previous paragraph, the CMS OOPC model uses the lowest cost sharing value for each service category to estimate out-of-pocket costs which may or may not be a relevant comparison between different plans for purposes of evaluating meaningful difference when variable cost sharing of this type is involved.

CMS remains committed to ensuring transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. It is also important to encourage competition, innovation, and provide access to affordable health care approaches that address individual needs. The current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions. As a result, the meaningful difference evaluation would not fully represent benefit and cost sharing differences experienced by enrollees and could lead to MA organizations to focus on CMS standards, rather than beneficiary needs, when designing benefit packages.

In order to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations, the evaluation process would have to use more varied and complex assumptions to identify plans that are not meaningfully different from one another. CMS believes that such an evaluation could result in more complicated and potentially confusing benefit designs to achieve differences between plans. This process may require greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries.

The current meaningful difference methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. To satisfy current CMS meaningful difference standards, MA organizations may have to change benefit coverage or cost sharing in certain plans to establish the necessary benefit value difference, even if substantial difference exists based on factors CMS is currently unable to incorporate into the evaluation (such as tiered cost sharing, and unique benefit packages based on enrollee health conditions). Although these changes in benefits coverage may be positive or negative, CMS is concerned the meaningful difference requirement results in organizations potentially reducing the value of benefit offerings. On the basis of bid review activities performed over the past several years, CMS is concerned that benefits may be decreased or cost sharing increased to satisfy the meaningful difference evaluation. These are unintended consequences of the existing meaningful difference evaluation and may restrict innovative benefit designs that address individual beneficiary needs and affordability.

Beneficiaries may also consider plan and Part B premiums when choosing among health plan options. Making changes to the existing meaningful difference evaluation to consider premiums differences as sufficient to distinguish among otherwise similar plans may limit the value of CMS's evaluation by introducing factors that plans can easily leverage, such as risk selection, costs, and margin, to satisfy the evaluation test without resulting in additional benefit value or choice for enrollees.

Stakeholders have expressed concern that without the meaningful difference evaluation the number of bids and plan choices will likely increase and make beneficiary decisions more difficult. The number of plan bids may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but CMS does not believe the number of *similar* plan options offered by the same MA organization in each county will necessarily increase significantly or create confusion in beneficiary decision-making. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help

beneficiaries, caregivers, and family members make informed plan choices among more individualized plan offerings. Based on the previously stated information, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased health care provider burden.

In addition, new flexibilities in benefit design may allow MA organizations to address different beneficiary needs within existing plan options and reduce the need for new plan options to navigate existing CMS requirements. In addition, MA organizations may be able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions if the MA organizations are not required to change benefit and cost sharing designs in order to satisfy §§ 422.254 and 422.256. Currently, MA organizations must satisfy CMS meaningful difference standards (and other requirements), rather than solely focusing on beneficiary purchasing needs when establishing a range of plan options.

CMS supports beneficiary decision-making by providing tools and materials that focus on key beneficiary purchasing criteria, such as eligibility to enroll in SNPs, need for Part D coverage, Part D formulary and benefit coverage, plan type preference (for example, HMO vs. PPO), network providers, medical benefit coverage, premiums, and the brand or organization offering the plan options. CMS is also taking steps to improve information available through MPF and 1–800–MEDICARE to help beneficiaries, caregivers, and family members make informed plan choices.

CMS continually evaluates consumer engagement tools and outreach materials (including marketing, educational, and member materials) to ensure information is formatted consistently so beneficiaries can easily compare multiple plans. CMS also provides annual guidance and model materials to MA organizations to assist them in providing resources, such as the plan's Annual Notice of Change and Evidence of Coverage, which contain valuable information for the enrollee to evaluate and select the best plan for their needs. To reinforce informed decision making, CMS invests substantial resources in engagement strategies such as 1–800–MEDICARE, MPF, standard and electronic mail, and social media to continuously communicate with beneficiaries, caregivers, family members, providers, community resources, and other stakeholders.

CMS will continue to furnish information to MA organizations and solicit comments on bid evaluation methodology through the annual Call Letter process or HPMS memoranda, as appropriate.

In addition, CMS is maintaining requirements around plans not misleading beneficiaries in communication materials, disapproving a bid if CMS finds that a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and non-renewing plans that fail to attract a sufficient number of enrollees over a sustained period of time (§§ 422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects these measures will continue to protect beneficiaries from discriminatory plan benefit packages and health plans that demonstrate a lack of beneficiary interest if the meaningful difference requirement is eliminated. For all these reasons, CMS proposes to remove §§ 422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS seeks comments and suggestions on the topics discussed in this section about making sure beneficiaries have access to innovative plans that meet their unique needs.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

Section 1851(c)(3)(A)(ii) of the Act provides the Secretary with the authority to implement default enrollment rules for the Medicare Advantage (MA) program in addition to the statutory direction that beneficiaries who do not elect an MA plan are defaulted to original (fee-for-service) Medicare. This provision states that the Secretary may establish procedures whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way.

We initially addressed default enrollment upon conversion to Medicare in rulemaking (70 FR 4606 through 4607) in 2005, indicating that we would retain the flexibility to implement this provision through future instructions and guidance to MA organizations. Such subregulatory guidance was established later that same year and was applicable to the 2006 contract year. As outlined in Chapter 2 of the Medicare Managed Care Manual, we established an optional enrollment mechanism, whereby MA organizations may develop processes and, with CMS approval, provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare. The guidance emphasized that MA organizations not limit seamless continuation of coverage to situations in which an enrollee becomes eligible for Medicare by virtue of age, but includes all newly eligible Medicare beneficiaries, including those whose Medicare eligibility is based on disability. We did not mandate that organizations implement a process for seamless continuation of coverage but, instead, gave organizations the option of implementing such a process for its enrollees who are approaching Medicare eligibility. From its inception, the guidance has required that individuals receive advance notice of the proposed MA enrollment and have the ability to ''opt out'' of such an enrollment prior to the effective date of coverage. This guidance has been in practice for the past decade for MA organizations that requested to use this voluntary enrollment mechanism, but we have encountered complaints and heard concerns about the practice. We are proposing new regulation text to establish limits and requirements for these types of default enrollments to address these concerns and our administrative experience with seamless continuation of coverage, commonly referred to as seamless conversion.

Based on our experience with the seamless conversion process thus far, we are proposing, to be codified at § 422.66(c)(2), requirements for seamless default enrollments upon conversion to Medicare. As proposed in more detail later in this section, such default enrollments would be into dual eligible special needs plans (D–SNPs) and be subject to five substantive conditions: (1) The individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; (3) the individual does not opt out of the default enrollment; (4) the MA

organization provides a notice that meets CMS requirements to the individual; and (5) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed. We are also proposing that coverage under these types of default enrollments begin on the first of the month that the individual's Part A and Part B eligibility is effective. We are also proposing changes to §§ 422.66(d)(1) and (d)(5) and 422.68 that coordinate with the proposal for § 422.66.

In the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter, we explained how entities that sponsor Medicaid managed care organizations (MCOs) and affiliated D–SNPs can promote coverage of an integrated Medicare and Medicaid benefit through existing authority for seamless continuation of coverage of Medicaid MCO members as they become eligible for Medicare. We received positive comments from state Medicaid agencies that supported this enrollment mechanism and requested that we clarify the process for approval of seamless continuation of coverage as a mechanism to promote enrollment in integrated D–SNPs that deliver both Medicare and Medicaid benefits. We also received comments from beneficiary advocates asking that additional consumer protections, including requiring written beneficiary confirmation and a special enrollment period for those individuals who transition from non-Medicare products to Medicare Advantage. We believe that our proposal, described later in this section, adequately addresses the concerns on which these requests are based, given that the default enrollment process would be permissible only for individuals enrolled in a Medicaid managed care plan in states that support this process. This means that the Medicare plan into which individuals would be defaulted would be one that is offered by the same parent organization as their existing Medicaid plan, such that much of the information needed by the MA plan would already be in the possession of the MA organization to facilitate the default enrollment process. Also, default enrollment would not be permitted if the state does not actively support this process, ensuring an accurate source of data for use by MA organizations to appropriately identify and notify individuals eligible for default enrollment.

On October 21, 2016,[29] in response to inquiries regarding this enrollment mechanism, its use by MA organizations, and the beneficiary protections currently in place, we announced a temporary suspension of acceptance of new proposals for seamless continuation of coverage. Based on our subsequent discussions with beneficiary advocates and MA organizations approved for this enrollment mechanism, it is clear that organizations attempting to conduct seamless continuation of coverage from commercial coverage (that is, private coverage and Marketplace coverage) find it difficult to comply with our current guidance and approval parameters. This is especially true of the requirement to identify commercial members who are approaching Medicare eligibility based on disability. Also challenging for these organizations is the requirement that they have the means to obtain the individual's Medicare number and are able to confirm the individual's entitlement to Part A and enrollment in Part B no fewer than 60 days before the MA plan enrollment effective date.

In addition, the ability for organizations to conduct seamless enrollment of individuals converting to Medicare will be further limited due to the statutory requirement that CMS remove Social Security Numbers (SSNs) from all Medicare cards by April 2019. A new Medicare number will replace the SSN-based Health Insurance Claim Number (HICN) on the new Medicare cards for Medicare transactions. Beginning in April 2018, we'll start mailing the new Medicare cards with the new number to all people with Medicare. Given the random and unique nature of the new Medicare number, we believe MA organizations will be limited in their ability to automatically enroll newly eligible Medicare beneficiaries without having to contact them to obtain their Medicare numbers, as CMS does not share Medicare numbers with organizations for their commercial members who are approaching Medicare eligibility. We note that contacting the individual in order to obtain the information necessary to process the enrollment does not align with the intent of default enrollment, which is designed to process enrollments and have coverage automatically shift into the MA plan without an enrollment action required by the beneficiary.

Organizations operating Medicaid managed care plans are better able to meet these requirements when states provide data, including the individual's Medicare number, on those about to become Medicare eligible. As part of coordination between the Medicare and Medicaid programs, CMS shares with states, via the State MMA file, data of individuals with Medicaid who are newly becoming entitled to Medicare; such data includes the Medicare number of newly eligible Medicare beneficiaries. MA organizations with state contracts to offer D–SNPs would be able to obtain (under their agreements with state Medicare agencies) the data necessary to process the MA enrollment submission to CMS. Therefore, we are proposing to revise § 422.66 to permit default enrollment only for Medicaid managed care enrollees who are newly eligible for Medicare and who are enrolled into a D–SNP administered by an MA organization under the same parent organization as the organization that operates the Medicaid managed care plan in which the individual remains enrolled. These requirements would be codified at § 422.66(c)(2)(i) (as a limit on the type of plan into which enrollment is defaulted) and (c)(2)(i)(A) (requiring existing enrollment in the affiliated Medicaid managed care plan as a condition of default MA enrollment). At paragraph (c)(2)(i)(B), we are also proposing to limit these default enrollments to situations where the state has actively facilitated and approved the MA organization's use of this enrollment process and articulates this in the agreement with the MA organization offering the D–SNP, as well as providing necessary identifying information to the MA organization.

The option of default enrollment can be particularly beneficial for Medicaid managed care enrollees who are newly eligible for Medicare, because in the case that the parent organization of the Medicaid managed care plan also offers a D–SNP, default enrollment promotes enrollment in a plan that offers some level of integration of acute care, behavioral health and, for eligible beneficiaries, long-term care services and supports, including institutional care, and home and community-based services (HCBS). This is in line with CMS' support of state efforts to increase enrollment of dually eligible individuals in fully integrated systems of care and the evidence [30] that such systems

[29] *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS_Memo_Seamless_Moratorium.pdf.*

[30] There is a growing evidence that integrated care and financing models can improve beneficiary experience and quality of care, including:

• Health Management Associates, *Value Assessment of the Senior Care Options (SCO)*

improve health outcomes. Further this proposal will provide states with additional flexibility and control. States can decide if they wish to allow their contracted Medicaid managed care plans to use default enrollment of Medicaid enrollees into D–SNPs and can control which D–SNPs receive default enrollments through two means: The contracts that states maintain with D–SNPs (§ 422.107(b)) and by providing the data necessary for MA organizations to successfully implement the process. Under our proposal, MA organizations can process default enrollments only for dual-eligible individuals in states where the contract with the state under § 422.107 approves it and the state identifies eligibility and shares necessary data with the organization.

To ensure that Medicaid beneficiaries considered for default enrollment upon their conversion to Medicare are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, we also propose, at § 422.66(c)(2)(i)(C) and (c)(2)(iv), that the MA organization must issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. The proposed revised notice [31] must include clear information on the D–SNP, as well as instructions to the individual on how to opt out (or decline) the default enrollment and how to enroll in Original Medicare or a different MA plan. This notice requirement aims to help ensure a smooth transition of eligible individuals into the D–SNP for those who choose not to opt out. All MA organizations currently approved to conduct seamless conversion enrollment issue at least one notice 60 days prior to the MA enrollment effective date, so our proposal would not result in any additional burden to these MA organizations using this process. Recent discussions with MA organizations currently conducting seamless conversion enrollment have revealed that several of them already include in their process additional outreach, including reminder notices and outbound telephone calls to aid in the transition. We believe that these additional outreach efforts are helpful and we would encourage their use under our proposal.

We also propose, in paragraph (c)(2)(i)(E) and (2)(ii), that MA organizations must obtain approval from CMS before implementing default enrollment. Under our proposal in paragraph (c)(2)(i)(B), CMS approval would be granted only if the applicable state approves the default enrollment through its agreement with the MA organization. MA organizations would be required to implement default enrollment in a non-discriminatory manner, consistent with their obligations under § 422.110; that is, MA organizations could not select for default enrollment only certain of the members of the affiliated Medicaid plan who were identified as eligible for default enrollment. Lastly, we propose that CMS may suspend or rescind approval at any time if it is determined that the MA organization is not in compliance with the requirements. We request comment whether this authority to rescind approval should be broader; we have considered whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization under this proposed regulation in order to assure that the regulation requirements are still being followed. We are particularly interested in comment on this point in conjunction with our alternative (discussed later in this section) proposal to codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.

Under our proposal, default enrollment of individuals at the time of their conversion to Medicare would be more limited than the default enrollments Congress authorized the Secretary to permit in section 1851(c)(3)(A)(ii) of the Act. However, we are also proposing some flexibility for MA organizations that wish to offer seamless continuation of coverage to their non-Medicare members, commercial, Medicaid or otherwise, who are gaining Medicare eligibility. As discussed in more detail below, affirmative elections would be necessary for individuals not enrolled in a Medicaid managed care plan, consistent with § 422.50. However, because individuals enrolled in an organization's commercial plan, for example would already be known to the parent organization offering both the non-Medicare plan and the MA plan and the statute acknowledges that this existing relationship is somewhat relevant to Part C coverage, we propose to amend § 422.66(d)(5) and to establish, through subregulatory guidance, a new and simplified positive (that is, ''opt in'') election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members. To reflect our change in policy with regard to a default enrollment process and this proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same entity as the individual's non-Medicare coverage, we are also proposing to add text in § 422.66(d)(5) authorizing a simplified election for purposes of converting existing non-Medicare coverage, commercial, Medicaid or otherwise, to MA coverage offered by the same organization. This new mechanism would allow for a less burdensome process for MA organizations to offer enrollment in their MA plans to their non-Medicare health plan members who are newly eligible for Medicare. As the MA organization has a significant amount of the information from the member's non-Medicare enrollment, this new simplified election process aims to make enrollment easier for the newly-eligible beneficiary to complete and for the MA organization to process. It would align with the individual's Part A and Part B initial enrollment period (and initial coordinated election period for MA coverage), provided he or she enrolled in both Medicare Parts A and B when first eligible for Medicare. This new election process would provide a longer period of time for MA organizations to accept enrollment requests than the time period in which MA organizations would be required to effectuate default enrollments, as organizations would be able to accept enrollments throughout the individual's Initial Coverage Election Period (ICEP), which for an aged beneficiary is the 7-month period that begins 3 months before the month in which the individual turns 65 and ends 3 months after the month in which the individual turns 65. We would use existing authority to create this new enrollment

Program, July 21, 2015, available at: *http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper_2015_07_21.pdf;*

• MedPAC chapter ''*Care coordination programs for dual-eligible beneficiaries,*'' June 2012, available at: *http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0;*

• Anderson, Wayne L., Zhanlian Fen, and Sharon K. Long, RTI International and Urban Institute, *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE), March 2016, available at: *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

[31] Enrollment requirements and burden are currently approved by OMB under control number 0938–0753 (CMS–R–267). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

mechanism which, if implemented, would be available to MA organizations in the 2019 contract year. We solicit comments on the proposed changes to the regulation text as well as the form and manner in which such enrollments may occur.

This optional simplified election process for the enrollment of non-Medicare plan members into MA upon their initial eligibility (or initial entitlement) for Medicare would provide individuals the option to remain with the organization that offers their non-Medicare coverage. A positive election in this circumstance provides an additional beneficiary protection for non-dually eligible individuals, so that they may actively choose a Medicare plan structure similar to that of their commercial, Medicaid or other non-Medicare health plans, as there may be significant differences between an organization's commercial plans, for example, and its MA plans in terms of provider networks, drug formularies, costs and benefit structures. While these differences may result in a more restrictive network, a mandated change in a primary care physician and increased out-of-pocket costs for converting enrollees, default enrollment of a dually eligible individual enrolled in a Medicaid plan into a D–SNP, triggers no premium liability or cost sharing for medical care or prescription drugs above levels that apply under Original Medicare. Further, the individual remains in the Medicaid managed care plan and is gaining additional Medicare coverage, which is not always the case in other contexts. We solicit comment on these coordinated proposals to implement section 1851(c)(3)(A)(ii) in general as discussed below and in two particular ways: (1) To permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and (2) to permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan. We further invite comments regarding whether the CMS approval of an organization's request to conduct default enrollment should be limited to a specific time frame. In addition, we are proposing amendments to §§ 422.66(d)(1) and 422.68 that are also related to MA enrollment. Currently, as described in the 2005 final rule (70 FR 4606 through 4607), § 422.66(d)(1) requires MA organizations to accept, during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, enrollment requests from an individual who is enrolled in a non-Medicare health plan offered by the MA organization and who meets MA eligibility requirements. To better reflect section 1851(c)(3)(A)(ii), we are proposing to amend § 422.66(d)(1) to add text clarifying that seamless continuations of coverage are available to an individual who requests enrollment during his or her Initial Coverage Election Period. In light of our proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same parent organization as the individual's non-Medicare coverage, we are also proposing a revision to § 422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made. This proposed revision would codify the subregulatory guidance that MA organizations have been following since 2006. This proposal is also consistent with the proposal at § 422.66(c)(2)(iii) regarding the effective date of coverage for default enrollments into D–SNPs. We also solicit comment on these related proposals.

In conclusion, we are proposing to add regulation text at § 422.66(c)(2)(i) through (iv) to set limits and requirements for a default enrollment of the type authorized under section 1851(c)(3)(A)(ii). We are proposing a clarifying amendment to § 422.66(d)(1) regarding when seamless continuation coverage can be elected and revisions to § 422.66(d)(5) to reflect our proposal for a new and simplified positive election process that would be available to all MA organizations. Lastly, we are proposing revisions to § 422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made.

We invite comments in general on our proposal, as well as on the alternatives presented. We recognize that our proposal narrows the scope of default enrollments compared to what CMS approved under section 1851(c)(3)(A) of the Act in the past. As we contemplated the future of the seamless conversion mechanism, we considered retaining processes similar to how the seamless conversion mechanism is outlined currently in section 40.1.4 of Chapter 2 of the Medicare Managed Care Manual and had been in practice through October 2016. We considered proposing regulations to codify that guidance as follows—

- Articulating the requirements for an MA organization's proposal to use the seamless conversion mechanism, including identifying eligible individuals in advance of Medicare eligibility;
- Establishing timeframes for processing and the effective date of the enrollment; and
- Requiring notification to individuals at least 60 days prior to the conversion of their right to opt-out or decline the enrollment.

In considering this alternative, we contemplated adding additional beneficiary protections, including the issuance of an additional notice to ensure that individuals understood the implication of taking no action. While this alternative would have led to increased use of the seamless conversion enrollment mechanism than what had been used in the past, the operational challenges, particularly in relation to the new Medicare Beneficiary Identification number may be significant for MA organizations to overcome at this time.

We also considered proposing regulations to limit the use of default enrollment to only the aged population. While this alternative would simplify a MA organization's ability to identify eligible individuals, we have concerns about disparate treatment among newly eligible individuals based on their reason for obtaining Medicare entitlement.

We invite comments on our proposal and the alternate approaches, including the following:

- Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.
- Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.

If commenters recommend one or more alternate approaches, we ask for suggested solutions that address the concerns noted in this discussion, particularly related to the requirement that plans identify commercial members who are approaching Medicare eligibility based on disability, as well as how plans could confirm MA eligibility and process enrollments without access to the individual's Medicare number.

8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

Beneficiaries who are dually eligible for both Medicare and Medicaid typically 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 unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible beneficiaries with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.

Integrated care options are increasingly available for dually eligible beneficiaries, which include a variety of integrated D–SNPs. D–SNPs can provide greater integrated care than enrollees would otherwise receive in other MA plans or Medicare Fee-For-Service (FFS), particularly when an individual is enrolled in both a D–SNP and Medicaid managed care organization offered by the same organization. D–SNPs that meet higher standards of integration, quality, and performance benchmarks—known as highly integrated D–SNPs—are able to offer additional supplemental benefits to support integrated care pursuant to § 422.102(e). D–SNPs that are fully integrated—known as Fully Integrated Dual-Eligible (FIDE) SNPs, as defined at § 422.2 provide for a much greater level of integration and coordination than non-integrated D–SNPs, providing all primary, acute, and long-term care services and supports under a single entity.

While enrollment in integrated care options continues to grow, there are instances in which beneficiaries may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D–SNPs and state re-procurements of Medicaid managed care organizations. Such disruptions can result in beneficiaries being enrolled in two separate organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same entity offers both benefit packages. In an effort to protect the continuity of integrated care for dually eligible beneficiaries, we are proposing a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries in instances where integrated care coverage would otherwise be disrupted.

Section 1851(c)(1) of the Act authorizes us to develop mechanisms for beneficiaries to elect MA enrollment, and we have used this authority to create passive enrollment. The current regulation at § 422.60(g) limits the use of passive enrollment to two scenarios: (1) In instances where there is an immediate termination of an MA contract; or (2) in situations in which we determine that remaining enrolled in a plan poses potential harm to beneficiaries. The passive enrollment defined in § 422.60(g) requires beneficiaries to be provided prior notification and a period of time prior to the effective date to opt out of enrollment from a plan. Current § 422.60(g)(3) provides every passively enrolled beneficiary with a special election period to allow for election of different Medicare coverage: Selecting a different managed care plan or opting out of MA completely and, instead, receiving services through Original Medicare (a FFS delivery system). A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.

Our proposal is a limited expansion of this regulatory authority to promote continued enrollment of dually eligible beneficiaries in integrated care plans to preserve and promote care integration under certain circumstances. The proposal includes use of these existing opt-out procedures and special election period. Therefore, we are proposing to redesignate these requirements from (g)(1) through (3) to (g)(3) through (g)(5) respectively, with minor revisions in proposed paragraph (g)(5) to describe the application of special election period and in proposed paragraph (g)(4) to make minor grammatical changes to the text to improve its readability and clarity.

Our proposal is to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D–SNP into another integrated D–SNP under certain circumstances. We anticipate that these proposed regulations would permit passive enrollments only when all the following conditions are met:

- When necessary to promote integrated care and continuity of care;
- Where such action is taken in consultation with the state Medicaid agency;
- Where the D–SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and
- Where certain other conditions are met to promote continuity and quality of care.

We expect that these factors would all occur in situations when affected beneficiaries would otherwise be experiencing an involuntary disruption in either their Medicare or Medicaid coverage. We anticipate using this new proposed authority exclusively in such situations.

All individuals would be provided with a special election period (which, as established in subregulatory guidance, lasts for 2 months), as described in § 422.62(b)(4), provided they are not otherwise eligible for another SEP (for example, under proposed § 423.38(c)(4)(ii)).

For illustrative purposes we have outlined two scenarios in which this proposed regulatory authority could be used to promote continued access to integrated care and maintain continuity of care for dually eligible individuals:

- *State Re-Procurement of Medicaid Managed Care Contracts:* In several states, dually eligible beneficiaries receive Medicaid services through managed care plans that the state selects through a competitive procurement process. Some states also require that the sponsors of Medicaid health plans also offer a D–SNP in the same service area to promote opportunities for integrated care. Dually eligible beneficiaries can face disruptions in coverage due to routine state re-procurements of Medicaid managed care contracts. Individuals enrolled in Medicaid managed care plans that are not renewed are typically transitioned to a separate Medicaid managed care plan. In such a scenario, dually eligible beneficiaries enrolled in the non-renewing Medicaid managed care plan's corresponding D–SNP product would now be enrolled in two separate organizations for their Medicaid and Medicare services, resulting in non-integrated coverage. Under this proposed regulation, CMS would have the ability, in consultation with the state Medicaid agency that contracts with integrated D–SNPs, to passively enroll dually eligible beneficiaries facing such a disruption into an integrated D–SNP that corresponds with their new Medicaid managed care plan, thereby promoting continuous enrollment in integrated care.

• *Non-Renewal of D–SNP Contracts:* Beneficiaries enrolled in an integrated D–SNP that non-renews its MA contract at the end of the contract year can face disruptions in integrated care coverage, requiring them to actively select a new MA plan or default into Original Medicare and a standalone prescription drug plan. While states are permitted to passively enroll beneficiaries for Medicaid coverage as defined in § 438.54(c), CMS is not permitted to do so for Medicare coverage when an MA plan non-renews at the end of the contract year, as current authority for passive enrollment is limited to midyear terminations. Rather, beneficiaries in the D–SNP that is non-renewing its contract would need to actively select and enroll in an MA plan that integrates their Medicare and Medicaid coverage in order to continue the same level of integrated care. Permitting CMS the ability to passively enroll D–SNP enrollees into other integrated D–SNP plans in consultation with the state Medicaid agency would support beneficiaries remaining in integrated care.

With a limited expansion of our passive enrollment regulatory authority, we can better promote integrated care and continuity of care for dually eligible beneficiaries. Therefore, we are proposing to redesignate the introductory text in § 422.60(g) as paragraph (g)(1), with a new heading, technical revisions to the existing text that specifies when passive enrollments may be implemented by CMS designated as (g)(1)(i) and (ii), and a new paragraph (iii). This new (g)(1)(iii) would authorize CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D–SNP into another integrated D–SNP, after consulting with the state Medicaid agency that contracts with the D–SNP or other integrated managed care plan, to promote continuity of care and integrated care.

We also propose to add a new paragraph (g)(2) to include a number of requirements that an MA plan would have to meet in order to qualify to receive passive enrollments under paragraph (g)(1)(iii). We also propose to include in paragraph (g)(1)(iii) a reference to new paragraph (g)(2) to make it clear that a contract with the state is also necessary for a D–SNP to be eligible to receive these passive enrollments. Specifically, we propose that in order to receive passive enrollments under the new authority, MA plans must be highly integrated, thereby restricting passive enrollment to those MA plans that operate as a FIDE SNP or meet the integration standard for a highly-integrated D–SNP, as defined in § 422.2 and described in § 422.102(e) respectively. In an effort to ensure continuity of care, acquiring MA plans would also be required to have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the integrated MA plan (or plans) from which beneficiaries are passively enrolled. MA plans receiving passive enrollment would also be required to not have any prohibition on new enrollment imposed by CMS and have appropriate limits on premium and cost-sharing for beneficiaries. If our proposed paragraphs (g)(1) and (g)(2) are finalized, we would describe in subregulatory guidance the procedure through which CMS would determine qualification for passive enrollment. We also propose that to receive these passive enrollments, that D–SNP must meet minimum quality standards based on MA Star Ratings; we direct the reader to the proposal at section III.A.12. of this rule regarding the MA Star Rating System. Our proposed regulation text refers to a requirement to have a minimum overall MA Star Rating of at least 3 stars, which represents average or above-average performance. The rating for the year prior to receipt of passive enrollment would be used in order to provide sufficient time for CMS, states, and MAOs to prepare for the passive enrollment process. Low-enrollment contracts or new plans without MA Star Ratings as defined in § 422.252 would also be eligible for passive enrollment under our proposal, as long as the plan meets all other proposed requirements.

Our goal with this proposed requirement is to ensure that the D–SNP plans receiving these passive enrollments provide high-quality care, coverage and administration of benefits. As passive enrollments, in some sense, are a benefit to a plan, by providing an enrollee and associated payments without the plan having successfully marketed to the enrollee, we believe that it is important that these enrollments are limited to plans that have demonstrated commitment to quality. Further, it is important to ensure that when we are making an enrollment decision for a beneficiary who does not make an alternative coverage choice that we are guided by the beneficiary's best interests, which are likely served by a plan that is rated as having average or above-average performance on the MA Stars Rating System. However, we recognize that MA Star Ratings do not capture performance for those services that would be covered under Medicaid, including community behavioral health treatment and long-term services and supports. We welcome comments on the process for determining qualification for passive enrollment under this proposal and particularly on the minimum quality standards. We request that commenters identify specific measures and minimum ratings that would best serve our goals in this proposal and are specific or especially relevant to coverage for dually eligible beneficiaries.

In addition to the proposed minimum quality standards and other requirements for a D–SNP to receive passive enrollments, we are considering limiting our exercise of this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs. We seek comment on this potential further limitation on exercise of the proposed passive enrollment regulatory authority to better promote integrated care and continuity of care. In particular, we seek stakeholder feedback how to calculate the projected impact on Medicare and Medicaid costs from exercise of this authority.

The intent of the proposed passive enrollment regulatory authority is to better promote integrated care and continuity of care—including with respect to Medicaid coverage—for dually eligible beneficiaries. As such, we would implement this authority in consultation with the state Medicaid agencies that are contracting with these plan sponsors for provision of Medicaid benefits.

We considered proposing new beneficiary notification requirements for passive enrollments that occur under proposed paragraph (g)(1)(iii). We considered requiring MA organizations receiving the passive enrollment to provide two notifications to all potential enrollees prior to their enrollment effective date. We acknowledge that under the Financial Alignment Initiative demonstrations, states are required to provide two passive enrollment notices. Under the passive enrollment authority proposed here, we would continue to encourage, but not require, a second notice or additional outreach to impacted individuals. Given the existing beneficiary notifications that are currently required under Medicare regulations and concerns regarding the quantity of notifications sent to beneficiaries, we are not proposing to modify the existing notification requirements, so these existing standards would apply for existing passive enrollments and for the newly proposed passive enrollment authority.

However, we solicit comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices. Our proposal redesignates the notice requirements to paragraph (g)(4) with minor grammatical revisions.

Finally, we propose a technical correction to a citation in § 422.60(g), which discusses situations involving an immediate termination of an MA plan as provided in § 422.510(a)(5). This citation is outdated, as the regulatory language at § 422.510(a)(5) has been moved to § 422.510(b)(2)(i)(B). We propose to replace the current citation with a reference to § 422.510(b)(2)(i)(B).

9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

a. Background

Section 1860D–4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering prescription drug benefits for Part D drugs through the use of a tiered formulary may request an exception to the plan sponsor's tiered cost-sharing structure. The statute requires such plan sponsors to have a process in place for making determinations on such requests, consistent with guidelines established by the Secretary. At the start of the Part D program, we finalized regulations at § 423.578(a) that require plan sponsors to establish and maintain reasonable and complete exceptions procedures. These procedures permit enrollees, under certain circumstances, to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary. Such an exception is granted when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement. The tiering exceptions regulations establish the general scope of issues that must be addressed under the plan sponsor's tiering exceptions process. Our goal with the exceptions rules codified in the Part D final rule (70 FR 4352) was to allow plan sponsors sufficient flexibility in benefit design to obtain pricing discounts necessary to offer optimal value to beneficiaries, while ensuring that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost-sharing called for under the law.

At the start of the program, most Part D formularies included no more than four cost-sharing tiers, generally with only one generic tier. For the 2006 and 2007 plan years respectively, about 83 percent and 89 percent of plan benefit packages (PBPs) that offered drug benefits through use of a tiered formulary had 4 or fewer tiers. Since that time, there have been substantial changes in the prescription drug landscape, including increasing costs of some generic drugs, as well as the considerable impact of high-cost drugs on the Part D program. Plan sponsors have responded by modifying their formularies and PBPs, resulting in the increased use of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers. The flexibilities CMS permits in benefit design enable plan sponsors to continue to offer comprehensive prescription drug coverage with reasonable controls on out of pocket costs for enrollees, but increasingly complex PBPs with more variation in type and level of cost-sharing. For the 2017 plan year, about 91 percent of all Part D PBPs offer drug benefits through use of a tiered formulary. Over 98 percent of those tiered PBPs use a formulary containing 5 or 6 tiers; of those, about 98 percent contain two generic-labeled tiers.

These changes and increased complexities, and more than a decade of program experience, lead us to believe that our current regulations are no longer sufficient to ensure that tiering exceptions are understood by beneficiaries and adjudicated by plan sponsors in the manner the statute contemplates. For this reason, we propose to amend §§ 423.560, 423.578(a) and 423.578(c) to revise and clarify requirements for how tiering exceptions are to be adjudicated and effectuated.

While section 1860D–4(g)(2) of the Act uses the terms ''preferred'' and ''non-preferred'' drug, rather than ''brand'' and ''generic'', it also gives the Secretary authority to establish guidelines for making a determination with respect to a tiering exception request. The statute further specifies that ''a non-preferred drug *could* be covered under the terms applicable for preferred drugs'' (emphasis added) if the prescribing physician determines that the preferred drug would not be as effective or would have adverse effects for the individual. The statute therefore contemplates that tiering exceptions must allow for an enrollee with a medical need to obtain favorable cost-sharing for a non-preferred product, but that such access be subject to reasonable limitations. Establishing regulations that allow plans to impose certain limitations on tiering exceptions helps ensure that all enrollees have access to needed drugs at the most favorable cost-sharing terms possible.

b. General Rules

We are proposing to revise § 423.578(a)(2) to read as follows: ''Part D plan sponsors must establish criteria that provide for a tiering exception consistent with paragraphs § 423.578(a)(3) through (a)(6) of this section.'' We believe that inserting a cross-reference to paragraph (a)(6), which establishes allowable limitations on tiering exceptions, and which we are also proposing to revise, would streamline and clarify the requirements for such exceptions. The proposed revisions would establish rules that more definitively base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels.

c. Limitations on Tiering Exceptions

We are also proposing to revise the regulations at § 423.578(a)(6) to specify when a Part D plan sponsor may limit tiering exceptions. We believe the current text, which permits a plan sponsor to exempt any dedicated generic tier from its tiering exceptions procedures, is being applied in a manner that restricts tiering exceptions more stringently than is appropriate. Specifically, Part D sponsors have been considering any tier that is labeled ''generic'' to be exempt from tiering exceptions even if the tier also contains brand name drugs. This has become even more problematic with the increase in the number of PBPs with more than one tier labeled ''generic''. Based on an analysis of 2017 plan data entered into the Health Plan Management System (HPMS), for all Part D plans using a tiered formulary, 62 percent have indicated at least two tiers that contain only generic drugs, and 7 percent have three such tiers. Combined with the allowable exemption of a specialty tier (used by 99.8 percent of tiered Part D plans in 2017), almost two-thirds of all tiered PBPs could exempt 3 of their 5 or 6 tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs. To ensure appropriate enrollee access to tiering exceptions, we are proposing to revise § 423.578(a)(6) to specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Under this proposal, however, plans would be required to approve tiering exceptions for non-preferred generic drugs when

the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs. As described in the following paragraph, we are also proposing at § 423.578(a)(6) to establish specific tiering exceptions policy for biological products.

Proposed § 423.578(a)(6)(iii) would specify that, ''If a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.'' We also propose to add the following definition to Subpart M at § 423.560:

Specialty tier means a formulary cost-sharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary. We note that, while the proposed definition of specialty tier does not refer to ''unique'' drugs as existing § 423.578(a)(7) does, we do not intend to change the criteria for the specialty tier, which has always been based on the drug cost. This proposal would retain the current regulatory provision that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on the plan's specialty tier. This policy is currently codified at § 423.578(a)(7), which would be revised and redesignated as § 423.578(a)(6)(iii). We believe that retaining the existing policy limiting the availability of tiering exceptions for drugs on the specialty tier is important because of the beneficiary protection that limits cost-sharing for the specialty tier to 25 percent coinsurance (up to 33 percent for plans that have a reduced or $0 Part D deductible), ensuring that these very high cost drugs remain accessible to enrollees at cost sharing equivalent to the defined standard benefit.

We also clarify that, if the specialty tier has cost sharing more preferable than another tier, then a drug placed on such other non-preferred tier is eligible for a tiering exception down to the cost sharing applicable to the specialty tier if an applicable alternative drug is on the specialty tier and the other requirements of § 423.578(a) are met. In other words, while plans are not required to allow tiering exceptions for drugs on the specialty tier to a more preferable cost-sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions.

We believe a shift in regulatory policy that establishes a distinction between non-preferred branded drugs, biological products, and non-preferred generic and authorized generic drugs, achieves needed balance between limitations in plans' exceptions criteria and beneficiary access, and aligns with how many plan sponsors already design their tiering exceptions criteria. Accordingly, we are proposing to revise § 423.578(a)(6) to clarify and establish additional limitations plans would be permitted to place on tiering exception requests. First, we are proposing new paragraphs (i) and (ii), which would permit plans to limit the availability of tiering exceptions for the following drug types to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee's condition:

- Brand name drugs for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)); and
- Biological products, including follow-on biologics, licensed under section 351 the Public Health Service Act.

With the proposed revisions, that approved tiering exceptions for brand name drugs would generally be assigned to the lowest applicable cost-sharing associated with brand name alternatives, and approved tiering exceptions for biological products would generally be assigned to the lowest applicable cost-sharing associated with biological alternatives. Similarly, tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternatives that are either brand or generic drugs (see further discussion later in this section related to assignment of cost-sharing for approved tiering exceptions to the lowest applicable tier). Given the widespread use of multiple generic tiers on Part D formularies, and the inclusion of generic drugs on mixed, higher-cost tiers, we believe these changes are needed to ensure that tiering exceptions for non-preferred generic drugs are available to enrollees with a demonstrated medical need. Procedures that allow for tiering exceptions for higher-cost generics when medically necessary promote the use of generic drugs among Part D enrollees and assist them in managing out of pocket costs.

We are also proposing at § 423.578(a)(6)(i) to codify that plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drug(s) for treating the enrollee's condition, where the alternatives include only the following drug types:

- Generic drugs for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), or
- Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)).

As discussed in the Call Letter, CMS collects Part D plan formulary data based on the National Library of Medicare RxNorm concept unique identifier (RxCUI), and not at the manufacturer-specific National Drug Code (NDC) level. This process does not allow us to clearly identify whether a plan sponsor includes coverage of authorized generic NDCs or not. We believe this position is consistent with how plans currently administer their formularies. Under this regulatory proposal, a plan sponsor could not completely exclude a lower tier containing only generic and authorized generic drugs from its tiering exception procedures, but would be permitted to limit the cost sharing for a particular brand drug or biological product to the lowest tier containing the same drug type. Plans would be required to grant a tiering exception for a higher cost generic or authorized generic drug to the cost sharing associated with the lowest tier containing generic and/or authorized generic alternatives when the medical necessity criteria is met.

d. Alternative Drugs for Treatment of the Enrollee's Condition

In response to the 2018 Call Letter and RFI, we received comments from plan sponsors and PBMs requesting that CMS provide additional guidance on how to determine what constitutes an alternative drug for purposes of tiering exceptions, including establishment of additional limitations on when such exceptions are approvable. The statutory language for tiering and formulary exceptions at sections 1860D–4(g)(2) and 1860D–4(h)(2) of the Act, respectively, specifically refers to a preferred or formulary drug ''for treatment of the same condition.'' We interpret this language to be referring to the condition as it affects the enrollee—that is, taking into consideration the individual's overall clinical condition,

including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee. The Part D statute at § 1860D–4(g)(2) requires that coverage decisions subject to the exceptions process be based on the medical necessity of the requested drug *for the individual* for whom the exception is sought. We believe that requirement reasonably includes consideration of alternative therapies for treatment of the enrollee's condition, based on the facts and circumstances of the case.

e. Approval of Tiering Exception Requests

We are proposing to revise § 423.578(c)(3) by renumbering the provision and adding a new paragraph (ii) to codify our current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost-sharing tier containing alternative drugs, *unless* such alternative drugs are not applicable pursuant to limitations set forth under proposed § 423.578(a)(6). We are also proposing to delete similar language from existing (c)(3) that proposed new paragraph (c)(3)(ii) would replace.

f. Additional Technical Changes and Corrections

Finally, we are proposing various technical changes and corrections to improve the clarity of the tiering exceptions regulations and consistency with the regulations for formulary exceptions. Specifically, we are proposing the following:

- Revise the introductory text of § 423.578(a) to clarify that a ''requested'' non-preferred drug for treatment of an enrollee's health condition may be eligible for an exception.
- Revise § 423.578(a)(1) to include ''tiering'' when referring to the exceptions procedures described in this subparagraph.
- Revise § 423.578(a)(4) by making ''conditions'' singular and by adding ''(s)'' to ''drug'' to account for situations when there are multiple alternative drugs.
- Revise § 423.578(a)(5) by removing the text specifying that the prescriber's supporting statement ''demonstrate the medical necessity of the drug'' to align with the existing language for formulary exceptions at § 423.578(b)(6). The requirement that the supporting statement address the enrollee's medical need for the requested drug is already explained in the introductory text of § 423.578(a).
- Redesignate paragraphs § 423.578(c)(3)(i) through (iii) as paragraphs § 423.578(c)(3)(i)(A) through (C), respectively. This proposed change would improve consistency between the regulation text for tiering and formulary exceptions.

We anticipate that the proposed changes to the tiering exceptions regulations will make this process more accessible and transparent for enrollees and less cumbersome for plan sponsors to administer. We also believe that, by helping plan sponsors ensure their tiering exceptions processes comply with CMS requirements, IRE overturn rates for tiering exception requests will remain low.

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

As discussed in section III.A.2 of this proposed rule, the MMA added section 1860D–1(b)(3)(D) to the Act to establish a special election period (SEP) for full-benefit dual eligible (FBDE) beneficiaries under Part D. This SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation (75 FR 19720). The SEP allows eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA–PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.

The MMA sought to strike a balance of promoting beneficiary plan choice, but also ensuring that FBDE beneficiaries who did not make an active election would still have Part D coverage. The statute directed the Secretary to enroll FBDE beneficiaries into a PDP if they did not enroll in a Part D plan on their own. (As noted previously, CMS extended the SEP through rulemaking to make it available to all other subsidy-eligible beneficiaries.) When the automatic enrollment of subsidy-eligible beneficiaries was originally proposed in rulemaking, we noted that beneficiaries would have the option to use the SEP if they determined there was a better plan option for them, and codified a continuous SEP (that is, that was available monthly).

At the time, we did not know on what factors FBDE beneficiaries would rely to make their plan choice. Now, with over 10 years of programmatic experience, we have observed certain enrollment trends in terms of FBDE and other LIS beneficiaries:

- Most LIS beneficiaries do not make an active choice to join a PDP. For plan year 2015, over 71 percent of LIS individuals in PDPs were placed into that plan by CMS.
- Once in a plan, whether it was a CMS-initiated enrollment or a choice they made on their own, most LIS beneficiaries do not make changes during the year. Of all LIS beneficiaries who were eligible for the SEP in 2016, less than 10 percent utilized it. Overall, we have seen slight growth of SEP usage over the past 5 years (for example, less than 8 percent in 2012, approximately 9 percent in 2014).
- A small subset (0.8 percent) of LIS beneficiaries use the SEP to actively enroll in a plan of their choice and then disenroll within 2 months.

While we know that the majority of LIS-eligible beneficiaries do not take advantage of the SEP, we have seen the Medicare and Medicaid environment evolve in such a way that it may be disadvantageous to beneficiaries if they changed plans during the year, let alone if they made multiple changes. States and plans have noted that they are best able to provide or coordinate care if there is continuity of enrollment, particularly if the beneficiary is enrolled in an integrated product (as discussed later in this section). We now know that in addition to choice, there are other critical issues that must be considered in determining when and how often beneficiaries should be able to change their Medicare coverage during the year, such as coordination of Medicare-Medicaid benefits, beneficiary care management, and public health concerns such as the national opioid epidemic (and the drug management programs discussed in section II.A.1). In addition, there are different care models available now such as dual eligible special needs plans (D–SNPs), Fully Integrated Dual Eligible (FIDE) SNPs, and Medicare-Medicaid Plans (MMPs) that are discussed later in this section and specifically designed to meet the needs of high risk, high needs beneficiaries.

Current enrollment trends demonstrate that while a majority of subsidy-eligible beneficiaries still receive their Part D coverage through standalone PDPs, an increasing percentage of beneficiaries are enrolled in MA–PDs and other capitated managed care products, including over one in three dually eligible beneficiaries. A smaller but rapidly growing subset are enrolled in capitated

Medicare managed care products that also integrate Medicaid services. For example:

- The MMA established D–SNPs to provide coordinated care to dually eligible beneficiaries. Between 2007 and 2016, growth in D–SNPs has increased by almost 150 percent.
- FIDE SNPs are a type of SNP created by the Affordable Care Act (ACA) in 2010 designed to promote full integration and coordination of Medicare and Medicare benefits for dually eligible beneficiaries by a single managed care organization. In 2017, there are 39 FIDE SNPs providing coverage to approximately 155,000 beneficiaries.
- MMPs, which operate as part of a model test under Section 1115(A) of the Act, are fully-capitated health plans that serve dually eligible beneficiaries though demonstrations under the Financial Alignment Initiative. The demonstrations are designed to promote full access to seamless, high quality integrated health care across both Medicare and Medicaid. In 2017, there are 58 MMPs providing coverage to nearly 400,000 beneficiaries.

The current SEP, especially in the context of these products that integrate Medicare and Medicaid, highlights differences in Medicare and Medicaid managed care enrollment policies. Bringing Medicare and Medicaid enrollment policies into greater alignment, even partially, is a mechanism to reduce complexity in the health care system and better partner with states. Both are important priorities for CMS.

In addition, the application of the continuous SEP carries different service delivery implications for enrollees of MA–PD plans and related products than for standalone enrollees of PDPs. At the outset of the Part D program, when drug coverage for dually eligible beneficiaries was transitioned from Medicaid to Medicare, there were concerns about how CMS would effectively identify, educate, and enroll dually eligible beneficiaries. While processes (for example, auto-enrollment, reassignment) were established to facilitate coverage, the continuous SEP served as a fail-safe to ensure that the beneficiary was always in a position to make a choice that best served their healthcare needs. Unintended consequences have resulted from this flexibility, including, as noted by the Medicare Payment Advisory Commission (MedPAC [32]), opportunities for marketing abuses.

Among the key obstacles the SEP (and resulting plan movement) can present are—

- Interfering with the coordination of care among the providers, health plans, and states;
- Hindering the ability for beneficiaries to benefit from case management and disease management;
- Wasting the effort and resources needed to conduct enrollee needs assessments and developing plans of care for services covered by Medicare and Medicaid;
- Limiting a plan's opportunity for continuous treatment of chronic conditions; and
- Diminishing incentives for plans to innovate and invest in serving potentially high-cost members.

While we still support in the underlying principle that LIS beneficiaries should have the ability to make an active choice, we find that plan sponsors are better able to administer benefits to beneficiaries, including coordination of Medicare and Medicaid benefits, and maximize care management and positive health outcomes, if dual and other LIS-eligible beneficiaries are held to the similar election period requirements as all other Part D-eligible beneficiaries. Therefore, we are proposing to amend § 423.38(c)(4) to make the SEP for FBDE and other subsidy-eligible individuals available only in certain circumstances. These circumstances would be considered separate and unique from one another, so there could be situations where a beneficiary could still use the SEP multiple times if he or she meets more than one of the conditions proposed as follows. Specifically, we are proposing to revise to § 423.38(c) to specify that the SEP is available only as follows:

- In new paragraph (c)(4)(i), eligible beneficiaries (that is, those who are dual or other LIS-eligible and meet the definition of at-risk beneficiary or potential at-risk beneficiary under proposed § 423.100) would be able to use the SEP once per calendar year.
- In new paragraph (c)(4)(iii), eligible beneficiaries who have been assigned to a plan by CMS or a State would be able to use the SEP before that election becomes effective (that is, opt out and enroll in a different plan) or within 2 months of their enrollment in that plan.
- In new paragraph (c)(9), dual and other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status would have an SEP to make an election within 2 months of the change, or of being notified of such change, whichever is later. This SEP would be available to beneficiaries who experience a change in Medicaid or LIS status regardless of whether they have been identified as potential at-risk beneficiaries or at-risk beneficiaries under proposed § 423.100. In addition, we are also proposing to remove the phrase ''at any time'' in the introductory language of § 423.38(c) for the sake of clarity.

The onetime annual SEP opportunity would be able to be used at any time of the year to enroll in a new plan or disenroll from the current plan, provided that their eligibility for the SEP has not been limited consistent with section 1860D–1(b)(3)(D) of the Act, as amended by CARA (as discussed in section III.A.2. of this proposed rule). We believe that the onetime annual SEP would still provide dually eligible beneficiaries adequate opportunity to change their coverage during the year if desired, but is also responsive to consistent feedback we have received from States and plans that have noted that the current SEP, which allows month-to-month movement, can disrupt continuity of care, especially in integrated care plans. They specifically noted that effective care management can best be achieved through continuous enrollment.

Beneficiaries who have been enrolled in a plan by CMS or a state (that is, through processes such as auto enrollment, facilitated enrollment, passive enrollment, default enrollment (seamless conversion), or reassignment), would be allowed a separate, additional use of the SEP, provided that their eligibility for the SEP has not been limited consistent with section 1860D–1(b)(3)(D) of the Act, as amended by CARA. These beneficiaries would still have a period of time before the election takes effect to opt out and choose their own plan or they would be able to use the SEP to make an election within 2 months of the assignment effective date. Once a beneficiary has made an election (either prior to or after the effective date) it would be considered ''used'' and no longer would be available. If a beneficiary wants to change plans after 2 months, he or she would have to use the onetime annual election opportunity discussed previously, provided that it has not been used yet. If that election has been used, the beneficiary would have to wait until they are eligible for another election period to make a change.

[32] Medicare Payment Advisory Commission, ''Report to Congress: Medicare Payment Policy,'' March 2008.

Under a new proposed SEP, individuals who have a change in their Medicaid or LIS-eligible status would have an election opportunity that is separate from, and in addition to, the two scenarios discussed previously. (As discussed in section III.A.2. of this rule, and unlike the other two conditions discussed previously, individuals identified as ''at risk'' would be able to use this SEP.) This would apply to individuals who gain, lose, or change Medicaid or LIS eligibility. We believe that in these instances, it would be appropriate to give these beneficiaries an opportunity to re-evaluate their Part D coverage in light of their changing circumstances. Beneficiaries eligible for this SEP would need to use it within 2 months of the change or of being notified of the change, whichever is later.

We considered multiple alternatives related to the SEP proposal. We describe two such alternatives in the following discussion:

Limit of two or three uses of the SEP per year. In 2016, 1.2 million beneficiaries used the SEP for FBDE or other subsidy-eligible individuals, including over 27,000 who used the SEP three or more times, and over 1,700 who used the SEP five or more times during the year. These SEP changes are in addition to changes made during the AEP and any other election periods for which a beneficiary may qualify. We believe that any overuse of the SEP creates significant inefficiencies and impedes meaningful continuity of care and care coordination. As such, we considered applying a simple numerical limit to the number of times the LIS SEP could be used by any beneficiary within each calendar year. We specifically considered limits of either two or three uses of the SEP per year.

Compared to our proposal to limit the use of the SEP to one time per calendar year, this alternative would permit more opportunities for midyear changes. However, it could still allow for a high level of membership churning. Relative to our proposal, it would also be less effective in limiting the opportunities for aggressive marketing to LIS beneficiaries outside of the AEP. We welcome comments on this alternative.

Limits on midyear MA–PD plan switching. We also considered a more complex option, drawing heavily on earlier MedPAC recommendations.[33] Under this alternative we would:

- Modify the SEP to prohibit its use to elect a non-integrated MA–PD plan. As such, the SEP would not be used for switching between MA–PD plans, movement from integrated products to a non-integrated MA–PD plan, or movement from Medicare FFS to an MA–PD plan. Beneficiaries would still be able to select non-integrated MA–PD plans during other enrollment periods, such as the AEP, the open enrollment period (OEP) outlined in section III.C.2. of this proposed rule, and any other SEP for which they may be eligible; and
- Allow continuous use of the dual SEP to allow eligible beneficiaries to enroll into FIDE SNPs or comparably integrated products for dually eligible beneficiaries through model tests under section 1115(A) of the Act.

This alternative would still permit continuous election of Medicare FFS with a standalone PDP throughout the year and a continuous option to change between standalone PDPs.

We believe this alternative would create greater stability among plans and limit the opportunities for misleading and aggressive marketing to dually-eligible individuals. It would also maintain the opportunity for continuous enrollment into integrated products to reflect our ongoing partnership with states to promote integrated care. However, this alternative would be more complex to administer and explain to beneficiaries, and it encourages enrollment into a limited set of MA plans compared to all the plans available to the beneficiary under the MA program. We welcome comments on this alternative.

We believe that our proposed approach to narrowing of the scope of the SEP preserves a dual or other LIS-eligible beneficiary's ability to make an active choice. As noted previously, less than 10 percent of the LIS population used the dual SEP in 2016. We acknowledge that even though this is a small percentage of the population, given the number of beneficiaries who receive Extra Help, this equates to over a million elections. We note, though, that of this group, the majority (74.5 percent) used the SEP one time. Under our proposal, this population would still be able to make an election, thus, we believe that the majority of beneficiaries would not be negatively impacted by these changes. We opted for our proposed approach, as opposed to the alternatives, because we believe it encourages continuity of enrollment and care, without overcomplicating both beneficiary understanding of how the SEP is available to them, as well as plan sponsor operational responsibilities.

If the proposal is finalized, we would revise our messaging and beneficiary education materials as necessary to ensure that dual and other LIS-eligible beneficiaries understand that the SEP is no longer an unlimited opportunity. We would also need to ensure that beneficiaries who are assigned to a plan by CMS or the State understand that they must use the SEP within 2 months after the new coverage begins if they wish to change from the plan to which they were assigned.

We note that other election periods, including the AEP, the new OEP, or other SEPs (for example, when moving to a new service area), would still be available to individuals. In addition, the proposed limitations would also apply to the Part C SEP established in sub-regulatory guidance for dual-eligible individuals or individuals who lose their dual-eligibility.

We welcome public comment on this proposal and the considered alternatives. Specifically, we seek input on the following areas:

- Are there other limited circumstances where the dual SEP should be available?
- Are there special considerations CMS should keep in mind if we finalize this policy?
- Are there other alternative approaches we should consider in lieu of narrowing the scope of the SEP?
- In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters?

11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

a. Introduction

We are committed to transforming the health care delivery system—and the Medicare program—by putting a strong focus on person-centered care, in accordance with the CMS Quality Strategy, so each provider can direct their time and resources to each beneficiary and improve their outcomes. As part of this commitment, one of our most important strategic goals is to improve the quality of care for Medicare beneficiaries. The Part C and D Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by health and drug plans, physicians, hospitals, and other Medicare providers. We currently publicly report the quality and performance of health and drug plans on the Medicare Plan Finder tool on *www.medicare.gov* in the form of summary and overall ratings for the contracts under which each MA plan (including MA–PD plans) and Part D plan is offered, with drill downs to

[33] Medicare Payment Advisory Commission, ''Report to Congress: Medicare Payment Policy,'' March 2008.

ratings for domains, ratings for individual measures, and underlying performance data. We also post additional measures on the display page [34] at *www.cms.gov* for informational purposes. The goals of the Star Ratings are to display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; 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, CMS has started to incorporate efforts to recognize the challenges of serving high risk, high needs populations while continuing the focus on improving health care for these important groups.

In this rule as part of the Administration's efforts to improve transparency, we propose to codify the existing Star Ratings System for the MA and Part D programs with some changes. As noted later in this section in more detail, the proposed changes include more clearly delineating the rules for adding, updating, and removing measures and modifying how we calculate Star Ratings for contracts that consolidate. Although the rulemaking process will create a longer lead time for changes, codifying the Star Ratings methodology will provide plans with more stability to plan multi-year initiatives, because they will know the measures several years in advance. We have received comments for the past several years from MA organizations and other stakeholders asking that CMS use **Federal Register** rulemaking for the Star Ratings System; we discuss in section III.12.c. (regarding plans for the transition period before the codified rules are used) how section 1832(b) authorizes CMS to establish and annually modify the Star Ratings System using the Advance Notice and Rate Announcement process because the system is an integral part of the policies governing Part C payment. We think this is an appropriate time to codify the methodology, because the rating system has been used for several years now and is relatively mature so there is less need for extensive changes every year; the smaller degree of flexibility in having codified regulations rather than using the process for adopting payment methodology changes may be appropriate. Further, by adopting and codifying the rules that govern the Star Ratings System, we are demonstrating a commitment to transparency and predictability for the rules in the system so as to foster investment.

b. Background

We originally acted upon our authority to disseminate information to beneficiaries as the basis for developing and publicly posting the 5-star ratings system (sections 1851(d) and 1852(e) of the Act). The MA statute explicitly requires that information about plan quality and performance indicators be provided to beneficiaries in an easy to understand language to help them make informed plan choices. These data are to include disenrollment rates, enrollee satisfaction, health outcomes, and plan compliance with requirements.

The Part D statute (at section 1860D–1(c)) imposes a parallel information dissemination requirement with respect to Part D plans, and refers specifically to comparative information on consumer satisfaction survey results as well as quality and plan performance indicators. Part D plans are also required by regulation (§ 423.156) to make Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data available to CMS and are required to submit pricing and prescription drug event data under statutes and regulations specific to those data. Regulations require plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans (§§ 422.152 and 423.153). In addition we may require plans to report statistics and other information in specific categories (§§ 422.516 and 423.514).

Currently, for similar reasons of providing information to beneficiaries to assist them in plan enrollment decisions, we also review and rate section 1876 cost plans on many of the same measures and publish the results. We also propose to continue to include 1876 cost contracts in the MA and Part D Star Rating system to provide comparative information to Medicare beneficiaries making plan choices. We propose specific text, to be codified at § 417.472(k), noting that 1876 cost contracts must agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (§ 17.472(j)) to make CAHPS survey data available to CMS. As is the case today, no quality bonus payments (QBP) would be associated with the ratings for 1876 cost contracts.

In line with §§ 422.152 and 423.153, CMS uses the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), CAHPS data, Part C and D Reporting requirements and administrative data, and data from CMS contractors and oversight activities to measure quality and performance of contracts. We have been displaying plan quality information based on that and other data since 1998.

Since 2007, we have published annual performance ratings for stand-alone Medicare PDPs. In 2008, we introduced and displayed the Star Ratings for Medicare Advantage Organizations (MAOs) for both Part C only contracts (MA-only contracts) and Part C and D contracts (MA–PDs). Each year since 2008, we have released the MA Star Ratings. An overall rating combining health and drug plan measures was added in 2011, and differential weighting of measures (for example, outcomes being weighted 3 times the value of process measures) began in 2012. The measurement of year to year improvement began in 2013, and an adjustment (Categorical Adjustment Index) was introduced in 2017 to address the within-contract disparity in performance revealed in our research among beneficiaries that are dual eligible, receive a low income subsidy, and/or are disabled.

The MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating. The Star Ratings provide ratings at various levels of a hierarchical structure based on contract type, and all ratings are determined using the measure-level Star Ratings. Contingent on the contract type, ratings may be provided and include overall, summary (Part C and D), and domain Star Ratings. Information about the measures, the hierarchical structure of the ratings, and the methodology to generate the Star Ratings is detailed in the annually updated Medicare Part C and D Star Ratings Technical Notes, referred to as Technical Notes, available at *http://go.cms.gov/partcanddstarratings*.

The MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care. The information included in the ratings is selected based on its relevance and importance such that it can meet the data needs of beneficiaries using it to inform plan choice. While encouraging improved health outcomes of beneficiaries in an efficient, person centered, equitable, and high quality manner is one of the

[34] *http://go.cms.gov/partcanddstarratings* (under the downloads).

primary goals of the ratings, they also provide feedback on specific aspects of care that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable, and valid. A delicate balance exists between measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden for the industry. Also, the beneficiary or his or her representative must have enough information to make an informed decision without feeling overwhelmed by the volume of data.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111–152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(C) of the Act provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to the MA organization to use as a rebate. Under the Act, Part D plan sponsors are not eligible for quality based payments or rebates. We finalized a rule on April 15, 2011 to implement these provisions and to use the existing Star Ratings System that had been in place since 2007 and 2008. (76 FR 21485–21490).[35] In addition, the Star Ratings measures are tied in many ways to responsibilities and obligations of MA organizations and Part D sponsors under their contracts with CMS. We believe that continued poor performance on the measures and overall and summary ratings indicates systemic and wide-spread problems in an MA plan or Part D plan. In April 2012, we finalized a regulation to use consistently low summary Star Ratings—meaning 3 years of summary Star Ratings below 3 stars—as the basis for a contract termination for Part C and Part D plans. (§§ 422.510(a)(14) and 423.509(a)(13)). Those regulations further reflect the role the Star Ratings have had in CMS' oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries.

The true potential of the use of the MA and Part D Star Ratings System to reach our goals and to serve as a catalyst for change can only be realized by working in tandem with our many stakeholders including beneficiaries, industry, and advocates. The following guiding principles have been used historically in making enhancements to the MA and Part D Star Ratings:

- Ratings align with the current CMS Quality Strategy.
- Measures developed by consensus-based organizations are used as much as possible.
- Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.
- Ratings are stable over time.
- Ratings treat contracts fairly and equally.
- Measures are selected to reflect the prevalence of conditions and the importance of health outcomes in the Medicare population.
- Data are complete, accurate, and reliable.
- Improvement on measures is under the control of the health or drug plan.
- Utility of ratings is considered for a wide range of purposes and goals.

++ Accountability to the public.

++ Enrollment choice for beneficiaries.

++ Driving quality improvement for plans and providers.

- Ratings minimize unintended consequences.
- Process of developing methodology is transparent and allows for multi-stakeholder input.

We are using these goals to guide our proposal and how we interpret and apply the proposed regulations once finalized. For each provision we are proposing, we solicit comment on whether our specific proposed regulation text best serves these guiding principles. We also solicit comment on whether additional or other principles are better suited for these roles in measuring and communicating quality in the MA and Part D programs in a comparative manner.

As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we would also like to solicit feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We welcome all comments on those topics, and will consider them for changes through this or future rulemaking or in connection with interpreting our regulations (once finalized) on the Star Rating system measures. However, we are particularly interested in receiving stakeholder feedback on the following topics:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.
- How CMS should measure overall improvement across the Star Ratings measures. We are requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustments could have on new entrants (that is, new MA organizations and/or new plans offered by existing MA organizations).
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.
- In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.
- Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.
- Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.

[35] The ratings were first used as part of the Quality Bonus Payment Demonstration for 2012 through 2014 and then used for payment purposes as specified in sections 1853(o) and 1854(b)(1)(C) and the regulation at 42 CFR 422.258(d)(7).

c. Basis, Purpose and Applicability of the Quality Star Ratings System

We propose to codify regulation text, at §§ 422.160 and 423.180, that identifies the statutory authority, purpose, and applicability of the Star Ratings System regulations we are proposing to add to part 422 subpart D and part 423 subpart D. Under our proposal, the existing purposes of the quality rating system—to provide comparative information to Medicare beneficiaries pursuant to sections 1851(d) and 1860D–1(c) of the Act, to identify and apply the payment consequences for MA plans under sections 1853(o) and 1854(b)(1)(C) of the Act, and to evaluate and oversee overall and specific performance by plans—would continue. To reflect how the Part D ratings are used for MA–PD plan QBP status and rebate retention allowances, we also propose specific text, to be codified at § 423.180(b)(2), noting that the Part D Star Rating will be used for those purposes.

We are proposing here, broadly stated, to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019. We are proposing some changes, such as how we handle consolidations from the current Star Ratings program, but overall the proposal is to continue the Star Ratings System as it has been developed and has stabilized. Data will be collected and performance will be measured using these proposed rules and regulations for the 2019 measurement period; the associated quality Star Ratings will be used to assign QBP ratings for the 2022 payment year and released prior to the annual coordinated election period held in late 2020 for the 2021 contract year. Application of the final regulations resulting from this proposal will determine whether the measures proposed in section III.A.12.i. of the proposed rule (Table 2) are updated, transitioned to or from the display page, and otherwise used in conjunction with the 2019 performance period.

Under our proposal, the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings. Section 1853(b) of the Act authorizes an advance notice and rate announcement to announce and seek comment for proposed changes to the MA payment methodology, which includes the Part C and D Star Ratings program. The statute identifies specific notice and comment timeframes, but that process does not require publication in the **Federal Register**. We have used the draft and final Call Letter, which are attachments to the Advance Notice and final Rate Announcement respectively,[36] to propose for comment and finalize changes to the quality Star Ratings System since the ratings became a component of the payment methodology for MA and MA–PD plans. (76 FR 214878 through 89). Because the Star Ratings System has been integrated into the payment methodology since the 2012 contract year (as a mechanism used to determine how much a plan is paid, and not the mechanism by which (or a rule about when) a plan is paid), the Star Ratings are part of the process for setting benchmarks and capitation rates under section 1853, and the process for announcing changes to the Star Ratings System falls within the scope of section 1853(b). Although not expressly required by section 1853(b), CMS has historically solicited comment on significant changes to the ratings system using a Request for Comment process before the Advance Notice and draft Call Letter are released; this Request for Comment [37] provides MAOs, Part D sponsors, and other stakeholders an opportunity to request changes to and raise concerns about the Star Ratings methodology and measures before CMS finalizes its proposal for the Advance Notice. We intend to continue the current process at least until the 2019 measurement period that we are proposing as the first measurement period under these new regulations, but we may discontinue that process at a later date as the rulemaking process may provide sufficient opportunity for public input. In addition, CMS issues annually the Technical Notes [38] that describe in detail how the methodology is applied from the changes in policy adopted through the Advance Notice and Rate Announcement process. We intend to continue the practice of publishing the Technical Notes during the preview periods. Under our proposal, we would also continue to use the draft and final Call Letters as a means to provide subregulatory application), interpretation, and guidance of the final version of these proposed regulations where necessary. Our proposed regulation text does not detail these plans for continued use of the current process and future for subregulatory guidance because we believe such regulation text would be unnecessary. We propose to codify the first performance period (2019) and first payment year (2022) to which our proposed regulations would apply at § 422.160(c) and § 423.180(c).

d. Definitions

There are a number of technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions for the respective subparts in part 422 and part 423 in paragraph (a) of §§ 422.162 and 423.182 respectively. Some proposed definitions are discussed in more detail later in this preamble in connection with other proposed regulation text related to the definition.

- *CAHPS* refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.
- *Case-mix adjustment* means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.
- *Categorical Adjustment Index (CAI)* means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy or have disability status in that contract (or plan as applicable).
- *Clustering* refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify

[36] Advance Notices and Rate Announcements are posted each year on the CMS Web site at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html*.

[37] Requests for Comment are posted at *http://go.cms.gov/partcanddstarratings* under the downloads.

[38] *http://go.cms.gov/partcanddstarratings* (under the downloads) for the Technical Notes.

the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

- *Consolidation* means when an MA organization/Part D sponsor that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.
- *Consumed contract* means a contract that will no longer exist after a contract year's end as a result of a consolidation.
- *Display page* means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.
- *Domain rating* means the rating that groups measures together by dimensions of care.
- *Dual Eligible (DE)* means a beneficiary who is enrolled in both Medicare and Medicaid.
- *HEDIS* is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.
- *Highest rating* means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.
- *Highly-rated contract* means a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).
- *HOS* means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.
- *Low Income Subsidy (LIS)* means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 for definition of a low-income subsidy eligible individual).
- *Measurement period* means the period for which data are collected for a measure or the performance period that a measures covers.
- *Measure score* means the numeric value of the measure or an assigned 'missing data' message.
- *Measure star* means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.
- *Overall Rating* means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.
- *Part C Summary Rating* means a global rating that summarizes the health plan quality and performance on Part C measures.
- *Part D Summary Rating* means a global rating of the prescription drug plan quality and performance on Part D measures.
- *Plan Benefit Package (PBP)* means a set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.
- *Reliability* means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation (''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).
- *Reward factor* means a rating-specific factor added to the contract's summary or overall (or both) rating if a contract has both high and stable relative performance.
- *Statistical significance* assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same. Although not part of the proposed regulatory definition, we clarify that CMS uses statistical tests (for example, t-test) to determine if a contract's measure value is statistically different (greater than or less than depending on the test) from the national mean for that measure, or whether conversely, the observed differences from the national mean could have arisen by chance.
- *Surviving contract* means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.
- *Traditional rounding rules* mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

e. Contract Ratings

Star Ratings and data reporting are at the contract level for most measures. Currently, data for measures are collected at the contract level including data from all PBPs under the contract, except for the following Special Needs Plan (SNP)-specific measures which are collected at the PBP level: Care for Older Adults—Medication Review, Care for Older Adults—Functional Status Assessment, and Care for Older Adults—Pain Assessment. The SNP-specific measures are rolled up to the contract level by using an enrollment-weighted mean of the SNP PBP scores. Subject to the discussion later in this section about the feasibility and burden of collecting data at the PBP (plan) level and the reliability of ratings at the plan level, we propose to continue the practice of calculating the Star Ratings at the contract level and all PBPs under the contract would have the same overall and/or summary ratings.

However, beneficiaries select a plan, rather than a contract, so we have considered whether data should be collected and measures scored at the plan level. We have explored the feasibility of separately reporting quality data for individual D–SNP PBPs, instead of the current reporting level. For example, in order for CAHPS measures to be reliably scored, the number of respondents must be at least 11 people and reliability must be at least 0.60. Our current analyses show that, at the PBP level, CAHPS measures could be reliably reported for only about one-third of D–SNP PBPs due to sample size

issues, and HEDIS measures could be reliably reported for only about one-quarter of D–SNP PBPs. If reporting were done at the plan level, a significant number of D–SNP plans would not be rated and in lieu of a Star Rating, Medicare Plan Finder would display that the plan is ''too small to be rated.'' However, when enough data are available, plan level quality reporting would better reflect the quality of care provided to enrollees in that plan. Plan-level quality reporting would also give states that contract with D–SNPs plan-specific information on their performance and provide the public with data specific to the quality of care for dual eligible (DE) beneficiaries enrolled in these plans. For all plans as well as D–SNPs, reporting at the plan level would significantly increase plan burden for data reporting and would have to be balanced against the availability of additional clinical information available at the plan level. Plan-level ratings would also potentially increase the ratings of higher-performing plans when they are in contracts that have a mix of high and low performing plans. Similarly, plan-level ratings would also potentially decrease the ratings of lower-performing plans that are currently in contracts with a mix of high and low performing plans. Measurement reliability issues due to small sample sizes would also decrease our ability to measure true performance at the plan level and add complexities to the rating system. We are soliciting comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures; we ask for comments about this for D–SNPs and for all plans as we continue to consider whether rating at the plan level is feasible or appropriate. In particular, we are interested in feedback on the best balance and whether changing the level at which ratings are calculated and reported better serves beneficiaries and our goals for the Star Ratings System.

We are also exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) to incorporate into the Star Ratings. Further, we are exploring if contract market area reporting is feasible when a contract covers a large geographic area. For example, when HEDIS reporting began in 1997, there were contract-specific market areas that evolved into reporting by market area for five states with large Medicare populations.[39] We are planning to continue work in this area to determine the best reporting level for each measure that most accurately reflects performance and minimizes to the extent possible plan reporting burden. As we consider alternative reporting units, we welcome comments and suggestions about requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure.

We propose to continue at this time calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA–PD, or PDP contract. We propose to codify this policy in regulation text at §§ 422.162(b) and 423.182(b). We also propose a cost plan regulation at § 417.472(k) to require cost contracts to be subject to the part 422 and part 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System as they are measured and rated like an MA plan. Specifically, we propose, at paragraph (b)(1) that CMS will calculate overall and summary ratings at the contract level and propose regulation text that cross-references other proposed regulations regarding the calculation of measure scoring and rating, and domain, summary and overall ratings. Further, we propose to codify, at (b)(2) of each section, that data from all PBPs offered under a contract will continue to be used to calculate the ratings for the contract. For SNP specific measures collected at the PBP level, we propose that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification, which is consistent with current practice. The proposed text is explicit that domain and measure ratings, other than the SNP-specific measures, are based on data from all PBPs under the contract.

f. Contract Consolidations

We are proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. We have historically permitted MAOs and Part D sponsors to consolidate contracts when a contract novation occurs or to better align business practices. As noted in MedPAC's March 2016 Report to Congress (*https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*), there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a QBP to higher Star Rating contracts that do receive a QBP as part of contract consolidations, which increases the size of the QBPs that are made to MAOs due to the large enrollment increase in the higher rated, surviving contract. We are worried that this practice results in masking low quality plans under higher rated surviving contracts. This does not provide beneficiaries with accurate and reliable information for enrollment decisions, and it does not truly reward higher quality contracts. We propose here to modify from the current policy the calculation of Star Ratings for surviving contracts that have consolidated. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, we propose to assign and display on Medicare Plan Finder 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. Under this proposal, the calculation of the measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores. The number of contracts this would impact is small relative to all contracts that qualify for QBPs. During the period from 1/1/2015 through 1/1/2017 annual consolidations for MA contracts ranged from a low of 7 in 2015 to a high of 19 in 2016 out of approximately 500 MA contracts. As proposed in §§ 422.162(b)(3)(i)–(iii) and 423.182(b)(3)(i)–(iii), CMS will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations. We believe that use of enrollment-weighted means will provide a more accurate snapshot of the performance of the underlying plans in the new consolidated contract, such that both information to beneficiaries and QBPs are not somehow inaccurate or misleading. We also propose, however, that the process of weighting the enrollment of each contract and applying this general rule would vary depending on the specific types of measures involved in order to take into account the measurement period and

[39] The following states were divided into multiple market areas: CA, FL, NY, OH, and TX.

data collection processes of certain measures. Our proposal would also treat ratings for determining quality bonus payment (QBP) status for MA contracts differently than displayed Star Ratings for the first year following the consolidation for consolidations that involve the same parent organization and plans of the same plan type.

