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

DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
7 CFR Part 1051

Milk in California; Federal Milk Marketing Order Promulgation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule establishes a Federal Milk Marketing Order (FMMO) regulating the handling of milk in California. This final rule issues a marketing order incorporating the entire state of California and adopts the same dairy product classification and pricing provisions used throughout the current FMMO system. The California FMMO provides for the recognition of producer quota as administered by the California Department of Food and Agriculture. More than the required number of producers for the California marketing area have approved the issuance of the order. This final rule also announces AMS’s intention to merge the information collection forms used to conduct the producer referendum with the reporting forms used in the other dairy marketing orders.

DATES:
Effective Date: This rule is effective October 17, 2018.
Applicability Date: All provisions of this rule apply to affected parties as of November 1, 2018.


SUPPLEMENTAL INFORMATION: This rule, in accordance with 7 CFR 900.14(c), is the Secretary’s final rule in this proceeding and issues a marketing order as defined in 7 CFR 900.2(j).

Accordingly, this final rule adopts amendments detailed in the proposed rule (83 FR 14110), with one minor technical correction to paragraph numbering in § 1051.73(c)(2). The proposed rule designated two consecutive paragraphs in that section as paragraph (c)(2)(vii). This final rule corrects the proposed rule by redesignating the second paragraph as paragraph (c)(2)(viii).

This rule is effective with publication of the Announcement of Advanced Prices and Pricing Factors on October 17, 2018 (see § 1051.53). Affected parties must comply with all provisions of this rule beginning November 1, 2018.

This administrative action is governed by the provisions of Sections 556 and 557 of Title 5 of the United States Code and is therefore excluded from the requirements of Executive Order 12866. This final rule is not considered an Executive Order 13771 regulatory action because it does not meet the definition of a “regulation” or “rule” under Executive Order 12866.

The amendments adopted in this final rule have been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect and will not preempt any state or local law, regulations, or policies, unless they present an irreconcilable conflict with this rule.

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 Agricultural Marketing Agreement Act of 1937 (AMAA), as amended (7 U.S.C. 601–674 and 7253), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the AMAA, any handler subject to a marketing order may request modification or exemption from such order by filing with the U.S. Department of Agriculture (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. A handler is afforded the opportunity for a hearing on the petition. After a hearing, USDA would rule on the petition. The AMAA provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review USDA’s ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) considered the economic impact of this action on small entities. Accordingly, AMS 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 so that small businesses will not be unduly or disproportionately burdened. Small dairy farm businesses have been defined by the Small Business Administration (SBA) (13 CFR 121.601) as those businesses having annual gross receipts of less than $750,000. The SBA’s definition of small agricultural service firms, which includes handlers that will be regulated under this marketing order, varies depending on the product manufactured. Small fluid milk and ice cream manufacturers are defined as having 1,000 or fewer employees. Small butter and dry or condensed dairy product manufacturers are defined as having 750 or fewer employees. Small cheese manufacturers are defined as having 1,250 or fewer employees.

For the purpose of determining which California dairy farms are “small businesses,” the $750,000 per year criterion was used to establish a production guideline that equates to approximately 315,000 pounds of milk per month. Although this guideline does not factor in additional monies that may be received by dairy farmers, it is a standard encompassing most small dairy farms. For the purpose of determining a handler’s size, if the plant is part of a larger company operating multiple plants that collectively exceed the employee limit for that type of manufacturing, the plant is considered a large business even if the local plant has fewer than the defined number of employees.

Interested persons were invited to present evidence at the hearing on the
probable regulatory and informational impact of the California FMMO on small businesses. Specific evidence on the number of large and small dairy farms in California (above and below the threshold of $750,000 in annual sales) was not presented at the hearing. However, data compiled by C DFA suggests that between 5 and 15 percent of California dairy farms would be considered small business entities. No comparable data for dairy product manufacturers was available.

Record evidence indicates that implementing the California FMMO would not impose a disproportionate burden on small businesses. Currently, the California dairy industry is regulated by a California State Order (CSO) that is administered and enforced by C DFA. While the CSO and FMMOs have differences, they both maintain similar classified pricing and marketwide pooling functions. Therefore, it is not expected that the regulatory change will have a significant impact on California small businesses.

The record evidence indicates that while the program is likely to impose some costs on the regulated parties, those costs would be outweighed by the benefits expected to accrue to the California dairy industry. In conjunction with the publication of the final decision (83 FR 14110), AMS released a Regulatory Economic Impact Analysis (REIA) to study the possible impacts of the California FMMO. The analysis reflects the provisions of this FMMO and may be viewed at www.ams.usda.gov/caorder.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this final rule also announces AMS’s intention to merge the OMB Report Forms under a California Federal Milk Marketing Order (from Milk Handlers and Milk Marketing Cooperatives, 0581–0298), and the forms used to conduct the producer referendum (Referendum Ballots, 0581–0300) with the reporting forms used in the rest of the dairy marketing orders (Report Forms Under the Federal Milk Marketing Order Program, 0581–0032). Any additional information collection and recordkeeping requirements that may be imposed under the order would be submitted to OMB for public comment and approval.