We propose to codify our new policy at §§ 422.162(b)(3) and 423.182(b)(3). First, we propose generally, at paragraph (b)(3)(i) of each regulation, that CMS will assign Star Ratings for consolidated contracts using the provisions of paragraph (b)(3). We are proposing in § 422.162(b)(3) both a specific rule to address the QBP rating following the first year after the consolidation and a rule for subsequent years. As Part D plan sponsors are not eligible for QBPs, the Part D regulation text is proposed without the QBP aspect. We propose in § 422.162(b)(3)(iv) and § 423.182(b)(3)(ii) the process for assigning Star Ratings for posting on the Medicare Plan Finder for the first 2 years following the consolidation.

For the first contract year following a consolidation, as proposed at paragraphs § 422.162(b)(3)(iv) and § 423.182(b)(3)(ii), we propose to use the enrollment-weighted means as calculated below to set Star Ratings for publication (and, in § 422.162(b)(3)(iii), use of certain enrollment-weighted means for establishing QBP status:

- The Star Ratings measure scores for the consolidated entity's first plan year would be based on enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures.
- The survey-based measures (that is, CAHPS, HOS, and HEDIS measures collected through CAHPS or HOS) would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. For example, for a contract consolidation that is effective January 1, 2021 the CAHPS sample for the 2021 Star Ratings would be pulled in January 2020 so enrollment in January 2020 would be used. The call center measures would use mean enrollment during the study period. We believe that these proposals for survey-based measures are more nuanced and account for how the data underlying those measures are gathered. By using the enrollment-weighted means we are reflecting the true underlying performance of both the surviving and consumed contracts.

For the second year following the consolidation, for all MA and Part D Sponsors, the Star Ratings would be calculated as follows:

- The enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts would be used for all measures except HEDIS, CAHPS, and HOS.
- The current reporting requirements for HEDIS and HOS already combine data from the surviving and consumed contract(s) following the consolidation, so we are not proposing any modification or averaging of these measure scores. For example, for HEDIS if an organization consolidates one or more contracts during the change over from measurement to reporting year, then only the surviving contract is required to report audited summary contract-level data but it must include data on all members from all contracts involved. For this reason, we are proposing regulation text that HEDIS and HOS measure data will be used as reported in the second year after consolidation.
- The CAHPS survey sample that would be selected following the consolidation would be modified to include enrollees in the sample universe from which the sample is drawn from both the surviving and consumed contracts. If there are two contracts (that is, Contract A is the surviving contract and Contract B is the consumed contract) that consolidate, and Contract A has 5,000 enrollees eligible for the survey and Contract B has 1,000 eligible for the survey, the universe from which the sample would be selected would be 6,000.

After applying these rules for calculating the measure scores in the first and second year after consolidation, CMS would use the other rules proposed in §§ 422.166 and 423.186 to calculate the measure, domain, summary, and overall Star Ratings for the consolidated contract. In the third year after consolidation and subsequent years, the performance period for all the measures would be after the consolidation, so our proposal is limited to the Star Ratings issued the first 2 years after consolidation.

When consolidations involve two or more contracts for health and/or drug services of the same plan type under the same parent organization combining into a single contract at the start of a contract year, we propose to calculate the QBP rating for that first year following the consolidation using the enrollment-weighted mean, using traditional rounding rules, of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of the year the Star Ratings were released. In November of each year following the release of the ratings on Medicare Plan Finder, the preliminary QBP ratings are displayed in the Health Plan Management System (HPMS) for the year following the Star Ratings year. For example, the first year the consolidated entity is in operation is plan year 2020; the 2020 QBP rating displayed in HPMS in November 2018 would be based on the 2019 Star Ratings (which are released in October 2018) and calculated using the weighted mean of the November 2018 enrollment of the surviving and consumed contracts. Because the same parent organization is involved in these situations, we believe that many administrative processes and procedures are identical in the Medicare health plans offered by the sponsoring organization, and using a weighted mean of what would have been their QBP ratings accurately reflects their performance for payment purposes. In subsequent years after the first year following the consolidation, QBPs status would be determined based on the consolidated entity's Star Rating posted on Medicare Plan Finder. Under our proposal, the measure, domain, summary, and in the case of MA–PD plans the overall Star Ratings posted on Medicare Plan Finder for the second year following consolidation would be based on the enrollment-weighted measure scores so would include data from all contracts involved. Consequently, the ratings used for QBP status determinations would reflect the care provided by both the surviving and consumed contracts.

In conclusion, we are proposing a new set of rules regarding the calculation of Star Ratings for consolidated contracts to be codified at paragraphs (b)(3)(i) through (iv) of §§ 422.162 and 423.182. In most cases, we propose that the Star Ratings for the first and second year following the consolidation to be an enrollment-weighted mean of the scores at the measure level for the consumed and surviving contracts. For the QBP rating for the first year following the consolidation, we propose to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. We solicit comment on this proposal and whether our separate treatment of different measure types during the first and second year adequately addresses the differences in how data are collected (and submitted) for those measures during the different

periods. We would also like to know whether sponsoring organizations believe that the special rule for consolidations involving the same parent organization and same plan types adequately addresses how those situations are different from cases where an MA organization buys or sells a plan or contract from or to a different entity and whether these rules should be extended to situations where there are different parent organizations involved. For commenters that support the latter, we also request comment on how CMS should determine that the same administrative processes are used and whether attestations from sponsoring organizations or evidence from prior audits should be required to support such determinations.

g. Data Sources

Under 1852(e) of the Act, MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. The Star Ratings System is based on information collected consistent with section 1852(e) of the Act. Section 1852(e)(3)(B) of the Act prohibits the collection of data on quality, outcomes, and beneficiary satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003; there is a limited exception for SNPs to collect, analyze, and report data that permit the measurement of health outcomes and other indicia of quality. The statute does not require that only the same data be collected, but that we do not change or expand the type of data collected until after submission of a Report to Congress (prepared in consultation with MA organizations and accrediting bodies) that explains the reason for the change(s). We clarify here that the types of data included under the Star Ratings System are consistent with the types of data collected as of November 1, 2003. Since 1997, Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. We have also been conducting the CAHPS survey since 1997 to measure beneficiaries' experiences with their health plans, and since 2007 we have been measuring experiences with drug plans with CAHPS. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. To some extent, these surveys have been revised and updated over time, but the same types of data—clinical measures, beneficiary experiences, and changes in physical and mental health, respectively—have remained the focus of these surveys. In addition, there are several measures in the Stars Ratings System that are based on performance that address telephone customer service, members' complaints, disenrollment rates, and appeals; however these additional measures are not collected directly from the sponsoring organizations for the primary purpose of quality measurement. These additional measures are calculated from information that CMS has gathered as part of the administration of the Medicare program, such as information on appeals forwarded to the Independent Review Entity under subparts M, enrollment, and compliance and enforcement actions.

The Part D program was implemented in 2006, and while there is no parallel provision regarding applicable Part D sources of data, we have used similar datasets, for example CAHPS survey data, for beneficiaries' experiences with prescription drug plans. Section 1860D–4(d) of the Act specifically directs the administration and collection of data from consumer surveys in a manner similar to those conducted in the MA program. All of these measures reflect structure, process, and outcome indices of quality that form the measurement set under Star Ratings. Since 2007, we have publicly reported a number of measures related to the drug benefit as part of the Star Ratings. For MA organizations that offer prescription drug coverage, we have developed a series of measures focusing on administration of the drug benefit. Similar to MA measures of quality relative to health services, the Part D measures focus on customer service and beneficiary experiences, effectiveness, and access to care relative to the drug benefit. We believe that the Part D Star Ratings are consistent with the limitation expressed in section 1852(e) of the Act even though the limitation does not apply to our collection of Part D quality data from Part D sponsors.

We intend to continue to base the types of information collected in the Part C Star Ratings on section 1852(e) of the Act, and we propose at § 422.162(c)(1) that the type of data used for Star Ratings will be data consistent with the section 1852(e) limits and data gathered from CMS administration of the MA program. In addition, we propose in § 422.162(c)(1) and in § 423.182(c)(1) to include measures that reflect structure, process, and outcome indices of quality, including Part C measures that reflect the clinical care provided, beneficiary experience, changes in physical and mental health, and benefit administration, and Part D measures that reflect beneficiary experiences and benefit administration. The measures encompass data submitted directly by MA organizations (MAOs) and Part D sponsors to CMS, surveys of MA and Part D enrollees, data collected by CMS contractors, and CMS administrative data. We also propose, primarily so that the regulation text is complete on this point, a regulatory provision at §§ 422.162(c)(2) and 423.182(c)(2) that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data as described in paragraph(c)(1) of each section. Our authority to collect quality data is clear under the statute and existing regulations, such as section 1852(e)(3)(A) and 1860D–4(d) and §§ 422.12(b)(2) and 423.156. We propose the paragraph (c)(2) regulation text to ensure that the quality ratings system regulations include a regulation on this point for readers and to avoid confusion in the future about the authority to collect this data. In addition, it is important that the data underlying the ratings are unbiased, accurate, and complete so that the ratings themselves are reliable. This proposed regulation text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.

h. Adding, Updating, and Removing Measures

We are committed to continuing to improve the Part C and D Star Ratings System by focusing on improving clinical and other outcomes. We anticipate that new measures will be developed and that existing measures will be updated over time. NCQA and the Pharmacy Quality Alliance (PQA) continually work to update measures as clinical guidelines change and develop new measures focused on health and drug plans. To address these anticipated changes, we propose in §§ 422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also propose to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019.

As discussed in more detail in the following paragraphs, we propose the following general rules to govern adding, updating, and removing measures:

- For data quality issues identified during the calculation of the Star Ratings for a given year, we propose to continue our current practice of

removing the measure from the Star Ratings.

- That new measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking but that prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act (that is the Call Letter attachment to the Advance Notice and Rate Announcement).
- That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be updated with regular updates from the measure stewards through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act when the changes are not substantive.
- That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be removed from use in the Star Ratings when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period; CMS would announce the removal using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Removal might be permanent or temporary, depending on the basis for the removal.

We are proposing specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking will not be necessary for certain updates or removals. Under this proposal, CMS would announce application of the regulation standards in the Call Letter attachment to the Advance Notice and Rate Announcement process under section 1853(b) of the Act.

First, we propose to codify, at §§ 422.164(a) and 423.184(a), regulation text stating the general rule that CMS would add, update, and remove measures used to calculate Star Ratings as provided in §§ 422.164 and 423.184. In each paragraph regarding addition, updating, and removal of measures and the use of improvement measures, we also propose rules to identify when these types of changes would not involve rulemaking based on application of the standards and authority in the regulation text. Under our proposal, CMS would solicit feedback of its application of the rules using the draft and final Call Letter each year.

Second, we propose, in paragraph (b) of these sections, that CMS would review the quality of the data on which performance, scoring, and rating of measures is done each year. We propose to continue our current practice of reviewing data quality across all measures, variation among organizations and sponsors, and measures' accuracy, reliability, and validity before making a final determination about inclusion of measures in the Star Ratings. The intent is to ensure that Star Ratings measures accurately measure true plan performance. If a systemic data quality issue is identified during the calculation of the Star Ratings, we would remove the measure from that year's rating under proposed paragraph (b).

Third, we propose to address the addition of new measures in paragraph (c).

In identifying whether to add a measure, we will be guided by the principles we listed in section III.A.12.b. of the proposed rule. Measures should be aligned with best practices among payers and the needs of the end users, including beneficiaries. Our strategy is to continue to adopt measures when they are available, nationally endorsed, and in alignment with the private sector, as we do today through the use of measures developed by NCQA and the PQA, and the use of measures that are endorsed by the National Quality Forum (NQF). We propose to codify this standard for adopting new measures at §§ 422.164(c)(1) and 423.184(c)(1). We do not intend this standard to require that a measure be adopted by an independent measure steward or endorsed by NQF in order for us to propose its use for the Star Ratings, but that these are considerations that will guide us as we develop such proposals. We also propose that CMS may develop its own measures as well when appropriate to measure and reflect performance in the Medicare program.

For the 2021 Star Ratings, we propose (at section III.A.12.) of the proposed rule to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. It is important to have a mix of different types of measures in the Star Ratings program to understand how all of the different facets of the provision of health and drug services interact. For example, process measures are evidence-based best practices that lead to clinical outcomes of interest. Process measures are generally easier to collect, while outcome measures are sometimes more challenging requiring in some cases medical record review and more sophisticated risk-adjustment methodologies.

Over time new measures will be added and measures will be removed from the Star Ratings program to meet our policy goals. As new measures are added, our general guidelines for deciding whether to propose new measures through future rulemaking will use the following criteria:

- Importance: The extent to which the measure is important to making significant gains in health care processes and experiences, access to services and prescription medications, and improving health outcomes for MA and Part D enrollees.
- Performance Gap: The extent to which the measure demonstrates opportunities for performance improvement based on variation in current health and drug plan performance.
- Reliability and Validity: The extent to which the measure produces consistent (reliable) and credible (valid) results.
- Feasibility: The extent to which the data related to the measure are readily available or could be captured without undue burden and could be implemented by the majority of MA and Part D contracts.
- Alignment: The extent to which the measure or measure concept is included in one or more existing federal, State, and/or private sector quality reporting programs.

We would balance these criteria as part of our decision making process so that each new measure proposed for addition to the Star Ratings meets each criteria in some fashion or to some extent. We intend to apply these criteria to identify and adopt new measures for the Star Ratings, which will be done through future rulemaking that includes explanations for how and why we propose to add new measures. When we identify a measure that meets these criteria, we propose to follow the process in our proposed paragraphs (c)(2) through (4) of §§ 422.164 and 423.184. We would initially solicit feedback on any potential new measures through the Call Letter.

As new performance measures are developed and adopted, we propose, at §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4), that they would initially be incorporated into the display page for at least 2 years but that we would keep a new measure on the display page for a longer period if CMS finds there are reliability or validity issues with the measure. As noted in the

Introduction, the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures as discussed later in this section. Here is an example timeline for adding a new measure to the Star Ratings. In this scenario, the new measure has already been developed by the NCQA and the PQA, and endorsed by the NQF. Otherwise, that process may add an extra 3 to 5 years to the timeline.

- January 2019: Solicit feedback on whether to add the new measure in the draft 2020 Call Letter.
- April 2019: Summarize feedback on adding the new measure in the 2020 Call Letter.
- 2020/2021: Propose adding the new measure to the 2024 Star Ratings (2022 measurement period) in a proposed rule; finalize through rulemaking (for 1/1/2022 effective date).
- 2020: Performance period and collection of data for the new measure and collection of data for posting on the 2022 display page.
- 2021: Performance period and collection of data for the new measure and collection of data for posting on the 2023 display page.
- Fall 2021: Publish new measure on the 2022 display page (2020 measurement period).
- January 1, 2022: Applicability date of new measure for Star Ratings.
- 2022: Performance period and collection of data for the new measure and collection of data for inclusion in the 2024 Star Ratings.
- Fall 2022: Publish new measure on the 2023 display page (2021 measurement period).
- Fall 2023: Publish new measure in the 2024 Star Ratings (2022 measurement period).
- 2025: QBP status and rebate retention allowances are determined for the 2025 payment year.

Fourth, at §§ 422.164(d) and 423.184(d) we propose to address updates to measures based on whether an update is substantive or non-substantive. Since quality measures are routinely updated (for example, when clinical codes are updated), we propose to adopt rules for the incorporation of non-substantive updates to measures that are part of the Star Ratings System without going through new rulemaking. As proposed in paragraphs (d)(1) of §§ 422.164 and 423.184, we would only incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure.

Substantive changes (for example, major changes to methodology) to existing measures would be proposed and finalized through rulemaking. In paragraphs (d)(2) of §§ 422.164 and 423.184, we propose to initially solicit feedback on whether to make the substantive measure update through the Call Letter prior to the measurement period for which the update would be initially applicable. For example, if the change announced significantly expands the denominator or population covered by the measure (for example, the age group included in the measures is expanded), the measure would be moved to the display page for at least 2 years and proposed through rulemaking for inclusion in Star Ratings. We intend this process for substantive updates to be similar to the process we would use for adopting new measures under proposed paragraph (c). As appropriate, the legacy measure may remain in the Star Ratings while the updated measure is on the display page if, for example, the updated measure expands the population covered in the measure and the legacy measure would still be relevant and measuring a critical topic to continue including in the Star Ratings while the updated measure is on display. Adding the updated measure to the Star Ratings would be proposed through rulemaking.

We propose to adopt rules to incorporate specification updates that are non-substantive in paragraph (d)(1). Non-substantive updates that occur (or are announced by the measure steward) during or in advance of the measurement period will be incorporated into the measure and announced using the Call Letter. We propose to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page. This is consistent with current practice.

In paragraph (d)(1)(i–v) of §§ 422.164 and paragraph (d)(1)(i–v) of 423.184, we propose to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period and how we would treat them under our proposal. The list includes updates in the following circumstances:

- If the change narrows the denominator or population covered by the measure with no other changes, the updated measure would be used in the Star Ratings program without interruption. For example, if an additional exclusion—such as excluding nursing home residents from the denominator—is added, the change would be considered non-substantive and would be incorporated automatically. In our view, changes to narrow the denominator generally benefit Star Ratings of sponsoring organizations and should be treated as non-substantive for that reason.
- If the change does not meaningfully impact the numerator or denominator of the measure, the measure would continue to be included in the Star Ratings. For example, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change would not be considered substantive because the sponsoring organization would generally benefit from that change. This type of administrative (billing) change has no impact on the current clinical practices of the plan or its providers, and thus would not necessitate exclusion from the Star Ratings System of any measures updated in this way.
- The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. For updates to address revisions to the clinical codes without change in the intent of the measure and the target population, the measure would remain in the Star Ratings program and would not move to the display page. Examples of clinical codes that might be updated or revised without substantively changing the measure include:

++ ICD–10–CM (''ICD–10'') code sets. Annually, there are new ICD 10 coding updates, which are effective from October 1 through September 30th of any given year.

++ Current Procedural Terminology (CPT) codes. These codes are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient.

++ Healthcare Common Procedure Coding System (HCPCS) codes. These codes cover items, supplies, and non-physician services not covered by CPT codes.

++ National Drug Code (NDC). The PQA updates NDC lists biannually, usually in January and July.

- If the measure specification change is providing additional clarifications such as the following, the measure would also not move to the display page since this does not change the intent of the measure but provides more information about how to meet the measure specifications:

++ Adding additional tests that would meet the numerator requirements.

++ Clarifying documentation requirements (for example, medical record documentation).

++ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.

• If the measure specification change is adding additional data sources, the measure would also not move to the display page because we believe such changes are merely to add alternative ways to collect the data to meet the measure specifications without changing the intent of the measure.

We solicit comment on our proposal to add non-substantive updates to measures and using the updated measure (replacing the legacy measure) to calculate Star Ratings. In particular, we are interested in stakeholders' views whether only non-substantive updates that have been adopted by a measure steward after a consensus-based or notice and comment process should be added to the Star Ratings under this proposed authority. Further, we solicit comment on whether there are other examples or situations involving non-substantive updates that should be explicitly addressed in the regulation text or if our proposal is sufficiently extensive.

In addition to updates and additions of measures, we are proposing rules to address the removal of measures from the Star Ratings to be codified in §§ 422.164(e) and 423.184(e). In paragraph (e)(1) of each section, we propose the two circumstances under which a measure would be removed entirely from the calculation of the Star Ratings. The first circumstance would be changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes. As clinical guidelines change, we would need the flexibility to remove measures from the Star Ratings that are not consistent with current guidelines. We are proposing to announce such subregulatory removals through the Call Letter so that removals for this reason are accomplished quickly and as soon as the disconnect with positive clinical outcomes is definitively identified. We note that this proposal is consistent with our current practice. For example, previously we retired the Glaucoma Screening measure for HEDIS 2015 after the U.S. Preventive Services Task Force concluded that the clinical evidence is insufficient to assess the balance of benefits and harms of screening for glaucoma in adults.

In addition to removal of measures because of changes in clinical guidelines, we currently review measures continually to ensure that the measure remains sufficiently reliable such that it is appropriate to continue use of the measure in the Star Ratings. We propose, at paragraph (e)(1)(ii), that we would also have authority to subregulatorily remove measures that show low statistical reliability so as to move swiftly to ensure the validity and reliability of the Star Ratings, even at the measure level. We will continue to analyze measures to determine if measure scores are ''topped out'' (that is, showing high performance across all contracts decreasing the variability across contracts and making the measure unreliable) so as to inform our approach to the measure, or if measures have low reliability. Although some measures may show uniform high performance across contracts and little variation between them, we seek evidence of the stability of such high performance, and we want to balance how critical the measures are to improving care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures. If, for example, performance in a given measure has just improved across all contracts, or if no other measures capture a key focus in Star Ratings, a ''topped out'' measure which would have lower reliability may be retained in Star Ratings. Under our proposal to be codified at paragraph (e)(2), we would announce application of this rule through the Call Letter in advance of the measurement period.

We request comment on these proposals regarding the processes to add, update, and remove Star Ratings measures.

i. Measure Set for Performance Periods Beginning on or After January 1, 2019

We are proposing the measures included in Table 2 to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings. The CAHPS measure specification, including case-mix adjustment, is described in the Technical Notes and at *ma-pdpcahps.org.* The HOS measure specification, including case-mix adjustment, is described at (*http://hosonline.org/globalassets/hos-online/survey-results/hos_casemix_coefficient_tables_c17.pdf*). These specifications are part of our proposal.

We are not proposing to codify this list of measures and specifications in regulation text in light of the regular updates and revisions contemplated by our proposals at §§ 422.164 and 423.184. We intend, as proposed in paragraph (a) of these sections, that the Technical Notes for each year's Star Ratings would include the applicable full list of measures.

BILLING CODE 4120–01–P

TABLE 2: PROPOSED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2019

The measure descriptions listed in this table are high-level descriptions. 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. For example, Star Ratings for the year 2020 are produced in the fall of 2019.

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 2020, the measurement period is referencing the January 1, 2018 to December 31, 2018 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.
3.

TABLE 2A: PART C MEASURES

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Breast Cancer Screening (BCS)	Percent of female plan members aged 52-74 who had a mammogram during the past 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0031	Clustering	MA-PD and MA-only
Colorectal Cancer Screening (COL)	Percent of plan members aged 50 to 75 who had appropriate screenings for colorectal cancer.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0034	Clustering	MA-PD and MA-only
Annual Flu Vaccine	Percent of plan members who received an influenza vaccination prior to flu season.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	CAHPS**	Most recent data submitted for the survey of enrollees	#0040	Relative Distribution and Significance Testing	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Improving or Maintaining Physical Health	Percent of plan members aged 65 or older whose physical health status was the same or better than expected after 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Outcome Measure Weight of 3	HOS***	Most recent data submitted for the survey of enrollees	Not Applicable	Clustering	MA-PD and MA-only
Improving or Maintaining Mental Health	Percent of plan members aged 65 or older whose mental health was the same or better than expected after 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Outcome Measure Weight of 3	HOS***	Most recent data submitted for the survey of enrollees	Not Applicable	Clustering	MA-PD and MA-only
Monitoring Physical Activity (PAO)	Percent of plan members aged 65 or older who had a doctor's visit in the past 12 months and who received advice to start, increase or maintain their level exercise or physical activity.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0029	Clustering	MA-PD and MA-only
Adult BMI Assessment (ABA)	Percent of plan members 18-74 years of age who had an outpatient visit and whose body mass index (BMI) was documented.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0421	Clustering	MA-PD and MA-only
Special Needs Plan (SNP) Care Management	Percent of eligible Special Needs Plan (SNP) enrollees who received a health risk assessment (HRA).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	Part C Plan Reporting	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Care for Older Adults (COA) – Medication Review	Percent of Special Needs Plan enrollees 66 years and older who received at least one medication review conducted by a prescribing practitioner or clinical pharmacist and the presence of a medication list in the medical record.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0553	Clustering	Special Needs Plans
Care for Older Adults (COA) – Functional Status Assessment	Percent of Special Needs Plan enrollees 66 years and older who received at least one functional status assessment.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Care for Older Adults (COA)– Pain Assessment	Percent of Special Needs Plan enrollees 66 years and older who received at least one pain assessment.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Osteoporosis Management in Women who had a Fracture (OMW)	Percent of female plan enrollees 67 - 85 who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 6 months after the fracture.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0053	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Eye Exam	Percent of diabetic enrollees 18-75 with diabetes (type 1 and type 2) who received an eye exam (retinal).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0055	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Kidney Disease Monitoring	Percent of diabetic enrollees 18-75 with diabetes (type 1 and type 2) who had medical attention for nephropathy.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0062	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Blood Sugar Controlled	Percent of diabetic enrollees 18-75 whose most recent HbA1c level is greater than 9%, or who were not tested.	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0059	Clustering	MA-PD and MA-only
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) for members 18-59 years of age and 60-85 years of age with diagnosis of diabetes or (150/90) for members 60-85 without a diagnosis of diabetes.	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
Rheumatoid Arthritis Management (ART)	Percent of plan members who were diagnosed with rheumatoid arthritis and who were dispensed at least one ambulatory prescription for a disease modifying anti-rheumatic drug (DMARD).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0054	Clustering	MA-PD and MA-only
Reducing the Risk of Falling (FRM)	Percent of plan members 65 years of age or older who had a fall or had problems with balance or walking in the past 12 months, who were seen by a practitioner in the past 12 months and received fall risk intervention from their current practitioner.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0035	Clustering	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Improving Bladder Control (MUI)	Percent of plan members 65 years of age or older who reported having a urine leakage problem in the past 6 months and who received treatment for their current urine leakage problem.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0030	Clustering	MA-PD and MA-only
Medication Reconciliation Post-Discharge (MRP)	Percent of plan members 18 years of age and older for whom medications were reconciled the date of discharge through 30 days after discharge (31 total days).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0554	Clustering	MA-PD and MA-only
Plan All-Cause Readmissions (PCR)	Percent of acute inpatient stays that were followed by an unplanned acute readmission for any diagnosis within 30 days, for members 65 years of age and older. Rates of readmission are risk-adjusted.	Managing Chronic (Long Term) Conditions	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
Getting Needed Care	Percent of the best possible score the plan earned on how easy it is for members to get needed care, including care from specialists.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Getting Appointments and Care Quickly	Percent of the best possible score the plan earned on how quickly members get appointments and care.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Customer Service	Percent of the best possible score the plan earned on how easy it is for members to get information and help from the plan when needed.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Rating of Health Care Quality	Percent of the best possible score the plan earned from members who rated the quality of the health care they received.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Rating of Health Plan	Percent of the best possible score the plan earned from members who rated the health plan.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Care Coordination	Percent of the best possible score the plan earned on how well the plan coordinates members' care. (This includes whether doctors had the records and information they needed about members' care and how quickly members got their test results.)	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and MA-only
Complaints about the Health Plan	Rate of complaints, logged into the Complaint Tracking Module (CTM), about the health plan per 1,000 members.	Member Complaints and Changes in the Health Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Complaints Tracking Module (CTM)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Members Choosing to Leave the Plan	Percent of plan members who chose to leave the plan.	Member Complaints and Changes in the Health Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Medicare Beneficiary Database Suite of Systems (MBDSS)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Health Plan Quality Improvement	Measure of a health plan's performance, whether improved or declined from 1 year to the next (§ 422.164(f)).	Member Complaints and Changes in the Health Plan's Performance	Improvement Measure Weight of 5	Star Ratings	The current and prior Star Ratings years	Not Applicable	Clustering	MA-PD and MA-only
Plan Makes Timely Decisions about Appeals	Percent of plan members who got a timely response when they made an appeal request to the health plan about a decision to refuse payment or coverage, including cases dismissed by the IRE because the plan has subsequently approved coverage/payment.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Reviewing Appeals Decisions	Percent of appeals where a plan's decision was "upheld" by the Independent Review Entity (IRE) of all the plan's appeals (upheld, overturned, and partially overturned appeals only) that the IRE reviewed.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Call Center – Foreign Language Interpreter and TTY Availability	Percent of time that TTY services and foreign language interpretation were available when needed by prospective members who called the health plan's prospective enrollee customer service phone number.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Call Center	Data collected first half of the year prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only, except for 1876 Cost Plans
Statin Therapy for Patients with Cardiovascular Disease (SPC)	Percent of plan members (males 21–75 years of age and females 40–75 years of age) who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and were dispensed at least one high or moderate-intensity statin medication.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only

* NCQA HEDIS Technical Specifications, Volume 2
** Medicare Advantage and Prescription Drug Plan CAHPS Survey Quality Assurance Protocols & Technical Specifications Manual (http://ma-pdpcahps.org/en/quality-assurance/)
*** NCQA HEDIS Specifications for the Medicare Health Outcomes Survey, Volume 6

TABLE 2B: PART D MEASURES

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
Call Center – Foreign Language Interpreter and TTY Availability	Percent of time that TTY services and foreign language interpretation were available when needed by prospective members who called the health plan's prospective enrollee customer service phone number.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Call Center	Data collected first half of the year prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP, except 1876 Cost Plans

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
Appeals Auto–Forward	Rate of cases auto-forwarded to the Independent Review Entity (IRE) because the plan exceeded decision timeframes for coverage determinations or redeterminations.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year two years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Appeals Upheld	Percent of appeals where a plan's decision was "upheld" by the Independent Review Entity (IRE) of all the plan's appeals (upheld, overturned, and partially overturned appeals only) that the IRE reviewed.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Complaints about the Drug Plan	Rate of complaints about the drug plan per 1,000 members.	Member Complaints and Changes in the Drug Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Complaints Tracking Module (CTM)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Members Choosing to Leave the Plan	Percent of plan members who chose to leave the plan.	Member Complaints and Changes in the Drug Plan's Performance experience and outcomes	Patients' Experience and Complaints Measure Weight of 1.5	Medicare Beneficiary Database Suite of Systems (MBDSS)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Drug Plan Quality Improvement	Measure of a drug plan's performance, whether improved or declined from1 year to the next (§ 422.184(f)).	Member Complaints and Changes in the Drug Plan's Performance	Improvement Measure Weight of 5	Star Ratings	The current and prior Star Ratings years	Not Applicable	Clustering	MA-PD and PDP
Rating of Drug Plan	Percent of the best possible score the plan earned from members who rated the prescription drug plan.	Member Experience with the Drug Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and PDP
Getting Needed Prescription Drugs	Percent of the best possible score the plan earned on how easy it is for members to get the prescription drugs they need using the plan.	Member Experience with the Drug Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and PDP

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
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
Medication Adherence for Diabetes Medications	Percent of plan members with a prescription for diabetes medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Hypertension (RAS antagonists)	Percent of plan members with a prescription for a blood pressure medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Cholesterol (Statins)	Percent of plan members with a prescription for a cholesterol medication (a *statin drug*) who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
MTM Program Completion Rate for CMR	Percent of Medication Therapy Management (MTM) program enrollees who received a Comprehensive Medication Review (CMR).	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Statin Use in Persons with Diabetes (SUPD)	Percent of the number of plan members 40-75 years old who were dispensed at least two diabetes medication fills and received a statin medication fill.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#2712	Clustering	MA-PD and PDP

* NCQA HEDIS Technical Specifications, Volume 2.

** Medicare Advantage and Prescription Drug Plan CAHPS Survey Quality Assurance Protocols & Technical Specifications Manual (*http://ma-pdpcahps.org/en/quality-assurance/*).

*** NCQA HEDIS Specifications for the Medicare Health Outcomes Survey (*http://www.hosonline.org/globalassets/hos-online/publications/hos_hedis_volume6_2017.pdf*).

BILLING CODE 4120–01–C

j. Improvement Measures

In the 2013 Part C and D Star Ratings, we implemented the Part C and D improvement measures (CY2013 Rate Announcement, *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf*). The improvement measures address the overall improvement or decline in individual measure scores from the prior to the current year. We propose to continue the current methodology detailed in the Technical Notes for calculating the improvement measures and to codify it at §§ 422.164(f) and 423.184(f). For a measure to be included in the improvement calculation, the measure must have numeric value scores in both the current and prior year and not have had a substantive specification change during those years. In addition, the improvement measure will not include any data on measures that are already focused on improvement (for example, HOS measures focused on improving or maintaining physical or mental health). The Part C improvement measure includes only Part C measure scores, and the Part D improvement measure includes only Part D measure scores. All measures meeting these criteria would be included in the improvement measures under our proposal at paragraph (f)(1)(i) through (iv) of §§ 422.164 and 423.184.

Annually, the subset of measures to be included in the improvement measures following these criteria would be announced through the Call Letter, similar to our proposal for regular updates and removal of measures. Under our proposal, once the measures to be used for the improvement measures are identified, CMS would determine which contracts have sufficient data for purposes of applying and scoring the improvement measure(s). Following current practices, the improvement measure score would be calculated only for contracts that have numeric measure scores for both years for at least half of the measures identified for use in the improvement measure. We propose this standard for determining contracts eligible for an improvement measure at paragraph (f)(2).

We propose at part §§ 422.164(f)(3) and (4) and 423.184(f)(3) and (4) the process for calculating the improvement measure score(s) and a special rule for any identified improvement measure for a contract that received a measure-level Star Rating of 5 in each of the 2 years examined, but whose associated measure score indicates a statistically significant decline in the time period. The improvement measure would be calculated in a series of distinct steps:

- The improvement change score (the difference in the measure scores in the 2-year period) would be determined for each measure that has been identified as part of an improvement measure and for which a contract has a numeric score for each of the 2 years examined.
- Each contract's improvement change score would be categorized as a significant change or not by employing a two tailed t-test with a level of significance of 0.05.
- The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.
- The improvement measure score would then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.
- The improvement measure score would be converted to a measure-level Star Rating using the hierarchical clustering algorithm.

The improvement measure score cut points would be determined using two separate clustering algorithms. Improvement measure scores of zero and above would use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero would be clustered to determine the cut points for 1 and 2 stars. The Part D improvement measure thresholds for MA–PDs and PDPs would be reported separately.

We propose a special rule in paragraph (f)(3) to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement measure calculation. This hold harmless provision was added in 2014 to avoid the unintended consequence for contracts that score 5 stars on a subset of measures in each of the 2 years. For any identified improvement measure for which a contract received a rating of 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change. The measure will be included in the count of measures used to determine eligibility for the improvement measure and in the denominator of the improvement measure score. The intent of the hold harmless provision for a contract that receives a measure rating of 5 stars for each year is to prevent the measure from lowering a contract's improvement measure when the contract still demonstrates high performance. We propose in section III.A.12. of this proposed rule another hold harmless provision to be codified at §§ 422.166(g)(1) and 423.186(g)(1).

We request comment on the methodology for the improvement measures, including rules for determining which measures are included, the conversion to a Star Rating, and the hold harmless provision for individual measures that are used for the determination of the improvement measure score.

k. Data Integrity

The data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful for the purposes we have proposed at §§ 422.160(b) and 423.180(b). As part of the current Star Ratings methodology, all measures and the associated data 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 measure data are incomplete, inaccurate, or biased. Data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors. When applicable (for example, data from the IRE, PDE, call center), CMS expects sponsoring organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified so CMS can address these errors.

We propose to codify at §§ 422.164(g) and 423.184(g) specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s). One example of such situations that give rise to such determinations includes a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements. Our modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies. This policy and

these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when deficiencies have been identified that show we cannot objectively evaluate a sponsor's performance in an area.

As a standard practice, we check for flags that indicate bias or non-reporting, check for completeness, check for outliers, and compare measures to the previous year to identify significant changes which could be indicative of data issues. CMS has developed and implemented Part C and Part D Reporting Requirements Data Validation standards to assure that data reported by sponsoring organizations pursuant to §§ 422.516 and 423.514 satisfy the regulatory obligation. Sponsor organizations should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications is posted on: *http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx.* Information about Data Validation of Reporting Requirements data is posted on: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.html* and *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.*

We propose, in paragraphs (g)(1)(i) through (iii), rules for specific circumstances where we believe a specific response is appropriate. First, we propose a continuation of a current policy: To reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of ''biased rate'' or BR based on an auditor's review of the data if a plan chooses to report; this proposal would also apply when a plan chooses not to submit and has an audit designation of ''non-report'' or NR. Second, we propose to continue to reduce Part C and D Reporting Requirements data, that is, data required pursuant to §§ 422.514 and 423.516, to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards/sub-standards for data directly used to calculate the associated measure. In our view, data that do not reach at least 95 percent on the data validation standards are not sufficiently accurate, impartial, and complete for use in the Star Ratings. As the sponsoring organization is responsible for these data and submits them to CMS, we believe that a negative inference is appropriate to conclude that performance is likely poor. Third, we propose a new specific rule to authorize scaled reductions in Star Ratings for appeal measures in both Part C and Part D.

The data downgrade policy was adopted to address instances when the data that would be used for specific measures are not reliable for measuring performance 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 sponsoring organization for the lack of data for the applicable measure. Without some policy for reduction in the rating for these measures, sponsoring organizations could ''game'' the Star Ratings and merely fail to submit data that illustrate poor performance. We believe that removal of the measure from the ratings calculation would unintentionally reward poor data compilation and submission activities such that our only recourse is to reduce the rating to 1 star for affected measures.

For verification and validation of the Part C and D appeals measures, we propose to use statistical criteria to determine if a contract's appeals measure-level Star Ratings would be reduced for missing IRE data. The criteria would allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. The completeness of the IRE data is critical to allow fair and accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the appeals measures.

In response to stakeholder concerns about CMS' prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.[40] The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.[41]

We propose to use multiple data sources whenever possible, such as the TMP data or information from audits to determine whether the data at the Independent Review Entity (IRE) are complete. Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.

CMS is proposing to reduce a contract's Part C or Part D appeal measures Star Ratings for IRE data that are not complete or otherwise lack integrity based on the TMP or audit information. The reduction would be applied to the measure-level Star Ratings for the applicable appeals measures. There are varying degrees of data issues and as such, we are proposing a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size fits all approach. The methodology would employ scaled reductions, ranging from a 1-star reduction to a 4-star reduction; the most severe reduction for the degree of missing IRE data would be a 4-star reduction which would result in a measure-level Star Rating of 1 star for the associated appeals measures (Part C or Part D). The data source for the scaled reduction is the TMP or audit data, however the specific data used for the determination of a Part C IRE data completeness reduction are independent of the data used for the Part D IRE data completeness reduction. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. We solicit comment on this proposal and its scope; we are looking in particular for comments related to how to use the process we are proposing

[40] This project was discussed in the November 28, 2016 HPMS memo, ''Industry-wide Appeals Timeliness Monitoring.'' *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf.*

[41] Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period.

in this proposal to account for data integrity issues discovered through means other than the TMP and audits of sponsoring organizations.

CMS' proposed scaled reduction methodology is a three-stage process using the TMP or audit information to determine: First, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, the basis for the estimate of the error rate; and finally, whether the estimated error rate is significantly greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.

Once the scaled reduction for a contract is determined using this methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. The minimum measure-level Star Rating is 1 star. If the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of 1 star for the appeals measure.

The error rate for the Part C and Part D appeals measures using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP data is dependent on the enrollment of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a 2-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.

The calculated error rate formula (Equation 1) for the Part C measures is proposed to be determined by the quotient of the number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period.

$$\text{Part C Calculated Error Rate} = \frac{\text{Number of cases not forwarded to the IRE}}{\text{Total number of cases that should have been forwarded to IRE}} \quad \textbf{Equation (1)}$$

The calculated error rate formula (Equation 2) for the Part D measures is proposed to be determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

$$\text{Part D Calculated Error Rate} = \frac{\text{Number of untimely cases not auto-forwarded to the IRE}}{\text{Total number of untimely cases}} \quad \textbf{Equation (2)}$$

The projected number of cases not forwarded to the IRE in a 3-month period would be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the TMP time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from 1-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 3.0. Contracts with mean enrollments of 50,000 but at most 250,000 that submitted data from a 2-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.5. Small contracts with mean enrollments less than 50,000 that submitted data for a 3-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.0.

Under this proposal, contract ratings would be subject to a possible reduction due to lack of IRE data completeness if both following conditions are met• The calculated error rate is 20 percent or more.

• The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract would not be subject to reductions for IRE data completeness issues.

If a contract is subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract would be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent.

The midpoint of the score interval would be determined using Equation 3.

$$Midpoint = Calculated\ Error\ Rate\ x \left(\frac{Total\ Number\ of\ Cases}{Total\ Number\ of\ Cases + z^2}\right) + \frac{1}{2}\left(\frac{z^2}{Total\ Number\ of\ Cases + z^2}\right) \quad \textbf{Equation (3)}$$

The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as $z\alpha/_2$ but for ease of presentation represented here as z. (The z value that will be used for the purpose of the calculation of the interval is 1.959964.).

For the Part C appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that should have been in the IRE for the Part C TMP data.

For the Part D appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 2. The total number of cases in

Equation 3 is the total number of untimely cases for the Part D appeals measures.

Letting the calculated error rate be represented by and the total number of cases represented as n, Equation 3 can be streamlined as Equation 4:

$$Midpoint = \hat{p}\left(\frac{n}{n+z^2}\right) + \frac{1}{2}\left(\frac{z^2}{n+z^2}\right) \quad \textbf{Equation (4)}$$

The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below:

$$Lower\ Bound = Midpoint - z \times \sqrt{\frac{1}{n+z^2}\left[\hat{p}(1-\hat{p})\left(\frac{n}{n+z^2}\right) + \frac{1}{4}\left(\frac{z^2}{n+z^2}\right)\right]} \quad \textbf{Equation (5)}$$

For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate would be compared to each of the thresholds in Table 3. If the contract's calculated lower bound is higher than the threshold, the contract would receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is being employed to determine whether the contract's error rate is significantly greater than the thresholds of 20 percent, 40 percent, 60 percent, and 80 percent. The proposed scaled reductions are in Table 3, and would be codified in narrative form at paragraph (g)(1)(iii)(D) of both regulations.

The reductions due to IRE data completeness issues would be applied after the calculation of the measure-level Star Rating for the appeals measures. The reduction would be applied to the Part C appeals measures and/or the Part D appeals measures.

It is important to note that a contract's lower bound could be statistically significantly greater than more than one threshold. The reduction would be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000 percent, the contract's estimated value is significantly greater than the thresholds of 20 percent, 40 percent, and 60 percent because the lower bound value 64.560000 percent is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80 percent. The contract would be subject to the reduction that corresponds to the 60 percent threshold, which is three stars.

TABLE 3—APPEALS MEASURE STAR RATINGS REDUCTIONS BY THE INCOMPLETE DATA ERROR RATE

Proposed thresholds using the lower bound of confidence interval estimate of the error rate (%)	Reduction for incomplete IRE data (stars)
20	1
40	2
60	3
80	4

We propose regulation text at § 422.164(g)(1)(iii)(A) through (N) and § 423.184(g)(1)(iii)(A) through (K) to codify these parameters and formulas for the scaled reductions. We note that the proposed text for the Part C regulation includes specific paragraphs related to MA and MA–PD plans that are not included in the proposed text for the Part D regulation but that the two are otherwise identical.

In addition, we propose in §§ 422.164(g)(2) and 423.184(g)(2) to authorize reductions in a Star Rating for a measure when there are other data accuracy concerns (that is, those not specified in paragraph (g)(1)). We propose an example in paragraph (g)(2) of another circumstance where CMS would be authorized to reduce ratings based on a determination that performance data are incomplete, inaccurate, or biased. We also propose this other situation would result in a reduction of the measure rating to 1 star.

We have taken several steps in past years to protect the integrity of the data we use to calculate Star Ratings. However, we welcome comments about alternative methods for identifying inaccurate or biased data and comments on the proposed policies for reducing stars for data accuracy and completeness issues. Further, we welcome comments on the proposed methodology for scaled reductions for the Part C and Part D appeals measures to address the degree of missing IRE data.

l. Measure-Level Star Ratings

We propose in §§ 422.166(a) and 423.186(a) the methods for calculating Star Ratings at the measure level. As part of the Part C and D Star Ratings System, Star Ratings are currently calculated at the measure level. To separate a distribution of 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 a set of cut points. We propose to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology; we propose to codify this policy in paragraphs (a)(1) of each section. We propose in paragraphs (a)(2) and (a)(3) of each section that for non-CAHPS measures, we would use a clustering methodology and that for CAHPS measures, we would use relative distribution and significance testing. Measure scores would be converted to a 5-star scale ranging from 1 to 5, with whole star increments for the cut points. A rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Consistent with current policy, we propose to use the two methodologies described as follows to convert measure scores to measure-level Star Ratings.

The clustering method would be applied to all Star Ratings measures, except for the CAHPS measures. For each individual measure, we would determine the measure cut points using all measure scores for all contracts required to report that do not have missing, flagged as biased, or erroneous data. For the Part D measures, we propose to determine MA–PD and PDP cut points separately. The scores would

be grouped such that scores within the same rating (that is 1 star, 2 stars, etc.) are as similar as possible, and scores in different ratings are as different as possible. The hierarchical clustering algorithm and the associated tree and cluster assignments using SAS (a statistical software package) are currently used to determine the cut points for the assignment of the measure-level Star Ratings. We intend to continue use of this software under this proposal, but improvements in statistical analysis will not result in rulemaking or changes in these proposed rules. Rather, we believe that the software used to apply the clustering methodology is generally irrelevant.

Conceptually, the clustering algorithm identifies natural gaps within the distribution of the scores and creates groups (clusters) that are then used to identify the cut points that result in the creation of a pre-specified number of categories. The Euclidean distance between each pair of contracts' measure scores serves as the input for the clustering algorithm. The hierarchical clustering algorithm begins with each contract's measure score being assigned to its own cluster. Ward's minimum variance method is used to separate the variance of the measure scores into within-cluster and between-cluster sum of squares components in order to determine which pairs of clusters to merge. For the majority of measures, the final step in the algorithm is done a single time with five categories specified for the assignment of individual scores to cluster labels. The cluster labels are then ordered to create the 1 to 5-star scale. The range of the values for each cluster (identified by cluster labels) is examined and would be used to determine the set of cut points for the Star Ratings. The measure score that corresponds to the lower bound for the measure-level ratings of 2 through 5 would be included in the star-specific rating category for a measure for which a higher score corresponds to better performance. For a measure for which a lower score is better, the process would be the same except that the upper bound within each cluster label would determine the set of cut points. The measure score that corresponds to the cut point for the ratings of 2 through 5 would be included in the star-specific rating category. In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters. Under our proposal to use clustering to set cut points, we would not require the same number of observations (contracts) within each rating and instead would use a data-driven approach.

As proposed in paragraphs (a)(2)(ii) of each section the improvement measures for Part C and Part D would require the clustering algorithm to be done twice for the identification of the cut points that would allow the conversion of the improvement measure scores to the star scale. The Part D improvement measure score clustering for MA–PDs and PDPs would be reported separately. Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating, while improvement scores less than zero would be assigned either 1 or 2 stars. The clustering would be conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero. For contracts with improvement scores greater than or equal to zero, the clustering process would result in three clusters with measure-level Star Ratings of 3, 4, or 5 with the lower bound of each cluster serving as the cut point for the associated Star Rating. For those contracts with improvement scores less than zero, the clustering algorithm would result in two clusters with measure-level Star Ratings of 1 or 2.

We propose in paragraphs (a)(3) of each section to use percentile standing relative to the distribution of scores for other contracts, measurement reliability standards, and statistical significance testing to determine star assignments for the CAHPS measures. This method would combine evaluating the relative percentile distribution of scores with significance testing and measurement reliability standards in order to maximize the accuracy of star assignments based on scores produced from the CAHPS survey. For CAHPS measures, contracts are first classified into base groups by comparisons to percentile cut points defined by the current-year distribution of case-mix adjusted contract means. Percentile cut points would then be rounded to the nearest integer on the 0–100 reporting scale, and each base group would include those contracts whose rounded mean score is at or above the lower limit and below the upper limit. Then, the number of stars assigned would be determined by the base group assignment, the statistical significance and direction of the difference of the contract mean from the national mean, an indicator of the statistical reliability of the contract score on a given measure (based on the ratio of sampling variation for each contract mean to between-contract variation), and the standard error of the mean score. Table 4, which we propose to codify at §§ 422.166(a)(3) and 423.186(a)(3), details the CAHPS star assignment rules for each rating. All statistical tests, including comparisons involving standard error, would be computed using unrounded scores.

We propose that if the reliability of a CAHPS measure score is very low for a given contract, less than 0.60, the contract would not receive a Star Rating for that measure. For purposes of applying the criterion for 1 star on Table 3, at item (c), low reliability scores would be defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The standard error would be considered when the measure score is below the 15th percentile (in base group 1), significantly below average, and has low reliability: In this case, 1 star would be assigned if and only if the measure score is at least 1 standard error below the unrounded cut point between base groups 1 and 2. Similarly, when the measure score is at or above the 80th percentile (in base group 5), significantly above average, and has low reliability, 5 stars would be assigned if and only if the measure score is at least 1 standard error above the unrounded cut point between base groups 4 and 5.

TABLE 4—CAHPS STAR ASSIGNMENT RULES

Star	Criteria for assigning star ratings
1	A contract is assigned one star if both criteria (a) and (b) are met plus at least one of criteria (c) and (d): (a) Its average CAHPS measure score is lower than the 15th percentile; AND (b) its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score; (c) the reliability is not low; OR (d) its average CAHPS measure score is more than one standard error (SE) below the 15th percentile.

TABLE 4—CAHPS STAR ASSIGNMENT RULES—Continued

Star	Criteria for assigning star ratings
2	A contract is assigned two stars if it does not meet the one-star criteria and meets at least one of these three criteria: (a) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; OR (b) its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; OR (c) its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.
3	A contract is assigned three stars if it meets at least one of these three criteria: (a) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, AND it is not statistically significantly different from the national average CAHPS measure score; OR (b) its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile, AND the reliability is low, AND the score is not statistically significantly lower than the national average CAHPS measure score; OR (c) its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile, AND the reliability is low, AND the score is not statistically significantly higher than the national average CAHPS measure score.
4	A contract is assigned four stars if it does not meet the 5-star criteria and meets at least one of these three criteria: (a) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability; OR (b) its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability; OR (c) its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.
5	A contract is assigned five stars if both criteria (a) and (b) are met plus at least one of criteria (c) and (d): (a) Its average CAHPS measure score is at or above the 80th percentile; AND (b) its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score; (c) the reliability is not low; OR (d) its average CAHPS measure score is more than one SE above the 80th percentile.

We request comments on our proposed methods to determine cut points. For certain measures, we previously published pre-determined 4-star thresholds. If commenters recommend pre-determined 4-star thresholds, we request suggestions on how to minimize generating Star Ratings that do not reflect a contract's ''true'' performance, otherwise referred to as the risk of ''misclassifying'' a contract's performance (for example, scoring a ''true'' 4-star contract as a 3-star contract, or vice versa, or creating ''cliffs'' in Star Ratings and therefore, potential benefits between plans with nearly identical Star Ratings on different sides of a fixed threshold), and how to continue to create incentives for quality improvement. We also welcome comments on alternative recommendations for revising the cut point methodology. For example, we are considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next. We welcome comments on these particular methodologies and recommendations for other ways to provide stability for cut points from year to year.

m. Hierarchical Structure of the Ratings

We propose to continue our existing policy to use a hierarchical structure for the Star Ratings. The basic building block of the MA Star Ratings System is, and under our proposal would continue to be, the measure. Because the MA Star Ratings System consists of a large collection of measures across numerous quality dimensions, the measures would be organized in a hierarchical structure that provides ratings at the measure, domain, Part C summary, Part D summary, and overall levels. The regulation text at §§ 422.166 and 423.186 is built on this structure and provides for calculating ratings at each ''level'' of the system. The organization of the measures into larger groups increases both the utility and efficiency of the rating system. At each aggregated level, ratings are based on the measure-level stars. Ratings at the higher level are based on the measure-level Star Ratings, with whole star increments for domains and half-star increments for summary and overall ratings; a rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Half-star increments are used in the summary and overall ratings to allow for more variation at the higher hierarchical levels of the ratings system. We believe this greater variation and the broader range of ratings provide more useful information to beneficiaries in making enrollment decisions while remaining consistent with the statutory direction in sections 1853(o) and 1854(b) of the Act to use a 5-star system. These policies for the assignment of stars would be codified with other rules for the ratings at the domain, summary, and overall level. Domain ratings employ an unweighted mean of the measure-level stars, while the Part C and D summary and overall ratings employ a weighted mean of the measure-level stars and up to two adjustments. We propose to codify these policies at paragraphs (b)(2), (c)(1) and (d)(1) of §§ 422.166 and 423.186.

n. Domain Star Ratings

Groups of measures that together represent a unique and important aspect of quality and performance are organized to form a domain. Domain ratings summarize a plan's performance on a specific dimension of care. Currently the domains are used purely for purposes of displaying data on Medicare Plan Finder to organize the measures and help consumers interpret the data. We propose to continue this policy at §§ 422.166(b)(1)(i) and 423.186(b)(1)(i).

At present, there are nine domains—five for Part C measures for MA-only and MA–PDs plans and four for Part D measures for MA–PDs. We propose to continue to group measures for purposes of display on Medicare Plan Finder and to continue use of the same domains as in current practice in §§ 422.166(b)(1)(i) and 423.196(b)(1)(i). The current domains are listed in Tables 5 and 6.

TABLE 5—PART C DOMAINS

Domain
Staying Healthy: Screenings, Tests and Vaccines.
Managing Chronic (Long Term) Conditions.
Member Experience with Health Plan.

TABLE 5—PART C DOMAINS—Continued

Domain
Member Complaints and Changes in the Health Plan's Performance.
Health Plan Customer Service.

TABLE 6—PART D DOMAINS

Domain
Drug Plan Customer Service.
Member Complaints and Changes in the Drug Plan's Performance.
Member Experience with the Drug Plan.
Drug Safety and Accuracy of Drug Pricing.

Currently, Star Ratings for domains are calculated using the unweighted mean of the Star Ratings of the included measures. They are displayed to the nearest whole star, using a 1–5 star scale. We propose to continue this policy at paragraph (b)(2)(ii). We also propose that a contract must have stars for at least 50 percent of the measures required to be reported for that domain for that contract type to have that domain rating calculated in order to have enough data to reflect the contract's performance on the specific dimension. For example, if a contract is rated only on one measure in Staying Healthy: Screenings, Tests and Vaccines, that one measure would not necessarily be representative of how the contract performs across the whole domain so we do not believe it is appropriate to calculate and display a domain rating. We propose to continue this policy by providing, at paragraph (b)(2)(i), that a minimum number of measures must be reported for a domain rating to be calculated.

o. Part C and D Summary Ratings

In the current rating system the Part C summary rating provides a rating of the health plan quality and the Part D summary rating provides a rating of the prescription drug plan quality. We are proposing, at §§ 422.166(c) and 423.186(c), to codify regulation text governing the adoption of Part C summary ratings and Part D summary ratings. An MA-only plan and a Part D standalone plan would receive a summary rating only for, respectively, Part C measures and Part D measures.

First, in paragraphs (c)(1) of each section, we propose the overall formula for calculating the summary ratings for Part C and Part D. Under current policy, the summary rating for an MA-only contract is calculated using a weighted mean of the Part C measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the categorical adjustment index (CAI); similarly, the current summary rating for a PDP contract is calculated using a weighted mean of the Part D measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the CAI. We propose in §§ 422.166(c)(1) and 423.186(c)(1) that the Part C and Part D summary ratings would be calculated as the weighted mean of the measure-level Star Ratings with an adjustment to reward consistently high performance (reward factor) and the application of the CAI, pursuant to paragraph (f) (where we propose the specifics for these adjustments) for Parts C and D, respectively.

Second, and also consistent with current policy, we propose an MA-only contract and PDP would have a summary rating calculated only if the contract meets the minimum number of rated measures required for its respective summary rating: A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated. The proposed regulation text would be codified as paragraph (c)(2)(i) of §§ 422.166 and 423.186. The same rules would be applied to both the Part C and Part D summary ratings for the minimum number of rated measures and flags for display. We would apply this regulation to require a MA–PD to have a Part C and a Part D summary rating if the minimum requirement of rated measures for each summary rating type is met. The improvement measures are based on identified measures that are each counted towards meeting the proposed requirement for the calculation of a summary rating. We propose (at paragraph (c)(2)(ii)) that the improvement measures themselves are not included in the count of minimum number of measures for the Part C or Part D summary ratings.

Third, we propose a paragraph (c)(3) in both §§ 422.166 and 423.186 to provide that the summary ratings are on a 1 to 5 star scale in half-star increments. Traditional rounding rules would be employed to round the summary rating to the nearest half-star. The summary rating would be displayed in HPMS and Medicare Plan Finder to the nearest half-star. As proposed in §§ 422.166(h) and 423.186(h), if a contract has not met the measure requirement for calculating a summary rating, the display in HPMS (and on Medicare Plan Finder) for the applicable summary rating would be the flag ''Not enough data available'' or if the measurement period is less than 1 year past the contract's effective date the flag would be ''Plan too new to be measured''.

We welcome comments on the calculations for the Part C and D summary ratings.

p. Overall Rating

The overall Star Rating is a global rating that summarizes the plan's quality and performance for the types of services offered by the plans under the rated contract. We propose at §§ 422.166(d) and 423.186(d) to codify the standards for calculating and assigning overall Star Ratings for MA–PD contracts. The overall rating for an MA–PD contract is proposed to be calculated using a weighted mean of the Part C and Part D measure level Star Ratings, respectively, with an adjustment to reward consistently high performance described in paragraph (f)(1) and the application of the CAI, pursuant to described in paragraph (f)(2).

Consistent with current policy, we propose at paragraph (d)(2) that an MA–PD would have an overall rating calculated only if the contract receives both a Part C and Part D summary rating, and scores for at least 50% of the measures are required to be reported for the contract type to have the overall rating calculated. As with the Part C and D summary ratings, the Part C and D improvement measures would not be included in the count for the minimum number of measures for the overall rating. Any measure that shares the same data and is included in both the Part C and Part D summary ratings would be included only once in the calculation for the overall rating; for example, Members Choosing to Leave the Plan and Complaints about the Plan. As with summary ratings, we propose that overall MA–PD ratings would use a 1 to 5 star scale in half-star increments; traditional rounding rules would be employed to round the overall rating to the nearest half-star. These policies are proposed as paragraphs (d)(2)(i) through (iv).

In accordance with our general proposed policy at §§ 422.166(h) and 423.186(h), the overall rating would be posted on HPMS and Medicare Plan Finder, with specific messages for lack of ratings for certain reasons. Applying that rule, if an MA–PD contract has only one of the two required summary ratings, the overall rating would not be calculated and the display in HPMS would be the flag ''Not enough data available.''

For QBP purposes, low enrollment contracts and new MA plans are defined in § 422.252. Low enrollment contract

means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan; new MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. Low enrollment contracts and new plans do not receive an overall or summary rating because of the lack of necessary data. However, they are treated as qualifying plans for the purposes of QBPs. Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7), provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). This determination is applied at the contract level and thus determines whether a contract (meaning all plans under that contract) is a qualifying contract. The statute, at section 1853(o)(3)(A)(iii) of the Act, provides for treatment of new MA plans as qualifying plans eligible for a specific QBP. We therefore propose, at §§ 422.166(d)(3) and 423.186(d)(3), that low enrollment contracts (as defined in § 422.252 of this chapter) and new MA plans (as defined in § 422.252 of this chapter) do not receive an overall and/or summary rating; they would be treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) of this chapter and announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This proposal would merely codify existing policy and practice.

q. Measure Weights

Prior to the 2012 Part C and D Plan Ratings (now known as Star Ratings), all individual measures included in the program were weighted equally, suggesting equal importance. Based on feedback from stakeholders, including health and drug plans and beneficiary advocacy groups, we moved to provide greater weight to clinical outcomes and lesser weight to process measures. Patient experience and access measures were also given greater weight than process measures, but not as high as outcome measures. The differential weighting was implemented to help create further incentives to drive improvement in clinical outcomes, patient experience, and access. These differential weights for measures were implemented for the 2012 Ratings following a May 2011 Request for Comments and adopted in the CY2013 Rate Announcement and Final Call Letter.

In the Contract Year 2012 Final Rule for Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs rule (79 FR 21486), we stated that scoring methodologies should also consider improvement as an independent goal. To this end, we implemented in the CY 2013 Rate Announcement the Part C and D improvement measures that measure the overall improvement or decline in individual measure scores from the prior to the current year. Given the importance of recognizing quality improvement as an independent goal, for the 2015 Star Ratings, we proposed and subsequently finalized through the 2015 Rate Announcement and final Call Letter an increase in the weight of the improvement measure from 3 times to 5 times that of a process measure. This weight aligns the Part C and D Star Ratings program with value-based purchasing programs in Medicare fee-for-service which heavily weight improvement.

We are proposing in §§ 422.166(e) and 423.186(e) to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). We are considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance. If we were to increase the weight, we are considering increasing it from a weight of 1.0 to between 1.5 and 3 similar to outcome measures. This increased weight would reflect CMS' commitment to serve Medicare beneficiaries by putting the patients first, including their assessments of the care received by plans. We solicit comment on this point, particularly the potential change in the weight of the patient experience/complaints and access measures.

Table 7 includes the proposed measure categories, the definitions of the measure categories, and the weights. In calculating the summary and overall ratings, a measure given a weight of 3 counts three times as much as a measure given a weight of 1. In section III.A.12. of this proposed rule, we propose (as Table 2) the measure set and include the category and weight for each measure; those weight assignments are consistent with this proposal. We propose that as new measures are added to the Part C and D Star Ratings, we would assign the measure category based on these categories and the regulation text proposed at §§ 422.166(e) and 423.186(e), subject to two exceptions. We propose in paragraphs (e)(2) of each section as the first exception, to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings. In subsequent years the weight associated with the measure weighting category would be used. This is consistent with current policy.

TABLE 7—MEASURE CATEGORIES, DEFINITIONS AND WEIGHTS

Measure category	Definition	Weight
Improvement	Part C and Part D improvement measures are derived through comparisons of a contract's current and prior year measure scores.	5
Outcome and Intermediate Outcome.	Outcome measures reflect improvements in a beneficiary's health and are central to assessing quality of care. Intermediate outcome measures reflect actions taken which can assist in improving a beneficiary's health status. Controlling Blood Pressure is an example of an intermediate outcome measure where the related outcome of interest would be better health status for beneficiaries with hypertension.	3
Patient Experience/Complaints.	Patient experience measures reflect beneficiaries' perspectives of the care and services they received.	1.5
Access	Access measures reflect processes and issues that could create barriers to receiving needed care. Plan Makes Timely Decisions about Appeals is an example of an access measure.	1.5

TABLE 7—MEASURE CATEGORIES, DEFINITIONS AND WEIGHTS—Continued

Measure category	Definition	Weight
Process	Process measures capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status.	1

In addition, we propose (at §§ 422.166(e)(3) and 423.186(e)(3)) a second exception to the general weighting rule for MA and Part D contracts that have service areas that are wholly located in Puerto Rico. We recognize the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of Low Income Subsidy (LIS). For the 2017 Star Ratings, we implemented a different weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico. We propose, at §§ 422.166(e)(3) and 423.186(e)(3), to continue to reduce the weights for the adherence measures to 0 for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico. We request comment on our proposed weighting strategy for Measure Weights generally and for Puerto Rico, including the weighting values themselves.

r. Application of the Improvement Measure Scores

Consistent with current policy, we propose at §§ 422.166(g) and 423.186(g) a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. We are proposing, in paragraphs (g)(1)(i) through (iii), a series of rules that specify when the improvement measure is included in calculating overall and summary ratings.

MA–PDs would have the hold harmless provisions for highly-rated contracts applied for the overall rating. For an MA–PD that receives an overall rating of 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded overall rating with and without the improvement measures is done. The overall rating with the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The overall rating without the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The higher overall rating would be used for the overall rating. For an MA–PD that has an overall rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the overall rating would exclude the improvement measure. For all others, the overall rating would include the improvement measure.

MA-only and PDPs would have the hold harmless provisions for highly-rated contracts applied for the Part C and D summary ratings, respectively. For an MA-only or PDP that receives a summary rating of 4 stars or more without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded summary rating with and without the improvement measure and up to two adjustments, the reward factor (if applicable) and CAI, is done. The higher summary rating would be used for the summary rating for the contract's highest rating. For MA-only and PDPs with a summary rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the summary rating would exclude the improvement measure. For all others, the summary rating would include the improvement measure. MA–PDs would have their summary ratings calculated with the use of the improvement measure regardless of the value of the summary rating.

In addition, at paragraph (g)(2), we also propose text to clarify that summary ratings use only the improvement measure associated with the applicable Part C or D performance.

We welcome comments on the hold harmless improvement provision we propose to continue to use, particularly any clarifications in how and when it should be applied.

s. Reward Factor (Formerly Referred to as Integration Factor)

In 2011, the integration factor was added to the Star Ratings methodology to reward contracts that have consistently high performance. The integration factor was later renamed the reward factor. (The reference to either reward or integration factor refers to the same aspect of the Star Ratings.) This factor is calculated separately for the Part C summary rating, Part D summary rating for MA–PDs, Part D summary rating for PDPs, and the overall rating for MA–PDs. It is currently added to the summary (Part C or D) and overall rating of contracts that have both high and stable relative performance for the associated summary or overall rating. The contract's performance will be assessed using its weighted mean relative to all rated contracts without adjustments.

The contract's stability of performance will be assessed using its weighted variance relative to all rated contracts at the same rating level (overall, summary Part C, and summary Part D). The Part D summary thresholds for MA–PDs are determined independently of the thresholds for PDPs. We propose to codify the calculation and use of the reward factor in §§ 422.166(f)(1) and 423.186(f)(1).

Annually, we propose to update the performance and variance thresholds for the reward factor based upon the data for the Star Ratings year, consistent with current policy. A multistep process would be used to determine the values that correspond to the thresholds for the reward factors for the summary and/or overall Star Ratings for a contract. The determination of the reward factors would rely on the contract's ranking of its weighted variance and weighted mean of the measure-level stars to the summary or overall rating relative to the distribution of all contracts' weighted variance and weighted mean to the summary and/or overall rating. A contract's weighted variance would be calculated using the quotient of the following two values: (1) The product of the number of applicable measures based on rating-type and the sum of the products of the weight of each applicable measure and its squared deviation [42] and (2) the product of one less than the number of applicable measures and the sum of the weights of the applicable measures. A contract's weighted mean performance would be

[42] A deviation is the difference between the performance measure's Star Rating and the weighted mean of all applicable measures for the contract.

found by calculating the quotient of the following two values: (1) The sum of the products of the weight of a measure and its associated measure-level Star Ratings of the applicable measures for the rating-type and (2) the sum of the weights of the applicable measures for the rating type. The thresholds for the categorization of the weighted variance and weighted mean for contracts would be based upon the distribution of the calculated values of all rated contracts of the same type. Because highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean is calculated both with and without the improvement measures.

A contract's weighted variance is categorized into one of three mutually exclusive categories, identified in Table 8A, based upon the weighted variance of its measure-level Star Ratings and its ranking relative to all other contracts' weighted variance for the rating type (Part C summary for MA–PDs and MA-only, overall for MA–PDs, Part D summary for MA–PDs, and Part D summary for PDPs), and the manner in which the highest rating for the contract was determined—with or without the improvement measure(s). For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance for the rating type (Part C summary, Part D summary) with the improvement measure. Similarly, a contract's weighted mean is categorized into one of three mutually exclusive categories, identified in Table 8B, based on its weighted mean of all measure-level Star Ratings and its ranking relative to all other contracts' weighted means for the rating type (Part C summary for MA–PDs and MA-only, overall, Part D summary for MA–PDs, and Part D summary for PDPs) and the manner in which the highest rating for the contract was determined—with or without the improvement measure(s). For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted means for the rating type (Part C summary, Part D summary) with the improvement measure. Further, the same threshold criterion is employed per category regardless of whether the improvement measure was included or excluded in the calculation of the rating. The values that correspond to the thresholds are based on the distribution of all rated contracts and are determined with and without the improvement measure(s) and exclusive of any adjustments. Table 8A details the criteria for the categorization of a contract's weighted variance for the summary and overall ratings. Table 8B details the criteria for the categorization of a contract's weighted mean (performance) for the overall and summary ratings. The values that correspond to the cutoffs are provided each year during the plan preview and are published in the Technical Notes.

TABLE 8A—CATEGORIZATION OF A CONTRACT BASED ON ITS WEIGHTED VARIANCE RANKING

Variance category	Ranking
Low	Below the 30th percentile.
Medium	At or above the 30th percentile to less than the 70th percentile.
High	At or above the 70th percentile.

TABLE 8B—CATEGORIZATION OF A CONTRACT BASED ON WEIGHTED MEAN (PERFORMANCE) RANKING

Weighted mean (performance) category	Ranking
High	At or above the 85th percentile.
Relatively High	At or above the 65th percentile to less than the 85th percentile.
Other	Below the 65th percentile.

These definitions of high, medium, and low weighted variance ranking and high, relatively high, and other weighted mean ranking would be codified in narrative form in paragraph (f)(1)(ii).

A contract's categorization for both weighted mean and weighted variance determines the value of the reward factor. Table 9 shows the values of the reward factor based on the weighted variance and weighted mean categorization; these values would be codified, as a chart, in paragraph (f)(i)(iii). The weighted variance and weighted mean thresholds for the reward factor are available in the Technical Notes and updated annually.

TABLE 9—CATEGORIZATION OF A CONTRACT FOR THE REWARD FACTOR

Weighted variance	Weighted mean (performance)	Reward factor
Low	High	0.4
Medium	High	0.3
Low	Relatively High	0.2
Medium	Relatively high	0.1
High	Other	0.0

We propose to continue the use of a reward factor to reward contracts with consistently high and stable performance over time. Further, we propose to continue to employ the methodology described in this subsection to categorize and determine the reward factor for contracts. As proposed in paragraphs (c)(1) and (d)(1), these reward factor adjustments would be applied at the summary and overall rating level.

t. Categorical Adjustment Index

A growing body of evidence links the prevalence of beneficiary-level social risk factors with performance on measures included in Medicare value-based purchasing programs, including MA and Part D Star Ratings. With support from our contractors, we undertook research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.[43] We have also reviewed reports about the impact of socio-economic status (SES) on quality ratings, such as the report published by the NQF posted at *www.qualityforum.org/risk_adjustment_ses.aspx* and the Medicare Payment Advisory Commission's (MedPAC) *Report to the Congress: Medicare Payment Policy* posted at *http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0.* We have more recently been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE [44]) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and we have been considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use in nine Medicare value-based purchasing programs. The report also included considerations for strategies to account for social risk factors in these programs. A January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[45]

We have also engaged NCQA and the PQA to examine their measure specifications used in the Star Ratings program to determine if re-specification is warranted. The majority of measures used for the Star Ratings program are consensus-based. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Thus, measure scores cannot be adjusted for differences in enrollee case mix unless required by the measure steward. Measure re-specification is a multiyear process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates have desirable attributes of relevance, scientific soundness, and feasibility:

- Relevance describes the extent to which the measure captures information important to different groups, for example, consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured.
- Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether the measure is valid, reliable, and precise.
- Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited.

The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.

Beginning with 2017 Star Ratings, we implemented the CAI that adjusts for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy and/or are dual eligible (LIS/DE) and/or have disability status. We developed the CAI as an interim analytical adjustment while we developed a long-term solution. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and beneficiaries with disabilities. By design, the CAI values are monotonic in at least one dimension (LIS/DE or disability status) and thus, contracts with larger LIS/DE and/or disability percentages realize larger positive adjustments. MA–PD contracts can have up to three rating-specific CAI adjustments—one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). MA-only contracts can have one adjustment for the Part C summary rating. PDPs can have one adjustment for the Part D summary rating. We propose to codify the calculation and use of the reward factor and the CAI in §§ 422.166(f)(2) and 423.186(f)(2), while we consider other alternatives for the future.

As is currently done today, the adjusted measure scores of a subset of the Star Ratings measures would serve as the foundation for the determination of the index values. Measures would be excluded as candidates for adjustment if the measures are already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures), if 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), if the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied, or if the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). We propose to codify these paragraphs for determining the measures for CAI values at paragraph (f)(2)(ii).The categorization of a beneficiary as LIS/DE for the CAI would rely on the monthly indicators in the enrollment file. For the determination of the CAI values, the measurement period would correspond to the previous Star Ratings year's measurement period. For the identification of a contract's final adjustment category for its application of the CAI in the current year's Star Ratings Program, the measurement period would align with the Star Ratings year. If a beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period, the

[43] The February release can be found at *https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performancedata.html.*

The September release can be found at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf.*

[44] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[45] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press—*https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social.*

beneficiary would be categorized as LIS/DE. For the categorization of a beneficiary as disabled, we would employ the information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems. Disability status would be determined using the variable original reason for entitlement (OREC) for Medicare. The percentages of LIS/DE and disability per contract would rely on the Medicare enrollment data from the applicable measurement year. The counts of beneficiaries for enrollment and categorization of LIS/DE and disability would be restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. Further, a beneficiary would be assigned to the contract based on the December file of the applicable measurement period. We propose to codify these paragraphs for determining the enrollment counts at paragraph (f)(2)(i)(B).

Using the subset of the measures that meet the basic inclusion requirements, we propose to select the measure set for adjustment based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. For the selection of the Part D measures, MA–PDs and PDPs would be independently analyzed. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately, and the difference between the LIS/DE and non-LIS/DE performance rates per contract would be calculated. CMS would use a logistic mixed effects model for estimation purposes that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract and LIS/DE.

Using the analysis of the dispersion of the within-contract disparity of all contracts included in the modelling, the measures for adjustment would be identified employing the following decision criteria: (1) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more or [46] (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We propose to codify these paragraphs for the selection criteria for the adjusted measures for the CAI at paragraph (f)(2)(iii).

The Part D measures for PDPs would be analyzed separately. In order to apply consistent adjustments across MA–PDs and PDPs, the Part D measures would be selected by applying the selection criteria to MA–PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. The measure set for adjustment of Part D measures for MA–PDs and PDPs would be the same after applying the selection criteria and pooling the Part D measures for MA–PDs and PDPs. We propose to codify these paragraphs for the selection of the adjusted measure set for the CAI for MA–PDs and PDPs at (f)(2)(iii)(C). We also seek comment on the proposed methodology and criteria for the selection of the measures for adjustment. Further, we seek comment on alternative methods or rules to select the measures for adjustment for future rulemaking.

Annually, while the CAI is being developed using the rules we are proposing here, we would release on *CMS.gov* an updated analysis of the subset of the Star Ratings measures identified for adjustment using this rule as ultimately finalized. Basic descriptive statistics would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. The set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter.

We propose, at paragraph (f)(2)(iv) of each regulation, to determine the adjusted measure scores for LIS/DE and disability status from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts. The approach employed to determine the adjusted measure scores approximates case-mix adjustment using a beneficiary-level, logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters would be LIS/DE and disability status.

The sole purpose of the adjusted measure scores is for the determination of the CAI values. The adjusted measure scores would be converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

All contracts would have their adjusted summary rating(s) and for MA–PDs, an adjusted overall rating, calculated employing the standard methodology proposed at §§ 422.166 and 423.186 (which would also be outlined in the Technical Notes each year), using the subset of adjusted measure-level Star Ratings and all other unadjusted measure-level Star Ratings. In addition, all contracts would have their summary rating(s) and for MA–PDs, an overall rating, calculated using the traditional methodology and all unadjusted measure-level Star Ratings.

For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled). The initial categories would be created using all groups formed by the initial LIS/DE and disabled groups. The total number of initial categories would be the product of the number of initial groups for LIS/DE and the number of initial groups for the disabled dimension.

The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled). The mean difference within each final adjustment category by rating-type (Part C, Part D for MA–PD, Part D for PDPs, or overall) would be the CAI values for the next Star Ratings year.

The percentage of LIS/DE is a critical element in the categorization of contracts into the final adjustment category to identify a contract's CAI. Starting with the 2017 Star Ratings, we applied an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS in Puerto Rico. The adjustment results in a modified percentage of LIS/DE beneficiaries that is subsequently used to categorize contracts into the final adjustment category for the CAI.

We propose to continue this adjustment and to calculate the contract-level modified LIS/DE percentage for Puerto Rico using the following sources of information: The most recent data available at the time of the development of the model of both the 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL, and

[46] The use of the word 'or' in the decision criteria implies that if one condition or both conditions are met, the measure would be selected for adjustment.

the Medicare enrollment data from the same measurement period used for the Star Ratings year.

The data to develop the model would be limited to the 10 states, drawn from the 50 states plus the District of Columbia, with the highest proportion of people living below the FPL as identified by the 1-year ACS estimates. Further, the Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states. A linear regression model would be developed using the known LIS/DE percentage and the corresponding DE percentage from the subset of MA contracts.

The estimated slope from the linear regression approximates the expected relationship between LIS/DE for each contract in Puerto Rico and its DE percentage. The intercept term is adjusted for use with Puerto Rico contracts by assuming that the Puerto Rico model will pass through the point (x, y) where x is the observed average DE percentage in the Puerto Rico contracts based on the enrollment data, and y is the expected average percentage of LIS/DE in Puerto Rico. The expected average percentage of LIS/DE in Puerto Rico (the y value) is not observable, but is estimated by multiplying the observed average percentage of LIS/DE in the 10 highest poverty states by the ratio based on the most recent 5-year ACS estimates of the percentage living below 150 percent of the FPL in Puerto Rico compared to the corresponding percentage in the set of 10 states with the highest poverty level. (Further details of the methodology can be found in the CAI Methodology Supplement available at *http://go.cms.gov/partcanddstarratings*.)

Using the model developed from this process, the estimated modified LIS/DE percentage for contracts operating solely in Puerto Rico would be calculated. The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent. All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

We propose to continue to employ the LIS/DE indicator for contracts operating solely in Puerto Rico while the CAI is being used as an interim analytical adjustment. Further, we propose that the modeling results would continue to be detailed in the appendix of the Technical Notes and the modified LIS/DE percentages would be available for contracts to review during the plan previews.

We propose to continue the use of the CAI while the measure stewards continue their examination of the measure specifications and ASPE completes their studies mandated by the IMPACT Act and formalizes final recommendations. Contracts would be categorized based on their percentages of LIS/DE and disability using the data as outlined previously. The CAI value would be the same for all contracts within each final adjustment category. The CAI values would be determined using data from all contracts that meet reporting requirements from the prior year's Star Rating data. The CAI calculation for the PDPs would be performed separately and use the PDP specific cut points. Under our proposal, CMS would include the CAI values in the draft and final Call Letter attachment of the Advance Notice and Rate Announcement each year while the interim solution is applied. The values for the CAI value would be displayed to 6 decimal places. Rounding would take place after the application of the CAI value and if applicable, the reward factor; standard rounding rules would be employed. (All summary and overall Star Ratings are displayed to the nearest half-star.)

While we consider the recommendations from the ASPE report, findings from measure developers, and work by NQF on risk adjustment for quality measures, we are continuing to collaborate with stakeholders. We are seeking to balance accurate measurement of genuine plan performance, effective identification of disparities, and maintenance of incentives to improve the outcomes for disadvantaged populations. Keeping this in mind, we continue to seek public comment on whether and how we should account for low SES and other social risk factors in the Part C and D Star Ratings.

We look forward to continuing to work with stakeholders as we consider the issue of accounting for LIS/DE, disability and other social risk factors and reducing health disparities in CMS programs. As we have stated previously, we are continuing to consider options to how to measure and account for social risk factors in our Star Ratings program. What we discovered though our research to date is, although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, the impacts of SES on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures. However, CMS would like to better understand whether, how, and to what extent a sponsoring organization's administrative costs differ for caring for low-income beneficiaries and we welcome comment on that topic. Administrative costs may include non-medical costs such as transportation costs, coordination costs, marketing, customer service, quality assurance and costs associated with administering the benefit. We continue our commitment toward ensuring that all beneficiaries have access to and receive excellent care, and that the quality of care furnished by plans is assessed fairly in CMS programs.

u. High and Low Performing Icons

Consistent with our current practice, we are proposing regulation text to govern assignment of high and low performing icons at §§ 422.166(i) and 423.186(i). We propose to continue current policy that a contract would receive a high performing icon as a result of its performance on the Part C and D measures. The high performing icon would be assigned to an MA-only contract for achieving a 5-star Part C summary rating, a PDP contract for a 5-star Part D summary rating, and an MA–PD contract for a 5-star overall rating.

We propose that a contract would receive a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon would be calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years (for example, the 2016, 2017, and 2018 Star Ratings). If the contract had any combination of Part C and Part D summary ratings of 2.5 or lower in all 3 years of data, it would be marked with a low performing icon. A contract must have a summary rating in either Part C or Part D for all 3 years to be considered for this icon. These rules would be codified at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i).

We also propose, at paragraph (i)(2)(ii), to continue our policy of disabling the Medicare Plan Finder online enrollment function for Medicare health and prescription drug plans with the low-performing icon to ensure that beneficiaries are fully aware that they are enrolling in a plan with low quality and performance ratings; we believe this is an important beneficiary protection to ensure that the decision to enroll in a low rated and low performing plan has been thoughtfully considered. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory

messaging of the plan's poorly rated performance and directed to contact the plan directly to enroll.

v. Plan Preview of Star Ratings

We propose in §§ 422.166(i)(3) and 423.186(i)(3) that CMS have plan preview periods before each Star Ratings release, consistent with current practice. Part C and D sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the first plan preview, we expect Part C and D sponsors to closely review the methodology and their posted numeric data for each measure. The second plan preview would include any revisions made as a result of the first plan preview. In addition, our preliminary Star Ratings for each measure, domain, summary score, and overall score would be displayed. During the second plan preview, we expect Part C and D sponsors to again closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments. As part of this regulation, we are proposing that CMS continue to offer plan preview periods, but are not codifying the details of each period because over time the process has evolved to provide more data to sponsors to help validate their data. We envision it to continue to evolve in the future and do not believe that codifying specific display content is necessary.

It is important that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. For measures that are based on data reported directly from sponsors, any issues or problems should be raised well in advance of CMS' plan preview periods. A draft version of the Technical Notes would be available during the first plan preview. The draft is then updated for the second plan preview and finalized when the ratings data have been posted to Medicare Plan Finder.

We welcome comments on the proposed plan preview process.

w. Technical Changes

We also propose a number of technical changes to other existing regulations that refer to the quality ratings of MA and Part D plans; we propose to make technical changes to refer to the proposed new regulation text that provides for the calculation and assignment of Star Ratings. Specifically, we propose:

- In § 422.258(d)(7), to revise paragraph (d)(7) to read: *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to the 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.
- In § 422.260(a), to revise the paragraph to read: *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA–PDs and Part C summary rating for MA-only contracts for the contract assigned pursuant to subpart 166 of this part 422.
- In § 422.260(b), to revise the definition of ''quality bonus payment (QBP) determination methodology'' to read: *Quality bonus payment (QBP) determination methodology* means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP.
- In § 422.504(a)(18), to revise paragraph (a)(18) to read: To maintain a Part C summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 166 of this part 422. A Part C summary plan rating is calculated as provided in § 422.166.
- In § 423.505(b)(26), to revise paragraph (b)(26) to read: Maintain a Part D summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in § 423.186.

We welcome comment on these technical changes and whether there are additional changes that should be made to account for our proposal to codify the Star Ratings methodology and measures in regulation text.

12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

Section 1860D–4(b)(1)(A) of the Act and § 423.120(a)(8)(i) require a Part D plan sponsor to contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. Section 423.505(b)(18) requires Part D plan sponsors to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

In the preamble to final rule published on January 28, 2005 (January 2005 final rule) (70 FR 4194) which implemented § 423.120(a)(8)(i) and § 423.505(b)(18), we indicated that standard terms and conditions, particularly for payment terms, could vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies were offered the same terms and conditions. We also stated that we viewed these standard terms and conditions as a ''floor'' of minimum requirements that all similarly situated pharmacies must abide by, but that Part D plans could modify some standard terms and conditions to encourage participation by particular pharmacies. We believe this approach strikes an appropriate balance between the any willing pharmacy requirement at section 1860D–4(b)(1)(A) of the Act and the provisions of section 1860D–4(b)(1)(B) of the Act, which permits Part D plan sponsors to offer reduced cost sharing at preferred pharmacies.

The balancing of these goals has led to the development of preferred pharmacy networks in which certain pharmacies agree to additional or different terms from the standard terms and conditions. This has resulted in the development of ''standard'' terms and conditions that in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation. This section is intended to clarify or modify our interpretation of the existing regulations to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement.

First, we intend to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business. Second, we propose to revise the definition of retail pharmacy and define mail-order pharmacy. Third, we propose to clarify our regulatory requirements for what constitutes ''reasonable and relevant'' standard contract terms and conditions. Finally, we propose to codify our existing guidance with respect to when a pharmacy must be provided with a

Part D plan sponsor's standard terms and conditions.

a. Any Willing Pharmacy Required for All Pharmacy Business Models

With the pharmaceutical distribution and pharmacy practice landscape evolving rapidly, and because pharmacies now frequently have multiple lines of business, many pharmacies no longer fit squarely into traditional pharmacy type classifications. For example, compounding pharmacies and specialty pharmacies, including but not limited to manufacturer-limited-access pharmacies, and those that may specialize in certain drugs, disease states, or both, are increasingly common, and Part D enrollees increasingly need access to their services. As noted previously, in implementing the any willing pharmacy provision, we indicated that standard terms and conditions could vary to accommodate different types of pharmacies so long as all similarly situated pharmacies were offered the same terms and conditions. In the original rule to implement Part D (70 FR 4194, January 28, 2005), we defined certain types of pharmacies (that is, retail, mail order, Long Term Care (LTC)/institutional, and I/T/U [Indian Health Service, Indian tribe or tribal organization, or urban Indian organization]) at § 423.100 to operationalize various statutory provisions that specifically mention these types of pharmacies (for example, section 1860D–4(b)(1)(C)(iv) of the Act). However, these definitions were never intended to limit the scope of the any willing pharmacy requirement. Nevertheless, we have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions.

Section 1860D–4(b)(1)(A) of the Act requires Part D plan sponsors to permit the participation of ''any pharmacy'' that meets the standard terms and conditions. Accordingly, it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type. Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider ''similarly situated'' pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.

Thus, Part D plan sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that they, for example, maintain a traditional retail business while also specializing in certain drugs or diseases or providing home delivery service by mail to surrounding areas. Or as another example, a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa. Later in this section we are proposing to codify our requirements for when a Part D sponsor must provide a pharmacy with a copy of its standard terms and conditions. These requirements, if finalized, would apply to all pharmacies, regardless of whether they fit into traditional pharmacy classifications or have unique or innovative business or care delivery models.

b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy

Since the inception of the Part D program, Part D statute, regulations, and sub-regulatory guidance have referred to ''mail-order'' pharmacy and services without defining the term ''mail order''. Unclear references to the term ''mail order'' have generated confusion in the marketplace over what constitutes ''mail-order'' pharmacy or services. This confusion has contributed to complaints from pharmacies and beneficiaries regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations. Additionally, pharmacies that are not mail-order pharmacies, but that may offer home delivery services by mail (relative to that pharmacy's overall operation), have complained because Part D plan sponsors classified them as mail-order pharmacies for network participation and required them to be licensed in all United States, territories, and the District of Columbia, as would be required for traditional mail-order pharmacies providing a mail-order benefit.

In creating the Part D program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added the convenient access provision of section 1860D–4(b)(1)(C) of the Act and the level playing field provision of section 1860D–4(b)(1)(D) of the Act. The convenient access provisions, as codified at § 423.120(a)(1)–(7), require Part D plan sponsors to secure the participation in their networks a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary) and includes special provisions for standards with respect to Long Term Care (LTC) and I/T/U pharmacies (as defined at § 423.100). The level playing field provision, as codified at § 423.120(a)(10), requires Part D plan sponsors to permit enrollees to receive the same benefits, including extended days' supplies, through a pharmacy (other than a mail-order pharmacy) (that is, a retail pharmacy), although the Part D plan sponsor may require the enrollee to pay a higher level of cost-sharing to do so.

We currently define ''retail pharmacy'' at § 423.100 to mean ''any licensed pharmacy that is *not a mail-order pharmacy* from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' Although we did not define ''non-retail pharmacy,'' § 423.120(a)(3) provides that ''a Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, ''including pharmacies offering home delivery *via mail-order* and institutional pharmacies,'' provided the convenient access requirements are met (emphasis added). In the preamble to our January 2005 final rule, we also stated, ''examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC) and hospital and other provider-based pharmacies, as well as Part D [plan]-owned and operated pharmacies that serve only plan members'' (see 70 FR 4249). We also stated ''home infusion pharmacies will not count toward Part D plans' pharmacy access requirements (at § 423.120(a)(1)) because they are not retail pharmacies'' (see 70 FR 4250).

Since 2005, our regulation at § 423.120(a) has included access requirements for retail, home infusion, LTC, and I/T/U pharmacies. While mail-order pharmacies could be considered

one of several subsets of non-retail pharmacies, we never defined the term mail-order pharmacy in regulation, nor have we specified access or service-level requirements at § 423.120(a) for mail-order pharmacies.

As discussed previously, our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255).

Nonetheless, despite this guidance and specific access requirements for LTC and HI pharmacies at § 423.120(a), some Part D plan sponsors interpreted ''including pharmacies offering home delivery via mail-order and institutional pharmacies'' at § 423.120(a)(3) to mean that any pharmacies, even retail pharmacies, that may offer home delivery services by mail are mail-order pharmacies. Although § 423.120(a)(3) specifically allows for access to non-retail pharmacies, and we intended ''including pharmacies offering home delivery via mail-order and institutional pharmacies'' to mean home infusion pharmacies, mail-order pharmacies, long-term care pharmacies, or other non-retail pharmacies that offer home delivery services by mail, some Part D plan sponsors began to require any interested pharmacies, even retail pharmacies, that may offer home delivery services by mail to contract as mail-order pharmacies in order to participate in the plan's contracted pharmacy network. Because Part D plan sponsors frequently require contracted mail-order pharmacies to be licensed in all United States, territories, and the District of Columbia, the classification of any pharmacies that may offer home delivery services by mail as mail-order pharmacies for purposes of contracting with Part D plan sponsors as a network pharmacy, including licensure requirements, led to complaints from beneficiaries and pharmacies, including retail, specialty, and other pharmacies.

Although the language at § 423.120(a)(3) is specific to non-retail pharmacies, there is a great deal of confusion regarding mail-order pharmacy in the Part D marketplace. We believe it is inappropriate to classify pharmacies as ''mail-order pharmacies'' solely on the basis that they offer home delivery by mail. Because the statute at section 1860D–4(b)(1)(D) of the Act discusses cost sharing in terms of mail order versus other non-retail pharmacies, mail-order cost sharing is unique to mail-order pharmacies, as we have proposed to define the term. For example, while a non-retail home infusion pharmacy may provide services by mail, cost-sharing is commensurate with retail cost-sharing. Therefore, to clarify what a mail-order pharmacy is, we propose to define mail-order pharmacy at § 423.100 as a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.

Although we propose to add the definition of mail-order pharmacy, we also believe that our existing definition of retail pharmacy has contributed, in part, to the confusion in the Part D marketplace. As discussed previously, the existing definition of ''retail pharmacy'' at § 423.100 means ''any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.'' This definition, given the rapidly evolving pharmacy practice landscape, may be a source of some confusion given that it expressly excludes mail-order pharmacies, but not other non-retail pharmacies such as home infusion or specialty pharmacies.

We note that Medicaid recently adopted a definition of ''retail community pharmacy.'' Pursuant to section 1927(k)(10) of the Act, as amended by section 2503 of the Affordable Care Act (ACA), for purposes of Medicaid prescription drug coverage, CMS defines ''retail community pharmacy'' at § 447.504(a) as ''an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the walk-in general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.'' Although this definition adds greater clarity about the locations or practice settings where retail pharmacies may be found, we were concerned that, for the purposes of the Part D program, the mention of additional types of pharmacies in our regulation could contribute to more confusion instead of less.

However, two aspects of this definition are similar to Part D statutory language in section 1860D–4(b)(1)(C) and (D) of the Act. The first is the concept that a retail pharmacy is open to dispense prescription medications to the walk-in general public, which echoes the requirement at section 1860D–4(b)(1)(C) of the Act that Part D plan sponsors secure the participation in their networks a sufficient number of pharmacies that dispense (other than mail order) drugs directly to patients. The second is the concept that prescriptions are dispensed at retail prices, or for the Part D program, retail cost-sharing, which echoes the requirement at section 1860D–4(b)(1)(D) of the Act that Part D plan sponsors permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. Because these concepts are consistent with the Part D statute, we believe their inclusion in our definition of retail pharmacy at § 423.100 would be appropriate.

Therefore, to clarify what a retail pharmacy is, we propose to revise the definition of retail pharmacy at § 423.100. First, we note that the existing definition of ''retail pharmacy'' is not in alphabetical order, and we propose a technical change to move it such that it would appear in alphabetical order. Second, we propose to incorporate the concepts of being open to the walk-in general public and retail cost-sharing such that the definition of retail pharmacy would mean ''any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.''

Although we were originally unsure whether Part D enrollees would need routine access to specialty drugs and specialty pharmacies beyond our out-of-network requirements (see 70 FR 4250), as the Part D program has evolved, the use of specialty drugs in the Part D program has grown exponentially and will likely continue to do so. The June 2016 MedPAC report (available at *http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf*) notes growth in the use of specialty drugs in the Part D program is currently outpacing other drugs and health spending, generally. Such drugs are often high-cost and complex, for

diseases including, but not limited to, cancer, Hepatitis C, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis. The report also highlights that each year since 2009, more than half of the United States Food and Drug Administration (FDA) approvals have been for specialty drugs. Because many specialty drugs can be self-administered on an outpatient basis, even in the patient's home, and for chronic or long-term use, increasing numbers of Part D enrollees need routine access to specialty drugs and specialty pharmacies. Nonetheless, because the pharmacy landscape is changing so rapidly, we believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace, and we decline to propose a definition of specialty pharmacy at this time.

Similar to specialty pharmacy, we also decline to further define non-retail pharmacy. The pharmacy types that we define and propose to modify and define in regulation describe functional lines of business that an individual pharmacy may have, solely, or in combination. However, unlike mail order, home infusion, I/T/U, FQHC, LTC, hospital, other institutional, other provider-based, and ''members-only'' Part D plan-owned and operated pharmacy types or lines of business that comprise ''non-retail'', the term ''non-retail'' does not, itself, define a unique pharmacy functional line of business, and does not lend itself to a clear definition. Consistent with statutory any willing pharmacy and preferred pharmacy provisions, mail-order pharmacies may be preferred or non-preferred. Part D plan sponsors may establish unique non-preferred mail-order cost-sharing, or may establish such non-preferred mail-order cost sharing commensurate with those for retail pharmacies.

We solicit comment on our proposed definition of mail-order pharmacy and our proposed modification to the definition of retail pharmacy. Specifically, we solicit comment regarding whether stakeholders believe these definitions strike the right balance to resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models.

c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions

As noted previously, since the beginning of the Part D program, we have considered standard terms and conditions for network participation to set a ''floor'' of minimum requirements by which all similarly situated pharmacies must abide. We further believe it is reasonable for a Part D plan sponsor to require additional terms and conditions beyond those required in the standard contract for network participation for pharmacies to have preferred status. Therefore, we implemented the requirements of section 1860D–4(b)(1)(A) of the Act by requiring that standard terms and conditions be ''reasonable and relevant,'' but declined to further define ''reasonable and relevant'' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.

We note that a pharmacy's ability to participate in a preferred or specially labeled subset of the Part D plan sponsor's larger contracted pharmacy network or to offer preferred cost sharing assumes that, at a minimum, the pharmacy is able to participate in the network. Where there are barriers to a pharmacy's ability to participate in the network at all, it raises the question of whether the standard (that is, entry-level) terms and conditions are reasonable and relevant.

It has been our longstanding policy that Part D plans cannot restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner that contravenes the convenient access protections of section 1860D–4(b)(1)(C) of the Act and § 423.120(a) of our regulations. (See Q&A at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf*). In 2006, we informed sponsors they cannot restrict access to drugs on the ''specialty/high cost'' tier to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (that is, a contracted network pharmacy that does not belong to the restricted subset). Since 2006, it has been our general policy that these types of special requirements for Part D plan sponsors to limit dispensing of specialty drugs be directly linked to patient safety or regulatory reasons.

As the specialty drug distribution market has grown, so has the number of organizations competing to distribute or dispense specialty drugs, such as pharmacy benefit managers (PBMs), health plans, wholesalers, health systems, physician practices, retail pharmacy chains, and small, independent pharmacies (see the URAC White Paper, ''Competing in the Specialty Pharmacy Market: Achieving Success in Value-Based Healthcare,'' available at *http://info.urac.org/specialtypharmacyreport*). CMS is concerned that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. In fact, we have received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple accrediting organizations, or additional Part D plan-/PBM-specific credentialing criteria, for network participation. We agree that there is a role in the Part D program for pharmacy accreditation, to the extent pharmacy accreditation requirements in network agreements promote quality assurance. In particular, we support Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy as a specialty or preferred pharmacy in the Part D plan sponsor's contracted pharmacy network. However, we do not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (as discussed previously). Moreover, we are especially concerned about anecdotal reports that allege such standard terms and conditions for network participation are waived, for example, when a Part D plan sponsor needs a particular pharmacy in its network in order to meet convenient access requirements, or even for certain pharmacies that received preferred pharmacy status.

If the premise of accreditation or Part D plan sponsor- or PBM-specific credentialing requirements is to ensure more stringent quality standards, then there is no reasonable explanation for why a quality-related standard term or condition could be waived for situations when the Part D plan sponsor needs a particular pharmacy in its contracted

pharmacy network in order to meet the convenient access standards or to designate a particular pharmacy with preferred pharmacy status. A term or condition which can be dropped in such situations is by definition not ''standard'' according to the plain meaning of the word. Waivers or inconsistent application of such standard terms and conditions is an explicit acknowledgement that such terms and conditions are not necessary for the ability of a pharmacy to perform its core functions, and are thus neither reasonable nor relevant for any willing pharmacy standard terms and conditions.

It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and § 423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.

Additionally, because a pharmacy's ability to dispense certain medications is not dependent on it having the ability to dispense other medications, it is not relevant for sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor. Consequently, consistent with our longstanding policy, discussed previously, we would not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so. We solicit comment on this topic.

d. Timing of Contracting Requirements

CMS has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor's contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. In other instances, pharmacies have told us that Part D plan sponsors delay sending them the requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor's network before the sponsor will provide a document containing the standard terms and conditions. CMS believes such actions have the effect of frustrating the intent of the any willing pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions.

To this end, we propose to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. The first deadline we propose to establish is the date by which Part D plan sponsors must have standard terms and conditions available for pharmacies that request them. By mid-September of each year, Part D plan sponsors have signed a contract with CMS committing them to delivering the Part D benefit through an accessible pharmacy network during the upcoming year and have provided information about that network to CMS for posting on the Medicare Plan Finder Web site. At that point, Part D plan sponsors should have had ample opportunity to develop standard contract terms and conditions for the upcoming plan year. Therefore, we propose to require at § 423.505(b)(18)(i) that Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year.

The second deadline we propose concerns the promptness of Part D plan sponsors' responses to pharmacy requests for standard terms and conditions. As discussed previously, we propose to require all Part D plan sponsors to have standard terms and conditions developed and ready for distribution by September 15. Therefore, we propose to require at § 423.505(b)(18)(ii) that, after that date and throughout the following plan year, Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request. Part D plan sponsors would be required to clearly identify for interested pharmacies the avenue (for example, phone number, email address, Web site) through which they can make this request. In instances where the Part D plan sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the Part D plan sponsor would be required to provide the confidentiality agreement within two business days after receipt of the pharmacy's request and then provide the standard terms and conditions within 2 business days after receipt of the signed confidentiality agreement. While Part D plan sponsors may ask pharmacies to demonstrate that they are qualified to meet the Part D plan sponsors' standard terms and conditions before executing the contract, Part D plan sponsors would be required to provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. If finalized, this proposed requirement would permit pharmacies to do their due diligence with respect to whether a Part D plan sponsor's standard terms and conditions are acceptable at the same time Part D plan sponsors are conducting their own review of the qualifications of the requesting pharmacy. We specifically seek comment on whether these timeframes are the right length to address our goal but are operationally realistic. We also request examples of situations where a longer timeframe might be needed.

13. Changes to the Days' Supply Required by the Part D Transition Process

We promulgated regulations under the authority of section 1860D–11(d)(2)(B) of the Act to require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on the prescription drug plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). These regulations are codified at § 423.120(b)(3). Specifically, these regulations require that a Part D sponsor ensure certain enrollees access to a temporary supply of drugs within the first 90 days under a new plan (including drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during this time period. In the outpatient setting, the supply must be for at least 30 days of medication, unless the prescription is written for less. In the LTC setting, this supply must be for up to at least 91 days and may be up to 98 days, consistent with the dispensing increment, unless a less amount is prescribed.

We propose to make two changes to these regulations. First, we propose to shorten the required transition days'

supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Second, we propose a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.

We provided our rationale for the transition fill days' supply requirement in the LTC setting in CMS final rule CMS–4085–F published on April 15, 2010 (75 FR 19678). In that final rule, we stated that for a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. We further stated that, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, we will require sponsors to honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. Thus, we required a Part D sponsor to provide a LTC resident enrolled in its Part D plan with at least a 31 day supply of a prescription with refills provided, if needed, up to a 93 days' supply (unless the prescription is written for less) (75 FR 19721). In a subsequent final rule published on April 15, 2011, we changed the 93 days' supply to 91 to 98 days' supply, as noted previously, to acknowledge variations in days' supplies that could result from the short-cycle dispensing of brand drugs in the LTC setting (76 FR 21460 and 21526).

We received and responded to a comment in the April 2010 final rule about transition and a longer timeframe in the LTC setting. We stated that a number of commenters supported our proposal of requiring an extended transition supply for enrollees residing in LTC facilities but that commenters requested that we provide the same protections to individuals requiring LTC in community-based settings. In our response to the comment, we indicated that residents of LTC institutions were more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary drugs. We further stated that we believed that community-based enrollees, in contrast, were less limited in their access to prescribing physicians and did not require an extended transition period to work with their physicians to successfully transition to a formulary drug. (75 FR 19721). Thus, the requirement to provide longer transition fill days' supply in the LTC setting was a result of our concerns that a longer timeframe would be needed in the LTC setting.

After more than 10 years of experience with Part D in LTC facilities, we have not seen the concerns that we expressed in the 2010 final rule materialize. We are not aware of any evidence that transition for a Part D beneficiary in the LTC setting necessarily takes any longer than it does for a beneficiary in the outpatient setting. We understand that it is common for Part D beneficiaries in the LTC setting to be cared for by on-staff or consultant physicians and other health professionals with prescriptive authority who are under contract with the LTC facility. Additionally, we also understand that Part D beneficiaries in the LTC setting are typically served by an on-site pharmacy or one under contract to service the LTC facility. Given this structure of the LTC setting, we understand that the LTC prescribers and pharmacies are readily available to address transition for Part D beneficiaries in the LTC setting. In addition, LTC facilities now have many years' experience with the Medicare Part D program generally and transition specifically.

While our concerns about the needed timeframe for transition in the LTC setting do not seem to have materialized, we have continuing concerns about drug waste and the costs associated with such waste in the LTC setting. Some of these concerns have been addressed by our rule requiring the short-cycle dispensing of brand drugs to Part D beneficiaries in LTC facilities in the April 2011 final rule. That rule, codified at 42 CFR 423.154, requires that all Part D sponsors require all network pharmacies servicing LTC facilities to dispense certain solid oral doses of covered Part D brand-name drugs to enrollees in such facilities in no greater than 14-day increments at a time to reduce drug waste. However, we now believe that CMS could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting. Therefore, we are proposing that the transition days' supply in the LTC setting be the same as it is in the outpatient setting.

Our second proposed change involves the current required 30 days' transition supply in the outpatient setting, which is codified at § 423.120(b)(3)(iii)(A). We have received a number of inquiries from Part D sponsors regarding scenarios involving medications that do not easily add up to a 30 days' supply when dispensed (for example, drugs that typically are dispensed in 28-day packages). Historically, our response to those inquiries has been that the regulation requires plans to provide at least 30 days of medication, which requires plans to dispense more than one package to comply with the text of the regulation. However, the intent of the regulation was for the transition fill in the outpatient setting to be for at least a month's supply. For this reason, we are proposing a change to the regulation from ''30 days'' to ''a month's supply.'' If finalized, this change would mean that the regulation would require that a transition fill in the outpatient setting be for a supply of at least a month of medication, unless the prescription is written by the prescriber for less. Therefore, the supply would have to be for at least the days' supply that the applicable Part D prescription drug plans has approved as its retail month's supply in its Plan Benefit Package submitted to CMS for the relevant plan year, again, unless the prescription is written by the prescriber for less.

Together, our two proposals—if finalized—would mean that § 423.120 (b)(3)(iii)(A) would be consolidated into § 423.120 (b)(3)(iii) to read that the transition process must ''[e]nsure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication.'' Section 423.120(b)(3)(iii)(B) would be eliminated.

Please note that we also are proposing in II.A.15. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes to revise § 423.120(b)(3)(i)(B) to state that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as specified under paragraph § 423.120(b)(3)(iv) or § 423.120(b)(6) of this section.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

Section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide ''appropriate notice'' to the Secretary, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) implements that requirement by defining appropriate notice as that given at least 60 days prior to such change taking effect during a given contract year. We have recognized that both current and prospective enrollees of a prescription drug plan need to have the most current formulary information by the time of the annual election period described in § 423.38(b) in order to enroll in the Part D plan that best suits their particular needs. To this end, § 423.120(b)(6) prohibits Part D sponsors and MA organizations from removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual election period described in § 423.38(b)(2) and 60 days subsequent to the beginning of the contract year associated with that annual election period. Our concern has been to prevent situations in which Part D sponsors change their formularies early in the contract year without providing appropriate notice as described in § 423.120(b)(5) to new enrollees. Thus, § 423.120(b)(6) has required that all materials distributed during the annual election period reflect the formulary the Part D sponsor will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals. Lastly, under § 423.128(d)(2)(iii), Part D sponsors must also provide current and prospective Part D enrollees with at least 60 days' notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. The general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141).

MedPAC observed that the continuity of a plan's formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled. While we agree with MedPAC's assertion, we acknowledge the need to balance formulary continuity with requests from Part D sponsors to provide greater flexibility to make midyear changes to formularies. Indeed, MedPAC made its observation in a report that suggested that CMS's rules regarding formulary changes warranted examination. There MedPAC pointed out, among other things, that CMS could provide Part D sponsors with greater flexibility to make changes such as adding a generic drug and removing its brand name version without first receiving agency approval. (MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, page 192.)

This proposed rule would implement MedPAC's recommendation by permitting generic substitutions without advance approval as specified later in this section. We have also taken this opportunity to examine our regulations to determine how to otherwise facilitate the use of certain generics. Currently, Part D sponsors can add drugs to their formularies at any time; however, there is no guarantee that enrollees will switch from their brand name drugs to newly added generics. Therefore, Part D sponsors seeking to better manage the Part D benefit may choose to remove a brand name drug, or change its preferred or tiered cost-sharing, and substitute or add its therapeutic equivalent. But even this takes some time: Under current regulations, Part D sponsors must submit formulary change requests to CMS and provide specified notice before removing drugs or changing their cost-sharing (except for unsafe drugs or those withdrawn from the market). As noted earlier, the general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Also, as detailed previously, § 423.120(b)(5)(i) requires 60 days' notice to specified entities prior to the effective date of changes and 60 days' direct notice to affected enrollees or a 60 day refill. The ability of Part D sponsors to make generic substitutions as approved by CMS is further limited by the fact that as detailed previously, under § 423.120(b)(6), Part D sponsors generally cannot remove drugs or make cost-sharing changes from the start of the annual election period (AEP) until 2 months after the plan year begins.

We propose to provide Part D sponsors with more flexibility to implement generic substitutions as follows: The proposed provisions would permit Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics—rather than having to wait until the direct notice and formulary change request requirements have been met. The proposed provisions would also allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. Related proposals would require advance general and retrospective direct notice to enrollees and notice to entities; clarify online notice requirements; except specified generic substitutions from our transition policy; and conform our definition of ''affected enrollees.'' Lastly, to address stakeholder requests for greater flexibility to make midyear formulary changes in general, we are also proposing to decrease the days of enrollee notice and refill required when (aside from generic substitution and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing will affect enrollees.

Specifically, we propose to add a new paragraph (b)(5)(iv) to § 423.120 to permit Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The Part D sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the Part D sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice. As proposed, we would permit Part D sponsors to substitute a generic drug for a brand name drug immediately rather than make that change effective, for instance, at the start of the next month. However, we solicit comment as to whether there would be a reason to require such a delay, especially given the fact that we are proposing not to require advance direct notice (rather, only advance general notice) or CMS approval. The proposed regulation would also require that, when generic drug substitutions occur, Part D sponsors must provide direct notice to affected enrollees and other specified notice to CMS and other entities. We also propose to specify in a revision to

§ 423.120(b)(3)(i)(B) that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug under paragraph (b)(6) of this section.

A proposed exception to § 423.120(b)(6) would permit Part D sponsors to make the above specified changes (removing covered Part D drugs from their formularies, or changing their cost-sharing, when substituting or adding their generic equivalents) during any time of the year. That section generally provides—with a current exception only for unsafe drugs and drugs removed from the market—that Part D sponsors generally cannot remove drugs or make cost-sharing changes between the beginning of the AEP and 60 days after the plan year begins. We believe that revising this provision would assist Part D sponsors by permitting substitutions to take place effect during a longer time period than is currently permitted. Given that the previous exception would permit generic substitutions prior to the start of the calendar year, we also propose to conform the definition of ''affected enrollees'' to clarify that applicable changes must affect their access to drugs during the current plan year.

We are aware that some may be concerned about not requiring advance CMS approval or advance direct notice to enrollees prior to making the permitted generic substitutions, or requiring a transition fill. But we would only permit immediate substitution when the generics are deemed therapeutically equivalent to the brand name drug being removed by the Federal Drug and Food Administration (FDA) and meet other requirements specified later in this section. This would not apply to follow-on biological products under current FDA guidance. The FDA has, in fact noted that, ''A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.'' (''Generic Drug Facts,'' see FDA Web site, *https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm*, accessed September 19, 2017, hereafter FDA, ''Abbreviated New Drug Application (ANDA): Generics''.) Additionally, immediate generic substitution has long been an established bedrock of commercial insurance, and we are not aware of any harm to the insured resulting from such policies.

Also, we do not believe a transition policy would be appropriate for these situations: The purpose of the transition process is to make sure that the medical needs of enrollees are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. If the proposal to permit Part D sponsors to immediately substitute generics for brand name drugs upon market release were finalized, most enrollees in this situation would not have had an opportunity to try the drug prior to the drug substitution to see how it worked for them. In other words, an enrollee could not be certain that a generic substitution would not work, would constitute an abrupt change in treatment, or that the enrollee would be better served by taking no medication rather than the generic unless he or she had previously tried the generic drug.

Moreover, we have built beneficiary protections into the proposed provisions. First, proposed § 423.120(b)(5)(iv)(A) addresses safety concerns by permitting Part D sponsors to add only therapeutically equivalent generic drugs. This means the FDA must have approved the generic drug in an abbreviated new drug application pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and it must be listed with the innovator drug in the publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book) in which the FDA identifies drug products approved on the basis of safety and effectiveness by the FDA, and be considered by the FDA to be therapeutically equivalent to the brand name drug.

Second, we share the concern that prospective enrollees could be misled by Part D sponsors that deliberately offer brand name drugs during open enrollment periods only to remove them or change their cost-sharing as quickly as possible during the plan year. We believe that our proposed provision would address such problems: Under proposed § 423.120(b)(5)(iv)(B), a Part D sponsor cannot substitute a generic for a brand name drug unless it could not have previously requested formulary approval for use of that drug. As a matter of operations, CMS permits Part D sponsors to submit formularies, and their respective change requests, only during certain windows. Under proposed § 423.120(b)(5)(iv)(B), a Part D sponsor could not remove a brand name drug or change its preferred or tiered cost-sharing if that Part D sponsor could have included its generic equivalent with its initial formulary submission or during a later update window.

However, to be certain, that we have not missed practical or other complications that would hinder the ability of Part D sponsors to timely seek approval within the CMS timeframes, we solicit comment as to whether we should consider immediate substitution, potentially in limited circumstances, of specified generics for which Part D sponsors could have previously requested formulary approval. At the same time, we remain mindful of beneficiary protections and are hesitant to simply permit substitution of any generics regardless of how long they have been on the market. Accordingly, we welcome suggestions of any other practical cut-offs, as well as information on possible effects on beneficiaries that could result if we were to permit Part D sponsors to substitute specified generics that have been on the market for longer time periods.

Third, we believe the two-pronged approach of the proposed provision would provide appropriate notice for this type of formulary change. The general notice requirement of proposed § 423.120(b)(iv)(C) would require that, before making any generic substitutions, a Part D sponsor provide all prospective and current enrollees with notice in the formulary and other applicable beneficiary communication materials stating that the Part D sponsor can remove, or change the preferred or tiered cost-sharing of, any brand name drug immediately without additional advance notice (beyond the general advance notice) when a new equivalent generic is added. This would, for instance, include the Evidence of Coverage (EOC). Proposed § 423.120(b)(iv)(C) would also require that this general notice advise prospective and current enrollees that they will get direct notice about any specific drug substitutions made that would affect them and that the direct notice would advise them of the steps they could take to request coverage determinations and exceptions. Therefore, the general notice would advise enrollees about what might take place before any changes occur.

When the Part D sponsor substitutes a generic for a brand name drug, the proposed direct notice provision, § 423.120(b)(5)(iv)(E), would require the Part D sponsor to provide affected enrollees with direct notice consistent with § 423.120(b)(5)(ii). We currently require Part D sponsors to provide this information 60 days before such changes are made. Under the proposed changes, enrollees would receive the same information they receive under the current regulation—the only difference being that the notice could be provided

after the effective date of the generic substitution. As discussed earlier, under the proposed provision Part D sponsors seeking to make immediate substitutions would be newly required to have previously provided general notice in beneficiary communication materials such as formularies and EOCs that certain generic substitutions could take place without additional advance notice.

We understand there may be concerns that the direct notice identifying the specific drug substitution would arrive after the formulary change has already taken place. As explained previously, we believe generic substitutions pose no threat to enrollee safety. Also, as noted earlier, we are proposing to revise § 423.120(b)(6) to permit generic substitutions to take place throughout the entire year. This means that, under the proposed provision, a Part D sponsor meeting all the requirements would be able to substitute a generic drug for a brand name drug well before the actual start of the plan year (for instance, if a generic drug became available on the market days after the summer update). There is nothing in our regulation that would prohibit advance notice and, in fact, we would encourage Part D sponsors to provide direct notice as early as possible to any beneficiaries who have reenrolled in the same plan and are currently taking a brand name drug that will be replaced with a generic drug with the start of the next plan year. We would also anticipate that Part D sponsors will be promptly updating the formularies posted online and provided to potential beneficiaries to reflect any permitted generic substitutions—and at a minimum meeting any current timing requirements provided in applicable guidance. At this time we are not proposing to set a regulatory deadline by which Part D sponsors must update their formularies before the start of the new plan year. However, if we were to finalize this provision and thereafter find that Part D sponsors were not timely updating their formularies, we would reexamine this policy. And we would note, as regards timing, that § 423.128(d)(2)(iii) requires that the current formulary posted online be updated at least monthly.

In cases in which the Part D sponsor would necessarily have to send notice after the fact, for example instances in which a drug is not released to the market until after the beginning of the plan year and the Part D sponsor then immediately makes a generic substitution, the proposed general notice would have already advised enrollees that they would receive information about any specific drug generic substitutions that affected them and that they would still be able to request coverage determinations and exceptions. While the timing would most likely mean most enrollees would only be able to make such requests after receiving a generic drug fill, in the vast majority of cases, an enrollee could not be certain that a generic substitution would not work unless he or she actually tried the generic drug. Additionally, we are strongly encouraging Part D sponsors to provide the retrospective direct notices of these generic substitutions (including direct notice to affected enrollees and notice to entities including CMS) no later than by the end of the month after which the change becomes effective. While sponsors are required to report this information to both enrollees and entities including CMS, we currently are not proposing to codify the end of month timing requirement; however, if we were to finalize this provision and thereafter find that Part D sponsors were not timely providing retrospective notice, we would reexamine this policy.

Fourth, enrollees would be protected from higher cost-sharing under proposed paragraph (b)(5)(iv)(A), which would require Part D sponsors to offer the generic with the same or lower cost-sharing and the same or less restrictive utilization management criteria as the brand name drug.

We also believe requirements and guidance regarding beneficiary communications will continue to provide beneficiary protections. Section 423.128(e)(5) currently requires Part D sponsors to furnish directly to enrollees an explanation of benefits (EOB) that includes any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5). As noted previously, § 423.128(d)(2)(iii) currently requires Part D sponsors to post at least 60 days' notice of removals and cost-sharing changes online for current and prospective Part D enrollees. In light of our proposal for generic substitutions described previously, we propose to modify § 423.128(d)(2)(iii) to require Part D sponsors to provide ''timely'' notice under 423.120(b)(5). This would mean that, under the proposed provision, a Part D sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes except when adding a therapeutically equivalent generic as specified, and as has currently been the requirement, removing unsafe or withdrawn drugs. Part D sponsors could provide online notice after the effective date of changes only in those limited instances.

As regards content, § 423.128(d)(2)(iii) requires—and would continue to do so under the proposed revisions—that Part D sponsors post online notice regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. Posting information online related to removing a specific drug or changing its cost-sharing solely to meet the content requirements of § 423.128(d)(2)(iii) cannot replace general notice under proposed § 423.120(b)(5)(iv)(C); direct notice to affected enrollees under § 423.120(b)(5)(ii); or notice to CMS when required under § 423.120(b)(5). For instance, as noted in the January, 28, 2005 final rule (70 FR 4265), we view online notification under § 423.128(d)(2)(iii) on its own as an inadequate means of providing specific information to the enrollees who most need it, and we consider it an additional way that Part D sponsors provide notice of formulary changes to affected enrollees.

However, we do not mean to restrict or otherwise affect other rules governing the provisions of materials online. For instance, if Part D sponsors were able to fulfill CMS marketing and beneficiary communications requirements by posting a specific document online rather than providing it in paper, the fact the document was posted online would not preclude it from providing general notice required under our proposed provisions. In other words, if otherwise valid, provision of general notice in a document posted online could suffice as notice as regards that specified document under proposed § 423.120(b)(5)(iv)(C). In contrast, we do not wish to suggest that posting one type of notice online would necessarily suffice to meet distinct notice requirements. For instance, providing the general advance notice that would be required under § 423.120(b)(5)(iv)(C) in a document posted online could not meet the online content requirements of § 423.128(d)(2)(iii) related to providing information about removing drugs or changing their cost-sharing. Nor, as noted previously, could the opposite apply: Posting the content required under § 423.128(d)(2)(iii) online could not fulfill the advance general notice requirements that would be required under proposed § 423.120(b)(5)(iv)(C) (or suffice to provide direct notice to affected enrollees under § 423.120(b)(5)(ii) or notice to CMS under § 423.120(b)(5)).

In addition to requiring the direct notice to affected enrollees discussed previously, proposed § 423.120(b)(iv)(D) would also require Part D sponsors to provide the following entities with

notice of the generic substitutions consistent with § 423.120(b)(5)(ii): CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. (To avoid repetition, we propose to revise the provision to refer to all of these entities as ''CMS and other specified entities'' for the purposes of § 423.120(b).) Even though, as proposed, a Part D sponsor that met all of the requirements would be able to make the generic substitution immediately without submitting any formulary change requests to CMS, the Part D sponsor must include the generic substitution in the next available formulary submission to CMS. We note that Part D plans can determine the most effective means to communicate formulary change information to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists and that, under our proposed provision, we would consider online posting sufficient for those purposes.

Lastly as part of our reexamination of the need to generally provide Part D sponsors greater flexibility in formulary changes, we plan to decrease the amount of direct notice required in cases where the removal of a drug or change in cost-sharing status will affect enrollees currently taking the drug. (This would contrast proposed notice requirements that would apply to immediate substitution of specified generics. There we would also require advance general notice that such changes can occur, and direct notice of the specific changes could be provided after their effective date.) Section 423.120(b)(5)(i) currently requires at least 60 days' notice to all entities prior to the effective date of changes and at least 60 days' direct notice to affected enrollees or a 60 day refill upon the request of an affected enrollee. We propose to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Beneficiaries would be affected, and therefore receive the 30 days' notice or a month refill, in cases in which, for instance, Part D sponsors planned to add prior authorization requirements as a result of new safety-related information or clinical guidelines. This proposal would permit Part D sponsors to institute formulary changes in half the time.

We are, again, aware that some may be concerned that we are reducing the number of days advance notice afforded to enrollees in these instances. But again, we believe current CMS requirements provide the necessary beneficiary protections, and that 30 (rather than 60) days' notice still will afford enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. Existing CMS regulations establish robust beneficiary protections in the coverage and appeals process, including expedited adjudication timeframes for exigent circumstances (maximum timeframe of 24 hours for coverage determinations and 72 hours for level 1 and 2 appeals), and a requirement that Part D plan sponsors automatically forward all untimely coverage determinations and redeterminations to the IRE for independent review. Further, while 60 days' notice is currently required, we have no evidence to suggest that beneficiaries are currently utilizing the full 60 days. The reduction to 30 days would align these requirements with the timeframes for transition fills. And, with over 11 years of program experience, we have no evidence to suggest that 30 days has been an insufficient temporary days supply for transition fills.

(Note we are also proposing to amend the refill amount to months (namely a month) rather than days (it was 60 days previously) to conform to a proposed revision to the transition policy regulations at § 423.120(b)(3).) For further discussion, see section III.A.15 of this proposed rule, Changes to the Transition.)

Summary: The following provides a high level summary of notice changes proposed in § 423.120(b). Details on these requirements appear in the preamble and proposed provisions. This summary does not address other proposed changes (for instance, changes to transition requirements); notice provisions we do not propose to change (for instance, notice for safety edits); or other rules that may also apply (for instance, marketing and beneficiary communications rules regarding formulary updates).

• Notice required for expedited substitutions of certain generics: Part D sponsors that would otherwise be permitted to make certain generic substitutions as specified under proposed § 423.120(b)(5)(iv) would be required to provide the following types of notice:

++ Advance general notice in the formulary and EOC and other applicable beneficiary communications stating that such changes may occur without notice.

++ Notice that identifies the specific drug substitution made—which may be provided after the effective date of the change—as follows:

—Direct notice to affected enrollees.
—Notice posted online for current and prospective enrollees.
—Notice to CMS.
—Notice to other entities.

• Notice and refill required for certain other midyear formulary changes: Part D sponsors that would be otherwise permitted to remove or change the preferred or tiered cost-sharing status of drugs would be required to provide the below types of notice and refills under proposed § 423.120(b)(5)(i) and (ii). However, these notice requirements do not apply when removing drugs deemed unsafe by the FDA or removed from the market by manufacturers (for applicable requirements see § 423.120(b)(5)(iii).)

• For affected enrollees—

++ Advance direct written notice at least 30 days prior to the effective date; or

++ Written notice of the change and a month supply of the brand name drug under the same terms as provided before the change; and

• For entities and other enrollees:

++ Advance notice identifying the specific drug changes to be made at least 30 days prior to the effective date of the change as follows:

—Notice posted online for current and prospective enrollees;
—Notice to CMS; and
—Notice to other entities.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Similar to the introduction of an abbreviated approval pathway for generic drugs provided by the Hatch-Waxman Act in 1984 to spur more competition through quicker approvals and introduction of lower cost therapeutic alternatives in the marketplace, Congress enacted the ''Biologics Price Competition and Innovation Act of 2009'' to balance innovation and consumer interests. Specifically, section 7002 of the ACA amended section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either ''biosimilar'' to or ''interchangeable'' with a United States Food and Drug Administration (FDA) licensed reference biological product. According to the FDA, ''a biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has

no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.'' However, ''an *interchangeable* biological product is biosimilar to an FDA-approved reference product *and* meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.'' (See *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/)* Biosimilar biological products are, by definition, not interchangeable, and are not substitutable without a new prescription. Follow-on biological products are listed in the FDA's *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations,* available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm*. Part D plan sponsors are also encouraged to monitor the FDA's Web site for new biologic (BLA) approvals at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu*.

Sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act specify lower Part D *maximum* copayments for low-income subsidy (LIS) eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) than are available for all other Part D drugs. Currently the statutory cost sharing levels are set at the maximums. CMS does not interpret the statutory language to mean that each plan can establish lower LIS cost sharing on drugs, but rather, that CMS, through rulemaking, could establish lower cost sharing than the maximum amount, and it would therefore be the same for all Part D plans.

For the Part D program, CMS defines a ''generic drug'' at § 423.4 as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved. Biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or the CMS definition of a generic drug at § 423.4. Consequently, follow-on biological products are subject to the higher Part D maximum copayments for LIS eligible individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit applicable to all other Part D drugs. While the statutory maximum LIS copayment amounts apply to all phases of the Part D benefit, the statute only specifies non-LIS maximum copayments for the catastrophic phase. CMS clarified the applicable LIS and non-LIS catastrophic cost sharing in a March 30, 2015 Health Plan Management System (HPMS) memorandum. We advised that additional guidance may be issued for interchangeable biological products at a later date.

Nonetheless, treatment of follow-on biological products, which are generally high-cost, specialty drugs, as brands for the purposes of non-LIS catastrophic and LIS cost sharing generated a great deal confusion and concern for plans and advocates alike, and CMS received numerous requests to redefine generic drug at § 423.4. Advocates expressed concerns that LIS enrollees were required to pay the higher brand copayment for biosimilar biological products. Stakeholders who contacted us asserted treatment of biosimilar biological products as brands for purposes of LIS cost-sharing creates a disincentive for LIS enrollees to choose lower cost alternatives. Some of these stakeholders also expressed similar concerns for non-LIS enrollees in the catastrophic portion of the benefit.

We agree and propose to revise the definition of generic drug at § 423.4 to include follow-on biological products approved under section 351(k) of the PHS Act (42 U.S.C. 262(k)) solely for purposes of cost-sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act. Lower cost sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program.

While CMS generally seeks to encourage the utilization of lower cost follow-on biological products, we propose to limit inclusion of follow-on biological products in the definition of generic drug to purposes of non-LIS catastrophic cost sharing and LIS cost sharing only because we want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We do not believe that would be appropriate because the same FDA requirements for generic drug approval (for example, therapeutic equivalence) do not apply to biosimilar biological products, currently the only available follow-on biological products. Accordingly, CMS currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. In these contexts, treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar biological products (as differentiated from interchangeable biological products) to be therapeutically equivalent. This could jeopardize Part D enrollee safety and may generate confusion in the marketplace through conflation with other provisions due to the many places in the Part D statute and regulation where generic drugs are mentioned. Therefore, we believe the proposed change to treat follow-on biological products as generics should be limited to purposes of non-LIS catastrophic and LIS cost sharing only.

We propose to modify the definition of generic drug at § 423.4 as follows:

- We propose to redesignate the existing definition as paragraph (i).
- We propose to add a new paragraph (ii) to state ''for purposes of cost sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D) of the Act only, a biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved.''

We solicit comment on this proposed change to the definition of generic drug at § 423.4.

16. Eliminating the Requirement To Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

CMS has the authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds ''necessary and appropriate,'' as well as authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing ''reasonable minimum standards'' for Part D sponsors. Using this authority we previously issued regulations to ensure that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. At that time, separate meaningful difference rules were concurrently adopted for MA and stand-alone PDPs. This section addresses proposed changes to our regulations pertaining strictly to meaningful

differences in PDP plan offerings. One of the underlying principles in the establishment of the Medicare Part D prescription drug benefit is that both market competition and the flexibility provided to Part D sponsors in the statute would result in the offering of a broad array of cost effective prescription drug coverage options for Medicare beneficiaries. We continue to support the concept of offering a variety of prescription drug coverage choices for Medicare beneficiaries consistent with our commitment to afford beneficiaries access to the prescription drugs they need.

PDP sponsors must offer throughout a PDP region a basic plan that consists of: Standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap phase; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences between each PDP sponsor's plan offerings in a PDP Region, our guidance allowed sponsors that offered a basic plan to offer additional basic plans in the same region, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans that provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100, or some combination of those features. As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. To that end, CMS sets differential out-of-pocket cost (OOPC) targets each year, using an analysis performed on the previous year's bid submissions, to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries. Published annually in the Call Letter, the threshold differentials are defined for a basic and enhanced plan, as well as for two enhanced plans, when offered by a parent organization in the same region. For example, in CY 2018, a basic and enhanced plan are required at minimum to provide for a $20 out-of-pocket difference, while two enhanced plans are required to have at least a $30 differential. Over the years, the thresholds have ranged from $18 to $23 between basic and enhanced plans, and from $12 to $34 between two enhanced plans. We issued regulations in 2010, at § 423.265(b)(2), that established our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute, and in guidance we have also limited to two the number of enhanced alternative plans that we approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at § 423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries.

We continue to be committed to maintaining benefit flexibility and efficiency throughout both the MA and Part D programs. We wish to continue the trend of using transparency, flexibility, program simplification, and innovation to transform the MA and Part D programs for Medicare enrollees to have options that fit their individual health needs. In our April 2017 Request for Information (RFI), we offered stakeholders the opportunity to submit their ideas on how to better accomplish these goals. In response to the RFI, we received two comments specific to the meaningful difference requirement for PDPs. One commenter urged us to eliminate meaningful difference requirements to allow market competition to determine the appropriate number and type of plan offerings. Alternatively, it was suggested that if the meaningful difference standard is retained, we should revise it to allow plans to be treated as meaningfully different based on differences in plan characteristics not previously considered by CMS. The commenter contends that the meaningful difference requirement, as currently applied, unfairly limits the number of plan offerings and beneficiary choices. Specifically, it was argued that the meaningful difference test does not recognize premiums as elements constituting meaningful differences, despite this being an extremely important factor for beneficiaries in making enrollment decisions. Another commenter recommended that we lower the OOPC differentials between basic and enhanced PDP offerings but at a minimum, we should lower the OOPC differential between enhanced PDP offerings.

While we received relatively few comments related to meaningful difference in response to the RFI, we did receive a number of comments both in support of and opposing the proposed increase in the meaningful difference threshold between enhanced PDP offerings we announced in the Draft CY 2018 Call Letter. Those in favor of our proposal believe that the increase would help to ensure that sponsors are offering meaningfully different plans and would minimize beneficiary confusion. Commenters opposed to the proposal argued that the increase would lead to more expensive plans and would effectively limit plan choice. They argued that expanding OOPC differentials would ultimately create more beneficiary disruption as sponsors would have to consolidate plans that do not meet the new threshold. This result would directly contradict our request that plan sponsors consider options to minimize beneficiary disruption. Commenters suggested that we should utilize OOPC estimates as they were originally intended, to ensure that beneficiaries receive a minimum additional value from enhanced plans. They added that steady and reasonable OOPC thresholds will give beneficiaries more consistent benefits and lower premiums.

We appreciate the importance of ensuring adequate plan choice for beneficiaries and the value of multiple plan offerings with a diversity of benefits, now and in the future. We agree with the argument that two enhanced plans offered by a plan sponsor could vary with respect to their plan characteristics and benefit design, such that they might appeal to different subsets of Medicare enrollees, but in the end have similar out-of-pocket beneficiary costs. We continue to believe however that a meaningful difference, that takes into account out-of-pocket costs, be maintained between basic and enhanced plans to ensure that there is a meaningful value for beneficiaries given the supplemental Part D premium associated with the enhanced plans. Therefore, effective for

Contract Year (CY) 2019, we propose to revise the Part D regulations at § 423.265 (b)(2) to eliminate the PDP EA to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area. We believe these proposed revisions will help us accomplish the balance we wish to strike with respect to encouraging competition and plan flexibilities while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. Anticipated impacts to this change include: (1) A modest increase in the number of plans that would be offered by PDP sponsors (if the EA to EA meaningful difference requirement was the sole barrier to a PDP sponsors offering a second EA plan in a region) and (2) a potential decrease in the average supplemental Part D premium.

We also announce our future intent to reexamine, with the benefit of additional information, how we define the meaningful difference requirement between basic and enhanced plans offered by a PDP sponsor within a service area. We recognize that the current OOPC methodology is only one method for evaluating whether the differences between plan offerings are meaningful, and will investigate whether the current OOPC model or an alternative methodology should be used to evaluate meaningful differences between PDP offerings. While we intend to conduct our own analyses, we also seek stakeholder input on how to define meaningful difference as it applies to basic and enhanced Part D plans. CMS will continue to provide guidance for basic and enhanced plan offering requirements in the annual Call Letter.

Beneficiaries can continue to rely on the many resources CMS makes available, such as the Medicare Plan Finder (MPF), 1–800–MEDICARE and the Medicare and You Handbook, to assist them and their caregivers in making the best plan choices that meet their individual health needs. To the extent that CMS finds its elimination results in potential beneficiary confusion or harm, CMS will consider reinstating the meaningful difference requirement through future rule making or consider taking other action.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

a. Introduction

Part D sponsors and their contracted PBMs have been increasingly successful in recent years at negotiating price concessions from pharmaceutical manufacturers, network pharmacies, and other such entities. Between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes.

The data Part D sponsors submit to CMS as part of the annual required reporting of direct or indirect remuneration (DIR) show that manufacturer rebates, which comprise the largest share of all price concessions received, have accounted for much of this growth.[47] The data also show that manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010. Rebate amounts are negotiated between manufacturers and sponsors or their PBMs, independent of CMS, and are often tied to the sponsor driving utilization toward a manufacturer's product through, for instance, favorable formulary tier placement and cost-sharing requirements.

The DIR data show similar trends for pharmacy price concessions. Pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other category of DIR received by sponsors and PBMs and now buy down a larger share of total Part D gross drug costs than ever before. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, again independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM.

When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor when it does not include such discounts. Finally, variation in the treatment of rebates and price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, as explained later in this section.

At the time the Part D program was established, we believed, as discussed in the Part D final rule that appeared in the January 28, 2005 **Federal Register** (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the manufacturer rebates and other price concessions they received, and that establishing a minimum threshold for the rebates to be applied at the point of sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Instead, because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005.

Therefore, in this request for information we discuss considerations related to and solicit comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. Feedback received will be used for consideration in future rulemaking on this topic.

b. Background

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under our current regulations at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point of sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, and is used to determine plan, beneficiary, manufacturer (in the

[47] Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug cost-related risk-sharing settlements, etc.

coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, when not explicitly *required* to do so for certain types of pharmacy price concessions, Part D sponsors can *choose* whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price. Specifically, section 1860D–2(d)(1)(B) of the Act merely requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' In other words, Part D sponsors are allowed, but generally not currently required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. To date, sponsors have elected to include rebates and other price concessions in the negotiated price at the point-of-sale only very rarely. All rebates and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year and are used in our calculation of final plan payments, which, under the statute, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR.

(1) Premiums and Plan Revenues

The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point of sale) comes in the form of a lower plan premium. A sponsor must factor into its plan bid an estimate of the DIR expected to be generated—that is, it must lower its estimate of plan liability by a share of the projected DIR—which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, price concessions that are applied post-point-of-sale, as DIR, reduce plan liability, and thus premiums, more than price concessions applied at the point of sale. When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing, as explained in this section, instead of plan and government liability; this is not the case when price concessions are applied post-point-of-sale, where the majority of the concession amount accrues to the plan, and the remainder accrues to the government. Therefore, to the extent that plan bids reflect accurate DIR estimates, the rebates and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums. The average Part D basic beneficiary premium has grown at an average rate of only about 1 percent per year between 2010 and 2015, and is projected to decline in 2018, due in part to sponsors' projecting DIR growth to outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 8.1 percent per year between 2010 and 2015, partly for the same reason.

However, any DIR received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums. The risk-sharing construct established under Part D by statute allows sponsors to retain as plan profit the majority of all DIR that is above the bid-projected amount.[48] Our analysis of Part D plan payment and cost data indicates that in recent years, DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts.

To capture the relative premium and other advantages that price concessions applied as DIR offer sponsors over lower point-of-sale prices, sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and, as explained below, shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

(2) Cost-Shifting

When manufacturer rebates and other price concessions are not reflected in the negotiated price at the point of sale (that is, applied instead as DIR at the end of the coverage year), beneficiary cost-sharing, which is generally calculated as a percentage of the negotiated price, becomes larger, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copay because Part D rules require that the copay amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low income cost-sharing subsidy, those higher costs are borne by the government. This potential for cost-shifting grows increasingly pronounced as manufacturer rebates and pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.[49] [50] [51] These effects of higher beneficiary cost-sharing under the current policies regarding the determination of negotiated prices must be weighed against the impact on beneficiary access to affordable drugs of the lower premiums that are currently charged for Part D coverage.

Moreover, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point of sale, when manufacturer rebates and pharmacy price concessions are not applied at the point of sale, the higher negotiated prices that result move Part D beneficiaries more quickly through the Part D benefit. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is highest (80 percent, paid as reinsurance) and plan liability, after the closing of the coverage gap, is lowest (15 percent). Part D program experience further suggests that sponsors are able to offset their already limited liability in the catastrophic phase by capturing additional rebates from manufacturers,

[48] Medicare shares risk with Part D sponsors on the drug costs for which they are liable using symmetrical risk corridors and through the payment of 80 percent reinsurance in the catastrophic phase of the benefit.

[49] Michele Heisler et al., ''The Health Effects of Restricting Prescription Medication Use Because of Cost,'' Medical Care, 626–634 (2004).

[50] Peter Bach, ''Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,'' The New England Journal of Medicine, 360, 626–633 (2009).

[51] Sonya Blesser Streeter et al., ''Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,'' Journal of Oncology Practice, 7, no. 3S, 46S–51S (2011).

the largest share of which, under current Part D rules, as explained previously, are allocated to reduce plan liability. Consistent with this benefit, we note that sponsors have negotiated more high price-high rebate arrangements, especially in recent years, which has caused the proportion of costs for which the plan sponsor is at risk to shrink when those higher rebates are not passed on at the point of sale. Under current rules, therefore, Part D sponsors may have weak incentives, and, in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available.

(3) Transparency and Differential Treatment

Given the significant growth in manufacturer rebates and pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, at least to some degree, the true price of a drug to the plan is not available to consumers at the point of sale, nor is it reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or the lowest-cost drug and pharmacy combination.

The quality of information available to consumers is even less conducive to producing efficient choices when rebates and other price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy. First, when some sponsors include price concessions in negotiated prices while others treat them as DIR, negotiated prices no longer have a consistent meaning across the Part D program, undermining meaningful price comparisons and efficient choices by consumers. Second, if a sponsor's bid is based on an estimate of net plan liability that is understated because the sponsor has been applying price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point of sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies price concessions at the point of sale or opts for lower net cost alternatives to high cost-highly rebated drugs when available. This lower bid results in a lower plan premium that must be paid by enrollees in the plan, which could allow the sponsor to capture additional market share. The resulting competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of rebates and price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.

c. Manufacturer Rebates to the Point of Sale

We are soliciting comment from stakeholders on how we might most effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construct [52] on costs to both beneficiaries and Medicare, competition, and efficiency under Part D. In this section, we put forth for consideration potential parameters for such a policy and seek detailed comments on their merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We specifically seek comment on how this issue could be addressed without increasing government costs and without reducing manufacturer payments under the coverage gap discount program. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible.

Specifically, we are considering requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. We will refer to the rebate amount that we would require be included in the negotiated price for a covered Part D drug as the ''point-of-sale rebate.'' Under such a policy, sponsors could apply as DIR at the end of the coverage year only those manufacturer rebates received in excess of the total point-of-sale rebates. In the unlikely event that total manufacturer rebate dollars received for a drug are less than the total point-of-sale rebates, the difference would be reported at the end of the coverage year as negative DIR.

[52] We use the term ''DIR construct'' to refer to how DIR is treated under current Part D payment rules and the advantages that accrue to Part D sponsors when they apply rebates and other price concessions as DIR at the end of the coverage year.

(1) Specified Minimum Percentage

We are considering setting the minimum percentage of manufacturer rebates that must be passed through at the point of sale at a point less than 100 percent of the applicable average rebate amount for drugs in the same drug category or class. For operational ease, we are considering setting the same minimum percentage, which we would specify in regulation, for all rebated drugs in all years—that is, the minimum percentage would not change by drug category or class or by year.

It is important to note that we are not considering requiring that 100 percent of rebates be applied at the point of sale. As explained earlier, the statutory definition of negotiated price in section 1860D–2(d)(1)(B) of the Act requires that ''negotiated prices shall *take into account* negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' (emphasis added). We believe this language, particularly when read in the context of the requirement in section 1860D–2(d)(2) of the Act that Part D sponsors report the aggregate price concessions made available ''by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers,'' contemplates that Part D sponsors have some flexibility in determining how to apply manufacturer rebates in order to reduce costs under the plan.

Furthermore, we are cognizant of the fact that while requiring that a higher share of rebates be included in the negotiated price would more meaningfully address the concerns highlighted earlier and lead to larger cost-sharing savings for *many* beneficiaries, doing so would also result in larger premium increases for *all* beneficiaries, as discussed in greater detail later in this section, and lower flexibility for Part D sponsors in regards to the treatment of manufacturer rebates, and thus, for some sponsors, weaker incentives to participate in the Part D program. We aim to set the minimum percentage of rebates that must be applied at the point of sale at a point that allows an appropriate balance between these outcomes and thus achieves the greatest possible increase in beneficiary access to affordable drugs.

We are soliciting comment on the minimum percentage of manufacturer rebates that should be reflected in the negotiated price in order to achieve this balance. We are also seeking comment on how and how often, if at all, that

minimum percentage should be updated by CMS, and what factors should be considered in making any such change. We request that commenters provide analytical justification for their ideas wherever possible. We also are seeking comment on the effect that specifying a minimum percentage of rebates that must be reflected in the negotiated price would have on the competition for rebates under Part D and the total rebate dollars received by Part D sponsors and PBMs.

(2) Applicable Average Rebate Amount

We are also particularly interested in stakeholder feedback regarding the following methodology to calculate the applicable average rebate amount, a specified minimum percentage of which would be required to be applied at the point of sale:

- *Rebate Year:* We are considering requiring that point-of-sale rebate amounts be based on average manufacturer rebates expected to be received for each drug category or class under the manufacturer rebate agreements for the current payment year, not historical rebate experience. To the extent that rebate agreements are structured with contingencies that would be unclear at the point of sale, sponsors would be required to base the point-of-sale rebate amount on a good faith estimate of the rebates expected to be received. We solicit comments on whether this approach would ensure that the price available to beneficiaries at the point of sale reflects the actual price of a drug at that time, or if an alternative approach would do so more effectively.
- *Rebated Drugs:* We are considering requiring that the average rebate amount be calculated using only drugs for which manufacturers provide rebates. We believe including non-rebated drugs in this calculation would serve only to drive down the average manufacturer rebates, which would dampen the intended effects of any change.

Additionally, we would likely consider each drug product with a unique 11-digit national drug code (NDC) separately for purposes of calculating the average rebate amount. PDE and rebate data submitted to CMS show that gross drug costs and rebate rates under a plan can vary even for the same drugs produced by the same manufacturer that are packaged differently and thus have different NDC–11 identifiers. Therefore, we believe that the average rebate amounts are more likely to be accurate when calculated based on the gross drug cost and rebate data at the 11-digit NDC level. We solicit comment on whether specifying such a requirement would also serve to ensure consistency in how average rebates are calculated across sponsors, which would make prices more comparable across Part D plans and enforcement easier.

- *Plan-Level Average:* We are considering requiring that average rebate amounts be calculated separately for each plan (that is, calculated at the plan-benefit-package level). In other words, the same average rebate amount would not apply to the point-of-sale price for a covered drug across all plans under one contract, nor across all contracts under one sponsor. We believe this approach would result in the calculation of more accurate average rebates because the PDE and rebate data that are submitted by sponsors demonstrate that gross drug costs and rebate levels are not the same across all plans under one contract, nor across all contracts under one sponsor. This approach would also largely be consistent with how sponsors develop cost estimates for their Part D bids because benefit designs, including formulary structure, and assumptions about enrollee characteristics and utilization vary by plan, even for multiple plans under one contract. Similarly, final payments are calculated by CMS at the plan level, based on the data submitted by the sponsor. We solicit comment on whether the most appropriate approach for calculating the average rebate amount for point-of-sale application would be to do so at the plan level, using plan-specific information, given that moving a portion of manufacturer rebates to the point of sale would impact plan liability and payments, or if another approach would be more appropriate.
- *Drug Category or Class:* We are considering requiring that the manufacturer rebate amount applied to the point-of-sale price for a covered drug be based on the plan's average rebate amount calculated for the rebated drugs in the same category or class. We are considering requiring sponsors to determine the average rebate amount at the therapeutic category or class level, rather than a drug-specific rebate amount, in order to maintain the confidentiality of any manufacturer-sponsor/PBM pricing relationship with respect to an individual drug. Given that rebate rates are typically negotiated at the individual drug level, we believe that the drug category/class-average approach we are considering would help maintain fair competition among drug manufacturers, as well as Part D sponsors, by preventing competitors from reverse engineering the particulars of any proprietary pricing arrangement. This approach would also increase price transparency over the status quo, especially at the drug category or class level, and improve market competition and efficiency under Part D as a result. In addition to feedback on this general approach and our rationale for it, we are seeking comment, in particular, on the drug classification system that Part D sponsors should be required to use to calculate their drug category/class-level average rebate amounts and why that system would be most appropriate for use in such a point-of-sale rebate policy. We also are seeking comment on the effect of calculating average rebates at the drug category/class level on competition and, in turn, on the total rebate dollars received.

We are also particularly interested in comments on how an average rebate amount should be calculated for a drug that is the only rebated drug in its drug category or class. An alternative approach would be necessary in this case because the average rebate amount calculated under the general approach we have described above would equal the drug-specific rebate amount, which, if included in the negotiated price, could result in the release of proprietary pricing information. We ask that commenters explain how any alternative they suggest for the only rebated drug scenario would address this concern and comment on the level of price transparency that would be achieved under the suggested alternative.

- *Weighting:* We are considering requiring that when calculating the applicable average rebate amount for a particular drug category, the manufacturer rebate amount for each individual drug in that category be weighted by the total gross drug costs incurred for that drug, under the plan, over the most recent month, quarter, year, or another time period to be specified in future rulemaking for which cost data is available. We believe a weighted average is more accurate than a simple average because sponsors do not receive the same level of rebates for all drugs in a particular drug category or class, and thus, contrary to the assumption underlying a simple average, not all drugs contribute equally to the final average rebate percentage for a drug category or class received by the sponsor under a plan at the end of a payment year. A gross drug cost-weighted average ensures that drugs with higher utilization, higher costs, or both will be more important to the final average rebate rate realized for the drug category or class than lower utilization, lower cost, or lower cost-lower utilization drugs in the category or class.

In the case of a drug with less time on the market than the time period for which cost data would be required under this weighting approach or of a plan that has not been active in the Part D program for the time period required under the weighting approach, we are considering requiring that the drug's rebate amount be weighted by a sponsor's projection of total gross drug costs for the plan that takes into account any plan-specific cost experience already available. If no plan-specific cost experience is available when calculating average rebate amounts, such as at the beginning of a payment year for a new plan, are considering requiring sponsors to use the same drug cost projections on which they base their Part D bids. Further, for operational ease, it appears the manufacturer rebates used in the calculation of the average rebate amount would need to include all manufacturer rebates received for the drug, including all point-of-sale rebates. Then, in order not to double count the point-of-sale rebates, the total gross drug costs used to weight the average under this methodology would have to be based on the drug's price at the point of sale before it is lowered by any manufacturer rebates or other price concessions applied at the point of sale. We are interested in stakeholder feedback on these considerations.

For an illustration of how the weighted-average rebate amount for a particular drug category or class would be calculated, see the point-of-sale rebate example later in this section.

- *Timing:* We are considering requiring Part D sponsors to recalculate the applicable average rebate amount every month, quarter, year, or another time period to be specified in future rulemaking, in order to ensure that the average reflects current cost experience and manufacturer rebate information. We believe that a requirement to recalculate the average rebate amount should balance the need to sustain a level of price transparency throughout the entire year with the additional burden on sponsors associated with more frequent updates. We are seeking comment on how often the applicable cost-weighted drug category/class-average rebate amount, and thus the point-of-sale rebate for any drug, should be recalculated.

(3) Point-of-Sale Rebate Drugs

We are considering limiting the application of any point-of-sale rebate requirement to only rebated drugs. Under this approach, the calculated average rebate amount would only be required to be applied to the point-of-sale prices for drugs that are rebated, with each drug identified by its unique NDC–11 identifier. The alternative would result in a manufacturer that provides no rebates for a particular drug benefiting from a direct competitor's rebate, as the competitor's rebate would be used to lower the negotiated price and thereby potentially increasing sales of the non-rebated drug. However, to be clear, under this potential approach, sponsors would maintain their flexibility to include in the negotiated price for any drug, including a non-rebated drug, manufacturer rebates and other price concessions above those required to be included in the negotiated price for rebated drugs under a point-of-sale rebate policy such as the one we describe here.

Moreover, in order to limit the impact on premiums for all beneficiaries of adopting a requirement that sponsors include a portion of manufacturer rebates in the negotiated price at the point of sale, we are also seeking comment on the merits or limitations of, a more targeted version of the policy approach that would require sponsors to pass through a minimum percentage of rebates at the point of sale only for specific drugs or drug categories or classes. Under this alternative approach, the point-of-sale rebate policy would apply only for drugs or drug categories or classes that most directly contribute to increasing Part D drug costs in the catastrophic phase of coverage or drugs with high price-high rebate arrangements; such drugs or drug categories or classes are likely to have the most significant impact on beneficiary costs and serve to increase program costs overall, as discussed previously. We are interested in stakeholder feedback on whether targeting the rebate requirement in such a way would effectively address the misaligned sponsor incentives and market inefficiencies that exist under Part D today as a result of the DIR construct. In addition to general comments on the alternative, more targeted policy approach, we are particularly interested in recommendations for the criteria that we might use to determine which drugs or drug categories or classes to target under such an alternative approach.

(4) Point-of-Sale Rebate Example

To illustrate how the weighted-average rebate amount for a particular drug class would be calculated under a point-of-sale rebate requirement that includes the features described earlier, we provide the following example: suppose drugs A, B, and C are the only three rebated drugs on the plan's formulary in a particular drug class. The negotiated prices, before application of the point-of-sale rebates, for the three drugs in the current time period are $200, $100, and $75, respectively. The manufacturer rebates expected by the plan in this payment year, given the information available in the current period, for drugs A, B, and C equal 20, 10, and 5 percent, respectively, of the drugs' pre-rebate negotiated prices. Over the previous time period, total gross drug costs incurred under the plan for drug A equaled $2 million, for drug B equaled $750,000, and for drug C equaled $150,000. Therefore, the gross drug cost-weighted average rebate rate for this drug class in the current time period is calculated as the following: [($2 million × 20 percent) + ($750,000 × 10 percent) + ($150,000 × 5 percent)]/($2 million + $750,000 + $150,000), or 16.64 percent. If we were to require that a minimum 50 percent of the average rebate be applied at the point of sale for all rebated drugs in this drug class (and the plan only applies the minimum required percentage), the final negotiated prices for drugs A, B, and C, now equal to $183.36, $91.68, and $68.76, respectively, would be 8.32 percent (50 percent of 16.64 percent) lower than the pre-rebated prices.

For each of the three drugs in this example, beneficiary out-of-pocket costs would be lower under the approach we are considering than under the status quo. Assuming, for instance, these drugs are subject to a 25 percent coinsurance, the enrollee's costs for the three drugs under this approach would be $45.84 (25 percent of $183.36) for drug A, $22.92 (25 percent of $91.68) for drug B, and $17.19 (25 percent of $68.76) for drug C. Under the status quo, the enrollee's costs would be $50 for drug A ($4.16 higher), $25 for drug B ($2.08 higher), and $18.75 for drug C ($1.56 higher).

Any difference between the rebates applied at the point of sale and those actually received would be captured as DIR through reporting at the end of the coverage year. Assume, for instance, that total gross drug costs for drugs A, B, and C equal $1.5 million, $1 million, and $200,000, respectively, in this period. The actual manufacturer rebates received, therefore, will equal $300,000, $100,000, and $10,000, respectively, for drugs A, B, and C in this period, based on the plan's expected rebate rates of 20, 10, and 5 percent, respectively, for the three drugs in this payment year. Based on the point-of-sale rebate rate calculated above for the applicable drug class and the total gross drug cost assumptions provided for the three drugs, we calculate the total point-of-

sale rebates in this period to be $124,786.48 (8.32 percent of $1.5 million) for drug A, $83,189.66 (8.32 percent of $1 million) for drug B, and $16,637.93 (8.32 percent of $200,000) for drug C. Therefore, the manufacturer rebates applied by the plan as DIR at the end of the coverage year for the three drugs, respectively, would be $175,215.52, $16,810.34, and –$6,637.93 and total $185,387.93 across the drug class.

(5) Additional Considerations

Under the policy approach that we are considering here for moving manufacturer rebates to the point of sale, the responsibility for calculating the appropriate point-of-sale rebate amount over the course of the year would fall on Part D sponsors given their role in administering the Medicare drug benefit. We would leverage existing reporting mechanisms to review the sponsors' calculations, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to collect point-of-sale rebate information, and the manufacturer rebates fields on the Summary and Detailed DIR Reports to collect final manufacturer rebate information at the plan and NDC levels. Differences between the manufacturer rebate amounts applied at the point of sale and rebates actually received would become apparent when comparing the data collected through those means at the end of the coverage year.

Additionally, we note that in accordance with § 423.505(k) of the Part D regulations, a Part D sponsor is required to certify the accuracy, completeness, and truthfulness of all data related to payment, including the PDE data and information on allowable costs that it submits for purposes of risk corridor and reinsurance payment. A Part D sponsor certifies its Part D cost data by signing and submitting attestations to CMS. By signing the attestations, the Part D sponsor certifies (based on best knowledge, information, and belief) that the PDE data, DIR data, and any other information provided for the purposes of determining payment to the plan for the applicable contract year are accurate, complete, and truthful. If we were to move forward with a point-of-sale rebate policy, we would also consider amending § 423.505(k) to add a new requirement that the CEO, CFO, or COO attest (based on best knowledge, information, and belief) to the accuracy, completeness, and truthfulness of the average rebate amount included in the negotiated price and reported on the PDE. The submission of accurate, complete, and truthful data regarding the average rebate amount included in the negotiated price would be necessary to ensure accurate reinsurance and risk corridor payments.

Under the approach we are considering, if a Part D sponsor discovers errors after the certification has been made (that is, after the attestation has been signed), the Part D sponsor would submit corrected PDE data, and, under most circumstances, CMS would reconcile the error through the reopening process described at § 423.346. All reopenings are at the discretion of CMS. CMS performs a global reopening approximately 4 years after the initial reconciliation for that contract year. A Part D sponsor's reopening request resulting from errors in PDE data discovered after the global reopening for the contract year in which the error occurred would be evaluated by CMS on a case by case basis. Any errors in the calculation of the average rebate amount that result in overpayments would be required to be reported and returned consistent with § 423.360 and the applicable subregulatory guidance on overpayments.

We note that prior to the submission of the attestation, and more specifically, prior to the PDE submission deadline for the initial reconciliation for a contract year, if a Part D sponsor discovers an issue with the average rebate amount included in the negotiated price and reported on the PDE, all affected PDEs would need to be adjusted or deleted in accordance with applicable CMS guidance. As of the publication of this request for information, the applicable guidance is October 6, 2011 CMS memorandum, *Revision to Previous Guidance Titled ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.''*

We encourage stakeholders to comment on what other enforcement and oversight mechanisms should be instituted to ensure compliance with any potential point-of-sale rebate requirement. We are particularly interested in stakeholder feedback on how we might ensure accurate rebate amounts are applied at the point of sale when rebate agreements are structured with contingencies that would be unclear at the point of sale.

We also seek stakeholder comment on what, if any, special considerations should be taken into account in the design of a point-of-sale rebate policy, for Part D employer group waiver plans (EGWPs). We are also interested in feedback on what particular effects requiring Part D sponsors to apply some manufacturer rebates at the point of sale would have on the EGWP market, as well as on how such a requirement might impact the retiree drug subsidy program.

Finally, we note that the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Under section 1860D–14A(g)(6) of the Act, the negotiated price used for coverage gap discounts is based on the definition of negotiated price in the version of § 423.100 that was in effect as of the passage of the Patient Protection and Affordable Care Act (PPACA). Under this definition, the negotiated price is ''reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor *has elected to pass through* to Part D enrollees at the point of sale'' (emphasis added). Because this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale, we are uncertain as to whether we would have the authority to require sponsors include in the negotiated price the weighted-average rebate amounts that would be required to be passed through under any potential point-of-sale rebate policy, for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale.

(6) Impacts of Applying Manufacturer Rebates at the Point of Sale

Under a point-of-sale rebate policy designed as we have described in this comment solicitation, beneficiaries would see lower prices at the pharmacy point-of-sale, and on Plan Finder, beginning immediately in the year the policy takes effect. Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low income beneficiaries, especially for those who use drugs in highly competitive, highly-rebated categories or classes. For low income beneficiaries whose out-of-pocket costs are subsidized through Medicare's low-income cost-sharing subsidy, cost-sharing savings resulting from lower point-of-sale prices would accrue to the government. Plan premiums would likely increase as a result of such a point-of-sale rebate policy—if some rebates are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability, which would have the effect of

increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations for the average beneficiary would likely be large enough to lower their overall out-of-pocket costs. The increasing cost of coverage under Part D plans as a result of rebates being applied at the point of sale likely would have a more significant impact on government costs, which would increase overall due to the significant growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.

Partially offsetting the increase in direct subsidy and low income premium subsidy costs for the government would be decreases in Medicare's reinsurance and low income cost-sharing subsidies. Decreases in Medicare's reinsurance subsidy result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low income cost-sharing subsidies would decrease if beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it.

The following tables summarize the 10-year impacts we have modeled for when 33, 66, 90, and 100 percent of all manufacturer rebates are applied at the point of sale: [53]

TABLE 10A—TOTAL IMPACTS FOR 2019 THROUGH 2028

[In $billions]

	33%	66%	90%	100%
Beneficiary Costs	−$19.6	−$39.1	−$53.2	−$56.9
Cost-Sharing	−28.8	−57.8	−78.9	−85.2
Premium	9.2	18.7	25.7	28.3
Government Costs	27.3	55.1	75.5	82.1
Direct Subsidy	62.8	128.1	177.4	200.0
Reinsurance	−21.7	−44.7	−62.2	−73.1
LI Cost-Sharing Subsidy	−16.6	−34.2	−47.7	−53.7
LI Premium Subsidy	2.9	5.9	8.1	8.9
Manufacturer Gap Discount	−9.7	−19.4	−26.4	−29.4

TABLE 10B—2019–2028 PER MEMBER-PER MONTH IMPACTS

	33%	66%	90%	100%
Beneficiary Costs	−$30.33	−$60.58	−$82.42	−$88.13
Cost-Sharing	−44.61	−89.50	−122.26	−131.97
Premium	14.29	28.92	39.83	43.84
Government Costs	42.38	85.40	117.01	127.22
Direct Subsidy	97.45	198.93	275.43	310.58
Reinsurance	−33.76	−69.57	−96.84	−113.75
LI Cost-Sharing Subsidy	−25.80	−53.06	−74.11	−83.42
LI Premium Subsidy	4.49	9.10	12.53	13.81
Manufacturer Gap Discount	−15.01	−30.02	−40.93	−45.48

TABLE 10C—2019–2028 IMPACTS—PERCENT CHANGE

	33%	66%	90%	100%
Beneficiary Costs	−3	−5	−7	−8
Cost-Sharing	−6	−12	−16	−17
Premium	4	7	10	11
Government Costs	2	4	5	6
Direct Subsidy	24	49	67	76
Reinsurance	−3	−7	−9	−11
LI Cost-Sharing Subsidy	−4	−9	−12	−14
LI Premium Subsidy	4	8	11	12
Manufacturer Gap Discount	−7	−13	−18	−20

While we did not account for behavioral changes when modeling these impacts, requiring rebates to be applied at the point of sale might induce changes in sponsor behavior related to drug pricing that would further reduce the cost of the Part D program for beneficiaries and taxpayers. Specifically, requiring that at least a minimum percentage of manufacturer rebates be used to lower the price at the point of sale could limit the potential for sponsors to leverage the benefits that accrue to them when price concessions are applied as DIR at the end of the

[53] Assumptions: (1) For purposes of calculating impacts only, we assume that total rebates will equal about 20 percent of allowable Part D drug costs projected for each year modeled, and that rebates are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, including the coverage gap phase.

(2) Used 2016 distribution of costs by benefit phase to form assumptions.

(3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

coverage year rather than as discounts at the point of sale, and thus potentially better align sponsors' incentives with those of beneficiaries and taxpayers. For example, we believe such an approach could reduce the incentive for sponsors to favor high cost-highly rebated drugs to lower net cost alternatives, when such alternatives are available, and also potentially increase the incentive for sponsors and PBMs to negotiate lower prices at the point of sale instead of higher DIR. We seek comment on the extent to which a point-of-sale rebate policy might be expected to further align the incentives for beneficiaries, sponsors, and taxpayers.

Finally, we believe requiring that some manufacturer rebates be applied at the point of sale as we are considering doing would improve price transparency and limit the opportunity for differential reporting of costs and price concessions, which may have a positive effect on market competition and efficiency. We solicit comment on whether basing the rebate applied at the point of sale on average rebates at the drug category/class level, as described previously, would meaningfully increase price transparency over the status quo by ensuring a consistent percentage of the rebates received are reflected in the price at the point of sale, while also protecting the details of any manufacturer-sponsor pricing relationship.

d. Pharmacy Price Concessions to Point of Sale

In recent years, a growing proportion of Part D sponsors and their contracted PBMs have entered into payment arrangements with Part D network pharmacies in which a pharmacy's reimbursement for a covered Part D drug is adjusted after the point of sale based on the pharmacy's performance on various measures defined by the sponsor or its PBM. Furthermore, we understand that the share of pharmacies' reimbursements that is contingent upon their performance under such arrangements has also grown steadily each year. As a result, sponsors and PBMs have been recouping increasing sums *from* network pharmacies after the point of sale (*pharmacy price concessions*) for ''poor performance'' relative to standards defined by the sponsor or PBM. These sums are far greater than those paid *to* network pharmacies after the point of sale (*pharmacy incentive payments*) for ''high performance.'' We refer to pharmacy price concessions and incentive payments collectively as *pharmacy payment adjustments.* These findings are largely based on the aggregate pharmacy payment adjustment data submitted to CMS by Part D sponsors as part of the annual required reporting of DIR, which show that performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased most dramatically after 2012.

In order to address the effects of the DIR construct, as it relates to pharmacy payment adjustments, on cost, competition, and efficiency under Part D, in the Part C and Part D final rule that appeared in the May 23, 2014 **Federal Register** (79 FR 29844), we amended the definition of ''negotiated prices'' at § 423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies, with an exception, which was intended to be narrow, allowed for contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the *reasonably determined exception*). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012 and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years. We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs.

Specifically, we have heard from several stakeholders that have suggested that the reasonably determined exception applies to all performance-based pharmacy payment adjustments. The amount of these adjustments, by definition, is contingent upon performance measured over a period that extends beyond the point of sale and, thus, cannot be known *in full* at the point of sale. Therefore, performance-based pharmacy payment adjustments cannot ''reasonably be determined'' at the point of sale as they cannot be known in full at the point of sale. We initially proposed, in a September 29, 2014 memorandum entitled *Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions,* that if the amount of the post-point of sale pharmacy payment adjustment could be reasonably approximated at the point of sale, the adjustment should be reflected in the negotiated price, even if the actual amount of the payment adjustment was subject to later reconciliation and thus not known in full at the point of sale. However, we did not finalize that interpretation because we determined that it was inconsistent with the existing regulation given that it would have effectively eliminated the reasonably determined exception from inclusion in the negotiated price for all pharmacy price concessions, as we stated in our follow-up memorandum of the same name released on November 5, 2014.

Given the predominance of performance-contingent pharmacy payment arrangements, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves meaningful price transparency, ensures that all pharmacy payment adjustments are taken into account consistently by all Part D sponsors, and prevents the shifting of costs onto beneficiaries and taxpayers. Therefore, we are soliciting comment from stakeholders on how we might update the requirements governing the determination of negotiated prices, to better reflect current pharmacy payment arrangements, so as to ensure that the reported price at the point of sale includes all pharmacy price concessions. In this section, we put forth for consideration one potential approach for doing so and seek comments on its merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible.

(1) All Pharmacy Price Concessions

We are considering revising the definition of negotiated price at § 423.100 to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy. We believe we have the discretion to require that all pharmacy price concessions be applied at the point of sale, and not just a share of the amounts as we discussed earlier for manufacturer rebates. Such a requirement would preserve the flexibilities provided under section 1860D–2(d)(1)(B) of the Act with respect to the treatment of manufacturer rebates, while also allowing for greater

transparency and consistency in the reporting of pharmacy price concessions. First, section 1860D–2(d)(2) of the Act, which provides the context critical to our interpretation that sponsors are granted flexibility in how to apply manufacturer rebates, does not contemplate price concessions from sources other than manufacturers, such as pharmacies, being passed through in various ways. Second, even when all price concessions from pharmacies are required to be applied at the point of sale, sponsors would retain the flexibility to determine how to apply manufacturer rebates and other price concessions received from sources other than pharmacies in order to reduce costs under the plan. Finally, we believe that requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices ''take into account'' at least some price concessions and, therefore, would be consistent with the plain language of section 1860D–2(d)(1)(B) of the Act. We are considering requiring all, and not only a share of, pharmacy price concessions be included in the negotiated price in order to maximize the level of price transparency and consistency in the determination of negotiated prices and bids and meaningfully reduce the shifting of costs from sponsors to beneficiaries and taxpayers.

(2) Lowest Possible Reimbursement

In order to effectively capture all pharmacy price concessions at the point of sale consistently across sponsors, we are considering requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow *from* network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow *to* network pharmacies and increase prices over the lowest reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that prescription under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible contingent incentive reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR. For an illustration of how negotiated prices would be reported under such an approach, see the example provided later in this section.

We are interested in public comment on whether requiring the negotiated price at the point of sale to reflect the lowest possible pharmacy reimbursement would effectively address recent developments in industry practices, that is, the growing prevalence of performance-based pharmacy payment arrangements, and ensure that all pharmacy price concessions are included in the negotiated price, and thus shared with beneficiaries, in a consistent manner by all Part D sponsors. By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. We are also interested in public comment on whether requiring the negotiated price to be the lowest possible pharmacy reimbursement would serve to maximize the cost-sharing savings accruing to beneficiaries by passing through all potential pharmacy price concessions at the point of sale.

Further, we are interested in public comment on whether this approach would be clearer for Part D sponsors to follow than the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We are interested in public comment on whether providing such additional clarity and thus limiting the need for interpretation of the requirements by Part D sponsors would improve consistency in the application of the requirements regarding pharmacy price concessions across sponsors, as well as reducing sponsor burden in terms of the resources necessary to ensure compliance in the absence of clear guidance. In addition, we welcome feedback on whether the change we describe here would improve the quality of pricing information available across Part D plans and thus improve market competition and cost-efficiency under Part D.

Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement, would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements and thus closer to the actual cost of the drug for the Part D sponsor. We are interested in public comment on whether such an outcome would help us to achieve meaningful price transparency. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties. Therefore, we seek comment on whether a requirement that the negotiated price reflect the lowest possible reimbursement to a network pharmacy, including all potential pharmacy price concessions, is likely to capture the actual price of the drug at a network pharmacy, or at least move closer to it.

Finally, we are considering requiring that all contingent incentive payments be excluded from the negotiated price because including the actual amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty. This pricing differential could potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price. We seek comment on whether such an approach would prevent this unintended consequence and thus avoid reducing the competitiveness of high performing pharmacies by increasing the negotiated price charged to the beneficiary at those pharmacies.

(3) Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under the approach we are considering, we provide the following example: Suppose that under a performance-based payment arrangement between a

Part D sponsor and its network pharmacy, the sponsor will: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy $100 at the point of sale, the pharmacy's final reimbursement under this arrangement would be: (1) $95 for poor performance; (2) $100 for average performance; or (3) $101 for high performance. However, under all performance scenarios, the negotiated price reported to CMS on the PDE at the point of sale for this drug would be $95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100). Any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. The sponsor would report $0 as DIR under the poor performance scenario ($95 minus $95), − $5 as DIR under the average performance scenario ($95 minus $100), and − $6 as DIR under the high performance scenario ($95 minus $101), for every covered claim for this drug purchased at this pharmacy.

(4) Additional Considerations

As with the policy approach that we described previously for moving manufacturer rebates to the point of sale, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point of sale, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect point-of-sale pharmacy price concessions information, and fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession information at the plan and NDC levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year.

Finally, as noted previously, the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap determined. Under section 1860D–14A(g)(6) of the Act, the definition of negotiated price used for coverage gap discounts is based on the regulatory definition of the negotiated price in the version of § 423.100 that was in effect as of the passage of the PPACA. As discussed previously, this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale. As such, we are uncertain as to whether we would have the authority to require sponsors include pharmacy price concessions in the negotiated price for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale.

(5) Impacts for Applying Pharmacy Price Concessions at the Point of Sale

Requiring that all pharmacy price concessions that sponsors and PBMs receive be used to lower the price at the point of sale, as we described earlier, would affect beneficiary, government, and manufacturer costs largely in the same manner as discussed previously in regards to moving manufacturer rebates to the point of sale. The difference is in the magnitude of the impacts given that sponsors and PBMs receive significantly higher sums of manufacturer rebates than of pharmacy price concessions. The following table summarizes the 10-year impacts we have modeled for moving all pharmacy price concessions to the point of sale: [54]

TABLE 11—2019–2028 POINT-OF-SALE PHARMACY PRICE CONCESSIONS IMPACTS

	Total (billions)	Per member-per month	Percent change
Beneficiary Costs	−$10.4	−$16.09	−1
Cost-Sharing	−16.1	−24.89	−3
Premium	5.7	8.79	2
Government Costs	16.6	25.65	1
Direct Subsidy	33.5	51.89	13
Reinsurance	−8.8	−13.74	−1
LI Cost-Sharing Subsidy	−9.9	−15.23	−3
LI Premium Subsidy	1.8	2.73	2
Manufacturer Gap Discount	−5.0	−7.69	−3

Moreover, while not accounted for when modeling these impacts, we seek comment on whether requiring that all pharmacy price concessions be included in the negotiated price, as we have described, would also lead to prices and Part D bids and premiums being more accurately comparable and reflective of relative plan efficiencies, with no unfair competitive advantage accruing to one sponsor over another based on a technical difference in how costs are reported. We are further interested in comments on whether this outcome could make the Part D market more competitive and efficient.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)

Section 4001 of the Balanced Budget Act of 1997 (BBA), added section

[54] Assumptions: (1) For purposes of calculating impacts only, we assume that pharmacy price concession will equal about 3 percent of allowable Part D costs projected for each year modeled, and that the concession amounts are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, including the coverage gap phase.

(2) Used 2016 distribution of costs by benefit phase to form assumptions.

(3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

1851(e) of the Act establishing specific parameters in which elections can be made and/or changed during open enrollment and disenrollment periods under the Medicare Advantage (MA) program. In addition, section 1851(e)(6) of the Act permits MA organizations, at their discretion, to choose not to accept enrollment requests during the open enrollment period (that is, choose to be closed to accept enrollments for all or a portion of the enrollment period). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1851(e)(2) of the Act to further establish open enrollment periods during which MA-eligible individuals were limited to a single election to (that is, enroll, disenroll, or change MA plans) during such period.

From 2007 to 2010, the Act outlined an Open Enrollment Period (OEP)—referred to hereafter as the ''old OEP''—which provided MA-eligible individuals one opportunity to make an enrollment change between January 1 and March 31. It permitted new enrollment into an MA plan from Original Medicare, switches between MA plans, and disenrollment from a MA plan to Original Medicare. During this old OEP, individuals were not allowed to make changes to their Part D coverage. Hence, an individual who had Part D coverage through a Medicare Advantage Prescription Drug plan (MA–PD plan) could only use the old OEP to switch to (1) another MA–PD plan; or (2) Original Medicare with a Prescription Drug Plan (PDP). This old OEP did not permit someone enrolled in either an MA-only plan or Original Medicare without a PDP to enroll in Part D coverage through this enrollment opportunity. The old OEP was codified at § 422.62(a)(5) in 2005 (see 70 FR 4587).

In 2010, section 3204 of the Patient Protection and Affordable Care Act modified section 1851(e)(2)(C) of the Act to no longer offer the old OEP and instead provide a different enrollment period for MA enrollees to leave the MA program and return to Original Medicare in the first 45 days of the calendar year. The statute further permitted individuals who utilized this disenrollment opportunity to enroll in a Part D plan upon their return to Original Medicare. On April 15, 2011, we amended § 422.62(a)(5) and codified §§ 422.62(a)(7) and 423.38(d) to conform with this statutory change and to establish the current Medicare Advantage Disenrollment Period (MADP) with its coordinating Part D enrollment period. These changes were effective for the 2011 plan year (76 FR 21442 and43).

Section 17005 of the 21st Century Cures Act (the Cures Act) modified section 1851(e)(2) of the Act to eliminate the MADP and to establish, beginning in 2019, a new OEP—hereafter referred to as the ''new OEP''—to be held from January 1 to March 31 each year. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), this new OEP allows individuals enrolled in an MA plan to make a one-time election during the first 3 months of the calendar year to switch MA plans or to disenroll from an MA plan and obtain coverage through Original Medicare. In addition, this provision affords newly MA-eligible individuals (those with Part A and Part B) who enroll in a MA plan, the opportunity to also make a one-time election to change MA plans or drop MA coverage and obtain Original Medicare. Newly eligible MA individuals can only use this new OEP during the first 3 months in which they have both Part A and Part B. Similar to the old OEP, enrollments made using the new OEP are effective the first of the month following the month in which the enrollment is made, as outlined in § 422.68(c). In addition, an MA organization has the option under section 1851(e)(6) of the Act to voluntarily close one or more of its MA plans to OEP enrollment requests. If an MA plan is closed for OEP enrollments, then it is closed to all individuals in the entire plan service area who are making OEP enrollment requests. All MA plans must accept OEP disenrollment requests, regardless of whether or not it is open for enrollment.

There are a few key differences between the old OEP and the new OEP as authorized by the Cures Act. Unlike the old OEP, this new OEP permits changes to Part D coverage for individuals who, prior to the change in election during the new OEP, were enrolled in an MA plan. As eligibility to use the new OEP is available only for MA enrollees, the ability to make changes to Part D coverage is limited to any individual who uses the OEP; however, the new OEP does not provide enrollment rights to any individual who is not enrolled in an MA plan during the applicable 3-month period. Individuals who use the new OEP to make changes to their MA coverage may also enroll in or disenroll from Part D coverage. For example, an individual enrolled in an MA–PD plan may use the new OEP to switch to: (1) Another MA–PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The new OEP would also allow an individual enrolled in an MA-only plan to switch to—(1) another MA-only plan; (2) an MA–PD plan; or (3) Original Medicare with or without a PDP. However, this enrollment period does not allow for Part D changes for individuals enrolled in Original Medicare, including those with enrollment in stand-alone PDPs.

In addition, individuals with enrollment in Original Medicare or other Medicare health plan types, such as cost plans, are not able use the new OEP to enroll in an MA plan, regardless of whether or not they have Part D. We note that the inability for an individual enrolled in Original Medicare to use the new OEP is a significant difference from the old OEP. Furthermore, and significantly different from the old OEP, unsolicited marketing is prohibited by statute during this period.

To implement the changes required by the Cures Act, we propose the following revisions:

- Amend current § 422.62(a)(5) and add §§ 423.38(e) and 423.40(e) to establish the new OEP starting 2019 and the corresponding limited Part D enrollment period.
- Amend §§ 422.62(a)(7), 422.68(f), 423.38(d) and 423.40(d) to end the MADP at the end of 2018.
- Remove current regulations in § 422.62(a)(3) and (a)(4) that outline historical OEPs which have not been in existence for more than a decade. As these past enrollment periods are no longer relevant to the current enrollment periods available to MA-eligible individuals, we are proposing to delete these paragraphs and renumber the enrollment periods which follow them. As such, we propose that § 422.62 (a)(5) become § 422.62 (a)(3), and both §§ 422.62 (a)(6) and (a)(7) be renumbered as §§ 422.62(a)(4) and (a)(5), respectively.
- Amend new redesignated paragraph (a)(4) (proposed to be redesignated from (a)(6)) to make two technical changes to replace the phrase ''as defined by CMS'' with ''as defined in § 422.2'' and to capitalize ''original Medicare.''
- As noted previously, and discussed in section III.C.7, §§ 422.2268 and 423.2268 would be revised to prohibit marketing to MA enrollees during the OEP.
- Conforming technical edits to update cross references in §§ 422.60(a)(2), 422.62(a)(5)(iii), and 422.68(c).

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

Sections 1857(e) and 1860D–12(b)(3)(D) of the Act specify that contracts with MA organizations and

Part D sponsors shall contain other terms and conditions that the Secretary may find necessary and appropriate. We have previously established that all Part C and Part D contracting organizations must have the necessary administrative and management arrangements to have an effective compliance program, as reflected in § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi). Effective compliance programs are those designed and implemented to prevent, detect and correct Medicare non-compliance, fraud waste and abuse and address improper conduct in a timely and well-documented manner. Medicare non-compliance may include inaccurate and untimely payment or delivery of items or medical services, complaints from providers and enrollees, illegal activities and unethical behavior. While there is no ''one-size fits all'' program for every contracting organization, there are seven core elements that must exist to have an effective compliance program that is tailored to the organization's unique operations, compliance risks, resources and circumstances. These 7 core elements are codified in current regulations at §§ 422.503(b)(4)(vi)(A) through (G) and 423.504(b)(4)(vi)(A) through (G). One of the 7 core elements is training and education. Compliance programs for Part C and Part D organizations must include training and education between the compliance officer and the sponsoring organization's employees, senior administrators, governing body members as well as their first-tier, downstream and related entities (FDRs).

FDRs have long complained of the burden of having to complete multiple sponsoring organizations' compliance trainings and the amount of time it can take away from providing care to beneficiaries. We attempted to resolve this burden by developing our own web-based standardized compliance program training modules and establishing, in a May 23, 2014 final rule (79 FR 29853 and 29855), which was effective January 1, 2016, that FDRs were required to complete the CMS training to satisfy the compliance training requirement. The mandatory use of the CMS training by FDRs was a means to ensure that FDRs would only have to complete the compliance training once on an annual basis. The FDRs could then provide the certificate of completion to all Part C and Part D contracting organizations they served, hence, eliminating the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation.

However, CMS continues to receive hundreds of inquiries and concerns from sponsors and FDRs regarding their difficulties with adopting CMS' compliance training to satisfy the compliance program training requirement. While CMS' previous market research indicated that this provision would mitigate the problems raised by FDRs who held contracts with multiple sponsors and who completed repetitive trainings for each sponsor with which they contract, in practice, we learned that the problems persisted. Many sponsors are unwilling to accept completion of the CMS training as fulfillment of the training requirement and identify which critical positions within the FDR are subject to the training requirement. As a result, FDRs are still being subjected to multiple sponsors' specific training programs. FDRs have the additional burden of taking CMS training and reporting completion back to the sponsor or sponsors with which they contract. Furthermore, the industry has indicated that the requirement has increased the burden for various Part C and Part D program stakeholders, including hospitals, suppliers, health care providers, pharmacists and physicians, all of which may be considered FDRs. Since the implementation of the mandatory CMS-developed training has not achieved the intended efficiencies in the administration of the Part C and Part D programs, we propose to delete the provisions from the Part C and Part D regulations that require use of the CMS-developed training. Additionally we propose to restructure § 422.503(b)(4)(vi)(C)(1) (with the proposed revisions) into two paragraphs (that is, paragraph (C)(1) and (C)(2)) to separate the scope of the compliance training from the frequency with which the training must occur, as these are two distinct requirements. With this proposed revision, the organization of § 422.503(b)(4)(vi)(C) will mirror that of § 423.504(b)(4)(vi)(C). Further, we propose to revise the text in § 423.504(b)(4)(vi)(C)(2) to track the phrasing in § 422.503(b)(4)(vi)(C)(2), as reorganized. The technical changes in the text eliminate any potential ambiguity created by different phrasing in what we intend to be identical requirements as to the timing requirements for the training. We believe these technical changes make the requirements easier to understand.

Furthermore, we believe that the broader requirement that plan sponsors provide compliance training to their FDRs no longer promotes the effective and efficient administration of the Medicare Advantage and Prescription Drug programs. Part C and Part D sponsoring organizations have evolved greatly and their compliance program operations and systems are well established. Many of these organizations have developed effective training and learning models to communicate compliance expectations and ensure that employees and FDRs are aware of the Medicare program requirements. Also, the attention focused on compliance program effectiveness by CMS' Part C and Part D program audits has further encouraged sponsors to continually improve their compliance operations.

CMS does not generally interfere in private contractual matters between sponsoring organizations and their FDRs. Our contract is with the sponsoring organization, and sponsoring organizations are ultimately responsible for compliance with all applicable statutes, regulations and sub-regulatory guidance, regardless who is performing the work. Additionally, delegated entities range in size, structure, risks, staffing, functions, and contractual arrangements which necessitates the sponsoring organization have discretion in its method of oversight to ensure compliance with program requirements. This may be accomplished through routine monitoring and implementing corrective action, which may include training or retraining as appropriate, when non-compliance or misconduct is identified.

We will continue to hold MA organizations and Part D sponsors accountable for the failures of their FDRs to comply with Medicare program requirements, even with these proposed changes. Existing regulations at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) require that every sponsor's contract must specify that FDRs must comply with all applicable federal laws, regulations and CMS instructions. Additionally, we audit sponsors' compliance programs when we conduct routine program audits, and our audit process includes evaluations of sponsoring organizations' monitoring and auditing of their FDRs as well as FDR oversight. Our audits also evaluate formulary administration and processing of coverage and appeal requests in the Part C and Part D programs. FDRs often perform some or all of these functions for sponsors, so if they are non-compliant, it will come to light during the program audit and the sponsoring organization is ultimately held responsible for the FDRs' failure to comply with program requirements.

Given that compliance programs are very well established and have grown more sophisticated since their inception, coupled with the industry's desire to perform well on audit, the

CMS training requirement is not the driver of performance improvement or FDR compliance with key CMS requirements. Given this accumulated program experience and the growing sophistication of the industry's compliance operations, as well as our continuing requirements on sponsors for oversight and monitoring of FDRs, we are proposing to delete not just the regulatory provision requiring acceptance of CMS' training as meeting the compliance training requirements, but also the reference to FDRs in the compliance training requirements codified at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). Specifically, we propose to remove the phrases in paragraphs (C)(1) and (C)(2) that refer to first tier, downstream and related entities and remove the paragraphs specific to FDR training at §§ 422.503(b)(4)(vi)(C)(2) and (3) and 423.504(b)(4)(vi)(C)(3) and (4); we are also proposing technical revisions to restructure § 422.503(b)(4)(vi)(C)(1) into two paragraphs and ensure that the remaining text is grammatically correct and consistent with Office of the Federal Register style. Compliance training would still be required of MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members. This change will allow sponsoring organizations, and the FDRs with which they contract, the maximum flexibility in developing and meeting training requirements associated with effective compliance programs. We invite comments concerning this proposal and suggestions on other options we can implement to accomplish the desired outcome.

3. Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))

Under section 1857(b) of the Act, CMS may not enter into a contract with a MA organization unless the organization complies with the minimum enrollment requirement. Under the basic rule at § 422.514(a), to provide health care benefits under the MA program, MA organizations must demonstrate that they have the capability to enroll at least 5,000 individuals, and provider sponsored organizations (PSOs) must demonstrate that they have the capability to enroll at least 1,500 individuals. If an MA organization intends to offer health care benefits outside urbanized areas as defined in § 422.62(f), then the minimum enrollment level is reduced to 1,500 for MA organizations and to 500 for PSOs. The statute permits CMS to waive this requirement in the first 3 years of the contract for an MA contract applicant. We have codified this authority at § 422.514(b) and limited it to circumstances where the MA contract applicant is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. We are proposing to revise § 422.514 regarding the minimum enrollment requirements to improve program efficiencies.

Currently, MA organizations, including PSOs, with an approved minimum enrollment waiver for their first contract year have the option to resubmit the waiver request for CMS in the second and third year of the contract. In conjunction with the waiver request, the MA organization must continue to demonstrate the organization's ability to operate and demonstrate that it has and uses an effective marketing and enrollment system, despite continued failure to meet the minimum enrollment requirement. In addition, the current regulation limits our authority to grant the waiver in the third year to situations where the MA organization has at least attained a projected number of enrollees in the second year. Since 2012, we have not received any waiver to the minimum enrollment requirement during the second and third year of the contract. Rather, we only received minimum enrollment waiver requests through the initial application process.

We believe the current requirement to resubmit the waiver in the second and third year of the contract is unnecessary. The statute does not require a reevaluation of the minimum enrollment standard each year and plainly authorizes a waiver ''during the first 3 contract years with respect to an organization.'' The current minimum enrollment waiver review in the initial MA contract application provides CMS the confidence to determine whether an MA organization may operate for the first 3 years of the contract without meeting the minimum enrollment requirement. CMS currently monitors low enrollment at the plan benefit package (PBP) level. We note that a similar provision in current § 422.506(b)(1)(iv) permits CMS to terminate an MA contract (or terminate a specific plan benefit package) if the MA plan fails to maintain a sufficient number of enrollees to establish that it is a viable independent plan option for existing or new enrollees. In addition, compliance with § 422.514 is required under § 422.503(a)(13). If an organization's PBP does not achieve and maintain enrollment levels in accordance with the applicable low and minimum enrollment policies in existing regulations, CMS may move to terminate the PBP absent an approved waiver from CMS during the first 3 years of the contract pursuant to § 422.510(a).

Under our proposal, we would only review and approve waivers through the MA application process as opposed to the current practice of reviewing annual requests and, potentially, requests from existing MA organizations that fail to maintain enrollment in the second or third year of operation.

We are proposing to revise the text in § 422.514(b) to provide that the waiver of the minimum enrollment requirement may be in effect for the first 3 years of the contract. Further, we are proposing to delete all references to ''MA organizations'' in paragraph (b) to reflect our proposal that we would only review and approve waiver requests during the contract application process. We also propose to delete current paragraphs (b)(2) and (b)(3) in their entirety to remove the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract. Finally, the proposed text also includes technical changes to redesignate paragraphs (b)(1)(i) through (iii) as (b)(1) through (3), consistent with regulation style requirements of the Office of the Federal Register.

4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)

As provided in sections 1852(c)(1) and 1860D–4(a)(1)(A) of the Act, Medicare Advantage (MA) organizations and Part D sponsors must disclose detailed information about the plans they offer to their enrollees ''at the time of enrollment and at least annually thereafter.'' This detailed information is specified in section 1852(c)(1) of the Act, with additional information specific to the Part D benefit also required under section 1860D–4(a)(1)(B) of the Act. Under § 422.111(a)(3), CMS requires MA plans to disclose this information to each enrollee ''at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.'' A similar rule for Part D sponsors is found at § 423.128(a)(3). Additionally, § 417.427 directs 1876 cost plans to follow the disclosure requirements in § 422.111 and § 423.128. In making the changes proposed here, we will also affect 1876 cost plans, though it is not necessary to change the regulatory text at § 417.427.

Sections 422.111(b) and 423.128(b) of the Part C and Part D program regulations, respectively, describe the information plans must disclose. The content listed in § 422.111(b) is found in

an MA plan's Evidence of Coverage (EOC) and provider directory. The content listed in § 423.128(b) is found in a Part D Sponsor's EOC, formulary, and pharmacy directory. Section 422.111(h)(2)(i) requires that plans must maintain an internet Web site that contains the information listed in § 422.111(b) and also states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site ''does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.''

We propose two changes to the disclosure requirements. First, we propose to revise §§ 422.111(a)(3) and 423.128(a)(3) to require MA plans and Part D Sponsors to provide the information in paragraph (b) of the respective regulations by the first day of the annual enrollment period, rather than 15 days before. In addition, we propose to modify the sentence in § 422.111(h)(2)(ii) which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of responsibility to provide hard copies to enrollees. We propose to revise the sentence slightly and add ''upon request'' to the existing regulatory language to make it clear when any document that is required to be delivered under paragraph (a) in a manner that includes provision of a hard copy upon request, posting the document on the Web site (whether that document is the EOC, SB, directory information or other materials) does not relieve the MA organizations of a responsibility to deliver hard copies upon request. We intend these proposals to provide CMS with the flexibility to permit delivery other than through mailing hard copies (which is the requirement today for all materials and information covered by § 422.111(a)), including through electronic delivery or posting on the Web site in conjunction with delivery of a hard copy notice describing how the information and materials are available. We believe this proposal will ultimately provide additional flexibility to plans to take advantage of technological developments and reduce the amount of mail enrollees receive from plans.

Prior to the 2009 contract year, §§ 422.111(a) and 423.128(a) required the provision of the materials in their respective paragraphs (b) at the time of enrollment and at least annually thereafter, but did not specify a deadline. In the September 18, 2008, final rule, CMS required MA organizations to send this material to current enrollees 15 days before the annual coordinated election period (AEP) (73 FR 54216). The rationale for this requirement was to provide beneficiaries with comprehensive information prior to the AEP so that they could make informed enrollment decisions.

However, we have found through consumer testing that the large size of these mailings overwhelmed enrollees. In particular, the EOC is a long document that enrollees found difficult to navigate. Enrollees were more likely to review the Annual Notice of Change (ANOC), a shorter document summarizing any changes to plan benefits beginning on January 1 of the upcoming year, if it was separate from the EOC. Sections 422.111(d) and 423.128(g)(2) require MA organizations and Part D sponsors to provide the ANOC to all enrollees at least 15 days before the AEP.

The ANOC is intended to convey all of the information essential to an enrollee's decision to remain enrolled in the same plan for the following year or choose another plan during the AEP. CMS's research and experience have indicated that the ANOC is particularly useful to and used by enrollees. Therefore, we are not proposing to change the §§ 422.111(d) and 423.128(g) requirements that the ANOC be received 15 days prior to AEP.

Unlike the ANOC, the EOC is a document akin to a contract that provides enrollees with exhaustive information about their medical coverage and rights and responsibilities as members of a plan. The provider directory, pharmacy directory, and formulary also contain information necessary to access care and benefits. As such, CMS requires MA organizations and Part D sponsors to make these documents available at the start of the AEP, so CMS proposes to amend §§ 422.111(a)(3) and 423.128(a)(3) to remove the current deadline and insert ''by the first day of the annual coordinated election period.'' To the extent that enrollees find the EOC, provider directory, pharmacy directory, and formulary useful in making informed enrollment decisions, CMS believes that receipt of these documents by the first day of the AEP is sufficient. Any changes in the plan rules reflected in these documents for the next year should be adequately described in the ANOC, which will be provided earlier.

This change would also provide an additional 2 weeks for MA organizations and Part D plan sponsors to prepare, review, and ensure the accuracy of the EOC, provider directory, pharmacy directory, and formulary documents. CMS considers the additional time for the EOC important due to the high number errors plans self-identify in the document through errata sheets they submit to CMS and mail to beneficiaries. In 2017, plans submitted 166 ANOC/EOC errata, which identified 221 ANOC errors and 553 EOC errors. Additional time to produce the EOC will give plans more time to conduct quality assurance and improve accuracy and result in fewer errata sheets in the future.

In addition to the proposed changes in §§ 422.111(a)(3) and 423.128(a)(3), we also propose to give plans more flexibility to provide the materials specified in § 422.111(b) electronically. The language in § 422.111(h)(2)(ii) requiring hard copies of the specified documents first appeared in the January 28, 2005, final rule (70 FR 4587) in § 422.111(f)(12). At that time, MA plans were not required to maintain a Web site, but if they chose to they were required to include the EOC, Summary of Benefits, and provider network information on the Web site. However, plans were prohibited from posting these documents online as a substitute for providing hard copies to enrollees. A subsequent final rule, published April 15, 2011, established that MA plans are required to maintain an internet Web site at § 422.111(h)(2) and moved the requirement that posting documents on the plan Web site did not substitute for hard copies from § 422.111(f)(12) to § 422.111(h)(2)(ii) (76 FR 21502).

There is no parallel to § 422.111(h)(2)(ii) in § 423.128. Instead, § 423.128(a) states that Part D sponsors must disclose the information in paragraph (b) in the manner specified by CMS. Section 423.128(d)(2)(i) requires Part D sponsors to maintain an internet Web site that includes information listed in § 423.128(b). CMS sub-regulatory guidance has instructed plans to provide the EOC in hard copy, but we believe that the regulatory text would permit delivery by notifying enrollees of the internet posting of the documents, subject to the right to request hard copies.[55] As explained previously regarding the changes to § 422.111, we intend for plans to have the flexibility to provide documents such as the Summary of Benefits, the EOC, and the provider network information in electronic format. We intend to change the relevant sub-regulatory guidance to coincide with this as well.

In the preamble to the 2005 final rule, we noted that the prohibition on

[55] Medicare Marketing Guidelines, section 60.6, issued July 20, 2017, *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines_Final072017.pdf.*

substituting electronic posting on the MA plan's internet site for delivery of hardcopy documents was in response to comments recommending this change (70 FR 4623). At the time, we did not think enough Medicare beneficiaries used the internet to permit posting the documents online in place of mailing them.

In the 12 years since the rule was finalized, research indicates that internet use has increased significantly among Medicare beneficiaries. Drawing on nationally representative surveys, the Pew Research Center found that 67 percent of American adults age 65 and older use the internet. Half of seniors have broadband available at home. Internet use increases even more among seniors age 65–69, of which 82 percent use the internet and 66 percent have broadband at home.[56] Electronic documents include advantages such as word search tools, the ability to magnify text, screen reader capabilities, and bookmarks or embedded links, all of which make documents easier to navigate. Given that the younger range of Medicare beneficiaries have a higher rate of internet access, we believe the number of beneficiaries who ''use the internet'' will only continue to grow with time. Posted electronic documents can also be accessed from anywhere the internet is available.

As mentioned previously, the EOC sometimes contains errors. To correct these, MA and Part D plans currently have to mail errata sheets and post an updated version online. The hardcopy version of the EOC is then out-of-date. Beneficiaries either have to refer to errata sheets in addition to the hardcopy EOC or go online to access a corrected EOC. Increasing beneficiary use of the electronic EOC ensures that beneficiaries are using the most accurate information. Under this proposal to permit flexibility for us to approve non-hard-copy delivery in some cases, we intend to continue requiring hardcopy mailings of any ANOC or EOC errata.

Plans have also continued to request CMS give plans the flexibility to provide the EOC electronically. They have frequently cited the expense of printing and mailing large documents. Medicaid managed care plans already have the flexibility to provide directories, formularies, and member handbooks (similar to the EOC) electronically, per §§ 438.10(h)(1), 438.10(h)4)(i), and 438.10(g)(3) respectively.

To begin addressing this, in the Medicare Marketing Guidelines released July 2, 2015, CMS notified plans that they could mail either a hardcopy provider and/or pharmacy directory or a hardcopy notice to enrollees instructing them where to find the directories online and how to request a hard copy. That guidance has been moved to Chapter 4, section 110.2.3, of the Medicare Managed Care Manual. If plans choose to mail a notice with the location of the online directory rather than a hard copy, the notice must include: A direct link to the online directory, the customer service number to call and request a hard copy, and if available the email address to request a hard copy. The notice must be distinct, separate, and mailed with the ANOC/EOC.[57] Section 60.4 of the Medicare Marketing Guidelines released July 20, 2017, extends the same flexibility to formularies, with the same required content in the notice identifying the location of the online formulary. As CMS has received few complaints from any source about this new process, allowing plans the option to use a similar strategy for additional materials is appropriate.

Upon finalizing this rule, we would issue sub-regulatory guidance to identify permissible manners of disclosure; we expect that guidance would be similar to the current guidance for the provider directory, pharmacy directory, and formulary regarding dissemination of the EOC. Importantly, this provision does not eliminate the requirement for plans to provide accessible formats of required documents. As recipients of federal funding, plans are obligated to provide materials in accessible formats upon request, at no cost to the individual, to individuals with disabilities, under Section 504 of the Rehabilitation Act of 1973 and to take reasonable steps to provide meaningful access, including translation services, to individuals who have limited English proficiency under Title VI of the Civil Rights Act of 1964.

To create this flexibility, CMS proposes modifying the sentence, ''Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees,'' to include ''upon request'' in § 422.111(h)(2)(ii) and to revise § 422.111(a) by inserting ''in the manner specified by CMS.'' These changes will align §§ 422.111(a) and 423.128(a) to authorize CMS to provide flexibility to MA plans and Part D sponsors to use technology to provide beneficiaries with information. CMS intends to use this flexibility to provide sponsoring organizations with the ability to electronically deliver plan documents (for example, the Summary of Benefits) to enrollees while maintaining the protection of a hard copy for any enrollee who requests such hard copy. As the current version of § 422.111(a) and (h)(2) require hard copies, we believe this proposal will ultimately result in reducing burden and providing more flexibility for sponsoring organizations.

5. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities

Section 1851(h) of the Act prohibits Medicare Advantage (MA) organizations from distributing marketing materials and application forms to (or for the use of) MA eligible individuals unless the document has been submitted to the Secretary at least 45 days (10 days for certain materials) prior to use and the document has not been disapproved. Further, in section 1851(j), the Secretary is authorized to adopt standards regarding marketing activities, and the statute identifies certain prohibited activities. While the Act requires the submission and review of the marketing materials and applications, it does not provide a definition of what materials fall under the umbrella term ''marketing.'' Sections 1806D–1(d)(3)(B)(iv) and 1860D–4(l) of the Act provide similar restrictions on use of marketing and enrollment materials and activities to promote enrollment in Part D plans.

Section 1876(c)(3)(C) of the Act states that no brochures, application forms, or other promotional or informational material may be distributed by cost plan to (or for the use of individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review, and (ii) the Secretary has not disapproved the distribution of the material. As delegated this authority by the Secretary, CMS reviews all such material submitted and disapproves such material upon determination that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation. Similar to 1851(h) of the Act, section 1876(c)(3)(C) of the Act focuses more on the review and approval of materials as opposed to providing an exhaustive list of materials that would qualify as marketing or promotional information and materials.

[56] Pew Research Center, May 2017, ''Tech Adoption Climbs Among Older Adults'', *http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/*.

[57] Medicare Managed Care Manual Chapter 4—Benefits and Beneficiary Protections, Rev. 121, issued April 22, 2016, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf*.

As part of the implementation of section 1876(c)(3)(C) of the Act, the regulation governing cost plans at § 417.428(a) refers to Subpart V of part 422 for marketing guidance. Throughout this proposal, the changes discussed for MA organizations/MA plans and prescription drug plan (PDP) sponsors/Part D plans applies as well to cost plans subject to the same requirements as a result of this cross-reference.

Section 422.2260(1)–(4) of the Part C program regulations currently identifies marketing materials as any materials that: (1) Promote the MA organization, or any MA plan offered by the MA organization; (2) inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization; (3) explain the benefits of enrollment in an MA plan, or rules that apply to enrollees; and (4) explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage. Section 423.2260(1)–(4) applies identical regulatory provisions to the Part D program.

Sections 422.2260(5) and 423.2260(5) provide specific examples of materials under the ''marketing materials'' definition, which include: General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet; marketing representative materials such as scripts or outlines for telemarketing or other presentations; presentation materials such as slides and charts; promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers); membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees; letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.; and membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or no claim specific notification information). Finally, §§ 422.2260(6) and 423.2260(6) provide a list of materials that are not considered marketing materials, including materials that are targeted to current enrollees; are customized or limited to a subset of enrollees or apply to a specific situation; do not include information about the plan's benefit structure; and apply to a specific situation or cover claims processing or other operational issues.

We are proposing several changes to Subpart V of the part 422 and 423 regulations. To better outline these proposed changes, they are addressed in four areas of focus: (1) Including ''communication requirements'' in the scope of Subpart V or parts 422 and 423, which will include new definitions for ''communications'' and ''communication materials;'' (2) amending §§ 422.2260 and 423.2260 to add (at a new paragraph (b)) a definition of ''marketing'' in place of the current definition of ''marketing materials'' and to provide lists identifying marketing materials and non-marketing materials; (3) adding new regulation text to prohibit marketing during the Open Enrollment Period proposed in section III.B.1 of this proposed rule; (4) technical changes to other regulatory provisions as a result of the changes to Subpart V. To the extent necessary, CMS relies on its authority to add regulatory and contract requirements to the cost plan, MA, and Part D programs to propose and (ultimately) adopt these changes. We note as well that sections 1851(h) and (j) of the Act (cross-referenced in sections 1860D–1 and 1860D–4(l)) of the Act address activities and direct that the Secretary adopt standards limiting marketing activities, which CMS interprets as permitting regulation of communications about the plan that do not rise to the level of activities and materials that specifically promote enrollment.

a. Revising the Scope of Subpart V To Include Communications and Communications Materials

The current version of Subpart V of parts 422 and 423 regulation focuses on marketing materials, as opposed to other materials currently referred to as ''non-marketing'' in the sub-regulatory Medicare Marketing Guidelines. This leaves a regulatory void for the requirements that pertain to those materials that are not considered marketing. Historically, the impact of not having regulatory guidance for materials other than marketing has been muted because the current regulatory definition of marketing is so broad, resulting in most materials falling under the definition. The overall effect of this combination—no definition of materials other than marketing and a broad marketing definition—is that marketing and communications with enrollees became synonymous.

With this CMS proposal to narrow the marketing definition, we believe there is a need to continue to apply the current standards to and develop guidance for those materials that fall outside of the proposed definition. We propose changing the title of each Subpart V by replacing the term ''Marketing'' with ''Communication.'' We propose to define in §§ 422.2260(a) and 423.2260(a) definitions of ''communications'' (activities and use of materials to provide information to current and prospective enrollees) and ''communications materials'' (materials that include all information provided to current members and prospective beneficiaries). We propose that marketing materials (discussed later in this section) would be a subset of communications materials. In many ways, the proposed definition of communications materials is similar to the current definition of marketing materials; the proposed definition has a broad scope and would include both mandatory disclosures that are primarily informative and materials that are primarily geared to encourage enrollment.

CMS also proposes, through revisions to §§ 422.2268 and 423.2268, to apply some of the current standards and prohibitions related to marketing to all communications and to apply others only to marketing. Marketing and marketing materials would be subject to the more stringent requirements, including the need for submission to and review by CMS. Under this proposal, those materials that are not considered marketing, per the proposed definition of marketing, would fall under the less stringent communication requirements.

In addition to these proposals related to defined terms and revising the scope of Subparts V in parts 422 and 423, we are proposing changes to the current regulations at §§ 422.2264 and 423.2264 and §§ 422.2268 and 423.2268 that are related to our proposal to distinguish between marketing and communications.

With regard to §§ 422.2264 and 423.2264, we are proposing the following changes:

- Deletion of paragraph (a)(3), which currently provides for an adequate written explanation of the grievance and appeals process to be provided as part of marketing materials. In our view grievance and appeals communications would not be within the scope of marketing as proposed in this rule.
- Deletion of paragraph (a)(4), which provides for CMS to determine that marketing materials include any other information necessary to enable beneficiaries to make an informed decision about enrollment. The intent of this section was to ensure that materials which include measuring or ranking mechanisms such as Star Ratings were a part of CMS's marketing review. We

propose deleting this section as the exclusion list to be codified at § 422.2260(c)(2)(ii) ensures materials that include measuring or ranking standards will be considered marketing, thus making §§ 422.2264(a)(4) and § 423.2264(a)(4) duplicative.

• Deletion of paragraph (e), which requires sponsoring organizations to provide translated materials in certain areas where there is a significant non-English speaking population. We propose to recodify these requirement as a general communication standard in §§ 422.2268 and 423.2268, at new paragraph (a)(7). As part of the redesignation of this requirement as a standard applicable to all communications and communication materials, we are also proposing revisions. First, we are proposing to revise the text so that it is stated as a prohibition on sponsoring organizations: For markets with a significant non-English speaking population, provide materials, as defined by CMS, *unless* in the language of these individuals. We propose adding the statement of ''as defined by CMS'' to the first sentence to allow the agency the ability to define the significant materials that would require translation. We propose deleting the word ''marketing'' so the second sentence now reads as ''materials'', to make it clear that the updated section applies to the broader term of communications rather than the more narrow term of marketing.

In addition, we are proposing to revise §§ 422.2262(d) and 423.2262(d) to delete the term ''ad hoc'' from the heading and regulation text in favor of referring to ''communication materials'' to conform to the addition of communication materials under Subpart V.

Current regulations at §§ 422.2268 and 423.2268 list prohibited marketing activities. These activities include items such as providing meals to potential enrollees, soliciting door to door, and marketing in provider settings. With the proposal to distinguish between overall communications and marketing activities, we are proposing to break out the prohibitions into categories: those applicable to all communications (activities and materials) and those that are specific to marketing and marketing materials. In reviewing the various standards under the current regulations to determine if they would apply to communications or marketing, we looked at the each standard as it applied to the new definitions under Subpart V. Prohibitions that offer broader beneficiary protections and are currently applicable to a wide variety of materials are proposed here to apply to communications activities and communication materials; this list of prohibitions is proposed as paragraph (a) Conversely, prohibitions that are currently targeted to activities and materials that are within the narrower scope of marketing and marketing materials are proposed at paragraph (b) as prohibitions on marketing. We are not proposing to expand the list of prohibitions but are proposing to notate which prohibitions are applicable to which category. The only substantive change is in connection with paragraph (a)(7), which we discuss earlier in this section. We welcome comment on our proposed distinctions between these types of prohibitions and whether certain standards or prohibitions from current §§ 422.2268 and 423.2268 should apply more narrowly or broadly than we have proposed.

b. Amending the Regulatory Definition of Marketing and Marketing Materials

In conjunction with adding new proposed communication requirements, we also propose a definition of ''marketing'' be codified in §§ 422.2260(b) and 423.2260(b). Under this proposal, we would delete the current text in that section defining only ''marketing materials'' to add a new definition of ''marketing'' and lists of materials that are ''marketing materials'' and that are not. Specifically, the term ''marketing'' would be defined as the use of materials or activities by the sponsoring organization (that is, the MA organization, Part D Sponsor, or cost plan, depending on the specific part) or downstream entities that are intended to draw a beneficiary's attention to the plan or plans and influence a beneficiary's decision making process when making a plan selection; this last criterion would also be met when the intent is to influence an enrollee's decision to remain in a plan (that is, retention-based marketing).

The current regulations address both prohibited marketing activities and marketing materials. The prohibited activities are directly related to marketing activities, but the current definition of ''marketing materials'' is overly broad and has resulted in a significant number of documents being classified as marketing materials, such as materials promoting the sponsoring organization as a whole (that is, brand awareness) rather than materials that promote enrollment in a specific Medicare plan. We believe that Congress' intent was to target those materials that could mislead or confuse beneficiaries into making an adverse enrollment decision. Since the original adoption of §§ 422.2260 and 423.2260, CMS has reviewed thousands of marketing materials, tracked and resolved thousands of beneficiary complaints through the complaints tracking module (CTM), conducted secret shopping programs of MA plan sales events, and investigated numerous marketing complaints. These efforts have provided CMS insight into the types of plan materials that present the greatest risk of misleading or confusing beneficiaries. Based on this experience, we believe that the current regulatory definition of marketing materials is overly broad. As a result, materials that pose little to no threat of a detrimental enrollment decision fall under the current broad marketing definition. As such, the materials are also required to follow the associated marketing requirements, including submission to CMS for potential review under limited statutory timeframes. CMS believes that the level of scrutiny required on numerous documents that are not intended to influence an enrollment decision, combined with associated burden to sponsoring organizations and CMS, is not justified. By narrowing the materials that fall under the scope of marketing, this proposal will allow us to better focus its review on those materials that present the greatest likelihood for a negative beneficiary experience.

We propose to more appropriately implement the statute by narrowing the definition of marketing to focus on materials and activities that aim to influence enrollment decisions. We believe this is consistent with Congress's intent. Moreover, the new definition differentiates between factually providing information about the plan or benefits (that is, the Evidence of Coverage (EOC)) versus persuasively conveying information in a manner designed to prompt the beneficiary to make a new plan decision or to stay with their current plan (for example, a flyer that touts a low monthly premium). As discussed later, the majority of member materials would no longer fall within the definition of marketing under this proposal. The EOC, subscriber agreements, and wallet card instructions are not developed nor intended to influence enrollment decisions. Rather, they are utilized for current enrollees to understand the full scope of and the rules associated with their plan. We believe the proposed new marketing definition appropriately safeguards potential and current enrollees while not placing an undue burden on sponsoring organizations. Moreover, those materials that would be

excluded from the marketing definition would fall under the proposed definition of communication materials, with what we believe are more appropriate requirements. CMS notes that enrollment and mandatory disclosure materials continue to be subject to requirements in §§ 422.60(c), 422.111, 423.32(b), and 423.128.

Second, we propose to revise the list of marketing materials, currently codified at §§ 422.2260(5) and 423.2260(5), and to include it in the proposed new §§ 422.2260(c)(1) and 423.2260(c)(1). The current list of examples includes: brochures; advertisements in newspapers and magazines, and on television, billboards, radio, or the internet, and billboards; social media content; marketing representative materials, such as scripts or outlines for telemarketing or other presentations; and presentation materials such as slides and charts. In conjunction with the proposed new definition of marketing, we are proposing to remove from the list of examples items such as membership communication materials, subscriber agreements, member handbooks, and wallet card instructions to enrollees, as they would no longer fall under the proposed regulatory definition of marketing. The proposed text complements the new definition by providing a concise non-exhaustive list of example material types that would be considered marketing.

Third, we propose to revise the list of exclusions from marketing materials, currently codified at §§ 422.2260(6) and 423.2260(6), and to include it in the proposed new §§ 422.2260(c)(2) and 423.2260(c)(2) to identify the types of materials that would not be considered marketing. Materials that do not include information about the plan's benefit structure or cost sharing or do not include information about measuring or ranking standards (for example, star ratings) will be excluded from marketing. In addition, materials that do mention benefits or cost sharing, but do not meet the definition of marketing as proposed here, would also be excluded from marketing. We also propose that required materials in § 422.111 and § 423.128 not be considered marketing, unless otherwise specified. Lastly, we are proposing to exclude materials specifically designated by us as not meeting the definition of the proposed marketing definition based on their use or purpose. The purpose of this proposed revision of the list of exclusions from marketing materials, as with the proposed marketing definition and proposed non-exhaustive list of marketing materials, is to maintain the current beneficiary protections that apply to marketing materials but to narrow the scope to exclude materials that are unlikely to lead to or influence an enrollment decision.

In the proposed changes to the exclusions from marketing materials, we intend to exclude materials that do not include information about the plan's benefit structure or cost-sharing. We believe that materials that do not mention benefit structure or cost sharing would not be used to make an enrollment decision in a specific Medicare plan, rather they would be used to drive beneficiaries to request additional information that would fall under the new definition of marketing. Similarly, we want to be sure it is clear that the use of measuring or ranking standards, such as the CMS Star Ratings, even when not accompanied by other plan benefit structure or cost sharing information, could lead a beneficiary to make an enrollment decision. It should be noted that our authority for similar requirements can be found under the current §§ 422.2264(a)(4) and 423.2264(a)(4). We believe this is clearer and more appropriately housed under the regulatory definition of marketing. As such, together with the proposed update to excluded materials, we will make the technical change to remove (a)(4) from §§ 422.2264 and 423.2264. In addition, we propose to exclude materials that mention benefits or cost sharing but do not meet the proposed definition of marketing. The goal of this proposal is to exclude member communications that convey important factual information that is not intended to influence the enrollee's decision to make a plan selection or to stay enrolled in their current plan. An example is a monthly newsletter to current enrollees reminding them of preventive services at $0 cost sharing.

In addition, we note the proposal excludes those materials required under § 422.111 (for MA plans) and § 423.128 (for Part D sponsors), unless otherwise specified by CMS because of their use or purpose. This proposal is intended to exclude post-enrollment materials that we require be disclosed and distributed to enrollees, such as the EOC. Such materials convey important plan information in a factual manner rather than to entice a prospective enrollee to choose a specific plan or an existing enrollee to stay in a specific plan. In addition, either these materials use model formats and text developed by us or are developed by plans based on detailed instructions on the required content from us; this high level of standardization by us on the front-end provides the necessary beneficiary protections and negates the need for our review of these materials before distribution to enrollees.

The proposed changes do not release cost plans, MA organizations, or Part D sponsors from the requirements in sections 1876(c)(3)(C), 1851(h), and 1860D–1(b)(1)(B)(vi) of the Act to have application forms reviewed by CMS as well. To clarify this requirement, we are proposing to revise § 417.430(a)(1) and § 423.32(b), which pertain to application and enrollment processes, to add a cross reference to §§ 422.2262 and 423.2262, respectively. The cross references directly link enrollment applications back to requirements related to review and distribution of marketing materials. These proposed changes update an old cross-reference, codify existing practices, and are consistent with language already in § 422.60(c).

c. Prohibition of Marketing During the Open Enrollment Period

The 21st Century Cures Act (the Cures Act) amended section 1851(e)(2) of the Act by adding a new continuous open enrollment and disenrollment period (OEP) for MA and certain PDP members. See section III.A.X for CMS's other proposal related to that provision. As part of establishing this OEP, the Cures Act prohibits unsolicited marketing and mailing marketing materials to individuals who are eligible for the new OEP. We are proposing to add a new paragraph (b)(9) to both proposed §§ 422.2268 and 423.2268 to apply this prohibition on marketing. However, we request comment on how the agency could implement this statutory requirement. The new OEP is not available for enrollees in Medicare cost plans; therefore, these limitations would apply to MA enrollees and to any PDP enrollee who was enrolled in an MA plan the prior year. CMS is concerned that it may be difficult for a sponsoring organization to limit marketing to only those individuals who have not yet enrolled in a plan during the OEP. One mechanism could be to limit marketing entirely during that period, but we are concerned that such a prohibition would be too broad We believe that using a ''knowing'' standard will both effectuate the statutory provision and avoid against overly broad implementation. We welcome comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through as mailing campaigns aimed at a more general audience.

d. Technical Changes to Other Regulatory Provisions as a Result of the Changes to Subpart V

As previously stated, because of the broad regulatory definition of marketing, the term marketing and communication became synonymous. With the proposed updates to Subpart V in both part 422 and part 423, a definition of the broader term communication would be added and the definition of marketing, as well as the materials that fall within the scope of that definition, would be narrowed. As a result, a number of technical changes will be needed to update certain sections of the regulation that use the term marketing. Accordingly, we propose the following technical changes in Part C:

- In § 422.54, we propose to update paragraphs (c)(1)(i) and (d)(4)(ii) to replace ''marketing materials'' with ''communication materials.''
- In § 422.62, we propose to update paragraph (b)(3)(B)(ii) by replacing ''in marketing the plans to the individual'' with ''in communication materials.''
- In § 422.102(d), we propose to use ''supplemental benefits packaging'' instead of ''marketing of supplemental benefits.''
- In § 422.206(b)(2)(i), we propose to replace ''§ 422.80 (concerning approval of marketing materials and election forms)'' with ''all applicable requirements under subpart V''.
- In § 422.503(b)(4)(ii), we propose to replace the term ''marketing'' with the term ''communication.''
- In § 422.510(a)(4)(iii), we propose to remove the word ''marketing'' so that the reference is to the broader Subpart V.

CMS has had longstanding authority to initiate ''marketing sanctions'' in conjunction with enrollment sanctions as a means of protecting beneficiaries from the confusion that stems from receiving information provided by a plan that is—as a result of enrollment sanctions—unable to accept enrollments. In this rulemaking, CMS is proposing to replace the term ''marketing'' with ''communications'' in § 422.750 and 422.752 to reflect its proposal for Subpart V. The intent of this proposal to change the terminology is not to expand the scope of CMS's authority with respect to sanction regulations. Rather, CMS intends to preserve the existing reach of its sanction authority it currently has—to prohibit any communications under the current broad definition of ''marketing materials'' from being issued by a sponsoring organization while that entity is under sanction. For this reason, CMS is proposing the following changes to §§ 422.750 and 422.752:

- In § 422.750, we propose to revise paragraph (a)(3) to refer to suspension of ''communication activities.''
- In § 422.752, we propose to replace the term ''marketing'' in paragraph (a)(11) and the heading for paragraph (b) with the term ''communications.''

We are not proposing any changes to the use of the term ''marketing'' in §§ 422.384, 422.504(a)(17), 422.504(d)(2)(vi), or 422.514, as those regulations use the term in a way that is consistent with the proposed definition of the term ''marketing,'' and the underlying requirements and standards do not need to be extended to all communications from an MA organization.

We also propose the following technical changes in Part D:

- In § 423.38(c)(8)(i)(C), we propose to revise the paragraph to read: ''The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials.''
- In § 423.504(b)(4)(ii), we propose to replace ''marketing'' with ''communications'' to reflect the change to Subpart V.

For the reasons explained in connection with our proposal to revise the Part C sanction regulations, we also propose the following changes:

- In § 423.505(b)(25), we propose to replace ''marketing'' with ''communications'' to reflect the change to Subpart V.
- In § 423.509(a)(4)(V)(A), we propose to delete the word ''marketing'' and instead simply refer to Subpart V.

We are not proposing any changes to the use of the term ''marketing'' in §§ 423.505(d)(2)(vi), 423.871(c), or 423.756(c)(3)(ii), as those regulations use the term in a way that is consistent with the proposed definition of the term ''marketing,'' and the underlying requirements and standards do not need to be extended to all communications from a PDP sponsor.

We solicit comment on the proposed technical changes, particularly whether a proposed revision here would be more expansive than anticipated or have unintended consequences for sponsoring organizations or for CMS's oversight and monitoring of the MA and Part D programs.

In conclusion, we believe that our proposal here—the proposed definitions of ''communications,'' ''communications materials,'' ''marketing,'' and ''marketing materials;'' and the various proposed changes to Subpart V; to distinguish between prohibitions applicable to communications and those applicable to marketing; and to conform § 417.430(a)(1) and § 423.32(b) to § 422.60(c) and reflect the statutory direction regarding enrollment materials; all maintain the appropriate level of beneficiary protection. These proposals will facilitate and focus our oversight of marketing materials, while appropriately narrowing the scope of what is considered marketing. We believe beneficiary protections are further enhanced by adding communication materials and associated standards under Subpart V. These changes allow us to focus its oversight efforts on plan marketing materials that have the highest potential for influencing a beneficiary to make an enrollment decision that is not in the beneficiary's best interest. We solicit comment on these proposals and whether the appropriate balance is achieved with the proposed regulation text.

6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636)

Sections 1860D–4(g) and (h) of the Act require the Secretary to establish processes for initial coverage determinations and appeals similar to those used in the Medicare Advantage program. In accordance with section 1860D–4(g) of the Act, § 423.590 establishes Part D plan sponsors' responsibilities for processing redeterminations, including adjudication timeframes. Pursuant to section 1860D–4(h) of the Act, § 423.600 sets forth the requirements for an independent review entity (IRE) for processing reconsiderations.

We are proposing changes to the adjudication timeframe for Part D standard redetermination requests for payment at § 423.590(b) and the related effectuation provision § 423.636(a)(2). Specifically, we are proposing to change the timeframe for issuing decisions on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request. This proposed 14-day timeframe for issuing a decision related to a payment request would also apply to the IRE reconsideration pursuant to § 423.600(d). We are not proposing to make changes to the existing requirements for making payment. When applicable, the Part D plan sponsor must make payment no later than 30 days from receipt of the request

for redetermination, or the IRE reconsideration notice, respectively.

Some of the feedback received from the RFI published in the 2018 Call Letter related to simplifying and establishing greater consistency in Part D coverage and appeals processes. The proposed change to a 14 calendar day adjudication timeframe for payment redeterminations, which would also apply to payment requests at the IRE reconsideration level of appeal, will establish consistency in the adjudication timeframes for payment requests throughout the plan level and IRE processes, as § 423.568(c) requires a plan sponsor to notify the enrollee of its determination no later than 14 calendar days after receipt of the request for payment. We believe affording more time to adjudicate payment redetermination requests (including obtaining necessary documentation to support the request) will ease burden on plan sponsors because it could reduce the need to deny payment redeterminations due to missing information. We also expect the proposed change to the payment redetermination timeframe would reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE.

In addition, having more time to gather information and process these requests could be beneficial to enrollees because decisions will be more fully informed, potentially resulting in fewer decisions having to undergo further appeal. While we acknowledge that some enrollees would have to wait longer for a decision, we note that the proposed changes are limited to payment requests where the enrollee has already received the drug, ensuring any delay would not adversely affect the enrollee's health. As noted previously, when coverage is approved, the plan would remain obligated to remit payment to affected enrollees within 30 days. Allowing plan sponsors and the IRE additional time to process payment appeal requests may assist these adjudicators in allocating resources in a manner that is most efficient and enrollee friendly, for example, ensuring adequate resources are directed to processing more time-sensitive pre-service requests where the enrollee has not yet obtained the drug, particularly during periods of increased case volume.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590)

Section 1852(g) of Act requires MA organizations to have a procedure for making timely determinations regarding whether an enrollee is entitled to receive a health service and any amount the enrollee is required to pay for such service. Under this statutory provision, the MA plan also is required to provide for reconsideration of that determination upon enrollee request.

In accordance with section 1852(g) of the Act, our current regulations at §§ 422.578, 422.582, and 422.584 provide MA enrollees with the right to request reconsideration of a health plan's initial decision to deny Medicare coverage. Pursuant to § 422.590, when the MA plan upholds initial payment or service denials, in whole or in part, it must forward member case files to an independent review entity (IRE) that contracts with CMS to review plan-level appeals decisions; that is, plans are required to automatically forward to the IRE any reconsidered decisions that are adverse or partially adverse for an enrollee without the enrollee taking any action.

Currently, MA plans are required to notify enrollees upon forwarding cases to the IRE, as set forth at § 422.590(f). CMS sub-regulatory guidance, set forth in Chapter 13 of the Medicare Managed Care Manual, specifically directs plans to mail a notice to the enrollee informing the individual that the plan has upheld its decision to deny coverage, in whole or in part, and thus is forwarding the enrollee's case file to the IRE for review. We have made a model notice available for plans to use for this purpose. (See Medicare Managed Care Manual, Chapter 13, § 10.3.3, 80.3, and Appendix 10.) In addition, the Part C IRE is required, under its contract with CMS, to notify the enrollee when the IRE receives the reconsidered decision for review. We are proposing to revise § 422.590 to remove paragraph (f) and redesignate the existing paragraphs (g) and (h) as (f) and (g), respectively. The Part C IRE is contractually responsible for notifying an enrollee that the IRE has received and will be reviewing the enrollee's case; thus, we believe the plan notice is duplicative and nonessential. Under this proposal, the IRE would be responsible for notifying enrollees upon forwarding all cases—including both standard and expedited cases. We will continue to closely monitor the performance of the IRE and beneficiary complaints related to timely and appropriate notification that the IRE has received and will be reviewing the enrollee's case.

We received feedback in response to the Request for Information included in the 2018 Call Letter related to simplifying and streamlining appeals processes. To that end, we believe this proposed change will help further these goals by easing burden on MA plans without compromising informing the beneficiary of the progress of his or her appeal. If this proposal is finalized, and plans are no longer required to notify an enrollee that his or her case has been sent to the IRE, we would expect plans to redirect resources previously allocated to issuing this notice to more time-sensitive activities such as review of pre-service and post-service coverage requests, improved efficiency in appeals processing, and provision of health benefits in an optimal, effective, and efficient manner.

8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

a. Legislative Background

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced

over time to ensure that the standards did not hold back progress in the industry. We discussed these processes in the November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified ''updating process'' when a non-HIPAA standard could be updated with a newer ''backward-compatible'' version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted non-HIPAA standard without modification, however, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**. We utilized this streamlined process when we published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0 for the specified transactions, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, we used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard for the specified transactions. On July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).

We finalized the NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, and retired NCPDP SCRIPT 8.1 and adopted the NCPDP SCRIPT 10.6 as the official Part D e-Prescribing Standard for the specified transactions in the CY 2013 Physician Fee Schedule, effective November 1, 2013. For a more detailed discussion, see the CY 2013 PFS final rule (77 FR 69329 through 69333).

c. Proposed adoption of NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in 423.160, and correction of a historic typographical error in the regulatory text which occurred when NCPDP SCRIPT 10.6 was initially adopted.

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who are interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP has developed the NCPDP SCRIPT standard for use by prescribers, dispensers, pharmacy benefit managers (PBMs), payers and other entities who wish to electronically transmit information about prescriptions and prescription-related information. NCPDP has periodically updated its SCRIPT standard over time, and three separate versions of the NCPDP SCRIPT standard, versions 5.0, 8.1 and most recently 10.6 have been adopted by CMS for the part D e-prescribing program through the notice and comment rulemaking process. We believe that our current proposal to adopt the NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for certain specified transactions, and to retire the current standard for those transactions would, among other things, improve communications between the prescriber and dispensers, and we welcome public comment on these proposals.

Our actions were, in part, precipitated by a May 24, 2017, letter from the NCPDP that requested our adoption of NCPDP SCRIPT Standard Version 2017071. This version was balloted and approved July 28, 2017. The letter noted the considerable amount of time that had passed since the last update to the current adopted standard (NCPDP SCRIPT 10.6), and that there were many changes to the NCPDP SCRIPT Standard version 2017071 that would benefit its users.

CMS reviewed the specifications for NCPDP SCRIPT Standard Version 2017071 and found that this version would allow users substantial improvements in efficiency. Version 2017071 supports communications regarding multi-ingredient compounds, thereby allowing compounded medication to be prescribed electronically. Previously prescriptions for compounds were handwritten and sent via fax to the dispenser, which often required follow up communications between the prescriber and pharmacy. The ability to process prescriptions for compounds electronically in lieu of relying on more time intensive interpersonal interactions would be expected to improve efficiency.

While we do not propose mandating its use at this time, one transaction supported by the proposed version of NCPDP SCRIPT would also provide interested users with a Census transaction functionality which is designed to service beneficiaries residing in long term care. The Census feature would trigger timely notification of a beneficiary's absence from a long term care facility, which would enable discontinuation of daily medication dispensing when a leave of absence occurs, thereby preventing the dispensing of unneeded medications. Version 2017071 also contains an enhanced Prescription Fill Status Notification that allows the prescriber to specify if/when they want to receive the notifications from the dispenser. It now supports data elements for diabetic supply prescriptions and includes elements which could be required for the pharmacy during the dispensing process which may be of value to prescribers who need to closely monitor medication adherence.

We therefore believe that the functionalities offered by NCPDP SCRPT 2017071 could offer efficiencies to the industry, and believe that it would be an appropriate e-prescribing standard for the transactions currently covered by the Medicare Part D program. Furthermore, NCPDP SCRIPT 2017071 supports transactions new to the part D e-prescribing program that we believe would prove beneficial to the industry. Therefore, in addition to the transactions for which prior versions of NCPDP SCRIPT were adopted (as reflected in the current regulations at 423.160(b)), we propose to require use of NCPDP SCRPT 2017071 for the following transactions:

- Prescription drug administration message,
- New prescription requests,
- New prescription response denials,
- Prescription transfer message,
- Prescription fill indicator change,
- Prescription recertification,
- Risk Evaluation and Mitigation Strategy (REMS) initiation request,
- REMS initiation response, REMS request, and
- REMS response.

We believe that transitioning to the new 2017071 versions of the transactions already covered by the current part D e-prescribing standard (version 10.6 of the NCPDP SCRIPT) will impose deminimus cost on the

industry as the burden in using the updated standards is anticipated to be the same as using the old standards for the transactions currently covered by the program. We are also proposing adoption of version 2017071 of the NCPDP SCRIPT standards for the nine new transactions to replace manual processes that currently occur. Reducing the manual processes currently used to support these transactions will improve efficiency, accuracy, and user satisfaction with the system. While system implementation may result in minimal expenses, we believe that these minimal expenses will be more than offset by rendering these manual transactions obsolete. That is, we believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 10.6 in favor of NCPDP SCRIPT 2017071 will result in significant costs.

As such, we are proposing to revise § 423.160(b)(1)(iv) so as to limit its application to transactions before January 1, 2019 and add a new § 423.160(b)(1)(v). The requirement at § 423.160(b)(1)(v) would identify the standards that will be in effect on or after January 1, 2019, for those that conduct e-prescribing for part D covered drugs for part D eligible beneficiaries. If finalized, those individuals and entities would be required to use NCPDP SCRIPT 2017071 to convey prescriptions and prescription-related information for the following transactions:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription request transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill/Resupply prescription request transaction.
- Refill/Resupply prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.
- Fill status notification.
- Prescription drug administration message.
- New prescription requests.
- New prescription response denials.
- Prescription transfer message.
- Prescription fill indicator change.
- Prescription recertification.
- Risk Evaluation and Mitigation Strategy (REMS) initiation request.
- REMS initiation response, REMS request
- REMS initiation response.
- REMS request.
- REMS response.

We are also proposing to adopt NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for the medication history transaction at § 423.160(b)(4). As a result, we are also proposing to retire NCPDP SCRIPT versions 8.1 and 10.6 for medication history transactions transmitted on or after January 1, 2019.

Furthermore, we propose to amend § 423.160(b)(1) by modifying § 423.160(b)(1)(iv) to limit usage of NCPDP SCRIPT version 10.6 to transactions before January 1, 2019.

In addition, we propose to add § 423.160(b)(1)(v) to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. Furthermore, we are proposing to amend § 423.160(b)(2) by adding § 423.160(b)(2)(iv) to name NCPDP SCRIPT Version 2017071 for the applicable transactions. Finally, we propose to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations. We seek comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed § 423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.

We are also proposing a technical correction of a prior regulation. On July 30, 2012, we published regulation (CMS–1590–P), which established version 10.6 as the Part D e-prescribing standard effective March 1, 2015 for certain electronic transactions that convey prescription or prescription related information, as listed in § 423.160(b)(2)(iii). However, despite the regulation clearly noting adoption of NCPDP SCRIPT 10.6 as the part D e-prescribing standard for the listed transactions, due to a typographical error, § 423.160(b)(1)(iv) references (b)(2)(ii) (NCPDP SCRIPT 8.1), rather than (b)(2)(iii) (NCPDP SCRIPT 10.6). We propose a correction of this typographical error by changing the reference at § 423.160 (b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii).

In proposing updates to the Part D E-Prescribing Standards CMS has reviewed specification documents developed by the National Council for Prescription Drug Programs (NCPDP). The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble to the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the materials.

Consistent with those requirements CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposed update to the Part D prescribing standards has relied on the NCPDP SCRIPT Implementation Guide Version 2017071 approved July 28, 2017. Members of the NCPDP may access these materials through the member portal at *www.ncpdp.org*; non-NCPDP members may obtain these materials for information purposes by contacting the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Mailstop C1–26–05, or by calling (410) 786– 3694.

9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§ 422.502 and 423.503)

In April 2010, we clarified our authority to deny contract qualification applications from organizations that have failed to comply with the requirements of a Medicare Advantage or Part D plan sponsor contract they currently hold, even if the submitted application otherwise demonstrates that the organization meets the relevant program requirements. As part of that rulemaking, we established, at § 422.502(b)(1) and § 423.503(b)(1), that we would review an applicant's prior contract performance for the 14-month period preceding the application submission deadline (see 75 FR 19684 through 19686). We conduct that review in accordance with a methodology we publish each year [58] and use to score each applicant's performance by assigning weights based on the severity of its non-compliance in several

[58] *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Final_2018_Application_Cycle_Past_Performance_Methodology.pdf.*

performance categories. Under the annual contract qualification application submission and review process we conduct, organizations must submit their application by a date, usually in mid-February, announced by us. We now propose to reduce the past performance review period from 14 months to 12 months.

We originally established the 14-month review period because it covered the time period from the start of the preceding contract year through the date on which CMS receives contract applications for the upcoming contract year. We believed at the time that the combination of the most recent complete contract year and the 2 months preceding the application submission provided us with the most complete picture of the most relevant information about an applicant's past contract performance. Our application of this authority since its publication has prompted comments from contracting organizations that the 14-month period is too long and is unfair as it is applied. In particular, organizations have noted that non-compliance that occurs during January and February of a given year is counted against an organization in 2 consecutive past performance review cycles while non-compliance occurring in all other months is counted in only one review cycle. The result is that some non-compliance is ''double counted'' based solely on the timing of the non-compliance and can, depending on the severity of the non-compliance, prevent an organization from receiving CMS approval of their application for 2 consecutive years.

Rather than creating a gap in the look-back period, as we were concerned in 2010, 75 FR 19685, we now believe a 12-month look-back period provides a more accurate period to consider. We believe it is still important to capture in each review cycle an applicant's most recent contract performance. Therefore, we propose to revise § 422.502(b)(1) and § 423.503(b)(1) to reduce the review period from 14 to 12 months. This would effectively establish a new review period for every application review cycle of March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted and would eliminate the counting of instances of non-compliance in January and February of each year in 2 separate application cycles. We also propose to have this review period change reflected consistently in the Part C and D regulation by revising the provisions of § 422.502(b)(2) and § 423.503(b)(2) to state that CMS may deny an application from an existing Medicare Advantage or Part D plan sponsor in the absence of a record of at least 12, rather than 14, months of Medicare contract performance by the applicant. We do not intend to change any other aspect of our consideration of past performance in the application process.

10. Preclusion List—Part D Provisions

a. Background

(1) 2014 Final Rule

On May 23, 2014, we published a final rule in the **Federal Register** titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29844). Among other things, this final rule implemented section 6405(c) of the Affordable Care Act, which provides the Secretary with the authority to require that prescriptions for covered Part D drugs be prescribed by a physician enrolled in Medicare under section 1866(j) of the Act (42 U.S.C. 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w–4(k)(3)(B)). More specifically, the final rule revised § 423.120(c)(5) and added new § 423.120(c)(6), the latter of which 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 (that is, original Medicare); or (2) a valid opt out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC).

The purpose of this change was to help ensure that Part D drugs are prescribed only by qualified prescribers. In a June 2013 report titled ''Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority'' (OEI–02–09–00608), the Office of Inspector General (OIG) found that the Part D program improperly paid for drugs prescribed by persons who did not appear to have the authority to prescribe. We also noted in the final rule the reports we received of prescriptions written by physicians with suspended licenses having been covered by the Part D program. These reports raised concerns within CMS about the propriety of Part D payments and the potential for Part D beneficiaries to be prescribed dangerous or unnecessary drugs by individuals who lack the authority or qualifications to prescribe medications. Given that the Medicare FFS provider enrollment process, as outlined in 42 CFR part 424, subpart P, collects identifying information about providers and suppliers who wish to enroll in Medicare, we believed that forging a closer link between Medicare's coverage of Part D drugs and the provider enrollment process would enable CMS to confirm the qualifications of the prescribers of such drugs. That is, requiring Part D prescribers to enroll in Medicare would provide CMS with sufficient information to determine whether a physician or eligible professional is qualified to prescribe Part D drugs.

We stated in the May 23, 2014 final rule that the compliance date for our revisions to new § 423.120(c)(6) would be June 1, 2015. We believed that this delayed date would give physicians and eligible professionals who would be affected by these provisions adequate time to enroll in or opt-out of Medicare. It would also allow CMS, A/B MACs, Medicare beneficiaries, and other impacted stakeholders sufficient opportunity to prepare for these requirements.

(2) 2015 Interim Final Rule

On May 6, 2015, we published in the **Federal Register** an interim final rule with comment period (IFC) titled ''Medicare Program; Changes to the Requirements for Part D Prescribers'' (80 FR 25958). This IFC made changes to certain requirements outlined in the May 23, 2014 final rule related to beneficiary access to covered Part D drugs.

First, we changed the compliance date of § 423.120(c)(6) from June 1, 2015 to January 1, 2016. This was designed to give all affected parties more time to prepare for the additional provisions included in the IFC before Part D drugs prescribed by individuals who are neither enrolled in nor opted-out of Medicare are no longer covered.

Second, we revised paragraph § 423.120(c)(6)(ii) to address a gap in § 423.120(c)(6) regarding certain types of prescribers; such prescribers included pharmacists who may be authorized under state law to prescribe medications but are ineligible to enroll in Medicare and thus, under § 423.120(c)(6), would not have their prescriptions covered. Revised paragraph (c)(6)(ii) stated that pharmacy claims and beneficiary requests for reimbursement for Part D prescriptions written by prescribers other than physicians and eligible professionals who are nonetheless permitted by state or other applicable law to prescribe medications (defined in § 423.100 as ''other authorized prescribers'') will not be rejected or denied, as applicable, by the pharmacy benefit manager (PBM) if all other requirements are met. This meant that

the enrollment requirement specified in § 423.120(c)(6) would not apply to other authorized prescribers—that is, to individuals who are ineligible to enroll in or opt out of Medicare because they do not meet the statutory definition of ''physician'' or ''eligible professional'' yet who are otherwise legally authorized to prescribe drugs.

Third, and to help ensure that beneficiaries would not experience a sudden lapse in Part D prescription coverage upon the January 1, 2016 effective date, we added a new paragraph § 423.120(c)(6)(v). This provision stated that a Part D sponsor or its PBM must, beginning on January 1, 2016 and upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor or PBM would otherwise be required to reject or deny, as applicable, under § 423.120(c)(6):

• Provide the beneficiary with:

++ A 3-month provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and

++ Written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS; and

• Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent the notice referred to in the previous paragraph.

The 3-month provisional supply and written notice were intended to (1) notify beneficiaries that a future prescription written by the same prescriber would not be covered unless the prescriber enrolled in or opted-out of Medicare, and (2) give beneficiaries time to make arrangements to continue receiving the prescription if the prescriber of the medication did not intend to enroll in or opt-out of Medicare.

(3) Preparations for Enforcement of Part D Prescriber Enrollment Requirement

Immediately after the publication of the previously mentioned May 23, 2014 final rule, we undertook major efforts to educate affected stakeholders about the forthcoming enrollment requirement. Particular focus was placed on reaching out to Part D prescribers with information regarding (1) the overall purpose of the enrollment process; (2) the important program integrity objectives behind § 423.120(c)(6); (3) the mechanisms by which prescribers may enroll in Medicare (for example, via the Internet based Provider Enrollment, Chain and Ownership System (PECOS); and (4) how to complete an enrollment application. Numerous prescribers have, in preparation for the enforcement of § 423.120(c)(6), enrolled in or opted out of Medicare, and we are appreciative of their cooperation in this effort. However, based on internal CMS data, as of July 2016 approximately 420,000 prescribers—or 35 percent of the total 1.2 million prescribers of Part D drugs—whose prescriptions for Part D drugs would be affected by the requirements of § 423.120(c)(6) have yet to enroll or opt out. Of these prescribers, 32 percent are dentists, 11 percent are student trainees, 7 percent are nurse practitioners, 6 percent are pediatric physicians, and 5 percent are internal medicine physicians.

Several provider organizations, moreover, have expressed concerns about the enrollment requirements. They have contended that (1) most prescribers pose no risk to the Medicare program; and (2) certain types of physicians and eligible professionals prescribe Part D drugs only very infrequently. Their general position, in short, is that the burden to the prescriber community would outweigh the payment safeguard benefits of § 423.120(c)(6). After the publication of the IFC, and based on our desire to give prescribers and other stakeholders more time to prepare for the enrollment requirements, we announced a phased-in enforcement of the enrollment requirements and stated that full enforcement would be delayed until January 1, 2019. (Information was posted at the following link: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Prescriber-Enrollment-Information.html*.) However, the concerns of these provider organizations remain.

We do recognize these concerns. We wish to reduce as much burden as possible for providers without compromising our program integrity objectives. In addition, over 400,000 prescribers remain unenrolled and, as a consequence, approximately 4.2 million Part D beneficiaries (based on analysis performed on 2015 and 2016 PDE data) could lose access to needed prescriptions when full enforcement of the enrollment requirement begins on January 1, 2019 unless their prescriber enrolls or opt outs or they change prescribers. We believe that an appropriate balance is possible between burden reduction and the need to protect Medicare beneficiaries and the Trust Funds. To this end, we propose several changes to § 423.120(c)(6).

b. Proposed Provisions

In accordance with section 1871 of the Act, within 3 years of the publication of the May 6, 2015 IFC, we must either publish a final rule or publish a notice of a different timeline. If we finalize the proposals described in this notice of proposed rulemaking, we would not finalize the provisions of the IFC. Instead, the proposals described in this publication would supersede our earlier rulemaking.

The effective date of our proposed provisions in § 423.120(c)(5) would be 60 days after the publication of a final rule. The effective date of our proposed revisions to § 423.120(c)(6) would be January 1, 2019.

(1) Prescriber NPI Validation on Part D Claims

(a) Provisions of § 423.120(c)(5)

Section 423.120(c)(5) states that before January 1, 2016, the following are applicable:

• In paragraph (c)(5)(i), we state that a Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

• In paragraph (c)(5)(ii), we state that a Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.

• In paragraph (c)(5)(iii), we state that the sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).

++ In paragraph (c)(5)(iii)(A), we state that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to (1) confirm that the NPI is active and valid; or (2) correct the NPI.

++ In paragraph (c)(5)(iii)(B), we state that if the pharmacy:

++ Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or

++ Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

• In paragraph (c)(5)(iv), we state that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

++ Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

++ Has verified that a submitted NPI was not in fact active and valid; and

++ The agreement between the parties explicitly permits such recoupment.

• In paragraph (c)(5)(v), we state that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

These provisions, which focus on NPI submission and validation, are no longer effective because the January 1, 2016 end-date for their applicability has passed. Since that time, however, and as explained in detail in section (b)(1)(b) below, congressional legislation requires us to revisit some of the provisions in former paragraph (c)(5) and, as warranted, to re-propose them in what would constitute a new paragraph (c)(5). We believe that these new provisions would not only effectively implement the legislation in question but also enhance Part D program integrity by streamlining and strengthening procedures for ensuring the identity of prescribers of Part D drugs. This would be particularly important in light of our preclusion list proposals.

(b) Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

MACRA was signed into law on April 16, 2015, just before the IFC was finalized. Section 507 of MACRA amends section 1860D–4(c) of the Act (42 U.S.C. 1395w–104(6)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders, beginning with plan year 2016.

In light of the enactment of MACRA, on June 1, 2015, we issued a guidance memo, ''Medicare Prescriber Enrollment Requirement Update'' (memo). The memo noted that § 423.120(c)(5) would no longer be applicable beginning January 1, 2016 due to the IFC we had just published, but that its provisions reflected certain existing Part D claims procedures established by the Secretary in consultation with stakeholders through the National Council for Prescription Drug Programs (NCPDP) that would comply with section 507 of MACRA, except one.

The provisions in § 423.120(c)(5) that reflected the procedures that would comply with section 507 of MACRA are the following:

• Paragraph (c)(5)(iii).
• Paragraph (c)(5)(iii)(A).
• Paragraph (c)(5)(iii)(B)(1). (Note that paragraph (c)(5)(iii)(B)(2) would not comply with section 507 because the sponsor has no evidence that the NPI is active or valid.)
• Paragraph (c)(5)(iv).
• Paragraph (c)(5)(v).

Given this, we are proposing to include these provisions in new paragraph (c)(5). They would be enumerated as, respectively, new paragraphs (c)(5)(ii), (c)(5)(ii)(A), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv). Current paragraphs (c)(5)(i), (c)(5)(ii), and (c)(5)(iii)(B)(2) would not be included in new paragraph (c)(5).

We also note that in the May 6, 2015 IFC, we revised § 423.120(c)(6)(i) to require a Part D plan sponsor to reject, or require its pharmaceutical benefit manager (PBM) to reject, a pharmacy claim for a Part D drug, unless the claim contains the NPI of the prescriber who prescribed the drug. This provision, too, reflects existing Part D claims procedures and policies that comply with section 507 of MACRA. We thus propose to retain this provision and seek comment on associated burdens or unintended consequences and alternative approaches. However, we wish to move it from paragraph (c)(6) to paragraph (c)(5) so that most of the NPI provisions in § 423.120 are included in one subsection. We believe this would improve clarity.

(2) Targeted Approach to Part D Prescribers

We believe that the most effective means of reducing the burden of the Part D enrollment requirement on prescribers, Part D plan sponsors, and beneficiaries without compromising our payment safeguard aims would be to concentrate our efforts on preventing Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries and the Trust Funds. In other words, rather than require the enrollment of Part D prescribers regardless of the possible level of risk posed, we propose to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers.

There is precedent for such a risk based approach. For instance, consistent with § 424.518, A/B MACs are required to screen applications for enrollment in accordance with a CMS assessment of risk and assignment to a level of ''limited,'' ''moderate,'' or ''high.'' Applications submitted by provider and supplier types that have historically posed higher risks to the Medicare program are subjected to a more rigorous screening and review process than those that present limited risks. Moreover, § 424.518 states that providers and suppliers that have had certain adverse actions imposed against them, such as felony convictions or revocations of enrollment, are placed into the highest and most rigorous screening level. We recognize that the risk based approach in § 424.518 applies to enrollment application screening rather than payment denials. However, we believe that using a risk-based approach would enable CMS to focus on prescribers who pose threats to the Medicare program and its beneficiaries, while minimizing the burden on those who do not. The process we envision and propose, which would replace the prescriber enrollment requirement outlined in § 423.120(c)(6) with a claims payment-oriented approach, would consist of the following components:

• Step 1: We would research our internal systems and other relevant data for prescribers who have engaged in behavior for which CMS:

++ Has revoked the prescriber's enrollment and the prescriber is under a reenrollment bar; or

++ Could have revoked the prescriber (to the extent applicable) if he or she had been enrolled in Medicare.

Concerning revocations, we have the authority to revoke a provider's or supplier's Medicare enrollment for any of the applicable reasons listed in § 424.535(a). There are currently 14 such reasons. When revoked, the provider or supplier is barred under § 424.535(c) from reenrolling in Medicare for a period of 1 to 3 years, depending upon the severity of the underlying behavior. We have an obligation to protect the Trust Funds from providers and suppliers that engage in activities that could threaten the Medicare program, its beneficiaries, and the taxpayers. In light of the significance of behavior that could serve as grounds for revocation, we believe that prescribers who have engaged in inappropriate activities should be the focus of our Part D program integrity efforts under § 423.120(c)(6).

• Step 2—We would review, on a case-by-case basis, each prescriber who—

++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the prescriber's revocation.

++ Has engaged in behavior for which CMS could have revoked the

prescriber to the extent applicable if he or she had been enrolled in Medicare.

The prescribers to be reviewed would be those who, according to PDE data and CMS' internal systems, are eligible to prescribe drugs covered under the Part D program. That is, our review would not be limited to those persons who are actually prescribing Part D drug, but would include those that potentially could prescribe drugs. We believe that the inclusion of these individuals in our review would help further protect the integrity of the Part D program.

We are also seeking comment on an alternative by which we would first identify, through PDE data, those providers who are prescribing drugs to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We anticipate that this could create delays in our ability to screen providers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries, especially in light of our efforts to address the opioids epidemic.

• Step 3—Based on the results of Steps 1 and 2, we would compile a ''preclusion list'' of prescribers who fall within either of the following categories:

++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

++ Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of prescribers in the Medicare Part D program. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances.

(i) Preclusion List

Considering the program integrity risk that the two previously mentioned sets of prescribers present, we must be able to accordingly protect Medicare beneficiaries and the Trust Funds. We thus propose to revise § 423.120(c)(6), as further specified in this proposed rule, to require that a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug prescribed by an individual on the preclusion list. We believe we have the legal authority for such a provision because sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program; also, section 1860D–12(b)(3)(D) of the Act authorizes the Secretary to add additional Part D contract terms as necessary and appropriate, so long as they are not inconsistent with the Part D statute. We note also that our proposal is of particular importance when considering the current nationwide opioid crisis. We believe that the inclusion of problematic prescribers on the preclusion list could reduce the amount of opioids that are improperly or unnecessarily prescribed by persons who pose a heightened risk to the Part D program and Medicare beneficiaries.

All grounds for revocation under § 424.535(a) reflect behavior or circumstances that are of concern to us. However, considering the variety of factual scenarios that CMS may come across, we believe it is necessary for CMS to have the flexibility to take into account the specific circumstances involved when determining whether the underlying conduct is detrimental to the best interests of the Medicare program. Accordingly, CMS would consider the following factors in making this determination:

• The seriousness of the conduct involved;

• The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

• Any other evidence that CMS deems relevant to its determination.

We emphasize that in situations where the prescriber was enrolled and then revoked, CMS' determination would not negate the revocation itself. The prescriber would remain revoked from Medicare.

We also recognize that unique circumstances behind the potential or actual inclusion of a particular prescriber on the preclusion list could exist. Of foremost importance would be situations pertaining to beneficiary access to Part D drugs. We believe that we should have the discretion not to include (or, if warranted, to remove) a particular individual on the preclusion list (who otherwise meets the standards for said inclusion) should exceptional circumstances exist pertaining to beneficiary access to prescriptions. This could include circumstances similar to those described in section 1128(c)(3)(B) of the Act, whereby the Secretary may waive an OIG exclusion under section 1128(a)(1), (a)(3), or (a)(4) of the in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. In making a determination as to whether such circumstances exist, we would take into account— (1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.

With respect to the foregoing, we solicit comment on the following issues:

++ Whether the actions referenced in § 424.535(a) are appropriate grounds for inclusion on the preclusion list.

++ Whether actions other than those referenced in § 424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.

++ Suggestions for means of monitoring abusive prescribing practices and appropriate processes for including such prescribers on the preclusion list.

(b) Replacement of Enrollment Requirement With Preclusion List Requirement

We are proposing to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. We also propose to generally streamline the existing regulations because, given that we would no longer be requiring certain prescribers to enroll or opt out, we would no longer need an exception for ''other authorized providers,'' as defined in § 423.100, for there would be no enrollment requirement from which to exempt them. Instead, we would require plan sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list. We believe this latter approach would better facilitate our dual goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks.

(ii) Updates to Preclusion List

The preclusion list would be updated on a monthly basis. Prescribers would be added or removed from the list based on CMS' internal data that indicate, for instance: (1) Prescribers who have recently been convicted of a felony that,

consistent with § 424.535(a)(33), CMS determines to be detrimental to the best interests of the Medicare program, and (2) prescribers whose reenrollment bars have expired. As a particular prescriber's status with respect to the preclusion list changes, the applicable provisions of § 423.120(c)(6) would control. To illustrate, suppose a prescriber in March 2020 is convicted of a felony that CMS deems detrimental to Medicare's best interests. Pharmacy claims for prescriptions written by the individual would thus be rejected by Part D sponsors or their PBMs upon the prescriber being added to the preclusion list. Conversely, a prescriber who was revoked under § 424.535(a)(4) but whose reenrollment bar has expired would be removed from the preclusion list; claims for prescriptions written by the individual would therefore no longer be rejected based solely on his or her inclusion on the preclusion list. CMS would regularly review the preclusion list to determine whether certain individuals should be added to or removed therefrom based on changes to their status.

Consistent with our application of a reenrollment bar to providers and suppliers that are enrolled in and then revoked from Medicare, we propose to keep an unenrolled prescriber on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber had he or she been enrolled and then revoked. For example, suppose an unenrolled prescriber engaged in behavior that, had he or she been enrolled, would have warranted a 2-year reenrollment bar. The prescriber would remain on the preclusion list for that same period of time. We note that in establishing such a time period, we would use the same criteria that we do in establishing reenrollment bars.

Prescribers who were revoked from Medicare or, for unenrolled prescribers, engaged in behavior that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of § 423.120(c)(6) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. However, the Part D claim rejections by Part D sponsors and their PBMs under § 423.120(c)(6) would only apply to claims for Part D prescriptions filled or refilled on or after the date he or she was added to the preclusion list; that is, sponsors and PBMs would not be required to retroactively reject claims based on the effective date of the revocation or, for unenrolled prescribers, the date of the behavior that could serve as a basis for an applicable revocation regardless of whether that date occurred before or after the effective date of this rule.

We do seek comment on a reasonable time period for Part D sponsors/PBMs to incorporate the preclusion list into their claims adjudication systems, and whether and how our proposed regulatory text needs to be modified to accommodate such a time period. We wish to avoid a situation where a Part D sponsor/PBM pays for prescriptions written by individuals on the preclusion list before the sponsors/PBMs have incorporated the list but later are unable to submit their PDEs, which CMS typically edits based on date of service.

(3) Provisional Coverage

The current text of § 423.120(c)(6)(v) states that a Part D sponsor or its PBM must, upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to deny in accordance with § 423.120(c)(6), furnish the beneficiary with (a) a provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and (b) written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS. The purpose of this provisional supply requirement is to give beneficiaries notice that there is an issue with respect to future Part D coverage of a prescription written by a particular prescriber.

Although CMS' proposed changes to § 423.120(c)(6) would significantly reduce the number of affected prescribers and, by extension, the number of impacted beneficiaries, we remain concerned that beneficiaries who receive prescriptions written by individuals on the preclusion list might suddenly no longer have access to these medications without provisional coverage and without notice, which gives beneficiaries time to find a new prescriber. Therefore, we propose to maintain the provisional coverage requirement consistent with what was finalized in the IFC, but with a modification. Additionally, many commercial plans are pursuing policies to address the opioid epidemic, such as limiting the amount of initial opioid prescriptions. Given the opioid epidemic, we are considering other solutions for when a beneficiary tries to fill an opioid prescription from a provider on the preclusion list. We seek comment as to what limits or other guardrails CMS should set with respect to number of doses, initial dosing, and type of product for opioid prescriptions for particular clinical presentations (including acute pain, chronic pain, hospice setting and so forth).

An alternative method of ensuring beneficiaries have access to opioids as necessary would be to require the sponsor immediately provide a transfer to a new provider when the first provider is on the preclusion list. The new provider should be able to make an assessment and either provide appropriate SUD treatment or continue the opioid or pain management regimen, as medically appropriate. We are interested to hear from commenters how to operationalize this and whether there is a better method to ensure appropriate medication is provided without transferring the beneficiary to a new provider. We are proposing a 90-day provisional coverage period in lieu of a 3-month drug supply/90-day time period established in existing § 423.120(c)(6), which was described on page 6 in the Technical Guidance on Implementation of the Part D Prescriber Enrollment Requirement (Technical Guidance) issued on December 29, 2015.[59] Under the existing regulation (which, as noted above, we have not enforced), a sponsor or MA–PD must track a separate 90-day consecutive time period for each drug covered as a provisional supply from the initial date-of-service; the sponsor or MA–PD must not reject a claim or deny a beneficiary's request for reimbursement until the 90-day time period has passed or a 3-month supply has been dispensed, whichever comes first. Under our proposal, however, a beneficiary would have one 90-day provisional coverage period with respect to an individual on the preclusion list. Accordingly, a sponsor/PBM would track one 90-day time period from the date the first drug is dispensed to the beneficiary pursuant to a prescription written by the individual on the preclusion list. This dispensing event would trigger a written notice and a 90-day time period for the beneficiary to fill any prescriptions from that particular precluded prescriber and to find another prescriber during that 90-day time period.

Our rationale for this change is that individuals on the preclusion list are demonstrably problematic. This has negative implications not only for the Trust Funds but also for beneficiary safety. Thus, it is imperative that a beneficiary switch to a new prescriber who is not on the preclusion list as soon as practicable. Under the current

[59] See *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Technical-Guidance-on-Implementation-of-the-Part-D-Prescriber-Enrollment-Requirement.pdf.*

prescriber enrollment requirement, the vast majority of prescribers who are not enrolled in or opted-out of Medicare likely do not pose a risk to the beneficiary or the Trust Funds, and therefore we can allow a 3-month provisional supply/90-day time period for each prescription written by such a prescriber. In addition, our proposed policy would eliminate the difficulty sponsors and PBMs have under the current ''per drug'' provisional supply policy in determining whether the beneficiary already received a provisional supply of a drug. We seek specific comment on the modifications we are proposing as to the provisional coverage and time period.

With respect to beneficiaries who would also be entitled to a transition, we are not proposing any change to the current policy. If a Part D sponsor determines when adjudicating a pharmacy claim that a beneficiary is entitled to provisional coverage because the prescriber is on the preclusion list, but the drug is off-formulary and the transition requirements set forth in § 423.120(b)(3) are also triggered, the beneficiary would not receive more than the applicable transition supply of the drug, unless a formulary exception is approved. We note that we considered proposing that the transition requirements would not apply during the provisional supply period in order to simplify the policy for situations when both apply to reduce beneficiary confusion. We seek comment on this or other alternatives for these situations.

We intend to allow the normal Part D rules (for example, edits, prior authorization, quantity limits) to apply during the 90-day provisional coverage period, but solicit comment on whether different limits should apply when opioids are involved, particularly when the reason for precluding the provider/prescriber relates to opioid prescribing.

(4) Appeals

In our revisions to § 423.120(c)(6), we propose to permit prescribers who are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. We believe that given the aforementioned pharmacy claim rejections that would be associated with a prescriber's appearance on the preclusion list, due process warrants that the prescriber have the ability to challenge this via appeal. Any appeal under this proposed provision, however, would be limited strictly to the individual's inclusion on the preclusion list. The proposed appeals process would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. In addition, wewould send written notice to the prescriber of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the prescriber of his or her appeal rights. This is to ensure that the prescriber is duly notified of the action, why it was taken, and his or her ability to challenge our determination.

Consistent with our proposed provision in § 423.120(c)(6) regarding appeal rights, we propose to update several other regulatory provisions regarding appeals:

- We propose to revise § 498.3(b) to add a new paragraph (20) stating that a CMS determination to include a prescriber on the preclusion list constitutes an initial determination. This revision would help enable prescribers to utilize the appeals processes described in § 498.5.

- In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the prescriber is entitled to a hearing before an administrative law judge (ALJ).

++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the Departmental Appeals Board (DAB) and the prescriber may seek judicial review of the DAB's decision.

These revisions are designed to include preclusion list determinations within the scope of appeal rights described in § 498.5. However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.

In addition, given that a beneficiary's access to a drug may be denied because of the application of the preclusion list to his or her prescription, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list.

c. Specific Regulatory Changes

Given the foregoing discussion, we propose the following regulatory changes:

- In § 423.100, we propose to delete the definition of ''other authorized prescriber'' and add the following:

++ Preclusion List means a CMS compiled list of prescribers who:

(1) Meet all of the following requirements: (A) The prescriber is currently revoked from the Medicare program under § 424.535.

(B) The prescriber is currently under a reenrollment bar under § 424.535(c).

(C) CMS determines that 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:

(i) The seriousness of the conduct underlying the prescriber's revocation;

(ii) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

(iii) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.

(ii) 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:

(i) The seriousness of the conduct involved.

(ii) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

(iii) Any other evidence that CMS deems relevant to its determination

- In paragraph (c)(5)(i), we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug. This requirement is consistent with existing policy.

- In paragraph (c)(5)(ii), we propose that the sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

- In paragraph (c)(5)(ii)(A), we propose that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

++ Confirm that the NPI is active and valid; or

++ Correct the NPI.

• In paragraph (c)(5)(ii)(B), we propose that if the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

• In paragraph (iii), we propose that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

++ Has complied with paragraph (ii) of this section;

++ Has verified that a submitted NPI was not in fact active and valid; and

++ The agreement between the parties explicitly permits such recoupment.

• In paragraph (iv), we propose that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

• In paragraph (c)(6)(i), we propose to state: ''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.'' This would help ensure that Part D sponsors comply with our proposed requirement that claims involving prescribers who are on the preclusion list should not be paid.

• In paragraph (c)(6)(ii), we propose to state as follows: ''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.'' As with paragraph (c)(6)(i), this would help ensure that Part D sponsors comply with our proposed requirement that payments not be made for prescriptions written by prescribers who are on the preclusion list.

• In paragraph (c)(6)(iii), we propose to state: ''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.'' This is to help ensure that— (1) the prescriber can be properly identified, and (2) prescribers who are on the preclusion list are not included in PDEs.

• In paragraph (c)(6)(iv), we propose to address the provisional coverage period and notice provisions as follows:

''(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.

(B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following: (*1*) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

(*i*) A 90-day provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary pursuant to prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed pursuant to a prescription written by the individual on the preclusion list.

(*ii*) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.

(*2*) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(*1*)(*ii*) of this section.''

• In new § 423.120(c)(6)(v), we propose that CMS would send written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion on the preclusion list and would inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list in accordance with 42 CFR part 498.

• In new § 423.120(c)(6)(vi), we propose that 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. In making a determination as to whether such circumstances exist, CMS would take into account—(1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.

• In § 498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that a prescriber is to be included on the preclusion list constitutes an initial determination.

• In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the prescriber is entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the DAB and the prescriber may seek judicial review of the DAB's decision.

11. Preclusion List—Part C/Medicare Advantage Cost Plan and PACE Provisions

a. Background

(1) 2016 Final Rule

On November 15, 2016, CMS published a final rule in the **Federal Register** titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' (81 FR 80169). This rule contained a number of requirements related to provider enrollment, including, but not limited to, the following:

• We added a new § 422.222 to require providers and suppliers that furnish health care items or services to

a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The term ''MA organization'' refers to both MA plans and MA plans that provide drug coverage, otherwise known as MA–PD plans.) We also updated §§ 417.478, 460.70, and 460.71 to reflect this requirement.

- We added a requirement in new § 422.204(b)(5) that required MA organizations to comply with the provider and supplier enrollment requirements referenced in § 422.222. A similar requirement was added to § 422.504.
- We revised §§ 422.510, 422.752, 460.40, and 460.50 to state that organizations and programs that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination.
- We revised § 422.501 to require that MA organization applications include documentation demonstrating that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believed that these new requirements, as they pertained to MA, were necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment. We also believed it would assist our efforts to prevent fraud, waste, and abuse, and to protect Medicare enrollees, by allowing us 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 Medicare items and services. Indeed, although § 422.204(a) requires MA organizations to have written policies and procedures for the selection and evaluation of providers and suppliers that conform with the credentialing and recredentialing requirements in § 422.204(b), CMS has not historically had direct oversight over all network providers and suppliers under contract with MA organizations. While there are CMS regulations governing how and when MA organizations can pay for covered services, those are tied to statutory provisions. We concluded that requiring Medicare enrollment in addition to the existing MA credentialing requirements would permit a closer review of MA providers and suppliers, which could, as warranted, involve rigorous screening practices such as risk-based site visits and, in some cases, fingerprint-based background checks, an approach we already take in the Medicare Part A and Part B provider and supplier enrollment arenas. The fact that CMS also has access to information and data not available to MA organizations was also relevant to our decision.

(2) Preparations for Part C Enrollment

As with our Part D enrollment requirement, we promptly commenced outreach efforts after the publication of the November 15, 2016 final rule. We communicated with Part C provider associations and MA organizations regarding, among other things, the general purpose of the enrollment process, the rationale for § 422.222, and the mechanics of completing and submitting an enrollment application. According to recent CMS internal data, approximately 933,000 MA providers and suppliers are already enrolled in Medicare and meeting the MA provider enrollment requirements. However, roughly 120,000 MA-only providers and suppliers remain unenrolled in Medicare, and concerns have been raised by the MA community over the enrollment requirement, principally over the burden involved in enrolling in Medicare while having to also undergo credentialing by their respective health plans.

We understand and share these concerns. We believe that the Medicare enrollment requirement could result in a duplication of effort and, consequently, impose a burden on MA providers and suppliers as well as MA organizations and beneficiaries in the form of limiting access to providers. While we maintain that Medicare enrollment, in conjunction with MA credentialing, is the most thorough means of confirming a provider's compliance with Medicare requirements and of verifying the provider's qualifications to furnish services and items, we believe that an appropriate balance can be achieved between this program integrity objective and the desire to reduce the burden on the provider and supplier communities. Given this, we propose to utilize the same ''preclusion list'' concept in MA that we are proposing for Part D (described in section III.B.9.) and to eliminate the current enrollment requirement in § 422.222. We believe this approach would allow us to concentrate our efforts on preventing MA payment for items and services furnished by providers and suppliers that could pose an elevated risk to Medicare beneficiaries and the Trust Funds, an approach, as previously mentioned, similar to the risk-based process in § 424.518. This would, we believe, minimize the burden on MA providers and suppliers.

b. Proposed Provisions

(1) Process

The process we envision and propose would, similar to the proposed Part D process, consist of the following components:

- Step 1: We would research our internal systems and other relevant data for individuals and entities that have engaged in behavior for which CMS:

++ Has revoked the individual's or entity's enrollment and the individual or entity is under a reenrollment bar; or

++ Could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

In light of the significance of any activity that would result in a revocation under § 424.535(a), we believe that individual and entities that have engaged in inappropriate behavior should be the focus of our Part C program integrity efforts.

- Step 2—CMS would review, on a case-by-case basis, each individual and entity that:

++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the revocation.

++ Has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare.

Similar to our approach with Part D and for the same reason, the individuals and entities to be reviewed would be those that— according to CMS' internal systems MA organization data, state board information, and other relevant data for individuals and entities who are or who could become eligible to furnish health care services or items. To avoid confusion, we refer to such parties in our proposed Part C preclusion list provisions as ''individuals'' and ''entities'' rather than ''providers'' and ''suppliers.'' This is because the latter two terms could convey the impression that the party in question must be actively furnishing health care services or items to be included on the preclusion list.

Similar to the Part D approach, we are also seeking comment on an alternative by which CMS would first identify through encounter data those providers or suppliers furnishing services or items to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We

anticipate that this could create delays in CMS' ability to screen providers or suppliers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries.

Based on the results of Steps 1 and 2, we would compile a preclusion list of individuals and entities that fall within either of the following categories:

++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

++ Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

We propose to update § 422.2 to add a definition of ''preclusion list'' consistent with both the foregoing discussion as well as our proposed definition of the same term for the Part D program.

We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of providers and suppliers in Medicare Advantage. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances.

In addition, we note that while there would be separate regulatory provisions for Part C and Part D, there would not be two separate preclusion lists: one for Part C and one for Part D. Rather, there would be a single preclusion list that includes all affected individuals and entities. Having one joint list, we believe, would make the preclusion list process easier to administer.

(2) Denial of Payment

Section 422.222(a) currently states that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:

- Network providers and suppliers.
- First-tier, downstream, and related entities (FDR).
- Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.
- Providers and suppliers participating in demonstration programs.
- Providers and suppliers in pilot program.
- Locum tenens suppliers.
- Incident-to suppliers.

We propose to revise this requirement to state than an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the preclusion list (as defined in § 422.2). We also propose to remove the language beginning with ''This requirement applies to all of the following providers and suppliers'' along with the list of applicable providers, suppliers, and FDRs. This is consistent with our previously mentioned intention to use the terms ''individuals'' and ''entities'' in lieu of ''providers'' and ''suppliers.''

We also propose that both basic and supplemental benefits should be subject to the payment prohibition that is tied to the preclusion list. We believe that restricting the payment prohibition to only one of these two categories would undercut the effectiveness of our preclusion list proposal.

We solicit comment on the following issues:

++ Whether the actions referenced in § 424.535(a) are appropriate grounds for inclusion on the preclusion list.

++ Whether actions other than those referenced in § 424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.

++ Suggestions for means of monitoring potentially abusive MA practices involving providers and suppliers, and appropriate processes for including such providers and suppliers on the preclusion list.

As stated earlier in reference to prescribers, the preclusion list would be updated on a monthly basis. Individuals and entities would be added or removed from the list based on CMS' internal data or other informational sources that indicate, for instance— (1) persons eligible to provide medical services who have recently been convicted of a felony that CMS determines to be detrimental to the best interests of the Medicare program; and (2) entities whose reenrollment bars have expired. As a particular individual's or entity's status with respect to the preclusion list changes, the applicable provisions of § 422.222 would control.

Individuals and entities that were revoked from Medicare or, for unenrolled individuals and entities, had engaged in conduct that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of § 422.222(a) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. The proposed payment denials under § 422.222(a), however, would only apply to health care items or services furnished on or after the date the individual or entity was added to the preclusion list; that is, payment denials would not be made retroactive to the date of the revocation or, for unenrolled individuals and entities, the conduct that could serve as a basis for an applicable revocation occurring before the effective date of the final rule. Likewise, health care items and services furnished by individuals and entities revoked from Medicare or engaging in conduct that could serve as a basis for an applicable revocation after the rule's effective date and that are subsequently added to the preclusion list would not be subject to retroactive payment denials under § 422.222(a); only the date on which the affected individual or entity is added to the preclusion list would be used to determine payment and the start date of payment denials under this proposal. We believe that this approach is the most consistent with principles of due process.

(3) MA Organization Compliance

Section 422.222 currently states that MA organizations that do not ensure that providers and suppliers comply with paragraph (a) may be subject to sanctions under § 422.750 and termination under § 422.510. We propose to revise this to state that MA organizations that do not comply with paragraph (a) may be subject to sanctions under § 422.750 and termination under § 422.510. This is to help ensure that MA organizations do not make improper payments for items and services furnished by individuals and entities on the preclusion list.

(4) Related Revisions

As discussed previously, in the November 15, 2016 final rule, we added or updated a number of other MA regulatory provisions (for example, § 422.501 and 422.510) in order to fully incorporate our new enrollment requirements. Because we are proposing to replace these enrollment requirements with an approach centered upon a preclusion list—and to help

ensure that providers, suppliers, MA organizations, PACE organizations, and other applicable stakeholders comply with our proposed requirements—we believe that these other MA regulatory provisions must also be revised to reflect this change. To this end, we propose the following revisions:

• Section 422.204(a) states that an MA organization must have written policies and procedures for the selection and evaluation of providers and suppliers. These policies must conform with the credentialing and recredentialing requirements in § 422.204(b). Under paragraph (b)(5), an MA organization must follow a documented process with respect to providers and suppliers that have signed contracts or participation agreements that ensures compliance with the provider and supplier enrollment requirements in § 422.222. To achieve consistency with our preclusion list proposals and to help facilitate MA organizations' compliance therewith, we propose to:

++ Establish a new § 422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

++ Delete § 422.204(b)(5) because it applies to the Part C enrollment process, which we are proposing to eliminate. Further, revising paragraph (b)(5) to address the preclusion list requirements could cause confusion, for paragraph (b) references providers and suppliers. We thus believe that creating a new paragraph (c) would better clarify our expectations.

• In 42 CFR part 417, subpart L, we address certain contractual requirements concerning health maintenance organizations (HMOs) and competitive medical plans (CMPs) that contract with CMS to furnish covered services to Medicare beneficiaries. Under § 417.478(e), the contract between CMS and the HMO or CMP must, among other things, provide that the HMO or CMP agrees to comply with ''Sections 422.222 and 422.224, which require all providers and suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked.'' Paragraph (e) adds that this requirement includes ''locum tenens suppliers and, if applicable, incident-to suppliers.''

Furthermore, § 417.484(b)(3) requires that the contract must provide that the HMO or CMP agrees to require all related entities to agree that ''All providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in Medicare in an approved status.'' We accordingly propose the following revisions:

++ We propose to revise § 417.478(e) to state as follows:

++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individual and entities on the preclusion list (defined in § 422.2 of this part) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

++ In new paragraph (e)(2), we propose to state that in applying the provisions of §§ 422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

++ We propose to revise § 417.484(b)(3) to state: ''That payments must not be made to individuals and entities that are included on the preclusion list (as defined in § 422.2).''

• In 42 CFR part 460, we address requirements relating to Programs of All-Inclusive Care for the Elderly (PACE). The PACE program is a state option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE. We propose to make the following changes to Part 460:

++ Section 460.40 states that, in addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46 if CMS determines that a PACE organization commits certain violations, one of which is outlined in paragraph (j) and reads: ''Employs or contracts with any provider or supplier that is a type of individual or entity that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.'' We propose to revise paragraph (j) to state: ''Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.''

++ Section 460.50(b) addresses grounds for which CMS or the state administering agency may terminate a PACE program agreement if CMS or the state administering agency determines that the conditions of paragraphs (b)(1) and (2) are met. In (b)(1), one of two conditions, outlined in paragraphs (b)(1)(i) and (ii), must be met. Paragraph (b)(1)(ii) states: ''The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including employing or contracting with any provider or supplier that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.'' We propose to revise paragraph (b)(1)(ii) by changing the current language beginning with ''including'' to read ''including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.'' We note that this change would not prohibit a PACE organization from employing or contracting with an individual or entity on the preclusion list. As previously discussed, the focus of our preclusion list proposals is on the denial of payment.

++ Section 460.68(a) lists certain categories of individuals who a PACE organization may not employ, as well as individuals and organizations with whom a PACE organization may not contract. Among these parties are those listed in paragraph (a)(4); specifically, those ''that are not enrolled in Medicare in an approved status, if the providers or suppliers are of the types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act.'' We propose to delete paragraph (a)(4), given our proposed removal of the Part C enrollment requirement.

++ Section 460.70(a) states that a PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100; various requirements that a contract between a PACE organization and a contractor must meet are listed in § 460.70(b). Paragraph (b)(1) states that the PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, those listed in paragraphs (b)(1)(i) through (iv). Paragraph (b)(1)(iv) reads: ''Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.'' Consistent with our proposed deletion of § 460.68(a)(4), we propose to delete § 460.70(b)(1)(iv). We note that we are not proposing to prohibit individuals and entities on the preclusion list from furnishing services

and items to PACE participants; we are merely proposing to prohibit payment for such services and items if provided by an individual or entity on the preclusion list.

++ Section 460.71(b) states that a PACE organization must develop a program to ensure that all staff furnishing direct participant care services meets the requirements outlined in paragraph (b). One of these requirements, listed in paragraph (b)(7), reads: ''Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.'' Similar to our proposed deletion of § 460.68(a)(4), we propose to delete paragraph (b)(7).

++ Section 460.86 addresses payments to excluded or revoked providers and suppliers as follows:

++ Paragraph (a) states that a PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program.

++ Paragraph (b) states: ''If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the PACE organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program.''

We propose to revise these paragraphs as follows:

++ Paragraph (a) would state: ''A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2 of this chapter.'' We are not proposing to include the current regulatory language ''or revoked'' in our revised paragraph. This is because, as outlined previously, there could be situations under revised § 422.222 where a revoked individual or entity would not be included on the preclusion list.

++ Paragraph (b) would state: ''If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''

• Section 422.501(c) states that in order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity (or an individual authorized to act for the entity (the applicant)), must fully complete all parts of a certified application. As part of the application, paragraph (c)(1)(iv) requires ''(d)ocumentation that all providers or suppliers in the MA or MA–PD plan that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in an approved status.'' Also, paragraph (c)(2) requires the following: ''The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in § 422.222 are enrolled in Medicare in an approved status.''

We propose to:

++ Revise paragraph (c)(1)(iv) to read: ''Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.''

++ Revise paragraph (c)(2) to replace the language beginning with ''including providing documentation . . . '' with ''including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.''

• Section 422.752(a) lists certain violations for which CMS may impose sanctions (as specified in § 422.750(a)) on any MA organization with a contract. One violation, listed in paragraph (a)(13), is that the MA organization ''(f)ails to comply with § 422.222 and 422.224, that requires the MA organization to ensure that providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.'' We propose to revise paragraph (a)(13) to read: ''Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals or entities, nor to individuals or entities on the preclusion list, defined in § 422.2.''

• Section 422.510(a)(4) lists various grounds by which CMS may terminate a contract with an MA organization. Paragraph (a)(4)(xiii) refers to the MA organization's failure ''to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.'' We propose to revise this paragraph to read: ''Fails to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.''

• Section 422.504 outlines provisions that the contract between the MA organization and CMS must contain. Under paragraph (a)(6), the MA organization must agree to adhere to, among other things, ''Medicare provider and supplier enrollment requirements.'' Pursuant to paragraph (i)(2)(v), moreover, the MA organization agrees to require all first tier, downstream, and related entities to agree that ''they will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with § 422.222.'' We propose to revise these two paragraphs as follows:

++ Paragraph (a)(6) would be revised to replace the language ''Medicare provider and supplier enrollment requirements'' with ''the preclusion list requirements in 422.222.''

++ Paragraph (i)(2)(v) would be revised to replace the language following ''they will'' with ''ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.''

• Section 422.224, which applies to MA organizations and pertains to payments to excluded or revoked providers or suppliers, contains provisions very similar to those in § 460.86:

++ Paragraph (a) states that an MA organization ''may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided.''

++ Paragraph (b) states: ''If an MA organization receives a request for

payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program.

We propose to revise these paragraphs as follows:

++ Paragraph (a) would state: ''An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

++ Paragraph (b) would state: ''If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''

In addition to the aforementioned proposals, CMS proposes to amend existing data submission requirements for risk adjustment to require MA organizations to include provider NPIs as part of encounter data submissions; CMS intends to use the NPI data to identify individuals and entities that, depending on the results of CMS investigation, may be included on the preclusion list proposed in this section. Pursuant to section 1853(a)(1)(C) and (a)(3)(B) of the Act, CMS adjusts the capitation rates paid to MA organizations to account for such risk factors as age, disability status, gender, institutional status, and health status and requires MA organizations to submit data regarding the services provided to MA enrollees. Implementing regulations at 42 CFR 422.310 set forth the requirements for the submission of risk adjustment data that CMS uses to risk-adjust payments. MA organizations must submit data, in accordance with CMS instructions, to characterize the context and purposes of items and services provided to their enrollees by a provider, supplier, physician, or other practitioner (OMB Control No. 0938–1152). Currently, risk adjustment data is submitted in two formats: comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data); and data in abbreviated formats (often referred to as RAPS data).

CMS requires that MA organizations and other entities submit encounter data using the X12 837 5010 format to fulfill the reporting requirements at 42 CFR 422.310, where ''X12'' refers to healthcare transactions, ''837'' refers to an electronic format for institutional (''837–I'') and professional (''837–P'') encounters, and ''5010'' refers to the most recent version of this national standard. The X12 837 5010 is one of the national standard HIPAA transaction and code set formats for electronic transmission of healthcare transactions. Records that MA organziations and other submitters send to CMS in the X12 837 5010 format are known as ''encounter data records.''

One of the required data elements on the X12 837 5010 encounter data record is the ''Billing Provider.'' The Billing Provider is identified through several data fields (for example, name field and address field), but a key data field for identifying the Billing Provider is the National Provider Identifier (NPI). The NPI was established as a national standard for a unique health identifier for health care providers, as part of HIPAA Administrative Simplification efforts for electronic transactions among trading partners. CMS announced its decision to implement the NPI for Medicare, in the final rule 69 FR 3434, published January 23, 2004. Billing Provider NPIs are required for X12N 837 5010 transactions (both institutional and professional), as established in the national implementation guides (known by the shorthand ''TR3 guides''): *Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Institutional (837)* and *Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Professional (837).* However, CMS has not incorporated this Billing Provider NPI requirement into its Part C MA regulations for submission of risk adjustment data. CMS has incorporated the Part D program requirement that plan sponsors submit NPIs on the Prescription Drug Event Record (77 FR 22072, published April 12, 2012).

We are proposing to amend § 422.310 by adding a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. While the NPI is a required data element for the X12 837 5010 format (as set forth in the TR3 guides cited in the Background), CMS has not codified a regulatory requirement that MA organizations include the Billing Provider NPI in encounter data records. The proposed amendment would implement that requirement.

We propose to include the phrase ''per CMS guidance'' to allow CMS to take into account situations where there is no bill (no claim for payment) in an MA organization's system. For example, CMS allows submission of chart review records (also submitted to CMS in the X12 837 5010 format) only for the purpose of submitting, correcting, and deleting diagnoses from encounter data records for the purposes of risk adjustment payment, based on medical record reviews (chart reviews). Thus, chart review records and encounters that are capitated (when there is no bill) would have different guidance for populating the Billing Provider NPI field than encounters for which a bill was received and adjudicated by the MA organization.

(5) Appeals

We propose to add a provision to § 422.222(a) that would permit individuals or entities that are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. Given the aforementioned payment denial that would ensue with the individual's or entity's inclusion on the preclusion list, due process warrants that the individual or entity have the ability to appeal this initial determination. Any appeal under this proposed provision, however, would be limited strictly to the individual's or entity's inclusion on the preclusion list. It would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. Individuals and entities that file an appeal pursuant to § 422.222(a) would be able to avail themselves of any other appeals processes permitted by law.

CMS would send written notice to the individual or entity of their inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights.

We also propose to update the following regulatory provisions regarding appeals. Note that these provisions would include references to preclusion list inclusions under § 422.222 (MA) and, as previously mentioned, § 423.120(c)(6).

• We propose to revise § 498.3(b) to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination. This change would help enable individuals and entities to utilize the appeals processes described in § 498.5:

• In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose 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 propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we propose 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.

These revisions are designed to include preclusion list determinations within the scope of appeal rights described in § 498.5. However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.

In addition, given that a beneficiary's access to health care items or services may be impaired because of the application of the preclusion list to his or her item or service, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list. We solicit comment whether additional beneficiary protections, such as notices to enrollees when an individual or entity that has recently furnished services or items to the enrollee is placed on the preclusion list or a limited and temporary coverage approval when an individual or entity is first placed on the preclusion list but is in the middle of a course of previously covered treatment, should also be included these rules upon finalization.

(6) Technical Changes

The title of § 422.222 reads: ''Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); cost HMO or CMP, and demonstration and pilot programs.'' We propose to change this to simply state ''Preclusion list'' so as to accord with our previously mentioned proposed changes. For this same reason, we propose to:

++ Change the title of § 422.224 from ''Payment to providers or suppliers excluded or revoked'' to ''Payment to individuals and entities excluded by the OIG or included on the preclusion list.''

++ Change the title of § 460.86 from ''Payment to providers or suppliers excluded or revoked'' to ''Payment to individuals or entities excluded by the OIG or included on the preclusion list.''

c. Specific Regulatory Changes

Given the foregoing discussion, we propose the following regulatory changes:

• In § 417.478, we propose to revise paragraph (e) as follows:

++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list (defined in § 422.2 of this chapter) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

++ In new paragraph (e)(2), we propose to state that in applying the provisions of §§ 422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

• In § 417.484, we propose to revise paragraph (b)(3) to state: ''That payments must not be made to individuals and entities included on the preclusion list, defined in § 422.2.''

• In § 422.2, we propose to add a definition of ''preclusion list'' that reads as follows:

++ Preclusion list means a CMS compiled list of individuals and entities that:

(1) Meet all of the following requirements:

(i) The individual or entity is currently revoked from Medicare under § 424.535.

(ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

(iii) 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 would consider the following factors:

(A) The seriousness of the conduct underlying the individual's or entity's revocation.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) 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:

(i) The seriousness of the conduct involved.

(ii) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and

(iii) Any other evidence that CMS deems relevant to its determination

• We propose to delete § 422.204(b)(5).

• We propose to establish a new § 422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

• We propose to delete the existing version of § 422.222(a) and replace it with the following:

++ In § 422.222, we propose to change the title thereof to ''Preclusion list''.

++ In paragraph (a)(1), we propose to state that an MA organization shall 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.

++ In paragraph (a)(2), we propose to replace the existing language therein with a provision stating 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 the inclusion and would 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.

++ In paragraph (b), we propose to state that an MA organization that does

not comply with paragraph (a) of § 422.222 may be subject to sanctions under § 422.750 and termination under § 422.510.

• In § 422.224, we propose to:

++ Change the title thereof to ''Payment to individuals and entities excluded by the OIG or included on the preclusion list.''

++ Revise paragraph (a) to state: ''An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2''.

++ Revise paragraph (b) to state: ''If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''

• We propose to revise § 422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance.

• In § 422.501(c), we propose to:

++ Revise paragraph (c)(1)(iv) to read: ''Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.''

++ Revise paragraph (c)(2) to replace the language beginning with ''including providing documentation . . .'' with ''including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.''

• In section 422.504, we propose to:

++ Replace the language in paragraph (a)(6) that reads ''Medicare provider and supplier enrollment requirements'' with ''the preclusion list requirements in § 422.222 and § 422.224.''

++ Revise paragraph (i)(2)(v) to read, ''they will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.''

• In § 422.510(a)(4), we propose to revise paragraph (xiii) to read: ''Fails to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.''

• In § 422.752, we propose to revise paragraph (a)(13) to read: ''Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities included on the preclusion list, defined in § 422.2.''

• In § 460.40, we propose to revise paragraph (j) to state: ''Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.''

• In § 460.50, we propose to revise paragraph (b)(1)(ii) by changing the current language following ''including'' to read ''making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.'' ''

• We propose to delete § 460.68(a)(4).

• We propose to delete § 460.70(b)(1)(iv).

• We propose to delete § 460.71(b)(7).

• In § 460.86, we propose to revise paragraphs (a) and (b) to state as follows:

++ Paragraph (a) would state: ''A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter.''

++ Paragraph (b) would state: ''If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.''

++ We also propose to change the title of § 460.86 to ''Payment to individuals and entities that are excluded by the OIG or are included on the preclusion list.''

• In § 498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination.

• In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose 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 propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we propose 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 DAB and the individual or entity may seek judicial review of the DAB's decision.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

Section 1852(e) of the Act requires that Medicare Advantage (MA) organizations have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees in the organization's MA plans. The statute requires that the MA organization include a Chronic Care Improvement Program (CCIP) as part of the overall QI Program

Our regulations at § 422.152 outline the QI Program requirements for MA organizations, which include the development and implementation of both Quality Improvement Projects (QIPs), at paragraphs (a)(3) and (d), and a CCIP, at paragraphs (a)(2) and (c). Both provisions require that the MA organization's QIP and CCIP address areas or populations identified by CMS.

The January 2005 final rule (70 FR 4587) addressed the QI provisions added to section 1852(e) of the Act by the Medicare Modernization Act of 2003 (MMA). In the final rule, we specified in § 422.152 that MA organizations must have ongoing QI Programs, which include chronic care programs. In addition, CMS provided MA organizations the flexibility to shape their QI efforts to the needs of their enrollees.

In the April 2010 final rule (75 FR 19677), CMS indicated concern that MA organizations were choosing QIPs and CCIPs that did not address QI areas that best reflected enrollee needs. Additionally, there were concerns that some projects focused more on improving processes rather than improving clinical outcomes. Therefore, we modified the regulation to provide for CMS to identify focus areas for QIPs and population areas for CCIPs. MA organizations retained the flexibility to identify topics for development of QIPs and CCIPs based on the needs of their population, but also had to implement QIPs and CCIPs as directed by CMS, which could identify general areas of focus that supported CMS quality strategies and initiatives.

During this time, CMS was also concerned that MA organizations were employing inconsistent methods in developing criteria for QIPs and CCIPs. As a result, CMS further modified the regulation to require MA organizations to report progress in a manner identified by CMS. This allowed CMS to review results and extrapolate lessons learned and best practices consistently across the MA program.

After making these regulation modifications, CMS issued a number sub-regulatory QIP and CCIP guidance documents to ensure that MA organizations measured progress in a consistent and meaningful way. For example, the new Plan-Do-Study-Act QI model required MA organizations to place some structure and parameters around their QIPs and CCIPs, ultimately leading to more consistency.

Over time, CMS found its implementation of the QIP and CCIP requirements had become burdensome and complex, rather than streamlining and conforming MA organizations' implementation of QIPs and CCIPs. For example, the complex sub-regulatory guidance led to a wide range of MA organization interpretations, resulting in extraneous, irrelevant, voluminous, and redundant information being reported to CMS. We gained little value from this information. As a result, we scaled down our sub-regulatory guidance in order to gain more concise and useful information with which to evaluate the outcomes and show any sort of attribution. However, we also found that the complex guidance did not necessarily produce better outcomes in the review of annual updates.

Continued evaluation through annual review of plan reported updates of the QIPs and CCIPs has led CMS to believe that the QIPs in particular do not add significant value. Through annual review of plan-reported updates, CMS has found that a number of QIPs implemented are duplicative of activities MA organizations are already doing to meet other plan needs and requirements, such as the CCIP and internal organizational focus on STAR Rating metrics. For example, we designated ''Reducing All-Cause Hospital Readmissions'' as the 2012 QIP topic. The QIPs for this topic often duplicated other CMS and MA organization care coordination initiatives aimed to improve transition of care across health care settings and reduce hospital readmissions. We found that many plans were already engaged in activities to reduce hospital readmissions because they are annually scored on their performance in this area (and many other areas) through Healthcare Effectiveness Data and Information Set (HEDIS). HEDIS are a set of plan performance and quality measures. Each year, MA organizations are required to report HEDIS data and are evaluated annually based on these measures. High performance on these measures also plays a large role in achieving high Star Ratings, which has beneficial payment consequences for MA organizations. This suggests that CMS direction and detailed regulation of QIPs is unnecessary as the Star Ratings program use of HEDIS measures (and other measures) incentivizes MA organizations sufficiently to focus on desired improvements and outcomes.

Therefore, we believe the removal of the QIP and the continued CMS direction of populations for required CCIPs would allow MA organizations to focus on one project that supports improving the management of chronic conditions, a CMS priority, while reducing the duplication of other QI initiatives. We propose to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements. In addition, in order to ensure that remaining cross references for other provisions in this section remain accurate, we will reserve paragraphs (a)(3) and (d). The removal of these requirements would reduce burden on both MA organizations and CMS.

Even with this proposed removal of the QIP requirements, the MA requirements for QI Programs would remain in place and be robust and sufficient to ensure that the requirements of section 1852(e) of the Act are met. As a part of the QI Program, each MA organization would still be required to develop and maintain a health information system; encourage providers to participate in CMS and HHS QI initiatives; implement a program review process for formal evaluation of the impact and effectiveness of the QI Program at least annually; correct all problems that come to its attention through internal, surveillance, complaints, or other mechanisms; contract with an approved Medicare Consumer Assessment of Health Providers and Systems (CAHPS®) survey vendor to conduct the Medicare CAHPS® satisfaction survey of Medicare plan enrollees; measure performance under the plan using standard measures required by CMS and report its performance to CMS; develop, compile, evaluate, and report certain measures and other information to CMS, its enrollees, and the general public; and develop and implement a CCIP. Further, CMS emphasizes here that MA organizations must have QI Programs that go beyond only performance of CCIPs that focus on populations identified by CMS. The CCIP is only one component of the QI Program, which has the purpose of improving care and provides for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality under section 1852(e) of the Act.

We believe this proposed change will allow MA organizations to maintain existing health improvement initiatives and take steps to reduce the risk of redundancies or duplication. The remaining elements of the QI Program, including the CCIP, will still maintain the intended purpose of the QI Program: That plans have the necessary infrastructure to coordinate care and promote quality, performance, and efficiency on an ongoing basis.

This proposal does not eliminate the CCIP requirements that MA organizations address populations identified by CMS and report project status to CMS as requested. Per the April 2010 rule (75 FR 19677), we still believe that these requirements are necessary to ensure that MA organizations are developing projects that positively impact populations identified by CMS and that progress is documented and reported in a way that is consistent with our requirements.

In conclusion, we are proposing to amend § 422.152 by:

- Deleting and reserving paragraphs (a)(3) and (d).

We solicit comments on this proposal, including whether additional revision to § 422.152 is necessary to eliminate redundancies CMS has identified in this preamble.

13. Reducing Provider Burden—Comment Solicitation

Health care providers are key partners in the delivery of Medicare benefits, and we are exploring ways to reduce burden

on providers (meaning institutions, physicians, and other practitioners) arising from requests for medical record documentation by MA organizations, particularly in connection with MA program requirements. We are interested in stakeholder feedback on the nature and extent of this burden of producing medical record documentation and on ideas to address the burden. We are particularly interested in burden experienced by solo providers. Please note that this is a solicitation for comment only and does not commit CMS to adopt any ideas submitted nor to making any changes to CMS audits or activities, including risk adjustment data validation (RADV) processes.

By law, CMS is required to adjust payments to MA organizations for their enrollees' risk factors, such as age, disability status, gender, institutional status, and health status. To this end, MA organizations are required in regulation (§ 422.310) to submit risk adjustment data to CMS—including diagnosis codes—to characterize the context and purposes of items and services provided to MA organization plan enrollees. Risk adjustment data refers to data submitted in two formats: Comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and data in abbreviated formats (often referred to as RAPS data). Under § 422.310, risk adjustment data that is submitted must be documented in the medical record and MA organizations will be required to submit medical records to validate the risk adjustment data. Finally, at § 422.310(d)(4), MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

To address concerns from providers about burdensome requests from MA organizations for their patients' medical record documentation, we are soliciting comment from stakeholders to more fully understand the issue and for ideas to accomplish reductions in provider burden. Specifically, we seek comment on the following:

- The nature and extent of medical record requests, including the following:
  - ++ Reasoning behind the request sent by the MA organization to the provider.
  - ++ Amount of time afforded to providers to respond to such requests.
  - ++ Frequency of requests for providers to submit medical records.
  - ++ Volume of medical records in a given request.
  - ++ Method of collection and submission of medical records.
  - ++ How narrowly or broadly the requests are framed (for example, whether the request is for a single visit, a specific condition, and for what timeframe).
  - ++ Extent to which requests are made pursuant to a *CMS-conducted* RADV audit, other CMS activities, or for other purposes (please specify what the other purposes are).
  - ++ Considerations that may be unique to solo providers.
  - ++ Impact on burden due to increased adoption of electronic health record systems.
  - ++ Specific examples of medical record requests (for example, anecdotes and/or the requests themselves, appropriately redacted of confidential information and PII/PHI).
- The nature and extent of requests related to medical record attestations, including the following:
  - ++ Reasoning behind the attestation request.
  - ++ Amount of time afforded to providers to respond to such requests.
  - ++ Frequency of requests for providers to sign attestations.
  - ++ Volume of requests.
  - ++ Level and duration for which attestations are requested (for example, for each medical record, for all medical records for a beneficiary for a particular date of service or for a particular year).
  - ++ Whether there is reduced burden associated with electronic signatures.
  - ++ Specific examples of medical record attestations and attestation requests.
- Ideas for improving the process around MA organizations requesting medical records and/or attestations that are not directly pursuant to CMS-conducted RADV audits. Specify the type of change the idea would necessitate: a statutory, regulatory, subregulatory, operational, or CMS-issued guidance such as best practices for MA organizations when requesting medical records and/or attestations, and how such a change may interact with other provisions, such as state law or Joint Commission requirements. If the ideas involve novel legal questions, analysis regarding our authority is welcome for our consideration. For each idea, describe the extent of provider burden reduction, quantitatively where possible, and any other consequences that implementing the idea may have on beneficiaries, providers, MA organizations, or CMS. Further, we encourage all relevant parties to respond to this request: MA organizations, providers, associations for these entities, and companies assisting MA organizations, providers, and hospitals with handling medical record requests.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements

a. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amends section 1857(e) of the Act to add medical loss ratio (MLR) requirements to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013 **Federal Register** (78 FR 31284), we published a final rule that codified the MLR requirements for Part C MA organizations, and Part D sponsors (including organizations offering cost plans that provide the Part D benefit) in the regulations at 42 CFR part 422, subpart X and part 423, subpart X.

For contract year 2014 and subsequent contract years, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (*see* §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement in section 1857(e)(4) of the Act creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the Health Care Reconciliation Act, also established a new MLR requirement under section 2718 of the Public Health Service Act (PHSA) that applies to issuers of employer group and individual market

private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the ''commercial MLR rules.'' Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

This proposed rule sets forth our proposed modifications to certain MLR requirements in the Medicare Part C and Part D programs.

b. Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420, 422.2430, 423.2420, and 423.2430)

(1) Fraud Reduction Activities

As explained in the February 22, 2013 proposed rule (78 FR 12428), we used the commercial MLR rules as a reference point for developing the Medicare MLR rules. We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. Although we believe it is important to maintain consistency between the commercial and Medicare MLR requirements, we also recognized that some areas of the commercial MLR rules would need to be revised to fit the unique characteristics of the MA and Part D programs.

One area of alignment between the commercial and Medicare MLR rules is the treatment of expenditures related to fraud reduction efforts, which we defined to include both fraud prevention and fraud recovery in both rules (*see* 78 FR 12433). The Medicare MLR regulations adopted the same definitions of activities that improve healthcare quality (also referred to as quality improvement activities, or QIA), as had been adopted in the commercial MLR regulations at 45 CFR 158.150 and 158.151, in order to facilitate uniform accounting for the costs of these activities across lines of business (*see* 78 FR 12435). Consistent with this policy of alignment, the Medicare MLR regulations at §§ 422.2430(b)(8) and 423.2430(b)(8) adopted the commercial MLR rules' exclusion of fraud prevention activities from QIA. The Medicare MLR regulations (§§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii)) further aligned with the commercial MLR rules' treatment of fraud-related expenditures by allowing the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, to be included in the MLR numerator as an adjustment to incurred claims. The Medicare MLR proposed rule (78 FR 12433) explained that we considered this approach to be appropriate because without such an adjustment, the recovery of paid fraudulent claims would reduce an MLR and could create a disincentive to engage in fraud reduction efforts. Allowing an adjustment to incurred claims to reflect claims payments recoveries up to the limit of fraud reduction expenses would help mitigate whatever disincentive might occur if fraud reduction expenses were treated solely as nonclaims and nonquality improving expenses. The Medicare MLR proposed rule echoed the December 7, 2011 commercial MLR final rule with comment period (76 FR 76577), where we had earlier expressed the view that allowing an unlimited adjustment for fraud reduction expenses would undermine the purpose of requiring issuers to meet the MLR standard.

We have reconsidered this position based on the specific characteristics of the MA and Part D programs, and are now proposing certain changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. First, we are proposing to revise the MA and Part D regulations by removing the current exclusion of fraud prevention activities from QIA at §§ 422.2430(b)(8) and 423.2430(b)(8). Second, we are proposing to expand the definition of QIA in §§ 422.2430 and 423.2430 to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. Third, we are proposing to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, in §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii). We note that the commercial MLR rules and the Medicaid MLR rules are outside the scope of this proposed rule.

We are proposing these changes to the Medicare MLR rules because we believe that limiting or excluding amounts invested in fraud reduction undermines the federal government's efforts to combat fraud in the Medicare program, and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide. Fraud prevention activities can improve patient safety, deter the use of medically unnecessary services, and can lead to higher levels of health care quality, which is part of the reason why we require such activities as a condition of participation in the MA and Part D programs.

MA organizations and Part D sponsors are required at §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi), respectively, to adopt an effective compliance program which includes measures that prevent, detect, and correct fraud. We believe that the proposed change to include all expenditures in connection with fraud reduction activities as QIA-related expenditures in the MLR numerator best aligns with this Medicare contracting requirement. We are concerned that the current rules could create a disincentive to invest in fraud reduction activities, which is only partly mitigated by the current adjustment to incurred claims for amounts recovered as a result of fraud reduction activities, up to the amount of fraud reduction expenses. We believe that it is particularly important that MA organizations and Part D sponsors invest in fraud reduction activities as the Medicare trust funds are used to finance the MA and Part D programs. We believe that including the full amount of expenses for fraud reduction activities as QIA will provide additional incentive to encourage MA organizations and Part D sponsors to develop innovative and more effective ways to detect and deter fraud.

We continue to believe that the minimum MLR requirement in section 1857(e)(4) of the Act is intended to create an incentive to reduce administrative costs, marketing, profits, and other such uses of the funds that plan sponsors receive, and to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. However, we also believe that MA organizations' and Part D sponsors' fraud reduction activities can potentially provide significant value to the government and taxpayers by reducing trust fund expenditures. When MA organizations and Part D sponsors prevent fraud and recover amounts paid for fraudulent claims, this lowers the overall cost of providing coverage to MA and Part D enrollees. Because MA organizations' and Part D sponsors' monthly payments are based in part on their claims experience in prior years, if MA organizations and Part D sponsors pay fewer fraudulent claims, this should be reflected in their subsequent cost projections, which would ultimately result in lower payments to MA organizations and Part D sponsors out of the Medicare trust funds, and could also result in lower premiums or additional supplemental benefits for beneficiaries.

Given the proposed change to include expenditures for fraud reduction activities in the QIA portion of the MLR numerator, we no longer believe that it

would be necessary or appropriate to include in incurred claims the amount of claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. As noted previously, we originally included an adjustment to incurred claims for claims payments recovered through fraud reduction efforts based on the rationale that, because the recovery of paid fraudulent claims reduces the amount of incurred claims in the MLR numerator, if expenditures for fraud reduction efforts were treated solely as nonclaims and nonquality improvement activities, this could create a disincentive to engage in fraud reduction activities. The adjustments to incurred claims under current §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii) mitigate the potential disincentive to invest in fraud reduction activities insofar as MA organizations' and Part D sponsors' recoveries of paid fraudulent claims do not result in a reduction to incurred claims. Because this adjustment to incurred claims is only available to the extent that an MA organization or Part D sponsor recovers paid fraudulent claims, it encourages MA organizations and Part D sponsors to invest in tracking down and recouping amounts that have already been paid, rather than in preventing payment of fraudulent claims. Under our proposal, claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, would no longer be included in the MLR numerator as an adjustment to incurred claims. Instead, all expenditures for fraud reduction activities would be included in the MLR numerator as QIA, even if such expenditures exceed the amount recovered through fraud reduction efforts. As a result, MA organizations and Part D sponsors will no longer have an incentive to use contract revenue to pursue recovery of paid fraudulent claims instead of investing in fraud prevention. We believe that effective fraud reduction strategies will include efforts to prevent payment of fraudulent claims, and we believe that the proposed inclusion of all fraud reduction activities as QIA in the MLR numerator will strengthen the incentive to engage in these vital activities.

In summary, we are proposing the following regulatory revisions:

- Remove and reserve §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii).
- In §§ 422.2430 and 423.2430, redesignate existing paragraphs (a)(1) and (a)(2) as (a)(2) and (a)(3), respectively.
- In §§ 422.2430 and 423.2430, add new paragraph (a)(4) that lists activities that are automatically included in QIA.
- Designate the introductory text of §§ 422.2430(a) and 423.2430(a) as paragraph (a)(1), and revise newly designated paragraph (a)(1) to specify that, for an activity to be included in QIA, it must either fall into one of the categories listed in newly redesignated (a)(2) and meet all of the requirements in newly redesignated (a)(3), or be listed in paragraph (a)(4).
- Remove and reserve §§ 422.2430(b)(8) and 423.2430(b)(8).

We solicit comment on these proposed changes, particularly whether our proposal is based on the best understanding of the motives and incentives applicable to MA organizations and Part D sponsors to engage in fraud reduction activities. We also solicit comment on the types of activities that should be included in, or excluded from, fraud reduction activities. In addition, we solicit comment on alternative approaches to accounting for fraud reduction activities in the MLR calculation. In particular, we are interested in receiving input on:

- Whether fraud reduction activities should be included in quality improvement activities as proposed, or whether we should create a separate MLR numerator category for fraud reduction activities;
- Whether fraud reduction activities should be subject to any or all of the exclusions at §§ 422.2430(b) and 422.2430(b). Although our proposal removes the exclusion of fraud prevention activities from QIA at §§ 422.2430(b)(8) and 423.2430(b)(8), it is possible that fraud reduction activities would be subject to one of the other exclusions under §§ 422.2430(b) and 423.2430(b), such as the exclusion that applies to activities that are designed primarily to control or contain costs (§§ 422.2430(b)(1) and 423.2430(b)(1)) or the exclusion of activities that were paid for with grant money or other funding separate from premium revenue (§§ 422.2430(b)(1) and 423.2430(b)(3).)

(2) Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

In the May 23, 2013 final rule (78 FR 31294), we stated that Medication Therapy Management (MTM) activities (defined at § 423.153(d)) qualify as QIA, provided they meet the requirements set forth in §§ 422.2430 and 423.2430. To meet these requirements, the activity must fall into one of the categories listed in current paragraph (a)(1) of those regulations, which means the activity must: (1) Improve health quality; (2) increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) be directed toward individual enrollees, specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. In our prior MLR rulemaking, we did not attempt to determine whether all MTM programs that comply with § 423.153(d) would necessarily meet the QIA requirements at § 422.2430 (for MA–PD contracts) and § 423.2430 (for stand-alone Part D contracts). Subsequent to publication of the May 23, 2013 final rule, we have received numerous inquiries seeking clarification regarding whether MTM programs are QIA. To address those questions and resolve any ambiguities or uncertainties, we are now proposing to specifically address MTM programs in the MLR regulations.

We propose to modify our regulations at §§ 422.2430 and 423.2430 by adding new paragraph (a)(4)(i), which specifies that all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA–PD plans (described in § 422.2420(a)(2)) are QIA. Each Part D sponsor is required to incorporate an MTM program into its plans' benefit structure, and the MTM Program Completion Rate for Comprehensive Medication Reviews (CMR) measure has been included in the Star Ratings as a metric of plan quality since 2016. We believe that the MTM programs that we require improve quality and care coordination for Medicare beneficiaries. We also believe that allowing Part D sponsors to include compliant MTM programs as QIA in the calculation of the Medicare MLR would encourage sponsors to ensure that MTM is better utilized, particularly among standalone PDPs that may currently lack strong incentives to promote MTM.

Furthermore, we have expressed concern that Part D sponsors may be restricting MTM eligibility criteria to limit the number of qualified enrollees, and we believe that explicitly including MTM program expenditures in the MLR numerator as QIA-related expenditures could provide an incentive to reduce any such restrictions. This is particularly important in providing individualized disease management in conjunction with the ongoing opioid

crisis evolving within the Medicare population. We hope that, by removing any restrictions or uncertainty about whether compliant MTM programs will qualify for inclusion in the MLR numerator as QIA, the proposed changes will encourage Part D sponsors to strengthen their MTM programs by implementing innovative strategies for this potentially vulnerable population. We believe that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund, as well as beneficiary savings in the form of reduced premiums. We solicit comment on these proposed changes.

(3) Additional Technical Changes to Calculation of the Medical Loss Ratio (§§ 422.2420 and 423.2420)

We are also proposing technical changes to the MLR provisions at §§ 422.2420 and 423.2420. In § 422.2420(d)(2)(i), we are replacing the phrase ''in § 422.2420(b) or (c)'' with the phrase ''in paragraph (b) or (c) of this section''. In § 423.2430, the regulatory text includes two paragraphs designated as (d)(2)(ii). We propose to resolve this error by amending § 423.2420 as follows:

- Revise paragraph (d)(2)(i) by adding at the end the text of the first paragraph designated as (d)(2)(ii).
- Remove the first paragraph designated as (d)(2)(ii).

c. Proposed Regulatory Changes to Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)

Our general approach when developing the current Medicare MLR regulations was to align the Medicare MLR requirements with the commercial MLR requirements. Consistent with this policy, we attempted to model the Medicare MLR reporting format on the tools used to report commercial MLR data in order to limit the burden on organizations that participate in both markets. However, as noted previously, we also recognized that there are some areas where the unique characteristics of the MA and Part D programs make it appropriate for the Medicare MLR reporting requirements to deviate from the rules that apply to commercial MLR reporting. Most beneficiaries are enrolled in plans offered by MA organizations and Part D sponsors that also participate in the commercial market, and these entities are familiar with the commercial MLR forms that they have had to submit since 2012 for the 2011 benefit year. In practice, however, these forms and reports have not been identical. We have become concerned, after having received two annual Medicare MLR reports at the time that this proposed rule is being published, that requiring health insurance issuers to complete a substantially different set of forms for Medicare MLR purposes has created an unnecessary additional burden. Our proposal to reduce the burden of the current Medicare requirement for MLR reporting aligns with the directive in the January 30, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

It is with these concerns in mind that we are proposing to reduce the current reporting burden to require the minimum amount of information needed for MLR reporting by organizations with contracts to offer Medicare benefits. Specifically, we are proposing that the Medicare MLR reporting requirements would be limited to the following data fields, as shown in Table 12: Organization name, contract number, adjusted MLR (which would be populated as ''Not Applicable'' or ''N/A'' for non-credible contracts as determined in accordance with §§ 422.2440(d) and 423.2440(d)), and remittance amount. We solicit comment on these proposed changes.

TABLE 12—MLR REPORTING FOR FULLY CREDIBLE, PARTIALLY CREDIBLE, AND NON-CREDIBLE CONTRACTS

Organization	Contract No.	Adjusted MLR (%)	Remittance amount
ABC, Inc	H1234	90.1	$0
XYZ, LLC	S4321	84.8	17,420
MAO1, LLC	H4321	N/A	N/A

We believe that it is important to note that although we are proposing a significant reduction in the amount of data that MA organizations and Part D sponsors must report to us, we are not proposing to change our authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 to determine that remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c), 422.2410(d), 423.2410(c), and 423.2410(d) were accurately calculated, reported, and applied. Moreover, MA organizations and Part D sponsors would continue to be required to retain documentation supporting the MLR figure reported and to make available to CMS, HHS, the Comptroller General, or their designees any information needed to determine whether the data and amounts submitted with respect to the Medicare MLR are accurate and valid, in accordance with §§ 422.504 and 423.505.

In addition, we have realized that the MLR Reporting Requirements at § 422.2460 do not include provisions that correspond to the provisions currently codified at § 423.2460(b) and (c). In the February 22, 2013 proposed rule (78 FR 12435), we proposed that the total revenue reported by MA organizations and Part D sponsors for MLR purposes would be net of all projected reconciliations, and that each MA and Part D contract's MLR would only be reported once and would not be reopened as a result of any payment reconciliation processes. In the May 23, 2013 final rule (78 FR 31293), we finalized these proposals without change. Although we explicitly proposed that both MA organizations and Part D sponsors would be required to report their revenues net of all projected reconciliations (78 FR 12435), and we did not indicate that only Part D sponsors would be affected by our proposal for each contract's MLR to be reported once and not reopened as a result of any payment reconciliation process (our discussion of this proposal in the final rule addressed how this policy would apply to both MA organizations and Part D sponsors (78 FR 31293)), regulatory provisions implementing the finalized proposals were only included in the Part D regulations, where they currently appear at § 423.2460(b) and (c); corresponding regulatory text was not added to the MA regulations. We are proposing to make a technical change to § 422.2460 by

incorporating provisions which parallel the language of current paragraphs (b) and (c) of § 423.2460 for purposes of the reporting requirements for contract year 2014 and subsequent contract years. This proposed technical change does not establish any new rules or requirements for MA organizations; it merely updates regulatory references that were overlooked in previous rulemaking.

In summary, we are proposing to revise the regulations at §§ 422.2460 and 423.2460 as follows:

- In § 422.2460, redesignate the existing regulation text as paragraph (a).
- Revise newly designated §§ 422.2460(a) and 423.2460(a) by adding ''from 2014 through 2017'' after the phrase ''For each contract year'' in the first sentence to limit the more detailed MLR reporting requirement to that period, making minor grammatical changes to clarify the text, and by adding ''under this part'' to modify the phrase ''for each contract''.
- In § 423.2460, redesignate existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively.
- In §§ 422.2460 and 423.2460, add a new paragraph (b) to require MA organizations and Part D plan sponsors with—

++ Fully credible and partially credible experience to report the MLR for each contract for the contract year along with the amount of any owed remittance; and

++ Non-credible experience, to report that such experience was non-credible.

For each, the proposed text cross-references the applicable regulations for the determination of credibility, and for the general remittance requirement.

- In newly redesignated § 423.2460(c), revise the text to refer to total revenue included in the MLR calculation rather than reports of that information.
- Add new paragraphs (c) and (d) to § 422.2460 that mirror the text in § 423.2460(c) and (d), as redesignated and revised.

d. Proposed Technical Changes to Medicare MLR Review and Non-Compliance and the Release of MLR Data (§§ 422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490)

We are proposing technical changes to the General Requirements, MLR review and non-compliance, and Release of MLR data provisions at §§ 422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490. These changes are being proposed in conformity with the more substantive regulatory text changes being proposed herein. These proposed technical changes do not establish any new rules or requirements for MA organizations or Part D sponsors. The proposed technical changes revise references to MLR reports in conformity with our proposal to scale back Medicare MLR reporting so that we only require the submission of a limited number of data points, as opposed to a full report.

2. Medicare Advantage Contract Provisions (§ 422.504)

Under the authority of section 1857(b) of the Act, CMS may enter into a contract with a Medicare Advantage (MA) organization, through which the organization agrees to comply with applicable requirements and standards. CMS has established and codified provisions of contracts between the MA organization and CMS at § 422.504. This proposed rule seeks to correct an inconsistency in the text that identifies the contract provisions deemed material to the performance of an MA contract.

Section 422.504(a) sets forth regulations and instructions at paragraphs (1) through (15) that are material to the performance of the MA contract in accordance to § 422.504(a)(16). This is inconsistent with the introductory regulatory text at § 422.504(a), which provides, ''An MA organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract.'' Further, both paragraphs (a) and (a)(15) fail to mention paragraphs (a)(17) and (a)(18).

We propose to correct the inconsistent language by revising the language in the introductory text in § 422.504(a) and deleting paragraph § 422.504(a)(16). With this revision, We will renumber current paragraphs §§ 422.504(a)(17) and (a)(18). The proposed revision to the paragraph (a) introductory text would provide that compliance with all contract terms listed in paragraph (a) is material.

3. Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, and 423.508)

Pursuant to section 1857(c)(1) of the Act, CMS enters into contracts with MA organizations for a period of 1 year. As implemented by CMS pursuant to that provision, these contracts automatically renew absent notification by either CMS or the MA organization to terminate the contract at the end of the year. Section 1860D–12(b)(3)(B) of the Act makes this same process applicable to CMS contracts with Part D plan sponsors. CMS has implemented these provisions in regulations that permit MA organizations and Part D plan sponsors to non-renew their contracts, with CMS approval and consent necessary depending on the timeframe of the sponsoring organization's notice to CMS that a non-renewal is desired. We are proposing to clarify its operational policy that any request to terminate a contract after the first Monday in June is considered a request for termination by mutual consent.

Under § 422.506(a)(2)(i) and § 423.507(a)(2)(i), contract non-renewals effective at the end of the 1-year contract term must be submitted to CMS in writing by the first Monday in June. There may be instances where CMS accepts a late non-renewal notice after the first Monday in June for an MA contract if the non-renewal is consistent with the effective and efficient administration of the contract under § 422.506(a)(3). There is no corresponding regulatory provision affording CMS such discretion for Part D contracts.

We have seen that many MA organizations do not understand that CMS treats non-renewals requested after the first Monday in June as an organization's request for a mutual termination pursuant to § 422.508 when determining whether it is in the best interest of the Medicare program to permit non-renewals in applying § 422.506(a)(3). Organizations that request a non-renewal of their contract after the first Monday in June, must receive written confirmation from CMS of the termination by mutual consent pursuant to § 422.508(a) (and § 423.508(a) if an MA–PD plan) to be effectively relieved of their obligation to participate in the MA or Part D programs during the upcoming contract year. CMS has received a number of late non-renewal requests and has received questions from MA organizations inquiring why their request was not treated as a contract non-renewal, but rather as a termination by mutual consent.

We propose to modify § 422.506(a)(3) to remove language that indicates late non-renewals may be permitted by CMS so that there would only be one process—mutual termination under §§ 422.508—that is applicable if CMS is not taking action under § 422.506(b) or § 422.510. Also, we propose to amend §§ 422.508 and 423.508 to clarify that organizations that request to non-renew a contract after the first Monday in June are in effect requesting that CMS agree to mutually terminate their contract.

4. Contract Request for a Hearing (§§ 422.664(b) and 423.652(b))

Under the authority of section 1857(a) of the Act, CMS enters into contracts with MA organizations which authorize

them to offer MA plans to Medicare beneficiaries. Similarly, CMS contracts with Part D plan sponsors according to section 1860D–12(a) of the Act. CMS determines that an organization is qualified to hold an MA contract through the application process established at 42 CFR 422, Subpart K. CMS evaluates the qualifications of potential Part D plan sponsors according to Subpart K of 42 CFR, part 423. If CMS denies an application, organizations have the right to appeal CMS's decision (under § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) using the procedures in subparts N of part 422 and part 423). This proposed rule seeks to correct an inconsistency in the text that identifies CMS's deadline for rendering its determination on appeals of application denials.

According to § 422.660(c) and § 423.650(c), CMS must issue a determination on appealed application denials by September 1 in order to enter into an MA contract for coverage starting January 1 of the following year. We codified this September 1 deadline in the April 15, 2010, final rule (45 FR 19699). As stated in the in the 2009 proposed rule (74 FR 54650 and 54651), we proposed to modify § 422.660(c) and § 423.660(c), which then specified that the notice of any decision favorable to a Part C or D applicant must be issued by July 15 for the contract in question to be effective on January 1 of the following year. However, in that rulemaking, we inadvertently overlooked other regulatory provisions that address the date by which a favorable decision must be made on an appeal of a CMS determination that an entity is not qualified for a Part C or Part D contract.

There is an inconsistency in regulations regarding the date by which an MA organization must receive a decision from CMS on an appeal. Section 422.660(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract to be effective on January 1. However, § 422.664(b)(1) specifies that if a final decision is not reached by July 15, CMS will not enter into a contract with the applicant for the following year. Similarly, there is an inconsistency in regulations regarding the date by which a Part D sponsor must receive a CMS decision on an appeal. Section 423.650(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 to be effective on January 1. However, § 423.652(b)(1) specifies that if a final decision is not reached on CMS's determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

We propose to modify § 422.664(b)(1) and § 423.652(b)(1) to align with the September 1 date codified in § 422.660(c) and § 423.650(c), which was codified on April 15, 2010.

5. Physician Incentive Plans—Update Stop-Loss Protection Requirements (§ 422.208)

Pursuant to section 1852(j)(4), MA organizations that operate physician incentive plans must meet certain requirements, which CMS has implemented in § 422.208. MA organizations must provide adequate and appropriate stop-loss insurance to all physicians or physician groups that are at substantial financial risk under the MA organization's physician incentive plan (PIP). The current stop-loss insurance deductible limits are identified in a table codified at § 422.208(f)(2)(iii).

Under the current regulation, an MA organization that operates a PIP must provide stop-loss protection for 90 percenter of actual costs of referral services that exceed the per patient deductible limit to all physicians and physician groups at financial risk under the PIP. The stop-loss protection may be per patient or aggregate. The current regulation contains a chart that identifies per-patient stop-loss deductible limits for single combined; separate institutional; and separate professional insurance. The current regulation establishes requirements for stop-loss attachment points (deductibles) based on the patient panel size and does not distinguish between at-risk or non-at-risk patients in that panel. There is no requirement for an MA organization to provide stop-loss protection when the physician or physician group has a panel of risk patients of more than 25,000; we are not proposing to change to this requirement. In recent years, CMS has received a number of requests to update the stop-loss insurance limits associated with PIP arrangements to better account for medical costs and utilization changes that have occurred since the final rule was published in the June 29, 2000 **Federal Register** (65 FR 40325) on.

We are not proposing to change the requirements that the MAO (in connection with the PIP) must provide aggregate stop-loss protection for 90 percentage of actual costs of referral services that are greater than 25 percent of potential income to all physicians and physician groups at financial risk under the PIP and that no stop-loss protection is required when the panel size of the physician or physician group is above 25,000. We are proposing three changes to update the existing regulation:

- Update the stop-loss deductible limits at § 422.208(f)(2)(iii) and codify the methodology that CMS would use to update the stop-loss deductible limits in the future to account for changes in medical cost and utilization;
- Authorize, at paragraph § 422.208(f)(3), MA organizations to use actuarially equivalent arrangements to protect against substantial financial loss under the PIP due to the risks associated with serving particular groups of patients.
- Modify paragraph 422.208(f)(2) to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients (FFS), who obtain some services from the physician or physician group to be included when determining the deductible.

We do not believe that other substantive requirements set forth in the PIP regulation, such as the determination of substantial financial risk based on a risk threshold of 25 percent of potential payments (see § 422.208(d)(2)), need to be updated regularly or have been rendered obsolete in the years since the regulation was initially adopted. Although we are not proposing a change to the determination of ''substantial financial risk,'' we appreciate that the regulatory standard (25% of potential payments) in § 422.208(d)(2) was adopted many years ago. Therefore, we seek comment on whether the definitions of ''substantial financial risk'' and ''risk threshold'' contained in the current regulation should be revisited, including whether the current identification of 25 percent of potential payments codified in paragraph (d)(2) remains appropriate as the standard in light of changes in medical cost.

b. Update Deductible Limits and Codify Methodology

Because of increases in medical costs and changes in utilization since the current regulatory standards for PIP stop-loss insurance were adopted, we are concerned that the current regulation requires stop-loss insurance on more generous and more expensive terms than is necessary. Our goal in developing this proposal was to identify the point at which most, if not all, physicians and physician groups would be subject to the substantial loss so that the requirement for the provision of

stop-loss protection and the parameters of that protection would be tailored to address that risk. We intend to avoid regulatory requirements that require protection that is broader than the minimum required under the statute. In developing the new minimum attachment points for the stop-loss protection that is required under the statute, one goal is to provide flexibility to MA organizations and the physicians and physician groups that participate in PIPs in selecting between combined stop-loss insurance and separate professional services and institutional services stop loss insurance.

In order to develop the specific attachment points, we engaged in a data-driven analysis using Part A and Part B claims data from 340,000 randomly selected beneficiaries from 2016. We assumed a multi-specialty practice and we estimated medical group income based on FFS claims, including payments for all Part A and Part B services. We used the central limit theorem to calculate the distribution of claim means for a multi-specialty group of any given panel size. This distribution was used to obtain, with 98% confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25% of its income derived from services that the physician or physician group personally rendered. We used projections of total income based on services provided personally by individual physicians and directly by physician groups because that is how we interpret ''potential payments'' as defined in the existing regulation. The point at which loss would exceed 25% of potential payments was set as the single combined per patient deductible in Table 13, which we describe in our proposed text at § 422.208(f)(2)(iii); we are not proposing to codify the table, but to codify the methodology for creating it so that the table itself may be updated by CMS as necessary. Nonetheless, Table 13 would be the table applicable for contract years beginning on or after January 1, 2019 until CMS reapplied the methodology and published an updated table under our proposal. We performed the analysis for multiple panel sizes, which are listed on Table 13. Table 13 also includes a 'net benefit premium' (NBP) column, which is used under our proposal to identify the attachment points for separate stop-loss insurance for institutional services and professional services. This NBP column is not needed for identification of the minimum attachment point (maximum deductible) for combined aggregate insurance. The NBP is computed by dividing the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

TABLE 13—COMBINED STOP-LOSS INSURANCE DEDUCTIBLES

Panel size	Single combined deductible	Net benefit premium (NBP) PMPY
400	$5,000	$5,922
800	10,000	4,891
1400	15,000	4,122
2,000	20,000	3,514
3,300	30,000	2,612
4,600	40,000	1,984
5,800	50,000	1,539
6,900	60,000	1,216
7,900	70,000	977
10,100	100,000	553
12,300	150,000	267
13,500	200,000	159
14,800	300,000	79
16,100	500,000	428
16,800	1,000,000	12
17,400–25,000	2,000,000	4
>25,000	No Stop Loss	0

We propose, at paragraph § 422.208 (f)(2)(iii), other significant provisions. Proposed paragraph § 422.208 (f)(2)(iii)(A) provides that the table (published by CMS using the methodology proposed in paragraph § 422.208(f)(2)(iv)) identifies the maximum attachment point/maximum deductible for per-patient-combined insurance coverage that must be provided for 90% of the costs above the deductible or an actuarial equivalent amount. For panel sizes and deductible amounts not shown in the tables, we propose that linear interpolation may be used to identify the required deductible for panel sizes between the table values. In addition, proposed paragraph § 422.208(f)(2)(iii)(B) provides that the table applies only for capitated risk.

In order to provide the attachment points for separate per patient insurance for institutional services and professional services, we propose to use the NBP from Table 13. This second table provides separate deductibles for physician and institutional services. Table 14 was calculated using a methodology similar to the calculation of Table 13. The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services. The central limit theorem was used to obtain the distribution of claim means, and deductibles were obtained at the 98 percent confidence level. We propose to codify the methodology and assumptions for Table 14 in § 422.208 (f)(2)(vi) and (f)(2)(vii).

BILLING CODE 4120–01–P

BILLING CODE 4120–01–C

The physician or physician group would look up the combined deductible in the second column of Table 13 and select the corresponding NBP in the

TABLE 14: SEPARATE STOP-LOSS INSURANCE DEDUCTIBLES

Professional Deductible (in thousands)	Institutional Deductibles (In Thousands) [Cells contain exact Net Benefit Premiums]																
	5	**10**	**15**	**20**	**30**	**40**	**50**	**60**	**70**	**100**	**150**	**200**	**300**	**500**	**1,000**	**2,000**	**No Stop Loss**
1	5,899	5,022	4,351	3,817	3,021	2,471	2,083	1,804	1,598	1,233	987	894	824	778	762	757	752
2	5,705	4,829	4,157	3,624	2,828	2,277	1,890	1,610	1,404	1,039	794	700	630	584	569	563	558
3	5,593	4,717	4,045	3,512	2,716	2,165	1,778	1,498	1,292	927	682	588	518	472	457	451	446
5	5,468	4,591	3,920	3,386	2,590	2,040	1,653	1,373	1,167	802	556	463	393	347	331	326	321
8	5,375	4,499	3,828	3,294	2,498	1,948	1,560	1,281	1,075	710	464	371	301	254	239	234	229
10	5,338	4,462	3,790	3,257	2,461	1,910	1,523	1,243	1,037	672	427	333	263	217	202	196	191
12	5,311	4,434	3,763	3,230	2,433	1,883	1,496	1,216	1,010	645	400	306	236	190	175	169	164
15	5,281	4,404	3,733	3,199	2,403	1,853	1,466	1,186	980	615	370	276	206	160	144	139	134
20	5,248	4,371	3,700	3,167	2,370	1,820	1,433	1,153	947	582	337	243	173	127	112	106	101
25	5,227	4,350	3,679	3,145	2,349	1,799	1,412	1,132	926	561	316	222	152	106	90	85	80
35	5,201	4,324	3,653	3,119	2,323	1,773	1,385	1,106	900	535	289	196	126	80	64	59	54
50	5,181	4,304	3,633	3,099	2,303	1,753	1,366	1,086	880	515	269	176	106	60	44	39	34
75	5,166	4,289	3,618	3,084	2,288	1,738	1,351	1,071	865	500	254	161	91	45	29	24	19
100	5,159	4,283	3,611	3,078	2,282	1,731	1,344	1,064	858	493	248	154	84	38	23	17	12
200	5,151	4,274	3,603	3,070	2,274	1,723	1,336	1,056	850	485	240	146	76	30	15	9	4
No stop loss	5,147	4,270	3,599	3,066	2,269	1,719	1,332	1,052	846	481	236	142	72	26	11	5	0

third column. If necessary, linear interpolation would be used. Finally, the physician or physician group would select any cell in the table in Table 14 whose numerical entry is greater than or equal to that NBP. The row and column labels for this cell are the corresponding professional and institutional deductibles for that selection. Any such selection would meet the requirement of the basic rule stated in paragraph (f)(2)(i). We are proposing to codify the use of this table of deductibles for separate stop-loss insurance professional services and institutional services based on the NBP in paragraph (f)(2)(v).

We solicit comment on our proposal, specifically the following:

- Whether our proposed regulation text at paragraphs (f)(2)(iv), (vi) and (vii) details the methodology for developing Tables 13 and 14 in sufficient detail.
- Whether our proposed regulation text clearly identifies how the tables would be used.
- Whether we should finalize a specific schedule, such as annually or every 3 years for updating the tables using the proposed methodologies in order to ensure that the maximum deductibles are consistent with medical cost and utilization trends.

d. Actuarially Equivalent Arrangements

Over the past several years, MA organizations, have requested an update to the tables as well as additional flexibilities around protection arrangements other than combined and separate per-patient stop-loss insurance. CMS believes that providing the flexibility to MA organizations to use actuarially equivalent arrangements is appropriate as the nature of the PIP negotiated between the MA organization and physicians or physician groups might necessitate other arrangements to properly and adequately protect physicians from substantial financial risk. Examples where actuarially equivalent modifications might be necessary, include: Global capitation arrangements that include some, but not all Parts A and B services; stop-loss policies with different coinsurances; stop-loss policies that use medical loss ratios (MLR), which generally pay specific stop-loss amounts only to the extent that the overall aggregate MLR for the physician group exceeds a certain amount; stop-loss policies for exclusively primary care physicians; and risk arrangements on a quota share basis, which occurs when less than full capitation risk is transferred from a plan to a physician or physician group. Therefore, we propose to add § 422.208(f)(3) to permit MA organizations to use other stop-loss protection arrangements; the proposal would allow actuaries to develop actuarially equivalent special insurances that are: Appropriately developed for the population and services furnished; in accordance with generally accepted actuarial principles and practices; and certified as meeting these requirements by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board. Under this proposal, CMS would review the attestation of the actuary certifying the special insurance arrangement. We solicit comment whether these proposed standards provide sufficient flexibility to MA organizations and physicians.

c. Non-Risk Patient Equivalents Included in Panel Size

We believe that the number of a physician group's non-risk patients should be taken into account when setting stop loss deductibles for risk patients. For example a group with 50,000 non-risk patients and 5,000 risk patients needs less protection than a group with only 3,000 non-risk patients and 5,000 risk patients. We propose, at § 422.208(f)(2)(iii) and (v), to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients, who obtain some services from the physician or physician group to be included in the panel size when determining the deductible. Under our proposal, NPEs are equal to the projected annual aggregate payments to a physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both the numerator and denominator are for physician services that are rendered by the physician or physician group. We propose that the deductible for the stop-loss insurance that is required under this regulation would be the lesser of: (1) The deductible for globally capitated patients plus up to $100,000 or (2) the deductible calculated for globally capitated patients plus NPEs. The deductible for these groups would be separately calculated using the tables and requirements in our proposed regulation at paragraph (f)(2)(iii) and (v) and treating the two groups (globally capitated patients and globally capitated patients plus NPEs) separately as the panel size. We propose the same flexibility for combined per-patient stop-loss insurance and the separate stop-loss insurances. We solicit comment on this proposal.

6. Changes to the Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)

Sections 103(b)(1)(B) and 103(b)(2) of the Medicare Improvements for Patients and Providers Act (MIPPA) revised section 1851(j)(2)(D) of the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents/brokers to enroll individuals in the MA plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised section 1860D–4(l)(2) of the Act to apply these same guidelines to Part D sponsors. We believe agents/brokers play a significant role in providing guidance and are, as such, in a unique position to influence beneficiary choice. CMS implemented these MIPPA-related changes in a May 23, 2014 final rule (79 FR 29960). The 2014 final rule revised the provisions previously established in the interim final rule (IFR) adopted on September 18, 2008 (73 FR 554226).

The IFR had established the previous compensation structure for agents/brokers as it applied to the MA and Part D programs. In particular, the IFR limited compensation for renewal enrollments to no greater than 50 percent of the rate paid for the initial enrollment on a 6-year cycle. This structure had proven to be complicated to implement and monitor, as it required the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment and calculate the renewal rate based on that initial payment. To the extent that there was confusion about the required levels of compensation or the timing of compensation, it seemed that there was an uneven playing field for MA organizations and Part D sponsors operating in the same geographic area.

In addition to the many inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, CMS found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. CMS's audit findings and monitoring efforts performed after implementation of the IFR showed that MA organizations and Part D sponsors were having difficulty correctly administering the compensation requirements.

Also, we were concerned that the structure as it existed before the 2014 revisions created an incentive for agents/brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan-type changes. That

compensation structure resulted in different payments when a beneficiary moved from one plan to another like plan in a different organization. In such situations, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the initial rate paid by the prior parent organization. Thus, in cases where the fair market value (FMV) for compensation had increased, or the other parent organization paid a higher commission, an incentive existed for the agent to move beneficiaries from one parent organization to another, rather than supporting the beneficiary's continued enrollment in the prior parent organization.

In a 2014 proposed rule (79 FR 1918), we proposed to simplify agent/broker compensation rules to help ensure that plan payments were correct and establish a level playing field that further limited the incentive for agents/brokers to move enrollees for financial gain rather than for the beneficiary's best interest. In the final rule published on May 23, 2014, we codified technical changes to the language established by the IFR relating to agent/broker compensation, choosing instead to link payment rates for renewal enrollments to current FMV rates rather than the rate paid for the original (that is, initial) enrollment. These changes also effectively removed the 6-year cycle from the payment structure. We codified these changes in §§ 422.2274(a), (b), and (h) for MA organizations and §§ 423.2274(a), (b), and (h) for Part D sponsors.

At that time, we should have also proposed to remove the language at § 422.2274(b)(2)(i), § 422.2274(b)(2)(ii), § 423.2274(b)(2)(i), and § 423.2274(b)(2)(ii), but we failed to do so. Since then, this language is no longer relevant, as the current compensation structure is not based on the initial payment. However, it has created confusion among plan staff and brokers.

We propose to make a technical correction to the existing regulatory language at § 422.2274(b) and § 423.2274(b). We propose to remove the language at §§ 422.2274(b)(2)(i), 422.2274(b)(2)(ii), 423.2274(b)(2)(i), and 423.2274(b)(2)(ii). Additionally, we would renumber the existing provisions under § 422.2274(b) and § 423.2274(b) for clarity.

7. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

Section 1851(h)(7) of the Act directs CMS to act in collaboration with the states to address fraudulent or inappropriate marketing practices. In particular, section 1851(h)(7)(A)(i) of the Act requires that MA organizations only use agents/brokers who have been licensed under state law to sell MA plans offered by those organizations. Section 1860D–4(l)(4) of the Act references the requirements in section 1851(h)(7) of the Act and applies them to Part D sponsors. We have codified the requirement in §§ 422.2272(c) and 423.2272(c).

In the April 15, 2011, final rule (76 FR 21503 and 21504), we codified a provision in §§ 422.2272(e) and 423.2272(e) that required MA organizations and Part D sponsors to terminate any employed agent/broker who became unlicensed. The provision also required MA organizations and Part D sponsors to notify any beneficiaries enrolled by the unqualified agent/broker of that agent/broker's status. Finally, the provision specified that the MA organization or Part D sponsor must comply with any request from the beneficiary regarding the beneficiary's options to confirm enrollment or make a plan change if the beneficiary requests such upon notification of the agent/broker's status.

Since implementation of the provision in §§ 422.2272(e) and 423.2272(e), we have become aware that the regulation does not allow latitude for punitive action in situations when a license lapses. The MA organization or Part D sponsor may terminate the agent/broker and immediately rehire the individual thereafter if licensure has been already reinstated or prohibit the agent/broker from ever selling the MA organization's or Part D sponsor's products again. Discussions with the industry indicate that these two options are impractical due to their narrow limits. We believe agents/brokers play a significant role in providing guidance to beneficiaries and are in a unique position to positively influence beneficiary choice. However, the statute directs CMS to require MA organizations and Part D sponsors to only use agents/brokers who are licensed under state law. We do not intend to change the regulation, at §§ 422.2272(c) and 423.2272(c), requiring agent/broker licensure as a condition of being hired by a plan, and will continue to review the licensure status of agents/brokers during those monitoring activities that focus on MA organizations' and Part D sponsors' marketing activities. CMS believes MA organizations and Part D sponsors should determine the level of disciplinary action to take against agents/brokers who fail to maintain their license and have sold MA/Part D products while unlicensed, so long as the MA organization or Part D plan complies with the remaining statutory and regulatory requirements.

We propose to delete §§ 422.2272(e) and 423.2272(e), the provisions that limit what MA organizations and Part D sponsors can do when they have discovered that a previously licensed agent/broker has become unlicensed. Nonetheless, CMS may pursue compliance actions upon discovery of MA organizations and Part D sponsors who allow unlicensed agents/brokers to continue selling their products in violation of §§ 422.2272(c) and 423.2272(c).

Note that deleting paragraph (e) from §§ 422.2272 and 423.2272 removes language describing the opportunity beneficiaries have to select a different MA or Part D plan when the broker who enrolled them was unlicensed at the time the beneficiaries enrolled. Removing paragraph (e) from §§ 422.2272 and 423.2272 does not eliminate the special enrollment period (SEP) that enrollees receive when it is later discovered that their agent/broker was not licensed at the time of the enrollment as that SEP exists under the authority of § 422.62(b)(4).

8. Codification of Certain Medicare Premium Adjustments as Initial Determinations (§ 405.924)

Current regulations at § 405.924(a) set forth Social Security Administration (SSA) actions that constitute initial determinations under section 1869(a)(1) of the Act. These actions at § 405.924(a) include determinations with respect to entitlement to Medicare hospital (Part A) or supplementary medical insurance (Part B), disallowance of an application for entitlement; a denial of a request for withdrawal of an application for Medicare Part A or Part B, or denial of a request for cancellation of a request for withdrawal; or a determination as to whether an individual, previously determined as entitled to Part A or Part B, is no longer entitled to these benefits, including a determination based on nonpayment of premiums.

In addition to the actions set forth at § 405.924(a), SSA, the Office of Medicare Hearings and Appeals (OMHA), and the Departmental Appeals Board (DAB) also treat certain Medicare premium adjustments as initial determinations under section 1869(a)(1) of the Act. These Medicare premium adjustments include Medicare Part A and Part B late enrollment and reenrollment premium increases made in accordance with sections 1818, 1839(b) of the Act, §§ 406.32(d),

408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301. Due to the effect that these premium adjustments have on individuals' entitlement to Medicare benefits, they constitute initial determinations under section 1869(a)(1) of the Act.

Accordingly, we are proposing to add a new paragraph (5) to § 405.924(a) to clarify that these premium adjustments, made in accordance with sections 1818 and 1839(b) of the Act, §§ 406.32(d) and 408.22 of this chapter, and 20 CFR 418.1301, constitute initial determinations under section 1869(a)(1) of the Act. Because this proposed change seeks only to codify existing processes related to premium adjustments, and not to alter existing processes or procedures, it applies only to Part A and Part B late enrollment and reenrollment penalties. Based on 1860D–13(b)(6)(C) of the Act, CMS does not consider Part D late enrollment and reenrollment penalties to be initial determinations. As a result, their appeal rights stop at the reconsideration level.

9. Eliminate Use of the Term ''Non-Renewal'' To Refer to a CMS-Initiated Termination (§§ 422.506, 422.510, 423.507 and 423.509)

Section 1857(c)(2) of the Act provides the bases upon which CMS may make a decision to terminate a contract with an MA organization. Under section 1860D 12(b)(3) of the Act, these same bases are available for a CMS termination of a Part D sponsor contract, as section 1860D–12(b)(3) of the Act incorporates into the Part D program the Part C bases by reference to section 1857(c)(2). Also, sections 1857(h) and 1860D 12(b)(3)(F) of the Act provide the procedures CMS must follow in carrying out MA organization or Part D sponsor contract terminations.

Although the Act only expressly refers to terminations, through rulemaking and subregulatory guidance, we have created two different processes relating to severing the contractual agreement between CMS and an MA organization or Part D sponsor. In accordance with sections 1857(h) and 1860D–12(b)(3)(F) of the Act, we have adopted regulations providing for distinct contract termination and bases and procedures for nonrenewal if contracts. Our regulations at §§ 422.506 and 422.510 provide for the nonrenewal and termination, respectively, of CMS contracts with MA organizations. The Part D regulations provide for similar procedures with respect to Part D sponsor contracts at §§ 423.507 and 423.509.

Each nonrenewal provision is divided into two parts, one governing nonrenewals initiated by a sponsoring organization and another governing nonrenewals initiated by CMS. Two features of the nonrenewal provisions have created multiple meanings for the term ''nonrenewal'' in the operation of the Part C and D programs, contributing, in some instances, to confusion within CMS and among contracting organizations surrounding the use of the term. The first feature is the difference between non renewals initiated by sponsoring organizations and those initiated by CMS with respect to the need to establish cause for such an action. The second is the partial overlap between CMS' termination authority and our nonrenewal authority. We propose to revise our use of terminology such that that the term ''nonrenewal'' only refers to elections by contracting organizations to discontinue their contracts at the end of a given year. We propose to remove the CMS initiated nonrenewal authority stated at paragraph (b) from both §§ 422.506 and 423.507 and modify the existing CMS initiated termination authority at §§ 422.510 and 423.509 to reflect this change.

MA organizations and Part D plan sponsors may elect to end the automatic renewal provision in Part C or Part D contracts and discontinue those contracts with CMS without cause, simply by providing notice in the manner and within the timeframes stated at § 422.506(a) and § 423.507(a). Thus, organizations are free to make a business decision to end their Medicare contract at the end of a given year and need not provide CMS with a rationale for their decision. By contrast, CMS may not end an MA organization or Part D plan sponsor's contract through nonrenewal without establishing that the contracting organization's performance has met the criteria for at least one of the stated bases for a CMS initiated contract nonrenewal in paragraphs (b) of those sections.

Contracting organizations often respond to changes in the Medicare markets or changes in their own business objectives by making decisions to end or modify their participation in the Part C and D programs. Thus, these organizations exercise their nonrenewal rights under § 422.506(a) and § 423.507(a) much more frequently than CMS conducts contract non renewals under § 422.506(b) and § 423.507(b). As a result, within CMS and among industry stakeholders, the term ''nonrenewal'' has effectively come to refer almost exclusively to MA organization and Part D plan sponsor initiated contract non renewals.

The termination authority allows us to provide notice of such an action at any time and make it effective at least 30 days after providing such notice to the contracting organization. By contrast, CMS may issue a nonrenewal notice of a contract no later than August 1, and the nonrenewal takes effect at the end of the current contract year. Yet, the result of both actions taken by CMS is the discontinuation, for cause (although the basis of that cause might be different), of an organization's MA or Part D contract.

The similarities between nonrenewal and termination are demonstrated by the extensive but not complete overlap in bases for CMS action under both processes. For example, both nonrenewal authorities incorporate by reference the bases for CMS initiated terminations stated in § 422.510 and § 423.509. The remaining CMS initiated nonrenewal bases (any of the bases that support the imposition of intermediate sanctions or civil money penalties (§§ 422.506(b)(iii) and § 423.507(b)(1)(ii)), low enrollment in an individual MA plan or PDP (§§ 422.506(b)(iv) and 423.507(b)(1)(iii)), or failure to fully implement or make significant progress on quality improvement projects (§ 422.506(b)(i))) were all promulgated in accordance with our statutory termination authority at sections 1857(c)(2) and 1860D–12(b)(3) of the Act and are all more specific examples of an organization's substantial failure to carry out the terms of its MA or Part D contract or its carrying out the contract in an inefficient or ineffective manner. Therefore, we propose striking these provisions from the nonrenewal portion of the regulation and adding them to the list of bases for CMS initiated contract terminations.

Finally, there are aspects of the notice requirements related to the CMS initiated nonrenewal authority that are useful in the administration of the Part C and D programs and which we propose preserving in the revised termination provision. Specifically, § 422.506(b)(2)(ii) requires notice to be provided by mail to a contracting organization's enrollees at least 90 days prior to the effective date of the nonrenewal, while § 422.510(b)(1)(ii) requires affected plan enrollees to be notified within 30 days of the effective date of the termination. We see a continuing benefit to the administration of the Part C and D programs in retaining the authority to ensure that, when possible, enrollees can be made aware of their plan's discontinuation at least by October 1 of a given year so that they can make the necessary plan choice

during the annual election period. Therefore, we propose adding provisions at §§ 422.510(b)(2)(v) and 423.509(b)(2)(v) to require that enrollees receive notice no later than 90 days prior to the December 31 effective date of a contract termination when we make such determination on or before August 1 of the same year.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 15—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($hr)	Adjusted hourly wage ($/hr)
Business Operations Specialist	13–1000	34.54	34.54	69.08
Compliance Officers	13–1041	33.77	33.77	67.54
Computer and Information Systems Managers	11–3021	70.07	70.07	140.14
Computer Programmer	15–1131	40.95	40.95	81.90
Health Diagnostic and Treating Practitioners	29–1199	40.77	40.77	81.54
Insurance Claim and Policy Processing Clerk	43–9041	19.61	19.61	39.22
Lawyers	23–1011	67.25	67.25	134.50
Medical and Health Service Manager	11–9111	52.58	52.58	105.16
Medical Secretary	43–6013	16.85	16.85	33.70
Office and Administrative Support Workers, All Other	43–9199	17.33	17.33	34.66
Physicians and Surgeons	29–1060	101.04	101.04	202.08
Physicians and Surgeons, all other	29–1069	98.83	98.83	197.66
Software Developers and Programmers	15–1130	48.11	48.11	96.22
Word Processors and Typists	43–9022	19.22	19.22	38.44

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a 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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

In section II.A.9 of this proposed rule, we are proposing a limited expansion of passive enrollment authority. More specifically, the new provisions at § 422.60(g) would allow CMS, in consultation with a state Medicaid agency, to implement passive enrollment procedures in situations where criteria identified in the regulation text are met. We propose the criteria based on our policy determination that passive enrollment is appropriate in those cases to promote integrated care and continuity of care for full-benefit dual eligible beneficiaries who are currently enrolled in an integrated D–SNP.

Under passive enrollment procedures, a beneficiary who is offered a passive enrollment is deemed to have elected enrollment in a plan if he or she does not affirmatively elect to receive Medicare coverage in another way. Plans to which individuals are passively enrolled under the proposed provision would be required to comply with the existing requirement under § 422.60(g) to provide a notification. The notice must explain the beneficiaries' right to choose another plan, describe the costs and benefits of the new plan, how to access care under the plan, and the beneficiary's ability to decline the enrollment or choose another plan. Providing notification would include mailing notices and responding to any beneficiary questions regarding enrollment.

We anticipate that there will be relatively few instances each year in which passive enrollment occurs under the new provisions at § 422.60(g). This is informed by our experience in implementing passive enrollments under the existing regulations at § 422.60(g), where in recent years there have been only one to two contract terminations annually where CMS allows passive enrollment. We estimate that approximately one percent of the 373 active D–SNPs would meet the criteria identified in the regulation text, and operate in a market where all of the conditions of passive enrollment are met and where CMS, in consultation with a state Medicaid agency, implements passive enrollment. Therefore, under the new provisions at § 422.60(g), we anticipate only four additional instances in which CMS allows passive enrollment each year.

We estimate it would take 10 hours at $69.08/hr for a business operations

specialist to develop the initial notice. We also estimate it would take 1 minute for a business operations specialist to electronically generate and submit a notice for each beneficiary that is offered passive enrollment. We estimate that approximately 5,520 full-benefit dual eligible beneficiaries would be sent a notice in each instance in which passive enrollment occurs, which reflects the average enrollment of currently active D–SNP plans. Four instances of passive enrollment annually would result in 22,080 beneficiaries being sent the notice (5,520 × 4 organizations) each year.

To develop the initial notice, we estimate a one-time burden of 40 hours (4 organizations × 10 hr) at a cost of $2,763.20 (40 hr × $69.08/hr) or $690.80 per organization ($2,763.20/4 organizations). To electronically generate and submit a notice to each beneficiary, we estimate a total burden of 368 hours (22,080 beneficiaries × 1 min/60) at a cost of $25,421.44 (368 hr × $69.08/hr) or $6,355.36 per organization ($25,421.44/4 organizations) annually.

Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995. However, we seek comment on our estimates for the overall number of respondents and the associated burden.

2. ICRs Regarding the Restoration of the MA Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38, and 423.40)

In section II.B.1. of this rule, we are proposing to codify the requirements for open enrollment and disenrollment opportunities at §§ 422.60, 422.62, 422.68, 423.38, and 423.40 that would eliminate the existing MADP and establish a MA Open Enrollment Period (OEP). This new OEP revises a previous OEP which would allow MA-enrolled individuals the opportunity to make a one-time election during the first 3 months of the calendar year to switch MA plans, or disenroll from an MA plan and obtain coverage through Original Medicare. Although no new data would be collected, the burden associated with this requirement would be the time and effort that it takes an MA organization to process an increased number of enrollment and disenrollment requests by individuals using this OEP, which is first available in 2019.

To estimate the potential increase in the number of enrollments and disenrollments from the new OEP, we considered the percentage of MA-enrollees who used the old OEP that was available from 2007 through 2010. For 2010, the final year the OEP existed before the MADP took effect, we found that approximately 3 percent of individuals used the OEP. While the parameters of the old OEP and new OEP differ slightly, we believe that this percentage is the best approximation to determine the burden associated with this change. In January 2017, there were approximately 18,600,000 individuals enrolled in MA plans. Using the 3 percent adjustment, we expect that 558,000 individuals (18.6 million MA beneficiaries × 0.03), would use the OEP to make an enrollment change.

a. Beneficiary Estimate (Current OMB Control Number 0938–0753 (CMS–R–267))

We estimate it would take a beneficiary approximately 30 minutes (0.5 hours) at $7.25/hour to complete an enrollment request. While there may be some cost to the respondents, there are individuals completing this form who are working currently, may not be working currently or never worked. Therefore, we used the current federal minimum wage outlined by the U.S. Department of Labor (*https://www.dol.gov/whd/minimumwage.htm*) to calculate costs. The burden for all beneficiaries is estimated at 279,000 hours (558,000 beneficiaries × 0.5 hour) at a cost of $2,022,750 (279,000 hour × $7.25/hour) or $3.63 per beneficiary ($2,022,750/558,000 beneficiaries).

b. MA Organization Estimate (Current OMB Ctrl# 0938–0753 (CMS–R–267))

There are currently 468 MA organizations in 2017. Not all MA organizations are required to be open for enrollment during the OEP. However, for those that are, we estimate that this enrollment period would result in approximately 1,192 enrollments per organization (558,000 individuals/468 organizations) during the OEP each year.

We estimate it would take approximately 5 minutes at $69.08/hour for a business operations specialist to determine eligibility and effectuate the changes for open enrollment. The burden for all organizations is estimated at 46,500 hours (558,000 beneficiaries × 5 min/60) at a cost of $3,212,220 (46,500 hour × $69.08/hour) or $6,864 per organization ($3,212,220/468 MA organizations).

Once the enrollment change is completed, we estimate that it will take 1 minute at $69.08/hour for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each of the 558,000 beneficiaries. The total burden to complete the notices is 9,300 hours (558,000 notices × 1 min/60) at a cost of $642,444 (9,300 hour × $69.08/hour) or $1.15 per notice ($642,444/558,000 notices) or $1,372.74 per organization ($642,444/468 MA organizations).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $69.08/hour for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden is estimated at 9,300 hours (558,000 notices × 1 min/60) at a cost of $642,444 (9,300 hour × $69.08/hour) or $1.15 per notice ($642,444/558,000 notices) or $1,372.74 per organization ($642,444/468 MA organizations).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $34.66/hour for an office and administrative support worker to perform record retention for the open enrollment period. In aggregate we estimate an annual burden of 46,500 hours (558,000 beneficiaries × 5 min/60) at a cost of $1,606,110 (46,500 hour × $34.66/hour) or $3,431.86 per organization ($1,606,110/468 MA organizations).

We estimate a total annual burden for all MA organizations resulting from this proposed provision to be 111,600 hours (46,500 hour + 9,300 hour + 9,300 hour + 46,500 hour) at a cost of $6,103,218 ($3,212,220 + $642,444 + $642,444 + $1,606,110). Per organization, we estimate an annual burden of 238 hours (111,600 hour/468 MA organizations) at a cost of $13,041 ($6,103,218/468 organizations). For beneficiaries we estimate a total annual burden of 279,000 hours at a cost of $2,022,750 and a per beneficiary burden of 30 minutes at $3.63.

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

3. ICRs Regarding Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68) OMB Control Number 0938–0753 (CMS–R–267)

In section II.A.8. of this rule we propose to revise § 422.66 and 422.68 by: Codifying the requirements for default enrollment that are currently set out in subregulatory guidance,[60]

[60] Chapter 2 of the Medicare Managed Care Manual found at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/*.

revising current practice to limit the use of this type of enrollment mechanism, and clarifying the effective date for ICEP elections. This would provide an MA organization the option to enroll its Medicaid managed care enrollees who are newly eligible for Medicare into an integrated D–SNP administered by the same MA organization that operates the Medicaid managed care plan. While our proposal restricts its use to individuals in the organization's Medicaid managed care plan that can be enrolled into an integrated D–SNP, the estimated burden for an organization that desires to use default enrollment and obtain CMS approval would not change. For those MA organizations that want to use this enrollment mechanism and request and obtain CMS approval, the administrative requirements would remain unchanged from the current practice. Enrollment requirements and burden are currently approved by OMB under control number 0938–0753 (CMS–R–267). Since this proposed rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

4. ICRs Regarding Timing and Method of Disclosure Requirements (§§ 422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) and 423.128(d)(2)) (OMB Control Number 0938–1051)

a. Timing of Disclosure (§§ 422.111(a)(3) and 423.128(a)(3))

In section II.B.4. of this rule, we propose to revise the timing and method of disclosing the information as required under § 422.111(a) and (b) and the timing of such disclosures under § 423.128(a) and (b). These regulations provide for disclosure of plan content information to beneficiaries. We would revise §§ 422.111(a)(3) and 423.128(a)(3) by requiring MA plans and Part D sponsors to provide the information in §§ 422.111(b) and 423.128(b) by the first day of the annual enrollment period, rather than 15 days before that period. Plans must still distribute the ANOC 15 days prior to the AEP. In other words, the proposed provision would provide the option of either submitting the EOC with the ANOC or waiting until the first day of the AEP, or sooner, for distribution. The provision simply gives plans that may need some flexibility the ability to rearrange schedules and defer a deadline. Consequently, there is no change in burden.

b. Method of Disclosure (§§ 422.111(h)(2) and 423.128(d)(2)) (OMB Control Number 0938–1051)

Sections 422.111(h)(2)(i) and 423.128(d)(2)(i) require that plans maintain a Web site which contains the information listed in §§ 422.111(b) and 423.128(b). Section 422.111(h)(2)(ii) states that the posting of the EOC, Summary of Benefits, and provider network information on the plan's Web site ''does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.'' There is no parallel to § 422.111(h)(2)(ii) in § 423.128 for Part D sponsors. Further, § 423.128(a) includes language providing that disclosures required under that section be ''in the manner specified by CMS.''

In § 422.111(h)(2)(ii), we propose to modify the sentence which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of its responsibility to provide hard copies of these documents to beneficiaries ''upon request.'' In addition, we propose to add the phrase ''in the manner specified by CMS'' in paragraph (a). These proposed revisions would give CMS the authority to permit MA plans the flexibility to provide the information in § 422.111(b) electronically when specified by CMS as a permissible delivery option, and better aligns with the provisions under § 423.128. We intend to continue to specify hardcopy mailing, as opposed to electronic delivery, for most documents that convey the type of information described in paragraph (b). CMS intends that provider and pharmacy directories, the plan's Summary of Benefits, and EOC documents would be those for which electronic posting and delivery of a hard copy upon request are permissible. Electronic delivery would reduce plan burden by reducing printing and mailing costs. Additionally, the IT systems of the plans are already set up to format and print these documents. Also, plans must provide hard copies upon request. To estimate the cost of printing these documents, we note that the CMS Trustee's report, accessible at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/*, lists 47.8 million beneficiaries in MA, Section 1876 cost,[61] and Prescription Drug contracts for contract year 2019.

Based on reports from the *InternetSociety.org* and Pew Research Center,[62] we estimate that 33 percent of these beneficiaries who are in MA and Prescription Drug contracts would prefer to opt in to receiving hard copies to receiving electronic copies. Thus, the savings comes from the 67 percent of beneficiaries who are in MA and Prescription Drug contracts that will not opt in to having printed copies mailed to them, namely 67 percent × 47.8 = 32,026,000 individuals.

The major expenses in printing an EOC include paper, toner, and mailing costs. The typical EOC has 150 pages. Typical wholesale costs of paper are between $2.50 and $5.00 for a ream of 500 sheets. We assume $2.50 per ream of 500 sheets. Since each EOC has 150 pages, we are estimating a cost of $0.75 per EOC [$2.50/(150 pages per EOC/500 sheets per ream)]. Thus, we estimate that the total savings from paper is $24,019,500 (32,026,000 EOCs × $0.75 per EOC).

Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 pages. We conservatively assumes a cost of $50 for 10,000 pages. Each toner would print 66.67 EOCs (10,000 pages per toner/150 pages per EOC) at a cost of $0.005 per page ($50/10,000 pages) or $0.75 per EOC ($0.005 per page × 150 pages). Thus, we estimate that the total savings on toner is $24,019,500 ($0.75 per EOC × 32,026,000 EOCs).

Regarding mailing costs, since a ream of paper with 2,000 8.5 inches by 11 inches pages weighs 20 pounds or 320 ounces it then follows that 1 sheet of paper weighs 0.16 ounces (320 ounces/2,000 pages). Therefore, a typical EOC of 150 pages weighs 24 ounces (0.016 ounces/page × 150 pages) or 1.5 pounds. Since commercial mailing rates are 13.8 cents per pound, the total savings in mailings is $6,629,382 ($0.138/pounds × 1.5 pound × 32,026,000 EOCs).

In aggregate, we estimate a savings (to plans for not producing and mailing hardcopy EOCs) of $54,668,382 ($24,019,500 + $24,019,500 + $6,629,382). We will submit the proposed requirements and burden to OMB for approval under OMB control number 0938–1051 (CMS–10260).

5. ICRs Regarding the Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152) (OMB Control Number 0938–1023)

In section II.B.12. of this rule, we are proposing the removal of the Quality Improvement Project (QIP) requirements (and CMS-direction of QIPs) from the Quality Improvement (QI) Program

[61] Per 42 CFR 417.427, cost plans must comply with § 422.111 and § 423.128.

[62] Global Internet Report, 2017, Internet Society, *http://www.internetsociety.org/globalinternetreport/2016/?gclid=EAIaIQobChMI-tz1nN_W1QIVgoKzCh1EVggBEAAYASAAEgLpj_D_BwE* and ''Tech Adoption Climbs Among Older Adults,'' Pew Research Center, *http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/*.

requirements, which would result in an annual savings of $12,663.75 to MA organizations. The driver of the anticipated savings is the removal of requirements to attest having a QIP annually.

To derive our savings, we estimate that it takes 1 MA organization staff member (BLS: Compliance Officer) 15 minutes (0.25 hour) at $67.54/hour to submit a QIP attestation. Currently, there are 750 MA contracts, and each contract is required to submit a QIP attestation. Therefore, we anticipate that there will be 750 QIP attestations annually.

Using these assumptions, we estimate that the removal of the QIP provision will result in a total savings of 187.5 hours (750 contracts × 0.25 hour) at $12,663.75 (187.5 hour × $67.54/hour) or $16.89 per contact ($12,663.75/750 contracts).

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1023 (CMS–10209).

6. ICRs Regarding Medicare Advantage Quality Rating System (§§ 422.162, 422.164, 422.166, 422.182, 422.184, and 422.186)

In section II.A.11. of this rule, we are proposing to codify the existing measures and methodology for the Part C and D Star Ratings program. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS' Star Ratings-related PRA packages including: OMB control number 0938–0701 for CAHPS (CMS–10203), OMB control number 0938–0732 for HOS (CMS–R–246), 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 this rule would not impose any new or revised requirements/burden, we are not making changes to any of the aforementioned control numbers.

7. ICRs Regarding Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))

CMS regulations provide Medicare Advantage (MA) organizations, including provider sponsored organizations, with the opportunity to request a waiver of CMS's minimum enrollment requirements at § 422.514(a) during the first 3 years of the contract. Regulations also require that MA organizations reapply for the minimum enrollment waiver in the second and third years of their contract. However, since CMS has not received or approved any waivers outside of the application process, CMS proposes to remove the requirement for MA organizations to reapply for the minimum enrollment waiver during years 2 and 3 of the contract under § 422.514(b)(2) and (3). CMS also proposes to modify § 422.514(b)(2) to clarify that CMS will only accept a waiver through the application process and allow the minimum enrollment waiver, if approved by CMS, to remain effective for the first 3 years of the contract. The requirement and burden associated with the submission of the minimum enrollment waiver in the application is currently approved by OMB under control number 0938–0935 (CMS–10237) which does not need to be revised.

8. ICRs Regarding Revisions to §§ 422 and 423 Subpart V, Communication/ Marketing Materials and Activities

In section II.B.5. of this rule, we are proposing to narrow the definition of ''marketing materials'' under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. We believe the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials that pose little risk to current or potential enrollees and are not traditionally considered ''marketing.'' Revisions to §§ 422.2260 and 423.2260 would provide a narrower definition than is currently provided for ''marketing materials.'' Consequently, this change decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.

We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D sponsors by reducing the number of materials required to be submitted to us for review.

To estimate the savings, we reviewed the most recent 12-month period of marketing material submissions from the Health Plan Management System, July 2016 through and including June 2017. As documented in the currently approved PRA package, we also estimates that it takes a plan 30 minutes at $69.08/hour for a business operations specialist to submit the marketing materials. To complete the savings analysis, we also must estimate the number of marketing materials that would have been submitted to and reviewed by CMS under the current regulatory marketing definition (note that while all materials that meet the regulatory definition of marketing must be submitted to CMS, not all marketing materials are prospectively reviewed by CMS). Certain marketing materials qualify for ''File and Use'' status, which means the material can be submitted to CMS and used 5 days after submission, without being prospectively reviewed by CMS. We estimates 90 percent of marketing materials are exempt from our prospective review because of the file and use process. Thus, we only prospectively review about 10 percent of the marketing materials submitted.

Marketing materials are coded using 4- or 5-digit numbers, based on marketing material type. The relevant codes and counts are summarized in Table 16.

BILLING CODE 4120–01–P

BILLING CODE 4120–01–C

TABLE 16: MARKETING MATERIAL SUBMISSION BURDEN ANALYSIS

Marketing Code	Description	Total Number of Materials Submitted Under Marketing Code	Description of Excluded Material(s)*	Number of Excluded Materials	Number of Materials that would no longer be Submitted	Hours per Response	Total Hours Saved	Wage Rate (Per Hour)	Cost Saved (in $)
1000	Enrollment and related documents	16495	Enrollment forms	981	15,514	0.5	7,757	$69.08	535,853.56
1100	ANOC/EOC/LIS Rider	6794		5,162	1,632	0.5	816	$69.08	56,369.28
2000	Disenrollment	5942	n/a	0	5942	0.5	2,971	$69.08	205,236.68
3000	Grievances	1564	n/a	0	1564	0.5	782	$69.08	54,020.56
4000	Advertisements	43965	General advertising that includes benefits information	32,974	10,991	0.5	5,495.5	$69.08	379,629
5000	Formulary Drug	1429	n/a		1,429	0.5	714.5	$69.08	49,397.66
6000	Presentations/Scripts/Surveys	2836	Enrollment scripts	1,169	1,407	0.5	703.5	$69.08	48,597.78
8000	Creditable Coverage/LEP	559			559	0.5	279.5	$69.08	19307.86
16000, 17000	Medicare Medicaid Plans		n/a	0	0	0.5	0	$69.08	0
30000	PACE		n/a	0	0	0.5	0	$69.08	0
Total		80,110		40,286	39,824	0.5	19,912	$69.08	$1,348,372.52

*Excluded materials are materials that still will require review.

By reducing the number of marketing materials submitted to CMS by 39,824 documents (80,110 current – 40,286 excluded) we estimate a savings of

19,912 hours (39,824 materials * 0.5 hours per material) at a cost savings of $1,348,372.52 (19,912 hours * 69.08 per hour). Some key points in the calculations are as follows:

- There were a total of 80,110 marketing materials submitted to CMS during the 12-month period sampled. These materials already exclude PACE program marketing materials (30000 Code) which are governed by a different authority and not affected by the proposed provision. The 80,110 figure also excludes codes 16000 and 1700 Medicare-Medicaid Plan (MMP) materials. The MMP materials are not being counted as the decision for review rests with the states and CMS.
- The statute is clear that ''applications,'' which CMS also refers to as enrollment or election forms, must be reviewed. Thus the 981 materials submitted under marketing code 1070, enrollment forms, must be subtracted from the 80,110.
- Marketing code 1100 includes the combined ANOC/EOC as well as the D–SNP standalone ANOC. CMS intends to split the ANOC and EOC and will still require the ANOC be submitted as a marketing material, whereas the EOC will no longer be considered marketing and not require submission. To account for the ANOC submission, CMS estimates that 5,162 ANOCs will still require submission.
- We do not expect any disenrollment or grievance forms (the 2000 and 3000 codes) to be required submissions under this proposal.
- Marketing code 4000 covers all advertisements which constitute 55 percent (43,965) of the 80,110 materials. The majority of these advertisements deal with benefits and enrollment. We estimate 25 percent of the 43,965 code 4000 documents (that is, 10,991 documents) would fall outside of the new regulatory definition of marketing and no longer require submission. Thus, we must subtract these 32,974 (43,965 − 10,991) from the 80,110.
- Marketing code 5000 covers formulary drugs. Although, as is currently the case, formularies will continue to be submitted to us for review in capacities outside of marketing, they will no longer fall under the new regulatory definition of marketing and hence would not be submitted separately for review as marketing materials.
- Marketing code 6000 includes sales scripts which are predominantly used to encourage enrollment, and would likely still fall under the scope of the new marketing definition. As such, we must subtract 1,169 documents (code 6013) from the 80,110 total marketing materials.
- Marketing code 8000 includes creditable coverage and late enrollment penalty (LEP) notices that will fall outside of the new regulatory definition of marketing and no longer require submission. Over the 12-month period sampled, this represents 559 material submissions.

The proposed requirements and burden will be submitted to OMB under control number 0938–1051 (CMS–10260).

9. ICRs Regarding Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

In section II.C.1. of this rule, we note that under current §§ 422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS the information needed to verify the MLR and remittance amount, if any, for each contract, such as: Incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 422.2410 or § 423.2410. Our proposed amendments to §§ 422.2460 and 423.2460 would reduce the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors would be required to report only that the contract is non-credible.

Our analysis of the estimated administrative costs related to the MLR reporting requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. The average number of MA and Part D contracts subject to the annual MLR reporting requirements for contract years 2014 to 2018 is 587. The total number of MA and Part D contracts is relatively stable year over year. To calculate the estimated administrative costs of MLR reporting under the proposed amendments to §§ 422.2460 and 423.2460, we assume that 587 MA and Part D contracts would be subject to the MLR reporting requirements in each contract year.

Our estimate for the amount of time that MAOs and Part D sponsors would spend on administrative tasks related to the MLR reporting requirements under this proposed rule is based on our current burden estimates that are approved by OMB under control number 0938–1232 (CMS–10476), where we estimated that, on average, MA organizations and Part D sponsors would spend approximately 47 hours per contract on administrative work related to Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, and conducting internal audits. Inadvertently, our currently approved estimate did not specify (or break out) the portion of the overall reporting burden that could be attributed solely to the tasks of preparing and submitting the MLR report. We are correcting that oversight by estimating that the burden for preparing and submitting the MLR report is approximately 11.5 hours (or 24.4 percent of the estimated 47 total hours spent on all administrative work related to the MLR reporting requirements) per contact.

We arrived at the 11.5-hour estimate by considering the amount of time it would take an MA organization or Part D sponsor to perform each of the following tasks: (1) Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions; (2) draft narrative descriptions of methodologies used to allocate expenses; (3) perform an internal review of the MLR report form prior to submission; (4) upload and submit the MLR report and attestation; and (5) correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.

We estimate that our proposal to scale back the MLR reporting requirements would reduce the amount of time spent on administrative work by 11 hours, from 47 hours to 36 hours.

Table 17 compares the estimated administrative costs related to the MLR reporting requirements under the current regulation and under this proposed rule. As indicated, this proposed rule estimates that MA organizations and Part D sponsors will spend on average 36 hours per MA or Part D contract on administrative work, compared to 47 hours per contract under the current rule. We estimate the average cost per hour of MLR reporting using wage data for computer and information systems managers, as we believe that the tasks associated with MLR reporting generally fall within the fields of data processing, computer programming, information systems, and systems analysis. Based on computer and information systems managers wage

data from BLS, we estimate that MA organizations and Part D sponsors would incur annual MLR reporting costs of approximately $5,045 per contract on average under our proposal, as opposed to $6,587 per contract under the current regulations. Consequently, the proposed changes would, on average, reduce the annual administrative costs by $1,542 per contract. Across all MA and Part D contracts, we estimate that the proposed changes would reduce the annual administrative burden related to MLR reporting by 6,457 hours, resulting in a savings of $904,884.

TABLE 17—ESTIMATED ADMINISTRATIVE BURDEN RELATED TO MEDICAL LOSS RATIO (MLR) REPORTING REQUIREMENTS

Type of burden	Total number of contracts/ reports	Estimated average hours per report	Estimated total hours	Estimated average cost per hour	Estimated total cost	Estimated average cost per contract/ report
Ongoing Costs (current regulations)	587	47	27,589	$140.14	$3,866,322	$6,587
Ongoing Costs (proposed regulation changes).	587	36	21,132	140.14	2,961,438	5,045
Change	No change	11	6,457	No change	904,884	1,542

Notes: The source data has been modified to reflect estimated costs for MA organizations and Part D sponsors. Values may not be exact due to rounding.

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1232 (CMS–10476).

10. ICRs Regarding Establishing Limitations for the Part D Special Enrollment Period for Dual Eligible Beneficiaries (§ 423.38(c)(4)) OMB Under Control Number 0938–0964

In section II.A.11. of this rule, we propose to revise § 423.38(c)(4) to limit the SEP for dual- and LIS-eligible individuals. The provision would make the SEP for FBDE or other subsidy-eligible individuals available only in the following circumstances:

- For beneficiaries who are making an allowable onetime-per-calendar-year election.
- For beneficiaries who have been assigned to a plan by CMS or a state (that is, through auto enrollment, facilitated enrollment, passive enrollment, or reassignment) and decide to change plans following notification of the change or within 2 months of the election effective date.
- For beneficiaries who have a change in their dual or LIS-eligible status.

In instances where an individual is not able to utilize the dual SEP because of the proposed limitations, we anticipate that there will be no change in burden. Under current requirements, if a beneficiary uses the dual SEP to disenroll from their plan, the plan would send a notice to the beneficiary to acknowledge the voluntary disenrollment request. If the beneficiary is subject to the dual SEP limitation, the plan would send a notice to deny their voluntary disenrollment request. The requirement to acknowledge the beneficiary request and address the resolution would be the same in both scenarios, but the content of the notice would be different. Enrollment processing and notification requirements are codified at § 423.32(c) and (d) and are not being revised as part of this rulemaking. Therefore, no new or additional information collection requirements are being imposed. Moreover, the requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

11. ICRs Related to Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128) OMB Under Control Number 0938–0964

In section II.A.15 of this rule, we propose to expedite certain generic substitutions and other midyear formulary changes and except applicable generic substitutions from the transition process. Excepting generic substitutions that would otherwise require transition fills from the transition process would lessen the burden for Part D sponsors because they would no longer need to provide such fills. Permitting Part D sponsors to immediately substitute newly approved generic drugs or to make other formulary changes sooner than has been required would allow Part D sponsors to take action sooner, but would not increase nor decrease paperwork.

While the proposed provisions would additionally require general notice that certain generic substitutions could take place immediately, Part D sponsors are already creating the documents in which that notice would appear such as formularies and EOCs. Similarly, § 423.128(d)(2)(ii) already requires Web sites to include information about drug removals and changes to cost-sharing. In other words, the proposed general notice requirement would not require efforts in addition to routine updates to beneficiary communications materials and Web sites. In theory, if Part D sponsors that would have been denied requests to make generic changes could do so under the proposed provision, they would have somewhat more of a burden since the proposed provision does require notice including direct notice to affected enrollees. However, our practice has been to approve all or virtually all generic substitutions that would meet the requirements of this proposed provision—which again means that the proposed provisions would just permit those substitutions to take place sooner.

The general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

12. ICRs Related to Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in Medicare Advantage, Cost Plans, and PACE

a. Preclusion List Requirements for Part D Sponsors

(1) Burden and Costs

In sections II.D.10 and 11. of this proposed rule, we are proposing in § 423.120(c)(6) to require that Part D sponsors cover a provisional supply of a drug before they reject a claim based on a prescriber's inclusion on the preclusion list. The proposed provision would also require that Part D sponsors provide written notice to the beneficiary of the prescriber's presence on the preclusion list and take reasonable efforts to furnish written notice to the prescriber. The burden associated with these provisions would be the time and

effort necessary for Part D adjudication systems to be programmed and for model notices to be created, generated, and disseminated.

(a) Part D System Programming

We estimate that it would take all 30 sponsors and PBMs with Part D adjudication systems a total of approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of § 423.120(c)(6). In 2020 and 2021, we do not anticipate any system costs. The sponsors and PBMs would need approximately 6 to 12 months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time software developers and programmers at $96.22/hour resulted in the aforementioned 93,600 hour figure (3 workers × 1,040 hour × 30 sponsors/PBMs) at a cost of $9,006,192 (93,600 × $96.22/hour) for 2019. There would be no burden associated with 2020 and 2021.

(b) Creation of Template Notices to Beneficiaries and Prescribers

As stated in the May 6, 2015 IFC, we estimate that 212 parent organizations would need to create two template notices to notify beneficiaries and prescribers under proposed § 423.120(c)(6). We project that it would take each organization 3 hours at $69.08/hour for a business operations specialist to create the two model notices. For 2019, we estimate a one-time total burden of 636 hours (212 organizations × 3 hours) at a cost of $43,935 (636 hour × $69.08/hour) or $207.24 per organization ($43,935/212 organizations). There would be no burden associated with 2020 and 2021.

The proposed system programing and notice development requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

(c) Preparation and Issuance of the Notices

We estimate that it would take an average of 5 minutes (0.083 hour) at $39.22/hour for an insurance claim and policy processing clerk to prepare and distribute the notices. We estimate that an average of approximately 800 prescribers would be on the preclusion list in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries would have been receiving prescriptions written by these prescribers and would therefore receive the notice referenced in § 423.120(c)(6). In 2019 we estimate a total burden of 6,640 hours (0.083 hour × 80,000 responses) at a cost of $260,421 (6,640 hour × $39.22/hour) or $1,228.40 per organization ($260,421/212 organizations).

In 2020 and 2021, we estimate that roughly 150 prescribers each year would be added to the preclusion list, though this would be largely offset by the same number of prescribers being removed from the list (for example, based on reenrollment after the expiration of a reenrollment bar or decision to remove them from the preclusion list) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of 1,245 hours (15,000 beneficiaries × 0.083 hours) at a cost of $48,829 (1,245 hour × $39.22/hour) or $325.53 per prescriber ($48,829/150 prescribers).

The proposed notice preparation and distribution requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

TABLE 18—ESTIMATED BURDEN OF PART D—NOTICE PREPARATION AND DISTRIBUTION

[In hours]

	2019	2020	2021	3-year average
Provisional Supply—Programming	93,600	0	0	31,200
Provisional Supply—Template Creation	636	0	0	212
Provisional Supply—Letter Preparation	6,640	1,245	1,245	3,043
Total	100,876	1,245	1,245	34,455

TABLE 19—ESTIMATED BURDEN OF PART D—NOTICE PREPARATION AND DISTRIBUTION

[In $]

	2019	2020	2021	3-year average
Provisional Supply—Programming	$9,006,192	$0	$0	$3,002,064
Provisional Supply—Template Creation	43,935	0	0	14,645
Provisional Supply—Notice Preparation	260,421	48,829	48,829	119,360
Total	9,310,548	48,829	48,829	3,136,069

(2) Savings

We believe that savings would accrue for the prescriber community from our proposed elimination of the requirement that prescribers enroll in Medicare in order to prescribe Part D drugs.

As previously explained in this proposed rule, approximately 420,000 prescribers have yet to enroll in Medicare via the CMS–855O application (OMB 0938–1135). We estimate that it would take 0.5 hours for a prescriber to complete a CMS–855O application. This is based on the following assumptions:

- A medical secretary would take 0.42 hours to prepare the application.
- A physician would take 0.08 hours to review and sign the application.

This would result in a per application cost of $30.32 ((0.42 hours × $33.70) + (0.08 hours × $202.08). Multiplying this figure by 420,000 applications results in a total savings of $12,734,400. We believe that these savings would accrue in 2019.

(3) Net Costs and Savings

We believe that a result of our proposed elimination of the Part D

enrollment requirement, the following net savings for prescribers would ensue:

TABLE 20—NET COSTS/SAVINGS

[In $]

	2019	2020	2021	3-year average
Costs	$9,310,548	$48,829	$48,829	$3,136,069
Savings	12,734,400	0	0	4,244,800
Net*	3,423,852	(48,829)	(48,829)	1,108,731

* Net costs denoted in parentheses.

b. Preclusion List Requirements for Part C

As previously explained in this proposed rule, approximately 120,000 MA providers and suppliers have yet to enroll in Medicare via the CMS–855 application. Of these providers and suppliers, and based on internal CMS statistics, we estimate that 90,000 would complete the CMS–855I (OMB No. 0938–0685), which is completed by physicians and non-physician practitioners; 24,000 would complete the CMS–855B (OMB control number 0938–0685), which is completed by certain Part B organizational suppliers; and 6,000 would complete the CMS–855A (OMB No. 0938–0685), which is completed by Part A providers and certain Part B certified suppliers. Therefore, we believe that savings would accrue for providers and suppliers from our proposed elimination of our MA/Part C enrollment. Table 21 estimates the burden hours associated with the completion of each form.

TABLE 21—CMS–855 APPLICATION BURDEN

Submission type	Number of respondents no longer required to enroll	Hours for completion by office personnel	Hours for a physician to review and sign	Hours for an authorized official to review and sign	Total hours for completion
CMS–855I	90,000	2.5	0.5	n/a	3
CMS–855B	24,000	4	n/a	1	5
CMS–855A	6,000	5	n/a	1	6

In projecting the savings involved, we assume a medical and health services manager would serve as the provider's or supplier's ''authorized official'' and would sign the CMS–855A or CMS–855B application on the provider's or supplier's behalf.

Therefore, we project the following total hour and cost burdens:

- CMS–855I: We estimate a total reduction in hour burden of 270,000 hours (90,000 applicants × 3 hours). With the cost of each application processed by a medical secretary and physician as being $185.29 (($33.70 × 2.5 hours) + ($202.08 × 0.5 hours)), we estimate a savings of $16,676,100 (90,000 applications × $185.29).
- CMS–855B: We estimate a total reduction in hour burden of 120,000 hours (24,000 applicants × 5 hours). With the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being $239.96 (($33.70 × 4 hours) + ($105.16 × 1 hour)), we estimate a total savings of $5,759,040 (24,000 applications × $105.16).
- CMS–855A: We estimate a total reduction in hour burden of 36,000 hours (6,000 applicants × 6 hours). With the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being $273.66 (($33.70 × 5 hours) + ($105.16 × 1 hour)), we estimate a total savings of $6,567,840 (24,000 applications × $273.66).

Given the foregoing, we estimate that providers and suppliers would experience a total reduction in hour burden of 426,000 hours (270,000 + 120,000 + 36,000) and a total cost savings of $32,102,980 ($9,667,660 + $5,759,040 + $16,676,100). We expect these reductions and savings to accrue in 2019 and not in 2020 or 2021. Nonetheless, over the OMB 3-year approval period of 2019–2021, we expect an annual reduction in hour burden of 142,000 hours and an annual savings of $10,700,933 ($32,102,800/3) under OMB Control No. 0938–0685.

We also propose to revise § 422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. We do not expect any additional burden from this particular proposal, for this activity is consistent with existing policy.

13. ICRs Regarding the Part D Tiering Exceptions ((§§ 423.560 and § 423.578(a) and (c))

In section II.A.9. of this rule, we are proposing various changes to § 423.578(a) and (c) related to the requirements for tiering exceptions criteria that Part D plan sponsors are required to establish. These changes include establishing a revised framework for treatment of tiering exception requests based on whether the requested drug is a brand name or generic drug or biological product, and where the same type of drug alternatives are located on the plan's formulary. The proposed changes also include clarification of appropriate cost-sharing assigned to approved tiering exception requests when preferred alternative drugs are on multiple lower-cost tiers. At the coverage determination level, if a plan issues a decision that is partially or fully adverse to the enrollee, it is already required to send written notice of that decision. The existing requirement to send written notice of an adverse coverage determination would

not change under the proposed changes related to tiering exceptions. We do not expect the proposed changes to significantly impact the overall volume or the approval rate of tiering exceptions requests, which represent a consistently low percentage of total request volume.

While the requirement to send a written denial notice is subject to the PRA, the requirement and burden are currently approved by OMB under control number 0938–0976 (CMS–10146). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

14. ICRs Regarding the Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (§ 423.153(f))

As discussed in section of this rule, proposed § 423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes ''lock-in'' as a tool to manage an at-risk beneficiary's access to coverage of frequently abused drugs. Part D plan sponsors would be required to notify at-risk beneficiaries about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the sponsor decides to implement a beneficiary-specific POS claim edit for opioids (OMB under control number 0938–0964 (CMS–10141)). However, the OMB control number 0938–0964 only accounts for the notices that are currently sent to beneficiaries who have a POS edit put in place to monitor opioid access (which would count as the initial notice described in the preamble and defined in § 423.153(f)(4)) and would not capture the second notice that at-risk beneficiaries would receive confirming their determination as such or the alternate second notice that potentially at-risk beneficiaries would receive to inform them that they were not determined to be at risk.

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. Given that there has not been a steady increase or decrease in edits, we have used the average, 923 edits annually, to assess burden under this rule. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber ''lock-in'' to OMS, to approximately 1,846 such limitations, we estimate 3,693 initial, and second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. We estimate it would take an average of 5 minutes (0.083 hours) at $39.22/hour for an insurance claim and policy processing clerk to prepare each notice. We estimate an annual burden of 307 hours (3,693 notices × 0.083 hour) at a cost of $12,040.54 (307 hour × $39.22/hour).

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA–PD parent organizations, based on plan year 2017 plan participation) would be subject to this requirement. We estimate that it will take on average 5 hours at $81.90/hour for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total; not per document). This would result in a total burden of 1,095 hours (5 hours × 219 sponsors) at a cost of $89,680.50 (1,095 hour × $81.90/hour).

In aggregate, the burden to upload and prepare these additional notices is 1,402 hours (307 hours + 1,095 hours) at a cost of $101,721 ($12,040 + $89,681).

Proposed revisions to § 423.38(c)(4) would limit the SEP for dual- or other LIS-eligible individuals who are identified as a potential at-risk beneficiary subject to the requirements of a drug management program, as outlined in § 423.153(f). As already codified in § 423.38(c)(4), this proposed SEP limitation would be extended to ''other subsidy-eligible individuals'' so that both full and partial subsidy individuals are treated uniformly. Once an individual is identified as a potential at-risk beneficiary, that individual will not be permitted to use this election period to make a change in enrollment.

Contingent with a Part D sponsor opting to implement a drug management program, Part D sponsors will identify, and submit to CMS, an individual's ''potential'' at-risk status and, if applicable, confirmed at-risk status. The Part D sponsor will include notification of the limitation of the duals' SEP in the required notice to the beneficiary that he or she has been identified as a potential at-risk beneficiary.

Therefore, the burden associated with the notification of the inability to use the duals' SEP is covered under the previous statement of burden.

Furthermore, we are proposing to codify that an at-risk beneficiary will have an election opportunity if their dual- or LIS-eligible status changes, that is, if they gain, lose or have a change in the level of the subsidy assistance. Also, if a beneficiary is eligible for another election period (for example, AEP, OEP, or other SEP), this SEP limitation would not prohibit the individual from making an election. This proposed provision, by creating a limitation for dually- and other LIS-eligible at-risk beneficiaries after the initial notification, would decrease sponsor burden in processing disenrollment and enrollment requests for dual- and LIS-eligible beneficiaries who wish to change plans.

We estimate that 1,846 beneficiaries would meet the criteria proposed to be identified as an at-risk beneficiary and have a limitation implemented. About 76 percent of the 1,846 beneficiaries are estimated to be LIS. Approximately 10 percent of LIS-eligible enrollees use the duals' SEP to make changes annually. Thus we estimate, at most, 140 changes per year (1,846 beneficiaries × 0.76 × 0.1) will no longer take place because of the proposed duals' SEP limitation. There are currently 219 Part D sponsors. This amounts to an average of 0.6 changes per sponsor per year (140 changes/219 sponsors). In 2016, there were more than 3.5888 Part D plan switches, and as such, a difference of 0.6 enrollments or disenrollments per sponsor will not impact the administrative processing infrastructure or human resources needed to process enrollments and disenrollments. Therefore, there is no change in burden for sponsors to implement this component of the provision.

We are proposing that reviews of at-risk determinations made under the processes at § 423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in part 423 Subparts M and U. Consistent with existing rules for redeterminations, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the notice of the determination to make such request, must affirmatively request IRE review of an adverse plan level appeal decision made under a plan sponsor's drug management program, and would have rights to an expedited redetermination. Revisions to regulations in part 423 Subparts M (§§ 423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, and 423.638) and U (§§ 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122 and 423.2126) are being proposed to account for reviews of at-risk determinations. The filing of an appeal is an information collection requirement that is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the

burden for preparing and filing the appeal is exempt from the requirements and collection burden estimates of the PRA; however, the burden estimate for appeals is included in the regulatory impact analysis.

In aggregate, these components of this provision would result in an annual net cost of $101,012.

The aforementioned requirements and burden, excluding beneficiary appeals, will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

TABLE 22—ESTIMATED BURDEN FOR THE CARA PROVISIONS

[In hours]

	2019	2020	2021	3-year average
Preparation and Upload Notices	1,402	0	0	467.3
SEP Limitation	0	0	0	0
Appeals	N/A	N/A	N/A	N/A
Total	1,402	0	0	467.3

TABLE 23—ESTIMATED BURDEN FOR THE CARA PROVISIONS

(In $)

	2019	2020	2021	3-Year average
Preparation and Upload Notices	$101,012	$0	$0	$33,670.7
SEP Limitation	0	0	0	0
Appeals	N/A	N/A	N/A	N/A
Total	101,012	0	0	33,670.7

C. Summary of Proposed Information Collection Requirements and Burden

TABLE 24—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory section(s) in title 42 of the CFR	OMB control No.*	Respondents	Responses	Burden per response	Total annual burden (hours)	Labor cost of reporting (hours)	Total cost ($)
422.60, 422.62, 422.68, 423.38, and 423.40 eligibility determination.	0938–0753	468	558,000	5 min	46,500	$69.08	$3,212,220
422.60, 422.62, 422.68, 423.38, and 423.40 notification.	0938–0753	468	558,000	1 min	9,300	69.08	642,444
422.60, 422.62, 422.68, 423.38, and 423.40 report to CMS.	0938–0753	468	558,000	1 min	9,300	69.08	642,444
422.60, 422.62, 422.68, 423.38, and 423.40 record keeping.	0938–0753	468	558,000	5 min	46,500	34.66	1,606,110
422.152 QIP	0938–1023	468	(750)	(15 min)	(188)	67.54	(12,664)
422.2260 and 423.2260 marketing materials.	0938–1051	805	(67,061)	(30 min)	(26,959)	69.08	(1,862,397)
422.2460 and 423.2460 MLR reporting.	0938–1232	587	(587)	(11 hr)	(6,457)	140.14	(904,884)
423.120(c)(6) create model notices.	0938–0964	212	212	3 hr	636	69.08	43,935
423.120(c)(6) 2019 prepare and distribute the notices.	0938–0964	212	80,000	0.083 hr	6,640	39.22	260,421
423.120(c)(6) 2020 and 2021 prepare and distribute the notices.	0938–0964	212	15,000	0.083 hr	1,245	39.22	48,829
423.153(f) notice preparation	0938–0964	219	3,693	0.083 hr	307	39.22	12,041
423.153(f) notice upload	0938–0964	219	3,693	5 hr	1,095	81.90	89,681
423.153(f) contract: Part D plan sponsors.	0938–0964	31	31	10 hr	310	134.50	41,695
423.153(f) contract: MA–PDs	0938–0964	188	188	20 hr	3,760	134.50	505,720
Subtotal: Private Sector Burden.		*805*	*2,266,419*	*varies*	*91,989*	*varies*	*4,325,595*
422.62, 423.38, and 423.40 complete enrollment.	0938–0753	18,600,000	558,000	30 min	279,000	7.25	2,022,750

TABLE 24—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulatory section(s) in title 42 of the CFR	OMB control No.*	Respondents	Responses	Burden per response	Total annual burden (hours)	Labor cost of reporting (hours)	Total cost ($)
Subtotal: Burden on Beneficaries.	.....	*18,600,000*	*558,000*	*30 min*	*279,000*	*7.25*	*2,022,750*
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC paper.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(24,019,500)
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC toner.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(24,019,500)
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC mailing.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(6,629,382)
Subtotal: Non-Labor Burden	.....	*n/a*	*(32,026,000)*	*n/a*	*n/a*	*n/a*	*(54,668,382)*
Total	.....	18,600,805	(29,201,581)	varies	370,989	varies	(48,320,037)

*OMB control numbers and corresponding CMS ID numbers: 0938–0753 (CMS–R–267), 0938–1023 (CMS–10209), 0938–1051 (CMS–10260), 0938–1232 (CMS–10476), and 0938–0964 (CMS–10141).

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS' Web site at Web site address at *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4182–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule approaches to improve the quality, accessibility and affordability of the Medicare Part C and Part D programs and to improve the CMS customer experience. While satisfaction with these programs remain high, these proposals are responsive to input we received from stakeholders while administering the program, as well as through a Request for Information process earlier this year. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program.

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), Section 1102(b) of the Social Security Act, Section 202 of the Unfunded Mandates Reform Act of 1995 (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 Regulatory Flexibility Analysis (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.

The health insurance industry was examined in depth in the RIA prepared for the proposed rule on establishment of the MA program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few, if any, ''insurance firms,'' including HMOs that fell below the size thresholds for ''small'' business established by the Small Business Administration (SBA). We assume that the ''insurance firms'' are synonymous with health plans that conduct standard transactions with other covered entities and are, therefore, the entities that will have costs associated with the new requirements finalized in this rule. At the time the analysis for the MA program was conducted, the market for health insurance was and remains, dominated by a handful of firms with substantial market share.

However, we estimate that the costs of this rule on ''small'' health plans do not approach the amounts necessary to be a ''significant economic impact'' on firms with revenues of tens of millions of dollars. Therefore, this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation proposed under Title XVIII, Title XIX, or Part B 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 rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $148 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this 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 MA Plans and Part D Sponsors, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. There are currently 468 MA plans and Part D Sponsors.

We assume each plan will have one designated staff member who will read the entire rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it would take approximately 15.6 hours for each person to review this proposed rule. For each MA plan that reviews the rule, the estimated cost is therefore, $1,640 (15.6 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $767,520 ($1,640 × 468 reviewers).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

C. Anticipated Effects

1. CARA Provisions

Proposed § 423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes ''lock-in'' as a tool to manage an at-risk beneficiary's access to coverage of frequently abused drugs.

Under CARA, potentially at-risk beneficiaries are to be identified under guidelines developed by CMS with stakeholder input. Also, the Secretary must ensure that the population of at-risk beneficiaries can be effectively managed by Part D plans. CMS considered a variety of options as to how to define the clinical guidelines. We provide the estimated population of potential at-risk beneficiaries under different guidelines that take into account that the beneficiaries may be overutilizing opioids, coupled with use of multiple prescribers and/or pharmacies to obtain them, based on retrospective review, which makes the population appropriate to consider for ''lock-in'' and a description of the various options. We note that the measurement year for the estimates was 2015.

For background, the current Part D Opioid Overutilization policy and Overutilization Monitoring System (OMS) has been successful at reducing high risk opioid overutilization. Under this policy, plans retrospectively identify beneficiaries at high risk of an adverse event due to opioids and use of multiple prescribers and pharmacies. CMS created the OMS to monitor plans' effectiveness in complying with the policy. The OMS criteria incorporate the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) (CDC Guideline) to identify beneficiaries who are possibly overutilizing opioids and are at high risk but the CDC Guideline is not a prescribing limit. CDC identifies 50 Morphine Milligram (MME) as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME.

Plans are expected to perform case management for each beneficiary identified in OMS and respond using standardized responses. If viewed as helpful by a prescriber, plans may implement a beneficiary-specific claim edit at the point-of-sale to prevent coverage of opioids outside of the amount deemed medically necessary by the prescriber. Plans may also implement an edit in the absence of prescriber response to case management.

TABLE 25—GUIDELINES TO IDENTIFY AT-RISK BENEFICIARIES

Option	Average MME	Number of opioid prescribers *and* opioid dispensing pharmacies		Estimated number of potentially at-risk Part D beneficiaries
1	>=90	4+	4+	33,053
	>=90	6+	1+	
2	>=90	4+	4+	52,998
	>=90	5+	1+	
3	>=90	3+	3+	103,832
	>=90	5+	1+	
4	>=90	3+	3+	152,652
	>=90	4+	1+	
5	>=90	3+	3+	319,133
	>=90	3+	1+	
	Average MME	Number of opioid prescribers *or* opioid dispensing pharmacies		Estimated number of potentially at-risk Part D beneficiaries
6	>=50	5+	5+	153,880
	Any MME level	7+	7+	

Under Option 1, CMS would propose to integrate the CARA lock-in provisions with our current Part D Opioid Overutilization Policy/Overutilization Monitoring System (OMS). We will propose to initially define frequently abused drugs as all and only opioids for the treatment of pain. The guidelines to identify at-risk beneficiaries would be the current Part D OMS criteria finalized for 2018 after stakeholder input. Plans that adopt a drug management program would have to engage in case management of the opioid use of all enrollees who meet these criteria, which would be reported through OMS and plans must provide a response for each case. The estimated number of potential

at-risk beneficiaries in 2019 using Option 1 is 33,053. Option 1 would allow plans to use pharmacy/prescriber lock in as an additional tool to address the opioid overutilization of identified at-risk beneficiaries.

Option 2, 3, 4, and 5 are operationally the same as Option 1, including 90 MME, but would identify approximately 52,998 to 319,133 beneficiaries in 2019 due to different clinical guidelines related to the number of opioid prescribers and opioid dispensing pharmacies. These options would result in up to 10 times the program size compared to Option 1.

Finally, under Option 6, the guidelines to identify potentially at-risk beneficiaries would not be fully integrated into our current OMS criteria. This option would identify beneficiaries whose opioid use is at the 50 MME level instead of 90, and the estimated number of potentially at-risk beneficiaries in 2019 is 153,880. Of these, approximately 29,000 would meet these criteria and the current OMS criteria. We seek comment on proposed Option 1 or if any of the alternative options may be currently viewed as manageable for Part D sponsors to implement.

In addition, while these criteria would identify far more potentially at-risk beneficiaries, we may have to implement these options in a way that plans that adopt a drug management program would not have to review the opioid use of all enrollees who meet these criteria. This would mean a change in the structure of the successful OMS or a separate administrative structure for prescription drug management programs.

As noted in section II. of this rule, we have chosen to propose Option 1. This approach is a cautious approach for the initial implementation year of the CARA ''lock-in'' provisions. We believe these provisions will result in the following savings to the program.

We estimate that the CARA provisions would result in a net savings of $10 million (the estimated savings of $13 million less the total estimated costs of $2,836,651 = $10,163,349, rounded to the nearest million) in 2019. The following are details on each of these savings.

We assume, based on past experience with OMS, that about 61 percent of at-risk beneficiaries may reduce prescriptions for frequently abused drugs and will no longer meet the clinical criteria. This means that prescriber and pharmacy lock-in would impact the remaining 39 percent of at-risk beneficiaries or 39 percent × 33,000 at-risk beneficiaries = 12,870 at-risk beneficiaries. We estimate that the average number of scripts per year on frequently abused drugs for those at-risk beneficiaries is about 48 and the average cost per script is about $106 in 2016. Our data show that those beneficiaries who would meet the proposed criteria for identification as an at-risk beneficiary and have a limitation placed on their access to opioids, have 4 opioids scripts per month on average. OACT anticipates between 10 and 30 percent reduction in prescriptions for frequently abused drugs would be possible through drug management programs and picked the average, 20 percent. Therefore, we believe there could be a 20 percent reduction in the prescriptions for frequently abused drugs for those 12,870 beneficiaries, resulting in a projected savings of about $13 million to Medicare in 2019.

Part D plan sponsors would also be required to send at-risk beneficiaries multiple notices to notify them of about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the Part D plan sponsors decide to implement a beneficiary-specific POS claim edit for opioids. Therefore, we anticipate limited additional burden for Part D plan sponsors to send certain at-risk beneficiaries an additional notice to indicate their lock-in status.

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. That results in approximately 923 edits annually. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber ''lock-in'' to OMS, to approximately 1,846 such limitations, we estimate 3,692 initial and second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. For purposes of this estimate, we assume that all beneficiaries who receive initial notices will be placed on an access limitation. We estimate it would take an average of 5 minutes (0.083 hours) at $39.22/hour for an insurance claim and policy processing clerk to prepare each notice. The burden of 307 hours (3,692 notices × 0.083 hour) at a cost of $12,040.54 (307 hour × $39.22/hr) in 2019 was estimated in section III of this rule.

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA–PD parent organizations) will be subject to this requirement. We estimate that it will take on average 5 hours at $81.90/hour for a computer programmer to upload the notices into their claims systems. This would result in a total burden of 1,095 hours (5 hours × 219 sponsors) at a cost of $89,680.50 (1,095 hour × $81.90/hr). In aggregate, the burden to prepare and upload these additional notices was estimated as 1,402 hours (307 hours + 1,095 hours) at a cost of $101,721 ($12,040 + $89,681) in 2019 in section III. of this proposed rule.

Part D plan sponsors may also renegotiate the contracts with network pharmacies and network prescribers in the case of MA–PDs. For Part D plan sponsors that contract with pharmacies only, we estimate it would take 10 hours at $134.50/hour for lawyers to conduct the PDP contract negotiations with network pharmacies. Considering 31 sponsors we estimate a total burden of 310 hours at a cost of $41,695 (310 hour × $134.50/hour). For MA–PDs who also contract with prescribers, we estimate that the annual burden for negotiating a contract with network providers who can prescribe controlled substances to be 3,760 hours (188 MA–PDs × 20 hours per sponsor) at a cost of $505,720 (3,760 hour × $134.50/hour). The total estimated burden associated with the contract negotiations from both PDP and MA–PD sources in 2019 was estimated as 4,070 hours (310 hours + 3,760 hours) at a cost of $547,415 ($41,695 + $505,720).

We estimate that, in order to implement pharmacy or prescriber lock-in, Part D plan sponsors would have to program edits into their pharmacy claims systems so that once they restrict an at-risk beneficiaries' access to coverage for frequently abused drugs through applying pharmacy or prescriber lock-in, claims at a non-selected pharmacies or associated with prescriptions for frequently abused drugs from non-selected prescribers would be rejected. We believe that most Part D plan sponsors with Medicaid or private lines of business will have existing lock-in programs in those lines of business to pull efficiencies from. We estimate it would take a total number of 26,280 labor hours across all 219 Part D plan sponsors (31 PDP parent organizations and 188 MA–PD parent organizations) at a wage of $81.90 an hour for computer programmers to program these edits into their existing systems. Thus, the total cost to program these edits is 26,280 hours × $81.90 = $2,152,332.

The right of an enrollee to appeal an at-risk determination will also have an associated cost. As explained, we estimate a total hourly burden of 178

hours at an annual estimated cost of $35,183 in 2019. As previously discussed, we estimate that 1,846 beneficiaries would meet the criteria for being identified as an at-risk beneficiary. Based on validated program data for 2015, 24 percent of all adverse coverage determinations were appealed to level 1. Given the nature of drug management programs, the extensive level of case management conducted by plans prior to making the at-risk determination, and the opportunity for an at-risk beneficiary to submit preferences to the plan prior to lock-in implementation, we believe it is reasonable to assume that this rate of appeal will be reduced by at least 50 percent for at-risk determinations made under a drug management program. Therefore, this estimate is based on an assumption that about 12 percent of the beneficiaries estimated to be subject to an at-risk determination (1,846) will appeal the determination. Hence, we estimate that there will be 222 level 1 appeals (1,846 × 12 percent). We estimate it takes 48 minutes (0.8 hours) to process a level 1 appeal. There is a statutory requirement that a physician with appropriate expertise make the determination for an appeal of an adverse initial determination based on medical necessity. Thus, we estimate an hourly burden of 178 hours (222 appeals × 0.8) at a cost of $197.66 per hour for physicians to perform these appeals. Thus the total cost in 2019 is estimated as $35,183 = 178 hours × $197.66.

In aggregate, this provision would result in a net savings of $13 million − ($101,721 + $547,415 + $2,152,332 + $35,183) = $13 million − $2,836,651 = $10,163,349 (or $10,000,000 if rounded to nearest million) in 2019.

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

The proposed provision would amend the regulation so that first-tier, downstream and related entities (FDR) no longer are required to take the CMS compliance training, which lasts 1 hour, and so that MA organizations and Part D sponsors no longer have a requirement to ensure that FDRs have compliance training. However, it is still the sponsoring organization's responsibility to manage relationships with its FDRs and ensure compliance with all applicable laws, rules and regulations. Furthermore, we would continue to hold sponsoring organizations accountable for the failures of its FDRs to comply with Medicare program requirements.

We believe that by deleting this provision we will reduce burden for sponsoring organizations and their FDRs. We estimate that the burden reduction will be roughly 1 hour for each FDR employee who would be required to complete the CMS training on an annual basis, under the current regulation at §§ 422.503(b)(4)(vi)(*C*) and 423.504(b)(4)(vi)(*C*). We do not know how many employees were required to take the CMS training, nor do we know the exact numbers of FDRs that were subject to the requirement. Sponsoring organizations have discretion in not only which of their contracted organizations meet the definition of an FDR, but also discretion in which employees of that FDR are subject to the training. But we know from public comments that PBMs, hospitals, pharmacies, labs, physician practice groups and even some billing offices were routinely subjected to the training. Unfortunately, the Medicare Learning Network (MLN) Matters® Web site is not able to track the number of people that took CMS' training, so we cannot use that as a data source. CMS has reviewed the Organization for Economic Co-operation and Development's (OECD) 2015 statistics which show a total of 20,076,000 people employed in the health and social services fields in the United States, although certainly not all of them were subject to CMS' training requirement (*See http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT*). Hospitals are one sector of the health industry that has been particularly vocal about the burden the current training requirement has placed on them and their staff. If we use hospitals as an example to estimate potential burden reduction, the OECD Web site states that there are 5,627 hospitals in the United States, employing 6,210,602 people. That is an average of 1,103 people per hospital. There are approximately 4,800 hospitals registered with Original Medicare. If we assume that each one of those hospitals holds at least one contract with a M A health plan and all of their employees were subjected to the training (4,800 × 1,103 × 1 hour) that is 5,294,400 hours of burden that would be eliminated by this proposal. If we add pharmacists, pharmacy technicians, billing offices, physician practice groups, we would expect further burden reduction. OECD has data for a few more sectors of the industry, including 295,620 pharmacists, 3,626,060 nurses and 820,251 physicians in the United States. Many of the physicians and nurses are likely represented in the 6 million employed by hospitals. Unfortunately we don't have data sources for all sectors of the industry. However, using hospital staff as a starting point and OECD's total figure of 20 million working in the health and social service fields, we estimate the burden reduction is likely 6 to 8 million hours each year. Again, we have no way to determine exactly how many FDRs there are or exactly how many staff would be expected to take the training under the current regulation, but we hope this example demonstrates the reduction in burden this proposal would mean for the industry. We request comment that would allow for more complete monetization of cost savings in the analysis of the final rule.

Although sponsors must still monitor FDRs and implement corrective actions when mistakes are found, we believe that they are currently already doing this. Therefore no additional burden complementing the reduction in burden is anticipated from this proposal to eliminate the CMS training.

3. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

For CY 2018 bids, 2,743 non-D–SNP non-employer plans (that is, HMO, HMO–POS, Local PPO, PFFS, and RPPO) used in house and/or consulting actuaries to address the meaningful difference requirement based on CY 2018 bid information. The most recent Bureau of Labor Statistics report states that actuaries made an average of $54.87 an hour in 2016, and we estimate that 2 hours per plan are required to fully address the meaningful difference requirement. The estimated hours are based on assumptions developed in consultation with our Office of the Actuary. We additionally allow 100 percent for benefits and overhead costs of actuaries, resulting in an hourly wage of $54.87 × 2 = $109.74. Therefore, we estimate a savings of 2 hours per plan × 2,743 plans = 5,486 hours reduction in hourly burden with a savings in cost of 5,486 hours × $109.74 = $602,033.64, rounded down to $0.6 million to be saved annually under this proposal.

The number of plan bids received by CMS may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. However, CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but do not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create more confusion in beneficiary decision-making related specifically to

the number of plan options. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices.

CMS does not believe this proposed change will have a significant impact on health care providers. The number of plans offered by organizations in each county are not expected to increase significantly as a result of this change and health care provider contracts with MA organizations typically include all of the organization's plans rather than having separate contracts for each plan. In addition, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased provider burden.

4. Physician Incentive Plans—Update Stop-Loss Protection Requirements (§ 422.208)

Some physician contracts with MA organizations provide that the MA organization pay the physician a capitated amount to assume financial responsibility for services (for example, hospital costs) that they do not personally render. CMS refers to capitations to physicians that include services the physicians do not render as ''global capitation.'' When physicians are globally capitated to the extent that they can lose more than 25 percent of their income, they are required to be covered by stop-loss insurance. We propose to replace the current insurance schedule in the regulation with updated stop-loss insurance requirements that would allow insurance with higher deductibles. The new schedule would result in a significant reduction to the cost of obtaining stop-loss insurance. The higher deductibles are consistent with the increase in medical costs due to inflation.

To determine the cost of different stop-loss insurance policies, we used claim distributions from original Medicare enrollees. Then, we assumed an average loading for administrative and profit of 20 percent. Using these assumptions, we estimate that plans and physicians would save an average of $100 per globally capitated member per year in total costs. The derivation of this $100 figure is as follows:

Under the current regulation at § 422.208(f)(2)(iii), stop-loss insurance for the provider (at the MA organization's expense) is needed only if the number of members in the physician's group at global risk under the MA plan is less than 25,000. The average number of members in the under 25,000 group estimated under the current regulation is 6,000 members. Ideally, to obtain an average, we should weight the panel sizes in the chart at § 422.208(f)(2)(iii) by the number of physician practices and the number of capitated patients per practice per plan. However, this information is not available. Therefore, we used the median of the panel sizes listed in the chart at § 422.208(f)(2)(iii), which is about 8,000. Since the per member per year (PMPY) stop-loss premiums are greater for a smaller number of patients, we lowered this 8,000 to 6,000 to reflect the fact that the distribution of capitated patients is skewed to the left. We use this rough estimate of 6,000 for its estimates.

For these 6,000 members, the current regulation at § 422.208(f)(2)(iii) (the chart) shows the physician needs stop-loss insurance for $37,000 in a combined attachment point (deductible). The $37,000 is obtained by using linear interpolation on the chart at § 422.208(f)(2)(iii), replacing panel sizes with midpoints of ranges and rounding to the nearest 1,000. To find the premium for a stop-loss insurance with a deductible of $37,000, we use Table 26, which reflects current insurance rates, that is, what would be charged today. By using linear interpolations on the columns with $30,000 and $40,000 and rounding to the nearest $1,000, we see that the PMPY premium for insurance with $37,000 combined attachment points is $2,000 PMPY. This $2,000 premium reflects the baseline charge today for a combined deductible of $37,000.

BILLING CODE 4120–01–P

BILLING CODE 4120–01–C

TABLE 26: COMBINED ATTACHMENT POINTS BEFORE INCLUDING NPEs

Professional & Institional Combined	5,000	10,000	15,000	20,000	30,000	40,000	50,000	60,000	70,000	100,000	150,000	200,000	300,000	500,000	1,000,000	2,000,000	No Stop Loss
Number of Risk Patients	400	800	1,400	2,000	3,300	4,600	5,800	6,900	7,900	10,100	12,300	13,500	14,800	16,100	16,800	17,400 to 25,000	> 25,000
Net Benefit Premium PMPY	5,922	4,891	4,122	3,514	2,612	1,984	1,539	1,216	977	553	267	159	79	28	12	4	0

NOTE: This table is valid for contract year 2019. Future year updates, if necessary, may be found in the annual Rate Announcement and Call Letter. Attachments points may be increased up to $100,000 by using NPEs.

Next, we compute the premium under the proposed rule. We still assume an average of 6,000 capitated members. However, the proposed rule allows higher deductibles corresponding to medical inflation. By using linear interpolation on the columns headed with 50,000 and 60,000 combined attachment points and rounding. We see that a deductible (combined attachment point) of $57,000 corresponds to 6,000 capitated members and a premium of $1,500 PMPY.

The savings in premium between using § 422.208(f)(iii) to calculate deductibles (combined attachment point) and using Table A to calculate deductibles is $2000 − $1500 = $500 PMPY. We assume that the average loading for profit and administrative costs is roughly 20 percent. So our PMPY savings is 20 percent × 500 = $100 PMPY. The remaining $500 − $100 = $400 in savings is on net benefits. That reduction does not produce any savings since the plans and physicians are simply trading claims for premiums.

In 2007, we estimated that 7 percent of enrollees were receiving services under capitated arrangements. Although we do not have more current data, based on CMS observation of managed care industry trends, we believe that the percentage is now higher, and we assume that 11 percent of enrollees are now paid under global capitation. There are currently 18.6 million MA beneficiaries. We estimate that about 18.6 million × 11 percent = 2,046,000 MA members are paid under some degree of global capitation. Thus, the total aggregate projected annual savings under this proposal is roughly $100 PMPY × 2,046,000 million beneficiaries paid under global capitation = $204.6 million.

The $204.6 million savings is removed from the plan bid, but not the CMS benchmark. If the benchmark exceeds the bid, Medicare pays the MA organization the bid (capitation rate and risk adjustment) plus a percentage of the difference between the benchmark and the bid, called the rebate. The rebate is based on quality ratings and allows Medicare to share in the savings to the plans; our experience with rebates shows that the average rebate is on the order of 2/3. We assumed that of the $204.6 million in annual savings, Medicare would save 35 percent × $204.6 million = $71,610,000, and the remaining 65 percent × $204.6 million = $132,990,000 would be paid to the plans. The plan portion of the savings we project for this proposal would fund extra benefits or possibly reduce cost sharing for plan members.

The figures for 2019 were updated for 2020 to 2023 using enrollment and inflation factors found in the CMS trustees report, accessible at: *https://www.cms.gov/reportstrustfunds*.

5. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

We propose to delete the limitation placed on MA organizations and Part D sponsors as to how they can respond to an agent/broker who has become unlicensed. We propose to delete a requirement that the MA plan or Part D plan terminate an unlicensed agent or broker and contact beneficiaries to notify them if they had been enrolled by the unlicensed agent or broker. We already require MA organizations and Part D sponsors to use only licensed agents/brokers. We have established the requirement to have a licensed agent or broker in a 2008 final rule (73 FR 54219). That burden assessment is not changing due to the proposal to remove paragraph (e) from these sections. The impact analysis for the specific provision at paragraph (e) of §§ 422.2272 and 423.2272 was established in rule-making in April 2011 (76 FR 21534). As for the impact of review and compliance activities that remain to plans after removing the narrow scope of compliance actions available to MA organizations and Part D sponsors, we do not believe this change would have a significant increase in burden or financial impact. Removing this requirement allows state Department of Insurance (DOI) requirements to take precedence in this situation. While some MA organizations and Part D sponsors may choose to make operational changes to ensure compliance, these changes are not based on this rule, but are required to meet existing requirements.

6. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage

We propose to revise our regulations at § 422.66 to permit default enrollment of Medicaid managed care plan members into an MA special needs plan for dual eligible beneficiaries. Upon a Medicaid managed care plan member becoming eligible for Medicare, qualification for enrollment into the MA special needs plan for dual eligibles is contingent on the following:

- State support for the default enrollment process, and
- The organization's ability to identify such individuals at least 90 days in advance of their Medicare eligibility; and
- To issue written notification of the enrollment a minimum of 60 days in advance.

Our proposal represents the partial codification of existing policy on seamless conversion enrollment that has been specified in subregulatory guidance for contract years 2006 and subsequent years, but with additional parameters and limits. Among the new limits proposed for seamless conversion default enrollments are allowing such enrollments only from the organization's Medicaid managed care plan into an integrated D–SNP and requiring facilitation from applicable state (in the form of a contract term and provision of data). This will result in the discontinuation of the use of the seamless conversion enrollment mechanism by some of the approved MA organizations. However, as this enrollment mechanism is voluntary and not required for participation in the MA program, we do not believe the proposed changes would have any impact to the Medicare Trust Funds. We invite comments on the potential impact of the proposed changes on MA organizations, Medicaid managed care plans and beneficiaries.

7. Restoration of the MA Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 & 423.40)

We expect that increasing the amount of time that MA-enrolled individuals are given to switch plans will result in slightly more beneficiaries selecting plans that receive Quality-Bonus Payments (QBP). This assessment reflects our observation that beneficiaries tend to choose plans with higher quality ratings when given the opportunity. The projected costs to the Government by extending the open enrollment period for the first 3 months of the calendar year are $9 million for CY 2019, $10 million in 2020, $10 million in 2021, $11 million in 2022, and $12 million in 2023.

In order to estimate the additional costs for the projection window 2019–2023, we first made an assumption that approximately 24,600 MA-enrolled individuals will switch health plans from one without a QBP to one with a QBP during the extended open enrollment period. The 24,600 enrollee assumption was determined by using a combination of published research and by observing historical enrollment information. Published research[1] shows that 10 percent of MA enrollees voluntarily switch MA plans and that MA enrollees who voluntarily switch plans change to plans with slightly higher star ratings than their original plan, with a modest improvement of

0.11 stars, on average. The Office of the Actuary confirmed these findings by analyzing CMS enrollment data and provided further detail. We estimate that of the 10 percent of MA plan enrollees who switch plans, 15 percent move to a higher rated plan. Of those who go to a higher rated plan, we estimate 40 percent move from a non-QBP plan to a QBP plan. We also estimate that one-fifth of these enrollees would take advantage of the new open enrollment period.

We apply these assumptions to the estimated MA enrollment for 2019, 20,512,000, which can be obtained from the CMS Trustee's Report available at *https://www.cms.gov/reportstrustfunds/*. We find that 24,600 (20,512,000 × 10 percent × 15 percent × 40 percent × 20 percent) people are expected to enroll in the proposed open enrollment period.

The $9 million in additional costs for 2019 was calculated by multiplying the 24,600 impacted enrollment by the expected 2019 bonus amount ($637.20). The Office of the Actuary experiences an average rebate percentage of 66 percent and an 86 percent backing out of the projected Part B premium. Hence, the net savings to the trust funds is estimated as $9 million = 24,600 enrollees × $637.20 (Bonus payment) × 66 percent (rebate percentage) × 86 percent (Reduction in Part B premium), rounding to $9 million.

Then, we applied trends from the Trustees Report to the 2019 estimate in order to project the costs for years 2020 to 2023. The data from the Medicare Payments to Private Health Plans, by Trust Fund (Table IV.C.2. of the 2017 Medicare Trustees Report) was used as the basis for the trends. The trend estimates are presented in the Table 27 that demonstrates the calculations and displays the cost estimates for each year 2019–2023.

TABLE 27—CALCULATION OF NET COSTS TO THE MEDICARE TRUST FUNDS FOR THE EXTENDED OPEN ENROLLMENT PERIOD

Year	2019 Base year (million)	Trend factor 2020	Trend factor 2021	Trend factor 2022	Trend factor 2023	Net costs (rounded to nearest million)
2019	9					9
2020	9	1.078				10
2021	9	1.078	1.084			10
2022	9	1.078	1.084	1.089		11
2023	9	1.078	1.084	1.089	1.086	12

8. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

We believe the proposed changes will result in a reduction of burden to Part D plan sponsors since they will have additional time to adjudicate requests for payment. We also expect a reduction in burden for the independent review entity (IRE) since the additional time for Part D plan sponsors to process these requests will result in fewer untimely payment redeterminations that must be auto-forwarded to the IRE. Based on recent program data, about 2,000 retrospective payment redetermination cases are auto-forwarded to the Part D IRE each plan year. If the proposed 14-day timeframe for payment redeterminations is implemented, we estimate that about 75 percent of the payment redetermination cases that are currently auto-forwarded to the Part D IRE due to the plan not being able to meet the adjudication timeframe will not be auto-forwarded under the 14 day timeframe; the longer timeframe will afford Part D plan sponsors an additional 7 days to process a payment request, including obtaining necessary supporting documentation, and to notify the enrollee of its decision. As a result, overall plan sponsor burden will be reduced by not having to auto-forward about 1,500 payment redetermination cases to the Part D IRE in a given plan year and the Part D IRE's workload will be reduced by the same number of cases. We estimate that it takes Part D plan sponsors an average of 15 minutes (0.25 hours) to assemble and forward a case file to the IRE, for an estimated savings of 375 hours (1500 cases × 0.25 hours). Using an adjusted hourly wage of $34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43–9199, ''All other office and administrative support workers,'' (based on a mean hourly salary of $17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in $34.66 an hour) the total estimated savings to plans is $12,998 (375 hours × $34.66). Since the proposed changes involve requests for payment where the enrollee has already received the drug, we do not believe the proposed changes will impose undue burden on enrollees.

9. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE

The proposed changes at § 422.590(f) would result in a slight reduction of burden to Part C plans by no longer requiring a Notice of Appeal Status for each case file forwarded to the IRE. The estimated savings of this proposed change is based on reduced plan administration costs. Using the number of partially and fully adverse cases, we estimate Part C plans forwarded 47,108 cases to the IRE in 2015. We estimate it will take 5 minutes (0.083 hours) to complete this notice. We used an adjusted hourly wage of $34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43–9199, ''All other office and administrative support workers,'' which gives a mean hourly salary of $17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in $34.66 an hour. Thus, the reduction in administrative time spent would be 0.083 hours × 47,108 cases = 3,926 hours with a consequent savings of 3,926 hours × $34.66 per hour = $136,064.

We do not believe the proposed change will adversely impact health plan enrollees. The notice we are proposing to eliminate is duplicative and enrollees will be notified by the IRE that their case was received by the IRE for review.

10. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities

CMS is proposing to narrow the definition of ''marketing materials'' under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. CMS believes the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials

that pose little risk to current or potential enrollees and are not traditionally considered ''marketing.'' The proposed change would add text to §§ 422.2260 and 423.2260 and provide a narrower definition than is currently provided for ''marketing materials.'' Consequently, this definition decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.

We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D Sponsors by reducing the number of materials required to be submitted to CMS for review.

In section IV.F. of this proposed rule, we estimated the reduced burden to industry at $1.3 million. There is also a reduced burden to the federal government since CMS staff are no longer obligated to review these materials. Although all marketing materials are submitted for potential review by the MA plans to CMS, not all materials are reviewed, since some MA plans, because of a history of compliance, have a ''file and use'' status which exempts their materials from routine reviews. We estimate that only 10 percent of submitted marketing materials are reviewed by CMS staff. Consequently, the savings to the federal government is 10 percent × 1.3 million = 0.13 million.

11. Part C & D Star Ratings

There has been a recent trend in the number of enrollees that have moved from lower Star Ratings contracts that do not receive a Quality Bonus Payment (QBP) to higher rated contracts that do receive a QBP as part of contract consolidations. The proposal is to codify the methodology of the assigned Star Ratings and to add requirements addressing when contracts have consolidated. The methodology and measures being proposed here are generally from recent practice and policies finalized under the section 1853(b) of the Act Rate Announcement. With regard to consolidations, the Star Ratings assigned would be based on the enrollment weighted average 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. We believe that the proposal would dissuade many plans from consolidating contracts since it would be possible for some plans to lose QBPs under certain scenarios. If less contracts consolidate to higher Star Ratings, less QBPs would be paid to plans and this would result in Trust Fund savings.

In order to estimate the savings amounts for the projection window 2019–2023, we first observed the number of enrollees that have been impacted by contract consolidations for the prior 3 contract years (2016 through 2018) using a combination of bid and CMS enrollment/crosswalk data. The number of enrollees observed are those that have moved from a non-QBP contract to a QBP contract and were found to be approximately 830,000 in 2016, 530,000 in 2017, and 160,000 in 2018. We assumed that the number of enrollees moving from a non-QBP contract to a QBP contract would be 200,000 starting in 2019 and increasing by 3 percent per year throughout the projection period. The 200,000 starting figure was chosen by observing the decreasing trend in the historical data as well as placing the greatest weight on the most recent data point. The 3 percent growth rate is approximately the projected growth in the MA eligible population during the 2019–2023 period.

Similarly, we calculated the net per member per month (PMPM) dollar impact of the QBP for those enrollees in contracts that consolidated to be $44.73 in 2018. Again, the PMPM impact was projected for the 2019–2023 period using the projected annual trend of 5 percent per year which is similar to the projected growth rate for MA expenditures and can be found in the 2017 Trustees Report. We also made an assumption that even under the proposed Star Rating methodology changes, there would still be 50 percent of the projected impacted enrollees that would consolidate or individually move from a non-QBP contract to a QBP contract when advantageous to the health plan (lessening the overall savings impact). Combining the assumptions previously described, as well as accounting for the average rebate percentage of 66 percent and backing out the projected Part B premium, the net savings to the trust funds were calculated to be $32 million for 2019, $35 million in 2020, $37 million in 2021, $40 million in 2022, and $44 million in 2023. The calculations for the five annual estimates are presented in Table 28.

TABLE 28—CALCULATIONS OF NET SAVINGS PER YEAR FOR STAR RATINGS

Year	Enrollment (3% annual trend)	PMPM cost (5% annual trend)	Number months per year	Percent not consolidating (%)	Average rebate percentage (%)	Backing out of Part B premium (%)	Net Savings ($ in millions)
2019	200,000	44.73×1.05	12	50	66	86	32
2020	$200,000 \times 1.03$	44.73×1.05^2	12	50	66	86	35
2021	$200,000 \times 1.03^2$	44.73×1.05^3	12	50	66	86	37
2022	$200,000 \times 1.03^3$	44.73×1.05^4	12	50	66	86	40
2023	$200,000 \times 1.03^4$	44.73×1.05^5	12	50	66	86	44

12. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types

a. Anticipated Effects

In considering the cost implications of this proposal, we received varied perspectives from stakeholders. Part D plan sponsors, PBMs, and manufacturers contend limited dispensing networks with accreditation requirements generate cost savings and add value. Specialty pharmacies contend the added value avoids additional costs. Independent community pharmacies, and beneficiaries contend broader competition and transparency will generate savings.

Because this provision clarifies existing any willing pharmacy requirements, consistent with OACT estimates, we do not anticipate additional government or beneficiary cost impacts from this provision.

TABLE 29—ESTIMATED AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2019 THROUGH 2023

Provision	Regulation section(s)	Calendar year ($ in millions)					Total CYs 2019–2023 ($ in millions)
		2019	2020	2021	2022	2023	
Federal Government (Medicare) Impacts							
Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types.	Various	0	0	0	0	0	0

b. Benefits

Proposed clarification of Any Willing Pharmacy rules, and clarification of the definition of retail pharmacy would account for recent changes in the pharmacy practice landscape and ensure that existing statutorily-required Any Willing Pharmacy provisions are extended to innovative pharmacy business and care delivery models.

Rural areas are predominantly served by independent community pharmacies. The National Community Pharmacist's Association (NCPA) estimates that ''independent pharmacies represent 52 percent of all rural retail pharmacies and there are over 1800 independent community pharmacies operating as the only retail pharmacy within their rural communities [63] [64].'' Additionally, these pharmacies are increasingly interested to diversify their business models to dispense specialty drugs. Consequently, we believe this proposal may support small businesses in rural areas and may help maintain beneficiary access to specialty drugs from community pharmacies.

13. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

The proposed revision of 423.265 eliminates the requirement for two enhanced benefit plans offered by a PDP organization in a service area to be ''substantially different''. If finalized this will result in increased plan flexibilities and a potential increase in beneficiary plan choice. We expect this provision to reduce plan burden and could provide a very modest savings to plans sponsors of approximately $60,000. The savings represent an estimate of the time not spent by certifying actuaries to ensure that a meaningful difference threshold is met between two PDP EA offerings. Based on the preliminary CY 2018 landscape, if all PDP organizations that submitted an EA benefit design had also submitted the maximum of two EA plans, the result would be approximately 275 EA to EA plan pairings that would have required actuary time spent in evaluation of the meaningful difference requirement. We further estimate that it would take an actuary 2 hours to write a meaningful difference requirement. Based on the Bureau of Labor Statistics (BLS) latest wage estimates, *https://www.bls.gov/oes/current/oes152011.htm*, the mean hourly wage for actuaries, occupation code 15–2011 is $54.87 which when multiplied by 2 to allow 100 percent for overhead and fringe benefits is $109.74 an hour. Thus our total estimated burden is 275 EAs × 2 Hours per EA = 550 hours at a cost of 550 × $109.74 = $60357. While there is potential savings for PDP plan sponsors under this proposal, these savings could be offset for organizations who make the business decision to prepare and submit additional bids if this proposal is finalized. If the EA to EA threshold was the sole barrier to a PDP sponsor offering a second EA plan, (that is, the sponsor currently only offers one enhanced plan), based on the CY2018 PDP landscape, we could anticipate a modest increase of approximately 125 additional enhanced plans (15 percent increase). Although we believe it unlikely that all PDP sponsors would opt to add an additional plan.

14. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans and PACE

The costs and savings, as reflected in the total net savings, associated with our preclusion list proposals would be those identified in the collection of information section of this rule: Specifically, (1) the system costs associated with the Part D preclusion list; (2) costs associated with the preparation and sending of written notices to affected Part D prescribers and beneficiaries; and (3) the savings that would accrue from individuals and entities no longer being required to enroll in or opt-out of Medicare to prescribe Part D drugs or furnish Part C services and items. Specifically, we project a total net savings, as described in detail in the collection of information portion of this rule, over the first 3 years of this rule of $35,526,652 ($3,423,852 for Part D + $32,102,800 for Part C), or a 3-year annual average of $11,842,217). Costs associated with an alternative approach are found in the Alternatives Considered portion of this section. We would be responsible for the development and monitoring of the preclusion list using its own resources. This would be funded as part of our screening activities. We do not anticipate a change in the number of individuals or entities billing for service, for we would only be denying payment to those parties that meet the conditions of the preclusion list. Costs associated with an alternative approach are found in the Alternatives Considered section of this rule.

We welcome public comment on these estimates, for stakeholder feedback could assist us in developing more concrete projections.

15. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

This provision would result in a total savings of $19,305 to the federal government. The driver of the savings is the removal of burden for federal employees to review Quality Improvement Project (QIP) attestations. MA organizations are required to annually attest that they have an ongoing QIP in progress and the Central Office reviews these attestation submissions. To estimate amounts, we considered how many QIP attestations are performed annually.

We estimate that—

• Central Office staff will require one person reviewing for 0.25 hours to review a single QIP attestation. The Central Office staff typically have higher

[63] National Community Pharmacist's Association letter to CMS Administrator, Seema Verma, June 7, 2017. Available at *http://www.ncpa.co/pdf/ncpa-medicaid-recommend-cms-june-2017.pdf*).

[64] National Community Pharmacist's Association comment letter to CMS–4159–P, March 2014. Available at *//www.ncpa.co/pdf/NCPA-Comments-to-CMS-Proposed-Rule-2015FINAL-3.7.14.pdf*.

GS levels. We assume a GS grade 13, step 5, with a mean wage of $51.48, which with an allowance of 100 percent for overhead and fringe benefits becomes $102.96. This is based on the 2017 publicly available wages found on the Office of Personnel Management Web site at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/*.

- We calculate the savings to the federal government by multiplying the number of anticipated QIP attestation submissions (750) times the number of CMS staff it takes to complete a review— (1) times the adjusted wage for that staff ($102.96) ($750 \times 1 \times \$102.96 \times 0.25$ hour), which equals $19,305.

Thus, the total savings of this provision are $31,968, of which $12,663.75 are savings to the industry, as indicated in section III. of this proposed rule, and $19,305 are savings to the federal government.

16. Reducing the Burden of the Medical Loss Ratio Reporting Requirements

Our proposal to significantly reduce the amount of MLR data submitted to CMS would eliminate the need for CMS to continue to pay a contractor, approximately $390,000 a year for the following:

- To perform initial analyses, or desk reviews, of the detailed MLR reports submitted by MA organizations.
- Part D sponsors in order to identify omissions and suspected inaccuracies and to communicate their findings to MA organizations and Part D sponsors in order to resolve potential compliance issues.

In addition, because we would be receiving only the minimum amount of data from MAOs and Part D sponsors, we expect that we would reduce the amount we pay to contractors for software development, data management, and technical support related to MLR reporting. We currently pays a contractor $300,000 each year for these services. Although we expect that MAOs and Part D sponsors would continue to use the HPMS or a similar system to submit and attest to their simplified MLR submissions, we would no longer need to maintain and update MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. We estimate, by eliminating these services, we would reduce our payments to contractors by approximately $100,000 a year.

In total, we estimate that the proposed changes to the MLR reporting requirements will save the government $490,000 a year. As noted in the Collection of Information section of this proposed rule, the proposed changes to the MLR reporting requirement will save MA organizations and Part D sponsors $904,884 a year. Thus, the total annual savings of this proposal are $1,446,417: $490,000 to the government and $904,884 to MA organizations and Part D sponsors.

We do not anticipate that our proposal to modify the regulations at §§ 422.2430 and 423.2430 to specify that Medication Therapy Management (MTM) programs that comply with § 423.153(d) are quality improvement activities (QIA) will significantly reduce stakeholder burden. As explained in section II.C.1.b.(2). of this proposed rule, we stated in the May 23, 2013 final rule (78 FR 31294) that MTM activities qualify as QIA, provided they meet the requirements set forth in §§ 422.2430 and 423.2430. We expect that most if not all MTM programs that comply with § 423.153(d) would already satisfy the QIA requirements set forth in current §§ 422.2430 and 423.2430. Therefore, we do not anticipate that the proposal to explicitly include MTM programs in QIA will have a significant impact on burden.

17. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

The proposed provisions would specifically permit Part D sponsors that meet our requirements to remove brand name drugs (or change their cost-sharing status) when replacing them with (or adding) newly approved generics without providing advance notice or submitting formulary change requests. We would also permit Part D sponsors to make such changes at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. A related proposal would except from our transition policy applicable generic substitutions and additions with cost-sharing changes. Lastly, we are proposing to decrease the days of enrollee notice and refill required in cases in which (aside from generic substitutions and drugs deemed unsafe or removed from the market) drug removal or changes in cost-sharing will affect enrollees.

The FDA has noted that generics are typically sold at substantial discounts from the branded price. (''Generic Drugs: Questions and Answers,'' see FDA Web site, *https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm*, accessed June 22, 2017.) However, we do not believe that significant savings will necessarily result from these proposed provisions, because historically Part D sponsors have been able to anticipate the generic launches well and migrate the brand scripts to generics smoothly once the generic drugs become available. The proposal could provide some administrative relief for Part D sponsors, although the savings won't be very significant.

In addition regardless of any first year effect, we do not believe there could be any significant effect for subsequent years. Our proposed changes would permit immediate specified generic substitutions throughout the plan year or a 30 rather than a 60 day notice period for certain substitutions. Part D sponsors submit for review each year an entirely new formulary and presumably the timing of substitutions would overlap across plan years a minimal amount of times.

18. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

a. Savings

Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost-sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow-on biological products instead of reference biological products. As discussed previously, this would reduce costs to Part D enrollees and generate savings for the Part D program.

In addition, we believe that reducing confusion in the marketplace surrounding this issue will improve beneficiary protections while improving enrollee incentives to choose follow-on biological products over reference biological products. (This proposed provision to classify follow-on biological products as generic drugs are for the purposes of cost sharing for non-LIS cost sharing in the catastrophic portion of the benefit and LIS enrollees in any phase of the benefit.) Improved incentives to choose lower cost alternatives will reduce costs to Part D enrollees and the Part D program. OACT estimates this proposal will provide a modest savings of $10 million in 2019, with savings increasing by approximately $1 million each year through 2028.

OACT anticipates some natural shift from reference biological products to follow-on biological products, but follow-on biological products' price differential and market share are lower

than that observed for small molecule generic drugs. Currently, Zarxio® data provide the only meaningful comparison available to date, as very limited data exist on the other six approved (as of September 14, 2017) follow-on biological products. The market dynamic between Neupogen® and Zarxio® has behaved consistent with OACT's anticipation and OACT expects other follow-on biological products to follow the similar pattern. Based on 2017 year-to-date data on the per script price difference between Neupogen® and Zarxio®, OACT estimated follow-on biological products to be 16 percent less expensive than their reference biological product. OACT estimates this proposal will result in a minor shift of an additional 5 percent of prescriptions to follow-on biological products by LIS enrollees under this proposal. Consequently, savings are not estimated to be significant at this time.

TABLE 30—ESTIMATED AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2019 THROUGH 2023

Provision	Regulation section(s)	Calendar year ($ in millions)					Total CYs 2019–2023 ($ in millions)
		2019	2020	2021	2022	2023	
Federal Government (Medicare) Impacts							
Treatment of Follow-On Biological Products as Generics for LIS Cost Sharing and Non-LIS Catastrophic Cost Sharing.	423.4	10	11	12	13	14	60

b. Benefits of Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost-sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow-on biological products instead of reference biological products. As discussed previously, this would reducing costs to Part D enrollees and generate savings for the Part D program.

19. Changes to the Days' Supply Required by the Part D Transition Process

We do not believe our proposal in this section would impose any new burden on any stakeholder. Since Part D sponsors and their PBMs already have prescription drug pharmacy claims systems programmed to provide transition to plan enrollees in the outpatient setting, they would only have to make a technical change to these systems that consists of changing the required number of days' supply if it is not already 30 days. In addition, Part D sponsors and their PBMs would have to cease treating these enrollees in the LTC setting separately from enrollees in the outpatient setting for purposes of transition. We also do not believe this proposal would impose any new burden on LTC facilities and the pharmacies that serve them. If finalized, we believe this regulation would eliminate the additional time that LTC facilities and pharmacies have to transition Part D patients that we now believe they do not need to effectuate the transition.

We believe this provision will produce cost-savings to the Medicare Part D program because it requires fewer drugs to be dispensed under transition, particularly in the LTC setting. However, we are unable to estimate the cost-savings, because it largely depends upon which and how many drugs are dispensed as transition drugs to Part D beneficiaries in the LTC setting in the future. Also, we are unable to determine which PDEs involve transition supplies in LTC in order to provide an estimate of future savings based on past experience with transition supplies in LTC in the Part D program.

G. Alternatives Considered

1. Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

The critical policy decision was how broadly or narrowly to classify follow-on biological products as generics. Overly broad classification might easily overstep the distinctions between generic drugs and follow-on biologics in statute and those drawn by the United States Food and Drug Administration (FDA), leading to confusion in the marketplace, and potentially jeopardizing Part D enrollee safety. Inappropriate utilization of biological products and increased need for additional medical services, in turn, increase costs to the Part D program. A narrow classification can appropriately resolve marketplace confusion while also improving Part D enrollee incentives to choose lower cost alternatives.

2. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types

The critical policy decision was how to strike the right balance to clarify confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models without prematurely and inappropriately interfering with highly volatile market forces.

3. Preclusion List

We considered a preclusion list that would embody preventive provisions that would place on the preclusion list not just those providers and suppliers who are prescribing Part D drugs or who are providing services to Medicare beneficiaries who are receiving their Medicare benefit from a MA plan. The savings and cost estimates associated with that alternative are based on the following. Prescription drug event (PDE) and encounter data identifies providers who furnish Part C services and items and prescribe Part D drugs to Medicare beneficiaries. Given the frequency with which MA organizations and Part D sponsors typically submit data to CMS, we estimate a delay of approximately 1 month in obtaining this data. Delays in the availability of this data and the screening and evaluation of the providers and prescribers will result in delays in the identification and inclusion of providers or prescribers on the preclusion list, which would occur after the service, item or drug was provided to the Medicare beneficiary. We estimate that it will cost the Trust Fund approximately $44.7 million if we do not proactively screen providers and prescribers and delay screening until after the PDE and encounter data is

available. We estimate an additional 1.4 million providers or prescribers would not be screened if we only rely on PDE and encounter data. The current Medicare provider population consists of approximately 2 million providers and historically we has revoked 0.4 percent of its existing Medicare enrolled providers., However this percentage could be higher or lower for the population of prescribers solely enrolled for prescribing. There are approximately 480,000 part C and D unenrolled providers and prescribers, 120,000 of which are billing Part C. Using the percentage of historical revocations, we estimate approximately 1,920 new revocations. Based on the approximate 1-month delay in the availability of the PDE and encounter data, three months for screening and an additional 3 months to evaluate the offenses, we anticipate approximately a 7-month delay in the provider or prescriber's inclusion on the preclusion list following the service, item or drug being provided to the beneficiary, if we do not perform proactive screening. The 7-month timeframe is dependent on whether the PDE and encounter data is timely. Using a cost avoidance of $3,324 per month average per provider and applying it to the estimated 1,920 new revocations, a delay in screening would cost the Trust Fund approximately $44.7 million ($3,324 \times 7 \times 1,920$). The $3,324 estimate is based on Medicare fee-for-service revocation data and may be higher or lower depending on whether the provider is an individual or organization and their provider type.

H. Accounting Statement

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 31 we have prepared an accounting statement showing the savings and transfers associated with the provisions of this final rule for CYs 2019 through 2023. Table 31 is based on Table 32 which lists savings, costs, and transfers by provision.

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS FROM CALENDAR YEARS 2019 TO 2023

[$ in millions]

Category	Savings		Period covered	Whom to whom
	Discount rate			
	7%	3%		
Net Annualized Monetized Savings	82.34	82.02	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Savings	87.26	86.79	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Cost	−4.92	−4.77	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Net Annualized Monetized Savings	13.80	13.82	CYs 2019–2023	Trust Fund.
Annualized Monetized Savings	13.80	13.82	CYs 2019–2023	Trust Fund.
Annualized Monetized Cost	0.00	0.00	CYs 2019–2023	Trust Fund.
Net Annualized Monetized Savings	68.54	68.20	CYs 2019–2023	Industry.
Annualized Monetized Savings	73.46	72.98	CYs 2019–2023	Industry.
Annualized Monetized Cost	−4.92	−4.77	CYs 2019–2023	Industry.
Transfers	155.90	154.95	CYs 2019–2023	Federal Government, MA plans and Part D Sponsors.

Note: Monetized figures in 2018 dollars. Positive numbers indicate aggregate annual savings at the giving percentage. Transfers are a separate line item. Savings and cost have been broken out separately for industry, the trust fund and aggregate. For example, the industry provisions with positive amounts had a level monetized amount of 72.32 at the 3 percent level but a cost of 11.87 at the 3 percent level resulting in an aggregate of 72.32 −11.87 = 60.45. Minor (cent) errors are due to rounding.

The following Table 32 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table.

BILLING CODE 4120–01–P

BILLING CODE 4120–01–C

TABLE 32: SAVINGS, COSTS, AND TRANSFERS BY PROVISION

	2019 Industry	2019 Trust Fund	2019 Transfers	2020 Industry	2020 Trust Fund	2020 Transfers	2021 Industry	2021 Trust Fund	2021 Transfers	2022 Industry	2022 Trust Fund	2022 Transfers	2023 Industry	2023 Trust Fund	2023 Transfers
Totals	90.3	13.6	231.5	57.7	13.63	250.5	60.8	13.63	271.8	63.9	13.6	295.0	67.1	14.6	
Tot savings	102.4	13.6		60.5	13.63		63.6	13.63		66.7	13.6		69.9	14.6	
Tot costs	-12.1	0	-15.1	-2.8	0	-16.1	-2.8	0	-16.1	-2.8	0	-17	-3	0	
Total Transfers			231.5			250.5			271.8			295			321.6
CARA	-2.8	13	0	-2.8	13	0	-2.8	13	0	-2.8	13	0	-2.8	14	0
OEP			-15.1			-16.1			-16.1			-17.1			-18.1
MLR	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0
Disclosure	54.7			57.6			60.7			63.8			67		
Marketing	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0
Meaningful Difference (Part C)	0.6			0.6			0.6			0.6			0.6		
Meaningful Difference (Pt D)	0.1			0.1			0.1			0.1			0.1		
Stop Loss (PIP)			204.6			220.6			238.9			259.1			281.7
Part C/D Preclusion	44.8			0			0			0			0		
Part C/D Preclusion	-9.3			0			0			0			0		
Follow on Biologics			10			11			12			13			14
Star Ratings			32			35			37			40			44

Note: This tables summarizes cost and savings by provision. Provisions not in the table are scored as 0. Numbers indicate millions of dollars. Positive numbers indicate savings while negative numbers indicate cost.

I. Conclusion

This proposed rule has a net savings of between $80 to $100 million for each of the next 5 years. The savings are equivalent to a level amount of about $80 million per year for both 7 percent and 3 percent interest rates. These aggregate savings are to industry ($68.20 million at the 3 percent level = $72.98 million savings—$4.77 million cost), and the Federal government and the Trust Fund ($13.82 million at the 3 percent level which reflects savings to the trust fund without any cost). Transfers between the Federal Government and Industry are between $230 and $320 million and are equivalent to a monetized level amount of about $270 million per year at the 3-percent and 7-percent levels. Both industry and the Federal government save from program efficiencies and reduced work.

J. Reducing Regulation and Controlling Regulatory Costs

This rule, if finalized as proposed, is expected to be an E.O. 13771 regulatory action. Details on the estimated costs and cost savings can be found in the preceding analysis.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

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, Incorporation by Reference, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, and 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 proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section § 405.924 is amended by adding paragraph (a)(5) to read as follows:

§ 405.924 Actions that are initial determinations.

(a) * * *

(5) An adjustment of premium for hospital or supplementary medical insurance as outlined in §§ 406.32(d), 408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 4. Section 417.430 is amended by revising paragraph (a)(1) to read as follows:

§ 417.430 Application procedures.

(a) * * *

(1) The application form must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.2262 of this chapter. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between HHS and its designees and the HMO or CMP.

* * * * *

■ 5. Section 417.472 is amended by adding paragraph (k) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(k) All cost contracts under section 1876 of the Act must agree to be rated under the quality rating system specified at subpart D of part 422, and for cost plans that provide the Part D prescription benefit, under the quality rating system specified at part 423 subpart D, of this chapter. Cost contacts are not required to submit data on or be rated on specific measures determined by CMS to be inapplicable to their contract or for which data are not available, including hospital readmission and call center measures.

■ 6. Section 417.478 is amended by revising paragraph (e) to read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e)(1) The prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list, defined in § 422.2 of this chapter, apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

(2) In applying the provisions of §§ 422.2, 422.222, and 422.224 of this chapter under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

■ 7. Section 417.484 is amended by revising paragraph (b)(3) to read as follows:

§ 417.484 Requirement applicable to related entities.

* * * * *

(b) * * *

(3) That payments must not be made to individuals and entities included on the preclusion list, defined in § 422.2 of this chapter.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 8. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 9. Section 422.2 is amended by adding the definition of ''Preclusion list'' in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Preclusion list means a CMS-compiled list of individuals and entities that—

(1) Meet all of the following requirements:

(i) The individual or entity is currently revoked from Medicare under § 424.535.

(ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

(iii) 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:

(A) The seriousness of the conduct underlying the individual's or entity's revocation.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) 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:

(A) The seriousness of the conduct involved.

(B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and

(C) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 10. Section 422.54 is amended by revising paragraphs (c)(1)(i) and (d)(4)(ii) to read as follows:

§ 422.54 Continuation of enrollment for MA local plans.

* * * * *

(c) * * *

(1) * * *

(i) Obtain CMS's approval of the continuation area, the communication materials that describe the option, and the MA organization's assurances of access to services.

* * * * *

(d) * * *

(4) * * *

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the communication materials.

* * * * *

■ 11. Section 422.60 is amended—

■ a. In paragraph (a)(2) by removing the reference ''§ 422.62(a)(3), (a)(4), and (a)(5) if'' and adding in its place the reference ''§ 422.62(a)(3) and (4) if''; and

■ b. Revising paragraph (g).

The revision reads as follows:

§ 422.60 Election process.

* * * * *

(g) Passive enrollment by CMS—(1) *Circumstances in which CMS may implement passive enrollment.* CMS may implement passive enrollment procedures in any of the following situations:

(i) Immediate terminations as provided in § 422.510(b)(2)(i)(B).

(ii) CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) CMS determines, after consulting with the State Medicaid agency that contracts with the dual eligible special needs plan described in paragraph (g)(2)(i) of this section, and that meets the requirements of paragraph (g)(2) of this section, that the passive enrollment will promote integrated care and continuity of care for a full-benefit dual eligible beneficiary (as defined in § 423.772 of this chapter and entitled to Medicare Part A and enrolled in Part B under title XVIII) who is currently enrolled in an integrated dual eligible special needs plan.

(2) *MA plans that may receive passive enrollments.* CMS may implement passive enrollment described in paragraph (g)(1)(iii) only into MA–PD plans that meet all the following requirements:

(i) Operate as a fully integrated dual eligible special needs plan as defined in § 422.2, or a specialized MA plan for special needs individuals that meets a high standard of integration, as described in § 422.102(e).

(ii) Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the plan (or plans) from which the beneficiaries are passively enrolled.

(iii) Have an overall quality rating of at least 3 stars under the rating system described in § 422.160 through § 422.166 for the year prior to the plan year passive enrollments take effect or is a low enrollment contract or new MA plan as defined in § 422.252.

(iv) Not have any prohibition on new enrollment imposed by CMS.

(v) Have limits on premiums and cost-sharing appropriate to full-benefit dual eligible beneficiaries.

(vi) Have the operational capacity to passively enroll beneficiaries and agree to receive the enrollments.

(3) *Passive enrollment procedures.* Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(4) *Beneficiary notification.* The MA organization that receives the passive enrollment must provide to the enrollee a notice that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary's ability to decline the enrollment or choose another plan. Such notice must be provided to all potential passively enrolled enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(5) *Special election period.* Individuals not otherwise eligible for a special election period at the time of passive enrollment will be provided with a special election period, in accordance with § 422.62(b)(4).

■ 12. Section § 422.62 is amended by—

■ a. Revising paragraphs (a)(3) through (5);

■ b. Removing paragraphs (a)(6) and (7); and

■ c. Revising paragraph (b)(3)(ii).

The revisions read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(3) *Open enrollment period for individuals enrolled in MA*—(i) *For 2019 and subsequent years.* Except as provided in paragraphs (a)(3)(ii) and (iii) and (a)(4) of this section, an individual who is enrolled in an MA plan may make an election once during the first

3 months of the year to enroll in another MA plan or disenroll to obtain Original Medicare. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e).

(ii) *Newly eligible MA individual.* For 2019 and subsequent years, a newly MA eligible individual who is enrolled in a MA plan may change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e).

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(3)(i) and (ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.

(4) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(5) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d) of this chapter.

(b) * * *

(3) * * *

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials as outlined in subpart V of this part.

* * * * *

■ 13. Section 422.66 is amended by revising paragraphs (c) and (d)(1) and (5) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(c) *Election by default: Initial coverage election period*—(1) *Basic rule.* Subject to paragraph (c)(2) of this section, an individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(2) *Default enrollment into MA special needs plan*—(i) *Conditions for default* enrollment. During an individual's initial coverage election period, an individual may be deemed to have elected a MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX offered by the organization provided all the following conditions are met:

(A) At the time of the deemed election, the individual remains enrolled in an affiliated Medicaid managed care plan. For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the MA special needs plan for individuals entitled to medical assistance under Title XIX or is offered by an entity that shares a parent organization with such MA organization;

(B) The state has approved the use of the default enrollment process in the contract described in § 422.107 and provides the information that is necessary for the MA organization to identify individuals who are in their initial coverage election period;

(C) The MA organization offering the MA special needs plan has issued the notice described in paragraph (c)(2)(iv) of this section to the individual;

(D) Prior to the effective date described in paragraph (c)(2)(iii) of this section, the individual does not decline the default enrollment and does not elect to receive coverage other than through the MA organization; and

(E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section.

(ii) *CMS approval of default enrollment.* An MA organization must obtain approval from CMS before implementing any default enrollment as described in this section. CMS may suspend or rescind approval when CMS determines the MA organization is not in compliance with the requirements of this section.

(iii) *Effective date of default enrollment.* Default enrollment in the MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX is effective the month in which the individual is first entitled to both Part A and Part B.

(iv) *Notice requirement for default enrollments.* The MA organization must provide notification that describes the costs and benefits of the MA plan and the process for accessing care under the plan and clearly explains the individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another plan. Such notification must be provided to all individuals who qualify for default enrollment under paragraph (c)(2) of this section no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section.

(d) * * *

(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who requests enrollment during his or her Initial Coverage Election Period and is enrolled in a health plan offered by the MA organization during the month immediately preceding the MA plan enrollment effective date, and who meets the eligibility requirements at § 422.50.

* * * * *

(5) *Election.* An individual who requests seamless continuation of coverage as described in paragraph (d)(1) of this section may complete a simplified election, in a form and manner approved by CMS that meets the requirements in § 422.60(c)(1).

* * * * *

■ 14. Section 422.68 is amended by revising paragraphs (a), (c), and (f) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as follows:

(1) If made prior to the month of entitlement to both Part A and Part B, it is effective as of the first day of the month of entitlement to both Part A and Part B.

(2) If made during or after the month of entitlement to both Part A and Part B, it is effective the first day of the calendar month following the month in which the election is made.

* * * * *

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (5), coverage is effective as of the first day

of the first calendar month following the month in which the election is made.

* * * * *

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(5), is effective the first day of the first month following the month in which the election is made.

■ 15. Section 422.100 is amended—

■ a. In paragraph (f)(2), by removing the phrase ''to services. and'' and adding in its place the phrase ''to services.''; and

■ b. By revising paragraphs (f)(4), (f)(5) introductory text, (f)(5)(ii), and (f)(6).

The revisions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(4) Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an out-of pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) of this section applies only to use of network providers. Such local PPO plans must include a total catastrophic limit annually determined by CMS using Medicare Fee-for-Service and to establish appropriate beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is—

* * * * *

(ii) Not greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate beneficiary out-of-pocket expenditures. CMS will set the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. CMS may use Medicare Fee-for-Service data to evaluate the possibility of discrimination and to establish non-discriminatory out-of-pocket limits and also use MA encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory.

* * * * *

■ 16. Section 422.101 is amended by revising paragraphs (d)(2) and (3) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* MA regional plans are required to establish a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate out-of-pocket limits. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(3) *Total catastrophic limit.* MA regional plans are required to establish a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits).

(i) This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Medicare Fee-for-Service, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section and may be no greater than the annual limit set by CMS using Medicare Fee-for-Service data.

(ii) CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

* * * * *

■ 17. Section 422.102 is amended by revising paragraph (d) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(d) *Supplemental benefits packaging.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

* * * * *

■ 18. Section 422.111 is amended by revising paragraphs (a) introductory text, (a)(3), and (h)(2)(ii) to read as follows:

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

* * * * *

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

* * * * *

(h) * * *

(2) * * *

(ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees upon request.

* * * * *

§ 422.152 [Amended]

■ 19. Section 422.152 is amended by removing and reserving paragraphs (a)(3) and (d).

■ 20. Sections 422.160, 422.162, 422.164 and 422.166 are added to Subpart D to read as follows:

Subpart D–Quality Improvement

* * * * *

Sec.

§ 422.160 Basis and scope of the Medicare Advantage Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part C.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system to be used in determining quality bonus payment (QBP) status and in determining rebate retention allowances.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by MA plans, where appropriate and possible to use data of the type described in § 422.162(c).

(c) *Applicability.* The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.

§ 422.162 Medicare Advantage Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.

Highest rating means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).

HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.

Low income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 of this chapter for definition of a low-income subsidy eligible individual).

Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation (''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3, or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

(b) *Contract ratings*—(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d) with both the reward factor and CAI applied as applicable, as described in § 422.166(f).

(2) *Plan benefit packages.* All plan benefit packages (PBPs) offered under an MA contract have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract except for Special Needs Plan (SNP)-specific measures collected at the PBP level. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations.* (i) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(iv) of this section. Paragraph (b)(3)(iii) of this section is applied to subsequent years that are not addressed in paragraph (b)(3)(ii) of this section for assigning the QBP rating.

(ii) For the first year after a consolidation, CMS will determine the QBP status of a contract using the enrollment-weighted means (using traditional rounding rules) of what would have been the QBP Ratings of the surviving and consumed contracts based on the contract enrollment in November of the year the preliminary QBP ratings were released in the Health Plan Management System (HPMS).

(iii) In subsequent years following the first year after the consolidation, CMS will determine QBP status based on the consolidated entity's Star Ratings displayed on Medicare Plan Finder.

(iv) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(B) For the second year after consolidation, CMS will use the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from the following data sources: HEDIS, CAHPS, and HOS. HEDIS and HOS measure data will be scored as reported. CMS will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.

(c) *Data sources.* (1) CMS bases Part C Star Ratings on the type of data specified in section 1852(e) of the Act and on CMS administrative data. Part C Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of MA plans' compliance with MA requirements and data submitted by plans.

(2) MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. MA organizations must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

§ 422.164 Adding, updating, and removing measures.

(a) *General.* CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality.* CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures.* (1) CMS will continue to review measures that are in alignment with the private sector, such as measures developed by NCQA and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum for adoption and use in the Part C and Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part C Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates.* For measures that are already used for Star Ratings, CMS will update measures so long as the

changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(v) Add alternative data sources.

(2) *Substantive updates.* For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or

(ii) A measure shows low statistical reliability.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part C and Part D improvement measures will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measures if the measures meet all of the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.

(iii) CMS will exclude any measures that are already focused on improvement in MA organization performance from year to year.

(iv) The Part C improvement measure will include only Part C measure scores; the Part D improvement measure will include only Part D measure scores.

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iv) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the two year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure score will be converted to a measure-level Star Rating using hierarchical clustering algorithms.

(vi) The Part D improvement measure scores for MA–PDs and PDPs will be determined using cluster algorithms in accordance with §§ 422.166(a)(2)(ii) through (iv) and 423.186(a)(2)(ii) through (iv) of this chapter. The Part D improvement measure thresholds for MA–PDs and PDPs would be reported separately.

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).

(i) CMS will reduce HEDIS measures to 1 star when audited data are submitted to NCQA with a designation of ''biased rate'' or BR based on an auditor's review of the data or a designation of ''nonreport'' or NR.

(ii) CMS will reduce measures based on data that an MA organization must submit to CMS under § 422.516 to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation

standards for data directly used to calculate the associated measure.

(iii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete. The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.

(B) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.

(C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.

(D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

(*1*) 20 percent, 1 star reduction.

(*2*) 40 percent, 2 star reduction.

(*3*) 60 percent, 3 star reduction.

(4) 80 percent, 4 star reduction.

(E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.

(F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(G) The scaled reduction is applied after the calculation for the appeals measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.

(H) The Part C Calculated Error is determined using the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. (The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the data collection or data sample period and the number of cases not forwarded to the IRE during the same period.)

(I) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

(J) The projected number of cases not forwarded to the IRE in a 3-month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.

(K) Contracts would be subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(1) The calculated error rate is 20 percent or more.

(2) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

(L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) through (iii) of this section, including a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements.

§ 422.166 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points.* CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA–PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures.* (i) The method minimizes differences within star categories and maximizes differences across star categories using the hierarchical clustering method.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures.* The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned 2 stars if it does not meet the 1 star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or

(B) Criterion (b) its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned 3 stars if it meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different

from the national average CAHPS measure score; or

(B)(*1*) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;

(*2*) The reliability is low; and

(*3*) The score is not statistically significantly lower than the national average CAHPS measure score.

(C)(*1*) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;

(*2*) The reliability is low; and

(*3*) The score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability.

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile.

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 5 domains for the MA Star Ratings are: Staying Healthy: Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints and Changes in the Health Plan's Performance; and Health Plan Customer Service. The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1- to 5- star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part C summary ratings.* (1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section with an adjustment to reward consistently high performance and the application of the CAI under paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated.

(ii) The Part C improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA–PD rating.* (1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance and the application of the CAI, under paragraph (f) of this section.

(2)(i) An MA–PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1- to 5-star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(v) Low enrollment contracts (as defined in § 422.252) and new MA plans (as defined in § 422.252) do not receive an overall and/or summary rating. They are treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) and as announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853 (b) of the Act.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Patient experience and complaint measures receive a weight of 1.5.

(iv) Access measures receive a weight of 1.5.

(v) Process measures receive a weight of 1.

(2) *Rules for new measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part C summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.

(1) *Reward factor.* This rating-specific factor is added to the both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA–PDs; Part C summary for MA–PDs and MA-only; and Part D summary for MA–PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA–PDs; Part C

summary for MA–PDs and MA-only; and Part D summary for MA–PDs and PDPs). The weighted mean and weighted variance are compared separately for MA–PD and standalone Part D contracts. The measure weights are specified in § 422.166(e). Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the value of the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical Adjustment Index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA–PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) MA–PD contracts may have up to three rating-specific CAI adjustments: One for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) An MA-only contract may be adjusted only once for the CAI for the Part C summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) CMS will announce the measures identified for inclusion in the calculations of the CAI under this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects models that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:

(A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.

(B) The LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

(C) The Part D measures for MA–PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.

(iv) The adjusted measures score for the selected measures are determined using the results from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part C summary, Part D summary for MA–PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (Part C, Part D for MA–PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Ratings' year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for each highest level rating for each contract-type (overall rating for MA–PD contracts and Part C summary rating for MA-only contracts), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).

(ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part C summary rating for MA–PDs will include the Part C improvement measure and the Part D summary rating for MA–PDs will include the Part D improvement measure.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ''Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ''Plan too new to be measured''.

(1) Medicare Plan Finder Performance icons. Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h):

(i) *High-performing icon.* The high performing icon is assigned to an MA-only contract for achieving a 5-star Part C summary rating and an MA–PD contract for a 5-star overall rating.

(ii) *Low-performing icon.* (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(2) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which MA organizations can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

■ 21. Section 422.204 is amended by removing paragraph (b)(5) and adding paragraph (c).

The addition reads as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

■ 22. Amend § 422.206 by revising paragraph (b)(2)(i) to read as follows:

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(b) * * *

(2) * * *

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with all applicable requirements under subpart V of this part.

* * * * *

■ 23. Section 422.208 is amended by revising paragraph (f)(2)(iii) and adding paragraphs (f)(2)(iv) through (vii) and (f)(3) to read as follows:

§ 422.208 Physician incentive plans: requirements and limitations.

* * * * *

(f) * * *

(2) * * *

(iii)(A) Stop-loss protection must cover 90 percent of costs above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible, for policies that pay 90 percent of costs above the deductible or an actuarial equivalent amount, for stop-loss insurance for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the table published by CMS that is developed using the methodology in paragraph (f)(2)(iv) of this section. For panel sizes not shown in the table, use linear interpolation between the table values.

(B) To apply this table, a physician or physician group may use linear interpolation to compute the deductible

for the globally capitated patients (DGCP) as well as the deductible for globally capitated patients plus NPEs (DGCPNPE). The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of DGCP+100,000 and DGCPNPE.

(iv) The table referenced in paragraph (f)(2)(iii) of this section will be created, updated, and published by CMS in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act), as necessary, using the following methodology:

(A) The table and the methodology in this paragraph (f)(2)(iv) only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements.

(B) If it is not a global capitation arrangement or is a different stop/loss arrangement, the tables developed using this methodology do not apply. The table is calculated using the following methodology and assumptions:

(*1*) CMS used the population of all Fee For Service (FFS) Part A and Part B claims for the most available recent year and assumed a multi-specialty practice since all physician claims were allowed.

(*2*) CMS's estimate of medical group income was derived from CMS claims files, which include payments for all Part A and Part B services.

(*3*) The central limit theorem was used to obtain the distribution of claim means for a multi-specialty group of any given panel size.

(*4*) The distribution was used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25 percent of the net income derived from services that the physicians personally rendered.

(*i*) This point is set as the deductible in the table described in paragraph (f)(2)(iii) of this section.

(*ii*) The 'net benefit premium' (NBP) column in that table is not used for computation of combined insurance but is used to determine the separate deductibles for physician/professional services and institutional services.

(*iii*) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

(v)(A) Insurance using separate deductibles for professional and institutional claims is permissible for contract years beginning on or after January 1, 2019 so long as the separate deductibles for institutional services and professional services are consistent with the table published by CMS using the methodology and assumptions in paragraphs (f)(2)(vi) and (vii) of this section. For deductible amounts not shown in the table use linear interpolation between the table values. The tables and methodology in paragraph (f)(2)(iv) of this section only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements. If it is not a global capitation arrangement or a different stop/loss arrangement, these tables do not apply.

(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) for the patient panel size from the table described in paragraph (f)(2)(iii) of this section. If the NBP is identified using interpolation from the values in the table described in paragraph (f)(2)(iii) of this section, interpolation is also used from the NBP values in the table described in paragraph (f)(2)(v)(A) of this section that are closest to the NBP identified by using the table described in paragraph (f)(2)(iii) of this section. TAs with combined stop-loss insurance, panel size may include non-risk patients. As with combined stop-loss insurance, the deductible for separate insurance that must be provided for the physician or physician group is the lesser of DGCP+100,000 and DGCPNPE.

(vi) The table described in (f)(2)(v) of this section is calculated using a methodology similar to the calculation of the table described in paragraph (f)(2)(iii) of this section.

(A) The population of all Part A and Part B claims was obtained.

(B) The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services.

(C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.

(vii) In determining the number of global risk patients for the types of services covered under Parts A and B of Medicare, commercial and Medicaid patients who are at global risk and in the same stop-loss risk pool may be included.

(A) The number of non-risk patient equivalents (NPEs) is equal to the projected annual aggregate payments to the physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both numerator and denominator are for physician services that are rendered by the physician or physician group.

(B) The lowest deductible shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section would generally not be available for sale from an insurance company. The number of risk patients and the net premiums are shown for the case where the MA plan might directly insure a contracted physician or physician group with protection at these lower deductibles.

(3) *Special insurance.* If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements.

(i) Develops the deductibles to be actuarially equivalent to those coverages in the tables.

(ii) Makes the computations in accordance with generally accepted actuarial principles and practices.

(iii) Is certified as meeting the requirements in paragraphs (f)(3)(i) and (ii) of this section by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

* * * * *

■ 24. Section 422.222 is revised to read as follows:

§ 422.222 Preclusion list.

(a)(1) 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.

(2) 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.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

■ 25. Section 422.224 is revised to read as follows:

§ 422.224 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) An MA organization may not pay, directly or indirectly, on any basis, for

items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

§ 422.254 [Amended]

■ 26. Section 422.254 is amended by removing paragraph (a)(4) and redesignating paragraph (a)(5) as paragraph (a)(4).

§ 422.256 [Amended]

■ 27. Section 422.256 is amended by removing paragraph (b)(4).

§ 422.258 [Amended]

■ 28. Section 422.258 is amended in paragraph (d)(7) introductory text by removing the phrase ''section 1852(e) of the Act)'' and adding in its place the phrase ''section 1852(e) of the Act) specified in subpart 166 of this part 422''.

■ 29. Section 422.260 is amended by revising paragraph (a) and revising the definition of ''Quality bonus payment (QBP) determination methodology'' in paragraph (b) to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA–PDs and Part C summary rating for MA-only contracts for the contract assigned under subpart D of this part

(b) * * *

Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. (Low enrollment contracts and new MA plans are defined in § 422.252.)

* * * * *

■ 30. Section 422.310 by adding paragraph (d)(5) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(d) * * *

(5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.

* * * * *

■ 31. Section 422.501 is amended by revising paragraphs (c)(1)(iv) and (2) to read as follows:

§ 422.501 Application requirements.

* * * * *

(c) * * *

(1) * * *

(iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

* * * * *

§ 422.502 [Amended]

■ 32. Section 422.502 is amended in paragraphs (b)(1) and (2) by removing the phrase ''14 months'' and adding in its place ''12 months'' each time it appears.

■ 33. Section 422.503 is amended—

■ a. In paragraph (b)(4)(ii), by removing the phrase ''financial and marketing activities'' and adding in its place ''financial and communication activities''; and

■ b. Revising paragraph (b)(4)(vi)(C).

The revision reads as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(C)(*1*) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization's chief executive and other senior administrators, managers and governing body members.

(*2*) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member.

* * * * *

■ 34. Section 422.504 is amended by—

■ a. Revising paragraphs (a) introductory text and (a)(6).

■ b. Removing paragraph (a)(16).

■ c. Redesignating paragraphs (a)(17) and (18) as paragraphs (a)(16) and (17), respectively; and

■ d. Revising newly redesignated paragraph (a)(17).

■ e. Revising paragraph (i)(2)(v).

The revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) *Agreement to comply with regulations and instructions.* The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. Compliance with the terms of this paragraph is material to the performance of the MA contract. The MA organization agrees—

* * * * *

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and the preclusion list requirements in §§ 422.222 and 422.224.

* * * * *

(17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in part 422 subpart D. A Part C summary plan rating is calculated as provided in § 422.166.

* * * * *

(i) * * *

(2) * * *

(v) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.

* * * * *

§ 422.506 [Amended]

■ 35. Section 422.506 is amended by—

■ a. Removing paragraph (a)(3);

■ b. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4); and

■ c. Removing and reserving paragraph (b).

■ 36. Section 422.508 is amended by adding paragraph (a)(3) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

(a) * * *

(3) If the organization submits a request to end the term of its contract after the deadline provided in § 422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program.

* * * * *

■ 37. Section 422.510 is amended by revising paragraphs (a)(4)(viii) and (xiii) and adding paragraphs (a)(4)(xiv) and (xv) and (b)(2)(v) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(viii) Substantially fails to comply with the requirements in subpart V of this part.

* * * * *

(xiii) Fails to meet the preclusion list requirements in accordance with § 422.222 and 422.224.

(xiv) The MA organization has committed any of the acts in § 422.752(a) that support the imposition of intermediate sanctions or civil money penalties under Subpart O of this part.

(xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(b) * * *

(2) * * *

(v) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days before to the effective date of the termination.

* * * * *

■ 38. Section 422.514 is amended by revising paragraph (b) to read as follows:

§ 422.514 Minimum enrollment requirements.

* * * * *

(b) *Minimum enrollment waiver.* For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(1)(i) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or

(ii) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in this paragraph (b)(1) and stop-loss insurance that is adequate and acceptable to CMS; and

(2) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

* * * * *

§ 422.590 [Amended]

■ 39. Section 422.590 is amended by removing paragraph (f) and redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

§ 422.664 [Amended]

■ 40. Section 422.664 is amended in paragraph (b)(1) by removing the phrase ''July 15'' and adding in its place ''September 1''.

■ 41. Section 422.750 is amended by revising paragraph (a)(3) to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) * * *

(3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS.

* * * * *

■ 42. Section 422.752 is amended by revising paragraphs (a)(11) and (13) and (b) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(11) Fails to comply with communication restrictions described in subpart V of this part or applicable implementing guidance.

* * * * *

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities on the preclusion list, defined in § 422.2.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under § 422.510(a), CMS may impose the intermediate sanctions at § 422.750(a)(1) and (3).

* * * * *

Subpart V—Medicare Advantage Communication Requirements

■ 43. The subpart heading for Subpart V is revised to read as set forth above.

■ 44. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

For the purposes of this section—

Communications means activities and use of materials to provide information to current and prospective enrollees.

Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication material.

Marketing means the use of materials or activities that meet the following:

(1) By the MA organization or downstream entities.

(2) Intended to draw a beneficiary's attention to a MA plan or plans.

(3) Influence a beneficiary's decision-making process when making a MA plan selection or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

Marketing materials include, but are not limited to the following:

(1) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

Marketing materials exclude materials that—

(1) Do not include information about the plan's benefit structure or cost sharing;

(2) Do not include information about measuring or ranking standards (for example, star ratings);

(3) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or

(4) Unless otherwise specified by CMS because of their use or purpose, are required under § 422.111.

■ 45. Section 422.2262 is amended by revising paragraph (d) to read as follows:

§ 422.2262 Review and distribution of marketing materials.

* * * * *

(d) Enrollee communication materials. Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

■ 46. Section 422.2264 is revised to read as follows:

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262, CMS determines that the materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written description of any supplemental benefits and services.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

■ 47. Section 422.2268 is amended by:

■ a. Removing the introductory text; and

■ b. Revising paragraphs (a) and (b).

The revisions read as follows:

§ 422.2268 Standards for MA organization communications and marketing.

(a) In conducting communication activities, MA organizations may not do any of the following:

(1) Provide information that is inaccurate or misleading.

(2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(3) Claim the MA organization is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may explain that the organization is approved for participation in Medicare.

(4) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition must not apply to MA plan names in effect on July 31, 2000.

(5) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).

(6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

(7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(4) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(5) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(6) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(7) Conduct sales presentations or distribute and accept MA plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(8) Conduct sales presentations or distribute and accept plan applications at educational events.

(9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.

(10) Knowingly target or send marketing materials to any MA enrollee during the Open Enrollment Period.

(11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(12) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(15) Provide meals to potential enrollees, which is prohibited, regardless of value.

* * * * *

§ 422.2272 [Amended]

■ 48. Section § 422.2272 is amended by removing paragraph (e).

§ 422.2274 [Amended]

■ 49. Section 422.2274 is amended by—

■ a. Redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv).

■ b. Redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii).

■ c. Removing paragraph (b)(2); and

■ d. Redesignating paragraph (b)(3) as paragraph (b)(2).

§ 422.2410 [Amended]

■ 50. Section 422.2410 is amended in paragraph (a) by removing the phrase

''an MLR'' and adding in its place the phrase ''the information required under § 422.2460''.

§ 422.2420 [Amended]

■ 51. Section 422.2420 is amended—
■ a. By removing and reserving paragraph (b)(2)(ix); and
■ b. In paragraph (d)(2)(i), removing the phrase ''in § 422.2420(b) or (c)'' and adding in its place the phrase ''in paragraph (b) or (c) of this section''.
■ 52. Section 422.2430 is amended by—
■ a. Redesignating paragraph (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;
■ b. Adding a paragraph (a) subject heading and revising newly redesignated paragraph (a)(1);
■ c. Adding paragraph (a)(4); and
■ d. Removing and reserving paragraph (b)(8).

The revision and addition read as follows:

§ 422.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by an MA organization to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4).

* * * * *

(4)(i) For an MA contract that includes MA–PD plans (described in § 422.2420(a)(2)), Medication Therapy Management Programs meeting the requirements of § 423.153(d) of this chapter.

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

* * * * *

■ 53. Section 422.2460 is revised to read as follows:

§ 422.2460 Reporting requirements.

(a) For each contract year, from 2014 through 2017, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the MA organization to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 422.2410.

(b) For contract year 2018 and for each subsequent contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 422.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

§ 422.2480 [Amended]

■ 54. Section 422.2480 is amended—
■ a. In the introductory text by removing the phrase ''reviews of reports submitted'' and adding in its place ''review of data submitted''.
■ b. In paragraph (d) introductory text by removing the phrase ''Reports submitted '' and adding in its place the phrase ''Data submitted''.

§ 422.2490 [Amended]

■ 55. Section 422.2490 is amended in paragraph (a) by removing the phrase ''information contained in reports submitted'' and adding in its place the phrase ''information submitted''.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 56. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

■ 57. Amend § 423.4 by revising the definition of ''Generic drug'' to read as follows:

§ 423.4 Definitions.

* * * * *

Generic drug means—

(1) A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved; and

(2) For purposes of cost sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D) of the Act only, a biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved.

* * * * *

■ 58. Amend § 423.32 by revising paragraph (b) introductory text and redesignating paragraphs (b)(i) and (ii) as (b)(1) and (2).

The revision reads as follows:

§ 423.32 Enrollment process.

* * * * *

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.2262.

* * * * *

■ 59. Section 423.38 is amended by—
■ a. Revising paragraph paragraphs (c) introductory text, (c)(4), and (c)(8)(i)(C);
■ b. Adding paragraph (c)(9);
■ c. Revising paragraph (d); and
■ d. Adding paragraph (e).

The revisions and additions read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA–PD plan (as provided at § 422.62(b) of this chapter), as applicable, under any of the following circumstances:

* * * * *

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who has not been identified as a ''potential at-risk beneficiary'' or ''at-risk beneficiary'' as defined in § 423.100 and—

(i) Making an allowable onetime-per-calendar-year election; or

(ii) Making an election after notification of a CMS or State-initiated enrollment action or within 2 months of that enrollment action's effective date.

* * * * *

(8) * * *

(i) * * *

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials as outlined in subpart V.

* * * * *

(9) The individual is making an election within 2 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment*

period. Through 2018, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(5), may also elect a PDP during this time.

(e) *Enrollment period to coordinate with MA open enrollment period.* For 2019 and subsequent years, an individual who makes an election as described in § 422.62(a)(3), may make an election to enroll in or disenroll from Part D coverage. An individual who elects Original Medicare during the MA open enrollment period may elect to enroll in a PDP during this time.

■ 60. Section 423.40 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 423.40 Effective dates.

* * * * *

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Through 2018, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(5) will be effective the first day of the month following the month in which the enrollment in the PDP is made.

(e) *PDP enrollment period to coordinate with the MA annual disenrollment period.* For 2019 and subsequent years, an enrollment made by an individual who elects Original Medicare during the MA open enrollment period as described in § 422.62(a)(3), will be effective the first day of the month following the month in which the election is made.

■ 61. Section § 423.100 is amended—

■ a. By revising the definition of ''Affected enrollee'';

■ b. By adding in alphabetical order definitions for ''At risk beneficiary'', ''Clinical guidelines'', ''Exempted beneficiary'', ''Frequently abused drug'', and ''Mail-Order pharmacy'';

■ c. By removing the definition of ''Other authorized prescriber'';

■ d. By adding in alphabetical order definitions for ''Potential at-risk beneficiary'', ''Preclusion List'', and ''Program size''; and

■ e. By revising the definition of ''Retail pharmacy''.

The revisions and additions read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing and such drug removal or cost-sharing change affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

At-risk beneficiary means a Part D eligible individual—

(1) Who is—

(i) Identified using clinical guidelines (as defined in § 423.100);

(ii) Not an exempted beneficiary; and

(iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor's drug management program in accordance with the requirements of § 423.153(f); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.

* * * * *

Clinical guidelines, for the purposes of a drug management program under § 423.153(f), are criteria—

(1) To identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs; and

(2) That are developed in accordance with § 423.153(f)(16) and published in guidance annually.

* * * * *

Exempted beneficiary means with respect to a drug management program, an enrollee who—

(1) Has elected to receive hospice care;

(2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(3) Has a cancer diagnosis.

Frequently abused drug means a controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors:

(1) The drug's schedule designation by the Drug Enforcement Administration.

(2) Government or professional guidelines that address that a drug is frequently abused or misused.

(3) An analysis of Medicare or other drug utilization or scientific data.

* * * * *

Mail-order pharmacy means a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual—

(1) Who is identified using clinical guidelines (as defined in § 423.100); or

(2) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.

Preclusion list means a CMS compiled list of prescribers who—

(1) Meet all of the following requirements:

(i) The prescriber is currently revoked from the Medicare program under § 424.535.

(ii) The prescriber is currently under a reenrollment bar under § 424.535(c).

(iii) 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:

(A) The seriousness of the conduct underlying the prescriber's revocation;

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and

(C) Any other evidence that CMS deems relevant to its determination; or.

(2) Meet both of the following requirements:

(i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.

(ii) 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 all of the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program.

(C) Any other evidence that CMS deems relevant to its determination.

* * * * *

Program size means the estimated population of potential at-risk beneficiaries in drug management

programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

* * * * *

Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.

* * * * *

■ 62. Section 423.120 is amended by—

■ a. Redesignating paragraph (b)(3)(i) introductory text and paragraphs (b)(3)(i)(A) through (D) as paragraphs (b)(3)(i)(A) introductory text and (b)(3)(i)(A)(*1*) through (*4*);

■ b. Adding a new paragraph (b)(3)(i)(B);

■ c. Revising paragraph (b)(3)(iii);

■ d. In paragraph (b)(5)(i) introductory text, by removing the figure ''60'' and adding in its place the figure ''30'' and by adding the phrase ''(for purposes of this paragraph (b)(5) these entities are referred to as ''CMS and other specified entities'') after the word ''pharmacists'';

■ e. In paragraph (b)(5)(i)(A), by removing the phrase ''60 days'' and adding in its place the phrase ''2 months'';

■ f. In paragraph (b)(5)(i)(B), by removing the figure ''60'' and adding in its place the figure ''30'';

■ g. In paragraph (b)(5)(iii), by removing the phrase '', CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists'' and adding in its place the phrase ''and CMS and other specified entities'';

■ h. Adding paragraph (b)(5)(iv);

■ i. In paragraph (b)(6), by removing the phrase ''under paragraphs (b)(5)(iii) of this section'' and adding in its place the phrase ''under paragraphs (b)(5)(iii) and (iv) of this section''; and

■ j. Revising paragraphs (c)(5) and (6).

The additions and revisions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(3) * * *

(B) Not apply in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as permitted under paragraphs (b)(5)(iv) and (b)(6) of this section.

* * * * *

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication.

* * * * *

(5) * * *

(iv) A Part D sponsor may immediately remove a brand name drug (as defined in § 423.4) from its Part D formulary or change the brand name drug's preferred or tiered cost-sharing without meeting the deadlines and refill requirements of paragraph (b)(5)(i) of this section provided that the Part D sponsor does all of the following:

(A) At the same time that it removes such brand name drug or changes its preferred or tiered cost-sharing, it adds a therapeutically equivalent (as defined in § 423.100) generic drug (as defined in § 423.4) to its formulary with the same or lower cost-sharing and the same or less restrictive utilization management criteria.

(B) The Part D sponsor previously could not have included such therapeutically equivalent generic drug on its formulary when it requested CMS formulary approval consistent with § 423.120(b)(2) because such generic drug was not yet available on the market.

(C) Before making any permitted generic substitutions, the Part D sponsor provides general notice to all current and prospective enrollees in its formulary and other applicable beneficiary communication materials advising them that—

(*1*) Such changes may be made at any time when a new generic is added in place of a brand name drug, and there may be no advance direct notice to the affected enrollees;

(*2*) If such a substitution should occur, affected enrollees will receive direct notice including information on the specific drugs involved and steps they may take to request coverage determinations and exceptions under §§ 423.566 and 423.578; and

(D) Before making any permitted generic substitutions, the Part D sponsor provides advance general notice to CMS and other specified entities.

(E) The Part D sponsor provides notice of any such formulary changes to affected enrollees and CMS and other specified entities consistent with the requirements of paragraphs (b)(5)(i) (as applicable) and (ii) of this section. This would include direct notice to the affected enrollees.

* * * * *

(c) * * *

(5)(i) A Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.

(ii) The sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(*1*) Confirm that the NPI is active and valid; or

(*2*) Correct the NPI.

(B) If the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

(iii) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraph (ii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(iv) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(6)(i) 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.

(ii) 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.

(iii) 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.

(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.

(B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraph (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following:

(*1*) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

(*i*) A provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary in accordance with prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed in accordance with a prescription written by the individual on the preclusion list.

(*ii*) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.

(*2*) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section.

(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.

(B) A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with 42 CFR part 498.

(vi) 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. In making a determination as to whether such circumstances exist, CMS takes into account—

(A) The degree to which beneficiary access to Part D drugs would be impaired; and

(B) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 63. Section 423.128 is amended by revising paragraph (d)(2)(iii) to reads as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(2) * * *

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(b)(5) regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

* * * * *

■ 64. Section 423.153 is amended by adding a sentence at the end of paragraph (a) and adding paragraph (f) to read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) * * *

A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section.

* * * * *

(f) *Drug management programs.* A drug management program must meet all the following requirements:

(1) *Written policies and procedures.* A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

(i) The appropriate credentials of the personnel conducting case management required under paragraph (f)(2) of this section.

(ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section.

(iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in § 423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plan.

(2) *Case management/clinical contact/prescriber verification*—(i) *General rule.* The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following:

(A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at risk beneficiary.

(B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary.

(C) In cases where the prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.

(ii) *Exception for identification by prior plan.* If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is clinically adequate and up to date.

(3) *Limitation on access to coverage for frequently abused drugs.* Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following:

(i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.

(ii) In accordance with paragraphs (f)(10) and (11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are—

(A) Prescribed for the beneficiary by one or more prescribers;

(B) Dispensed to the beneficiary by one or more network pharmacies; or

(C) Specified in both paragraphs (f)(3)(ii)(A) and (C) of this section.

(iii)(A) If the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal.

(B) If the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) or prescriber(s) or both, as applicable—

(*1*) In accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal; and

(*2*) Except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(4) *Requirements for limiting access to coverage for frequently abused drugs.* (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following:

(A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.

(B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate.

(C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.

(ii) If the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section.

(iii) The sponsor has met the case management requirement in paragraph (f)(2)(i) of this section if—

(A) The beneficiary meets paragraph (2) of the definition of a potential at-risk beneficiary or an at-risk beneficiary; and

(B) The sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate.

(iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under paragraph (f)(3)(ii)(A) of this section unless—

(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and

(B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.

(5) *Initial notice to a beneficiary.* (i) A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.

(ii) The notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary.

(*2*) A description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits).

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at § 423.580 *et seq.*

(*4*) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under paragraph (f)(3)(ii) of this section.

(*5*) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including the following:

(*i*) An explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.

(*ii*) The timeframe for the sponsor's decision

(*iii*) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(*6*) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(*4*) of this section.

(*7*) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program.

(*8*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i) of this section.

(6) *Second notice.* (i) Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary.

(ii) The second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary.

(*2*) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including—

(*i*) The limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and

(*ii*) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(*3*) The prescriber(s) or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor.

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580 *et seq.,* including—

(*i*) A description of both the standard and expedited redetermination processes; and

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*5*) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs.

(*6*) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(*5*) of this section.

(*7*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(6)(i) of this section.

(7) *Alternate second notice.* (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary.

(ii) The alternate second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(*1*) The sponsor has determined that the beneficiary is not an at-risk beneficiary.

(*2*) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs.

(*3*) If applicable, the SEP limitation no longer applies.

(*4*) Clear instructions that explain how the beneficiary may contact the sponsor.

(*5*) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(ii) The Part D sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required in accordance with paragraph (f)(7)(i) of this section.

(8) *Timing of notices.* (i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section.

(ii) Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may immediately provide a second notice described in paragraph (f)(6) of this section to a beneficiary for whom the gaining sponsor received a notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan, and such identification had not been terminated in accordance with paragraph (f)(14) of this section, if the sponsor is implementing either of the following:

(A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i) of this section.

(B) A limitation on access to coverage as described in paragraph (f)(3(ii) of this section, if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under paragraph (f)(9) of this section.

(9) *Beneficiary preferences.* Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following:

(i) Review such preferences.

(ii) If the beneficiary is—

(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s).

(B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s).

(iii) The sponsor must inform the beneficiary of the selection in—

(A) The second notice; or

(B) If the second notice is not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission.

(10) *Exception to beneficiary preferences.* (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary.

(ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with—

(A) At least 30 days advance written notice of the change; and

(B) A rationale for the change.

(11) *Reasonable access.* In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following:

(i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account—

(*1*) Geographic location;

(*2*) Beneficiary preference;

(*3*) The beneficiary's predominant usage of a prescriber or pharmacy or both;

(*4*) The impact on cost-sharing; and

(*5*) Reasonable travel time.

(ii) Reasonable access to frequently abused drugs in the case of—

(A) Individuals with multiple residences;

(B) Natural disasters and similar situations; and

(C) The provision of emergency services.

(12) *Selection of prescribers and pharmacies.* (i) A Part D plan sponsor must select, as applicable—

(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and

(B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.

(ii)(A) For purposes of this paragraph (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy must collectively be treated as one pharmacy.

(B) For purposes of this paragraph (f)(12) of this section, in the case of a group practice, all prescribers of the group practice must be treated as one prescriber.

(13) *Confirmation of selections(s).* (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs.

(ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection.

(14) *Termination of identification as an at-risk beneficiary.* The identification of an at-risk beneficiary as such must terminate as of the earlier of the following:

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary.

(ii) The end of a 12-calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.

(15) *Data disclosure.* (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled.

(ii) A Part D sponsor that operates a drug management program must disclose any data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner specified by CMS. The data and information disclosures must do all of the following:

(A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.

(B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries;

(C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

(D) Transfer case management information upon request of a gaining sponsor as soon as possible but not later than 2 weeks from the gaining sponsor's request when—

(*1*) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and

(*2*) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(16) *Clinical guidelines.* Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that—

(i) Are developed with stakeholder consultation;

(ii) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of this factors;

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

■ 65. Section 423.160 is amended by
■ a. Revising paragraph (b)(1)(iv);
■ b. Adding paragraph (b)(1)(v);
■ c. Revising paragraph (b)(2)(iii);
■ d. Adding paragraph (b)(2)(iv);
■ e. Revising paragraph (b)(4); and
■ f. Adding paragraph (c)(1)(vii).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(1) * * *

(iv) From March 1, 2015 until January 1, 2019, the standards specified in paragraphs (b)(2)(iii), (b)(3), (b)(4)(i), (b)(5)(iii), and (b)(6).

(v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.

(2) * * *

(iii) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 10, Release 6 (Version 10.6), November 12, 2008 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill/Resupply prescription request transaction.

(H) Refill/Resupply prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(M) Fill status notification.

(iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill/Resupply prescription request transaction.

(H) Refill/Resupply prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(M) Fill status notification.

(N) Prescription drug administration message.

(O) New prescription requests.

(P) New prescription response denials.

(Q) Prescription transfer message.

(R) Prescription fill indicator change.

(S) Prescription recertification.

(T) REMS initiation request.

(U) REMS initiation response.

(V) REMS request.

(W) REMS response.

* * * * *

(4) *Medication history.* Medication history to provide for the

communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers and dispensers:

(i) Until January 1, 2017, Either the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporate by reference in paragraph (c)(1)(v) of this section, or the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(vi) of this section.

(ii) On or after January 1, 2019, the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section).

* * * * *

(c) * * *

(1) * * *

(vii) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017.

* * * * *

■ 66. Sections 423.180, 423.182, 423.184 and 423.186 are added Subpart D to read as follows:

Subpart D—Cost Control and Quality Improvement Requirements

* * * * *

Sec.

§ 423.180 Basis and scope of the Part D Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part D.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by Part D plans, where appropriate and possible to use data of the type described in § 423.182(c).

(c) *Applicability.* The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year.

§ 423.182 Part D Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

Highest rating means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).

Low-income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 for definition of a low-income subsidy eligible individual).

Measurement period means the period for which data are collected for a measure or the performance period that a measures covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (''signal'') rather than random variation (''noise''); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

(b) *Contract ratings*—(1) *General.* CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and weighted in accordance with § 423.186(a). Domain ratings are the average of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted average of the individual measure ratings for Part C or Part D in accordance with § 423.186(c). Overall Star Ratings are calculated by using the weighted average of the individual measure ratings in accordance with § 423.186(d) with both the reward factor and CAI applied as applicable, as described in § 423.186(f).

(2) *Plan benefit packages.* All plan benefit packages (PBPs) offered under an MA contract or PDP plan sponsor have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization or PDP plan sponsor. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations.* (i) In the case of contract consolidations involving two or more contracts for health and/or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(ii) of this section.

(ii) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(B) For the second year after consolidation, CMS will use the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from CAHPS. CMS will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.

(c) *Data sources.* (1) Part D Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Beneficiary experiences, benefit administration information, clinical data, and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of Part D plans' compliance with contract requirements, data submitted by plans, and CMS administrative data.

(2) Part D sponsors are required to collect, analyze, and report data that permit measurement of indices of quality. Part D sponsors must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) to CMS on a timely basis as requested by CMS.

§ 423.184 Adding, updating, and removing measures.

(a) *General.* CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality.* CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures.* (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance and the Pharmacy Quality Alliance or endorsed by the National Quality Forum for adoption and use in the Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part D Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates.* For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional qualifiers that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions; or

(v) Add alternative data sources.

(2) *Substantive updates.* For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1), CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of the performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes, or

(ii) A measure shows low statistical reliability.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part D improvement measure will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measure if the measures meet all the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change, from the previous year.

(iii) The Part D improvement measure will include only Part D measure scores.

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iii) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure score will be converted to a measure-level Star Rating using hierarchical clustering algorithms.

(vi) The Part D improvement measure scores for MA–PDs and PDPs will be determined using cluster algorithms in accordance with § 423.186(a)(2)(ii). The Part D improvement measure thresholds for MA–PDs and PDPs would be reported separately.

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measures.

(i) CMS will reduce measures based on Part D reporting requirements data to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/sub-standards for data directly used to calculate the associated measure.

(ii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete.

(A) The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(B) The data submitted for the timeliness monitoring project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.

(C) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.

(D) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.

(E) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

(*1*) 20 percent, 1 star reduction.

(*2*) 40 percent, 2 star reduction.

(*3*) 60 percent, 3 star reduction.

(*4*) 80 percent, 4 star reduction.

(F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(G) The scaled reduction is applied after the calculation for the appeals measure-level star ratings. If the application of the scaled reduction results in a measure-level star rating less than one-star, the contract will be assigned one-star for the appeals measure.

(H) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

(I) The projected number of cases not forwarded to the IRE in a 3-month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.

(J) Contracts would be subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(*1*) The calculated error rate is 20 percent or more; and

(*2*) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

(K) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(*1*) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(*2*) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) and (ii) of this section, including a contract's failure to adhere to CAHPS reporting requirements.

§ 423.186 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points.* CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, we propose to determine MA–PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures.* (i) The method minimizes differences within star categories and maximize differences across star categories using the hierarchical clustering method.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures.* The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned two stars if it does not meet the 1 star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability.

(B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned three stars if it meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score.

(B)(*1*) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;

(*2*) The reliability is low; and

(*3*) The score is not statistically significantly lower than the national average CAHPS measure score.

(C)(*1*) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;

(*2*) The reliability is low; and

(*3*) The score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and

the measure does not have low reliability.

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile.

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part D summary ratings.* (1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have a summary rating calculated.

(ii) The Part D improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA–PD rating.* (1) The overall rating for a MA–PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f).

(2)(i) An MA–PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Patient experience and complaint measures receive a weight of 1.5.

(iv) Access measures receive a weight of 1.5.

(v) Process measures receive a weight of 1.

(2) *Rules for new measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part D summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.

(1) *Reward factor.* This rating-specific factor is added to both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA–PDs and Part D summary for MA–PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA–PDs and Part D summary for MA–PDs and PDPs). The weighted mean and weighted variance are compared separately for MA–PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean will be calculated both with and without the improvement measures. For an MA–PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical adjustment index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE)/or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA–PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) A MA–PD contract may be adjusted up to three times with the CAI: one for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) A PDP contract may be adjusted only once for the CAI: For the Part D summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) CMS will announce the measures identified for inclusion in the calculations of the CAI in accordance with this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects model that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:

(A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.

(B) The LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

(C) The Part D measures for MA–PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.

(iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary level measure scores that adjust for the average within contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part D summary for MA–PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled (using the enrollment data that parallels the previous Star Ratings year's data) would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (Part D for MA–PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Rating's year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries

with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for each highest rating for each contract-type (overall rating for MA–PD contracts and Part D summary rating for PDPs), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest rating, CMS applies the following rules:

(i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).

(ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part D summary rating for MA–PDs will include the Part D improvement measure.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag ''Not enough data available.'' If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag ''Plan too new to be measured''.

(i) *Medicare Plan Finder performance icons.* Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph:

(1) *High-performing icon.* The high performing icon is assigned to a Part D plan sponsor for achieving a 5-star Part D summary rating and an MA–PD contract for a 5-star overall rating.

(2) *Low-performing icon.* (i) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(ii) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(3) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which Part D plan sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

■ 67. Section 423.265 is amended by revising paragraph (b)(2) to read as follows.

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered ''substantially different,'' each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

* * * * *

§ 423.503 [Amended]

■ 68. Section 423.503 is amended in paragraphs (b)(1) and (2) by removing the phrase ''14 months'' and adding in its place ''12 months'' each time it appears.

■ 69. Section 423.504 is amended by revising paragraphs (b)(4)(ii) and (b)(4)(vi)(C) to read as follows.

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and communication activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

* * * * *

(vi) * * *

(C)(*1*) Each Part D plan sponsor must establish and implement effective training and education for its compliance officer and organization employees, the Part D sponsor's chief executive and other senior administrators, managers and governing body members.

(*2*) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, and new appointment to a chief executive, manager, or governing body member.

* * * * *

■ 70. Section 423.505 is amended—

■ a. By revising paragraph (b)(18);

■ b. In paragraph (b)(25), by removing the word ''marketing'' and adding in its place the word ''communication''; and

■ c. By revising paragraph (b)(26).

The revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:

(i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.

(ii) Providing a copy of a standard contract to a requesting pharmacy within 2 business days after receiving such a request from the pharmacy.

* * * * *

(26) Maintain a Part D summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in § 423.186.

* * * * *

§ 423.507 [Amended]

■ 71. Section 423.507 is amended by removing and reserving paragraph (b).

■ 72. Section 423.508 is amended by revising paragraph (a) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent. If the PDP sponsor submits a request to end the term of its contract after the deadline provided in § 423.507(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (b) through (f) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare Part D program.

* * * * *

■ 73. Section 423.509 is amended by revising paragraph (a)(4)(v)(A) and adding paragraphs (a)(4)(xiii) and (xiv) and (b)(2)(v) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(4) * * *

(v) * * *

(A) Requirements in subpart V of this part.

* * * * *

(xiii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(xiv) Following the issuance of a notice to the sponsor no later than August 1, CMS must terminate, effective December 31 of the same year, an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(b) * * *

(2) * * *

(v) In the event that CMS issues a termination notice to a Part D plan sponsor on or before August 1 with an effective date of the following December 31, the Part D plan sponsor must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

* * * * *

■ 74. Section 423.558 is amended by adding paragraph (a)(4) to read as follows:

§ 423.558 Scope.

(a) * * *

(4) Review of at-risk determinations made under a drug management program in accordance with § 423.153(f).

* * * * *

■ 75. Section 423.560 is amended by revising the definitions of ''Appeal'', ''Grievance'', ''Reconsideration'', and ''Redetermination'' and adding in alphabetical order a definition for ''Specialty tier'' to read as follows:

§ 423.560 Definitions.

* * * * *

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with § 423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews.

* * * * *

Grievance means any complaint or dispute, other than one that involves a coverage determination or at-risk determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

* * * * *

Reconsideration means a review of an adverse coverage determination or at-risk determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination or at-risk determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

Specialty tier means a formulary cost-sharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary.

■ 76. Section 423.562 is amended by revising paragraph (a)(1)(ii), adding paragraph (a)(1)(v), and revising paragraph (b)(4) to read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(ii) Use a single, uniform exceptions and appeals process which includes procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128(b)(7) and (d)(1)(iv).

* * * * *

(v) If the Part D plan sponsor has established a drug management program under § 423.153(f), appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations.

* * * * *

(b) * * *

(4) If dissatisfied with any part of a coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f), all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination or at-risk determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of the redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination or at-risk determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination or at-risk determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.1970.

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination or at-risk determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in § 423.1974.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination or at-risk determination, in whole or in part, the right to judicial review of the decision if the amount in

controversy meets the requirements in § 423.1976.

* * * * *

■ 77. Section 423.564 is amended by revising paragraph (b) to read as follows:

§ 423.564 Grievance procedures.

* * * * *

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b) and at-risk determinations made under a drug management program in accordance with § 423.153(f). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

* * * * *

■ 78. Section 423.578 is amended by—
■ a. Revising paragraphs (a) introductory text, (a)(1) and (2), (a)(4) introductory text, and (a)(5) and (6);
■ b. Removing paragraph (a)(7); and
■ c. Revising paragraph (c)(3).

The revisions read as follows:

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.

(1) The tiering exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) Part D plan sponsors must establish criteria that provide for a tiering exception, consistent with paragraphs (a)(3) through (6) of this section.

* * * * *

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition—

* * * * *

(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(6) Limitations on tiering exceptions: A Part D plan sponsor is permitted to design its tiering exceptions procedures such that an exception is not approvable in the following circumstances:

(i) To cover a brand name drug, as defined in § 423.4, at a preferred cost-sharing level that applies only to alternative drugs that are—

(A) Generic drugs, for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

(B) Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act.

(ii) To cover a biological product licensed under section 351 of the Public Health Service Act at a preferred cost-sharing level that does not contain any alternative drug(s) that are biological products.

(iii) If a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.

* * * * *

(c) * * *

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under paragraph (a) of this section is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies to preferred alternative drugs. If the plan's formulary contains alternative drugs on multiple tiers, cost-sharing must be assigned at the lowest applicable tier, under the requirements in paragraph (a) of this section.

* * * * *

■ 79. Section 423.580 is revised to read as follows:

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.1978) or an at-risk determination under a drug management program in accordance with § 423.153(f) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

■ 80. Section 423.582 is amended by revising paragraphs (a) and (b) to read as follows:

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination or the at-risk determination under a drug management program in accordance with § 423.153(f). The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination or the at-risk determination under a drug management program in accordance with § 423.153(f).

* * * * *

■ 81. Section 423.584 is amended by revising paragraph (a) to read as follows:

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in

§ 423.566(b) or an at-risk determination made under a drug management program in accordance with § 423.153(f). (This does not include requests for payment of drugs already furnished.)

* * * * *

■ 82. Section 423.590 is amended by revising paragraphs (a), (b)(1) and (2), the paragraph (f) subject heading, and paragraphs (f)(1) and (g)(3)(i) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits or review of an at-risk determination.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1) or (3) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination or at-risk determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) * * *

(1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 14 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 14 calendar days from the date it receives the request for redetermination.

* * * * *

(f) *Who must conduct the review of an adverse coverage determination or at-risk determination.* (1) A person or persons who were not involved in making the coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f) must conduct the redetermination.

* * * * *

(g) * * *

(3) * * *

(i) For adverse drug coverage redeterminations, or redeterminations related to a drug management program in accordance with § 423.153(f), describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

* * * * *

■ 83. Section 423.602 is amended by revising paragraph (b)(2) to read as follows:

§ 423.602 Notice of reconsideration determination by the independent review entity.

* * * * *

(b) * * *

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination or redetermination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.1970;

* * * * *

■ 84. Section 423.636 is amended by revising paragraph (a)(2) and adding paragraphs (a)(3) and (b)(3) to read as follows:.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) * * *

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(3) *Review of an at-risk determination.* If, on redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(b) * * *

(3) *Review of an at-risk determination.* If, on appeal of an at-risk determination made under a drug management program in accordance with § 423.153(f), the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

■ 85. Section 423.638 is revised to read as follows:

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) Reversals by the Part D plan sponsor—

(1) *Requests for benefits.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(2) *Review of an at-risk determination.* If, on an expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) Reversals other than by the Part D plan sponsor—

(1) *Requests for benefits.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Review of an at-risk determination.* If the expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f) by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan

sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.652 [Amended]

■ 86. Section 423.652 is amended paragraph (b)(1) by removing the phrase ''July 15'' and adding in its place ''September 1''.

■ 87. Section 423.750 is amended by revising paragraph (a)(3) to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) * * *

(3) Suspension of communication activities to Medicare beneficiaries by a Part D plan sponsor, as defined by CMS.

* * * * *

■ 88. Section 423.752 is amended by revising paragraphs (a)(9) and (b) to read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(9) Fails to comply with communication restrictions described in subpart V or applicable implementing guidance.

* * * * *

(b) Suspension of enrollment and communications. If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose the intermediate sanctions at § 423.750(a)(1) and (3).

* * * * *

■ 89. Section 423.756 is amended by revising paragraph (c)(3)(ii) introductory text to read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(c) * * *

(3) * * *

(ii) In instances where intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

* * * * *

■ 90. Section 423.1970 is amended by revising paragraph (b) to read as follows:

§ 423.1970 Right to an ALJ hearing.

* * * * *

(b) *Calculating the amount in controversy in specific circumstances.* (1) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(2) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), CMS uses the projected value of the drugs subject to the drug management program to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year.

* * * * *

§ 423.2018 [Amended]

■ 91. Section 423.2018 is amended—

■ a. In paragraph (a)(1), by removing the phrase ''appealed coverage determination was made'' and adding in its place the phrase ''appealed coverage determination or at-risk determination was made''; and

■ b. In paragraph (a)(2), by removing the phrase ''after the coverage determination to be considered'' and adding in its place the phrase ''after the coverage determination or at-risk determination to be considered''.

§ 423.2020 [Amended]

■ 92. Section 423.2020 is amended in paragraph (c)(1) by removing the phrase ''the coverage determination, and'' and adding in its place the phrase ''the coverage determination or at-risk determination, and''.

§ 423.2022 [Amended]

■ 93. Section 423.2022 is amended by—

■ a. Removing the first appearance of paragraph the (b) subject heading and paragraph (b)(1) introductory text; and.

■ b. In paragraph (b)(1)(i) by removing the phrase ''the coverage determination, redetermination,'' and adding in its place the phrase ''the coverage determination or at-risk determination, redetermination,''.

§ 423.2032 [Amended]

■ 94. Section 423.2032 is amended in paragraph (a) by removing the phrase ''the coverage determination, redetermination,'' and adding in its place the phrase ''the coverage determination or at-risk determination, redetermination,''.

§ 423.2036 [Amended]

■ 95. Section 423.2036 is amended in paragraph (e) by removing the phrase ''a coverage determination'' and adding in its place the phrase ''a coverage determination or at-risk determination''.

§ 423.2038 [Amended]

■ 96. Section 423.2038 is amended in paragraph (c) by removing the phrase ''may be made, and'' and adding in its place the phrase ''may be made, or an enrollee's at-risk determination should be reversed, and''.

§ 423.2046 [Amended]

■ 97. Section 423.2046 is amended in paragraph (a)(1)(iii) by removing the phrase ''the coverage determination.'' and adding in its place the phrase ''the coverage determination or at-risk determination.

§ 423.2056 [Amended]

■ 98. Section 423.2056 is amended—

■ a. In paragraph (a)(1) by removing the phrase ''appealed coverage determination'' and adding in its place the phrase ''appealed coverage determination or at-risk determination'', and

■ b. In paragraph (e) by removing the phrase ''the coverage determination to be considered in the appeal.'' and adding in its place ''the coverage determination or at-risk determination to be considered in the appeal.''

§ 423.2062 [Amended]

■ 99. Section 423.2062 is amended in paragraph (b) by removing the phrase ''coverage determination being considered and does not have precedential effect'' and adding in its place the phrase ''coverage determination or at-risk determination being considered and does not have precedential effect''.

§ 423.2122 [Amended]

■ 100. Section 423.2122 is amended—

■ a. In paragraph (a)(1) by removing the phrase ''the coverage determination.'' and adding in its place the phrase ''the coverage determination or at-risk determination'';

■ b. In paragraph (a)(3) by removing the phrase ''a coverage determination is made'' and adding in its place ''a coverage determination or at-risk determination is made'' and by removing the phrase ''after the coverage determination considered'' and adding in its place ''after the coverage determination or at-risk determination considered''.

§ 423.2126 [Amended]

■ 101. Section 423.2126 is amended in paragraph (b) by removing the phrase ''coverage determination to be considered in the appeal.'' and adding in its place the phrase ''coverage determination or at-risk determination to be considered in the appeal.''

Subpart V—Part D Communication Requirements

■ 102. The subpart V heading is amended to read as set forth above.

■ 103. Section 423.2260 is amended by—

■ a. Revising the section heading;

■ b. Adding in alphabetical order definitions for ''Communications'', ''Communications materials'', and ''Marketing''; and

■ c. Revising the definition of ''Marketing materials''.

The revisions and additions read as follows:

§ 423.2260 Definitions.

* * * * *

Communications means activities and use of materials to provide information to current and prospective enrollees.

Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication materials.

Marketing means the use of materials or activities that meet the following:

(1) By the Part D sponsor or downstream entities.

(2) Intended to draw a beneficiary's attention to a Part D plan or plans.

(3) Influence a beneficiary's decision making process when making a Part D plan selection or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

Marketing materials—

(1) Include, but are not limited to following:

(i) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(2) Exclude the following materials:

(i) Information about the plan's benefit structure or cost sharing;

(ii) Information about measuring or ranking standards (for example, star ratings);

(iii) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or

(3) Unless otherwise specified by CMS because of their use or purpose, are required under § 423.128.

■ 104. Section 422.2262 is amended by revising paragraph (d) to read as follows:

§ 422.2262 Review and distribution of marketing materials.

* * * * *

(d) *Enrollee communication materials.* Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

■ 105. Section 423.2264 is revised to read as follows:

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 423.2262 of this part, CMS determines that the materials—

(a) Provide to Medicare beneficiaries interested in enrolling, adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges in a format (and, where appropriate, print size) and using standard terminology that may be specified by CMS.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in written materials notice that the Part D sponsor is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

■ 106. Section 423.2268 is revised to read as follows:

§ 423.2268 Standards for Part D Sponsor communications and marketing.

(a) In conducting communication activities, Part D sponsors may not do any of the following:

(1) Provide information that is inaccurate or misleading.

(2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(3) Claim the Part D sponsor is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. It may explain that the organization is approved for participation in Medicare.

(4) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(5) Display the names and/or logos of co-branded network providers or pharmacies on the sponsor's member identification card, unless the names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).

(6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

(7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Market non-health care/non-prescription drug plan related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(4) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(5) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(6) Distribute marketing materials for which, before expiration of the 45-day period, the Part D sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the Part D sponsor, its marketing representatives, or CMS.

(7) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(8) Conduct sales presentations or distribute and accept plan applications at educational events.

(9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.

(10) Knowingly target or send marketing materials to any Part D enrollee, whose prior year enrollment was in an MA plan, during the Open Enrollment Period.

(11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(12) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(15) Provide meals to potential enrollees, which is prohibited, regardless of value.

§ 423.2272 [Amended]

■ 107. Section 423.2272 is amended by removing paragraph (e).

§ 423.2274 [Amended]

■ 108. Section 423.2274 is amended—

■ a. By redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv);

■ b. By redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii);

■ c. By removing paragraph (b)(2);

■ d. By redesignating paragraph (b)(3) as paragraph (b)(2); and

■ e. In newly redesignated paragraph (b)(2)(iii), by removing the phrase ''from an MA plan,'' and adding the phrase ''from a Part D sponsor,'' in its place.

§ 423.2410 [Amended]

■ 109. Section 423.2410 is amended in paragraph (a) by removing the phrase ''an MLR'' and adding in its place the phrase ''the information required under § 423.2460''.

§ 423.2420 [Amended]

■ 110. Section 423.2420 is amended by—

■ a. Removing and reserving paragraph (b)(2)(viii);

■ b. Revising paragraph (d)(2)(i); and

■ c. Removing the first paragraph designated as (d)(2)(ii).

The revision reads as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(d) * * *

(2)

(i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method.

* * * * *

■ 111. Section 423.2430 is amended by—

■ a. Redesignating paragraphs (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;

■ b. Revising newly redesignated paragraph (a)(1);

■ c. Adding paragraph (a)(4); and

■ d. Removing and reserving paragraph (b)(8).

The revisions and additions read as follows:

§ 423.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by a Part D sponsor to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

* * * * *

(4)(i) Medication Therapy Management Programs meeting the requirements of § 423.153(d).

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

* * * * *

■ 112. Section 423.2460 is revised to read as follows:

§ 423.2460 Reporting requirements.

(a) For each contract year, from 2014 through 2017, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract year 2018 and for each subsequent contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 423.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

§ 423.2480 [Amended]

■ 113. Section 423.2480 is amended—

■ a. In the introductory text by removing the phrase ''reviews of reports submitted'' and adding in its place ''review of data submitted''; and

■ b. In paragraph (d) introductory text by removing the phrase ''Reports submitted under'' and adding in its place the phrase ''Data submitted under''.

§ 423.2490 [Amended]

■ 114. Section 423.2490 is amended in paragraph (a) by removing the phrase ''information contained in reports submitted'' and adding in its place the phrase ''information submitted''.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 115. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

■ 116. Section 460.40 is amended by revising paragraph (j) to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(j) Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

■ 117. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.50 Termination of PACE program agreement.

* * * * *

(b) * * *

(1) * * *

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

* * * * *

§ 460.68 [Amended]

■ 118. Section 460.68 is amended by removing paragraph (a)(4).

§ 460.70 [Amended]

■ 119. Section 460.70 is amended by removing paragraph (b)(1)(iv).

§ 460.71 [Amended]

■ 120. Section 460.71 is amended by removing paragraph (b)(7).

■ 121. Section 460.86 is revised to read as follows:

§ 460.86 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter.

(b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

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

■ 122. The authority for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–7j, and 1395hh).

■ 123. Section 498.3 is amended by adding paragraph (b)(20) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(20) An individual or entity is to be included on the preclusion list as defined in § 422.2 or § 423.100 of this chapter.

* * * * *

■ 124. Section 498.5 is amended by adding paragraph (n) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) *Appeal rights of individuals and entities on preclusion list.* (1) 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).

(2) If CMS or the individual or entity under paragraph (n)(1) of this section is dissatisfied with a reconsidered determination under paragraph (n)(1) of this section, or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

(3) If CMS or the individual or entity under paragraph (n)(2) of this section is dissatisfied with a hearing decision as described in paragraph (n)(2) of this section, CMS or the individual or entity may request Board review and the individual or entity has a right to seek judicial review of the Board's decision.

Dated: October 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–25068 Filed 11–16–17; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 82, No. 227

Tuesday, November 28, 2017

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

78.....50820
80.....50820
87.....50820
90.....50820
101.....50820

Proposed Rules:

1.....50598
25.....52864
51.....55970
52.....55970
54.....51180
96.....56193

48 CFR

Ch. 1.....51526
1.....51527, 51773
4.....51527, 51773
9.....51527, 51773
17.....51527, 51773
22.....51358, 51527, 51773
42.....51526, 51773
52.....51358, 51527, 51773
Ch. 9.....50491
1009.....53426
1052.....53426

Proposed Rules:

Ch. 12.....51178

49 CFR

40.....52229

Proposed Rules:

Ch. I.....51178
Ch. II.....51178
Ch. III.....51178
Ch. V.....51178
Ch. VI.....51178
Ch. VII.....51178
Ch. VIII.....51178
Ch. X.....51178
Ch. XI.....51178

50 CFR

Ch. I.....50532
20.....51538
32.....51940, 52009
36.....52009
300.....52849, 56177
Ch. IV.....50532
622.....50839, 51577, 51777, 52248, 55952, 56178
635.....55512, 55520
648.....51578, 51778, 52249, 52675, 52851, 53430, 55522, 56180
660.....51166, 55775
679.....51168, 52011, 55053, 55055, 55953
680.....52011

Proposed Rules:

Ch. I.....51382
17.....50606, 52262, 55550
91.....56201
224.....51186
226.....51186
300.....52700
622.....55074
648.....51492, 51594
660.....51381, 55551, 56204
697.....52871

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 21, 2017

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.