Prior Documents in This Proceeding

Notice of Hearing: Issued July 27, 2015; published August 6, 2015 (80 FR 47210); Notice to Reconvene Hearing: Issued September 25, 2015; published September 30, 2015 (80 FR 58636); Recommended Decision and Opportunity To File Written Exceptions: Issued February 6, 2017; published February 14, 2017 (82 FR 10634); Documents for Official Notice: Issued August 8, 2017; published August 14, 2017 (82 FR 37827); Information Collection—Producer Ballots: Issued September 27, 2017, published October 2, 2017 (82 FR 45795); Delay of Rulemaking: Issued February 1, 2018; published February 6, 2018 (83 FR 5215); Ratification of Record: Issued March 14, 2018; published March 19, 2018 (83 FR 11903); and Final Decision: Issued March 23, 2018; published April 2, 2018 (83 FR 14110).

Findings and Determinations

The findings and determinations hereinafter set forth are hereby ratified and confirmed, except where they may conflict with those set forth herein. (1) Findings upon the basis of the hearing record.

The promulgation of the marketing agreement and order is based on the record of a public hearing held September 22 through November 18, 2015 in Clovis, California. The hearing was held to receive evidence on four proposals submitted by dairy farmers, handlers, and other interested parties. Notice of this hearing was published in the Federal Register on August 6, 2015 (80 FR 47210), pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure (7 CFR part 900).

Upon the basis of the evidence introduced at the public hearing and its record, it is found that:

(a) The order as hereby promulgated, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the AMAA;

(b) The parity prices of milk, as determined pursuant to section 2 of the AMAA, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions that affect market supply and demand for milk in California. The minimum prices specified in the tentative marketing agreement and order, as hereby established, are prices that will reflect the aforesaid factors, ensure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(c) The tentative marketing agreement and order, as hereby established, will regulate the handling of milk in the same manner as, and applies only to, persons in the respective classes of industrial and commercial activity specified in, marketing agreements upon which a hearing has been held.

(2) Determinations.

It is hereby determined that:

(a) The refusal or failure of handlers (excluding cooperative associations specified in section 8c(9) of the AMAA) of more than 50 percent of the milk marketed within the specified marketing areas to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the AMAA;

(b) The issuance of this order establishing the California order is the only practical means pursuant to the declared policy of the AMAA of advancing the interests of producers as defined in the order as hereby promulgated; and

(c) The issuance of this order establishing the California order is favored by at least two-thirds of the producers who were engaged in the production of milk for sale in the respective marketing areas.

List of Subjects in 7 CFR Part 1051

Milk marketing orders.

Order Establishing the Order Regulating the Handling of Milk in the California Marketing Area

It is therefore ordered, that on and after the effective date hereof, the handling of milk in the California marketing area shall be in conformity to and in compliance with the terms and conditions of the order.

For the reasons stated in the preamble, the Agricultural Marketing Service adds 7 CFR part 1051 to read as follows:

PART 1051—MILK IN THE CALIFORNIA MILK MARKETING AREA

Subpart A—Order Regulating Handling

General Provisions

Sec. 1051.1 General provisions.

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1051.2 California marketing area.

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1051.4 Plant.

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1051.51 Class I differential and price.
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Subpart A—Order Regulating Handling
General Provisions
§ 1051.1 General provisions.
The terms, definitions, and provisions in part 1000 of this chapter apply to this part unless otherwise specified. In this part, all references to sections in part 1000 refer to part 1000 of this chapter.

Definitions
§ 1051.2 California marketing area.
The marketing area means all territory within the bounds of the following states and political subdivisions, including all piers, docks, and wharves connected therewith and all craft moored thereat, and all territory occupied by government (municipal, State, or Federal) reservations, installations, institutions, or other similar establishments if any part thereof is within any of the listed states or political subdivisions:
California
All of the State of California.

§ 1051.3 Route disposition.
See § 1000.3.

§ 1051.4 Plant.
See § 1000.4.

§ 1051.5 Distributing plant.
See § 1000.5.

§ 1051.6 Supply plant.
See § 1000.6.

§ 1051.7 Pool plant.
Pool plant means a plant, unit of plants, or system of plants as specified in paragraphs (a) through (f) of this section, but excluding a plant specified in paragraph (b) of this section. The pooling standards described in paragraphs (c) and (f) of this section are subject to modification pursuant to paragraph (g) of this section:
(a) A distributing plant, other than a plant qualified as a pool plant pursuant to paragraph (b) of this section or § 1051.7(b) of any other Federal milk order, from which during the month 25 percent or more of the total quantity of fluid milk products physically received at the plant (excluding concentrated milk received from another plant by agreement for other than Class I use) are disposed of as route disposition or are transferred in the form of packaged fluid milk products to other distributing plants. At least 25 percent of such route disposition and transfers must be to outlets in the marketing area.
(b) Any distributing plant located in the marketing area which during the month processed at least 25 percent of the total quantity of fluid milk products physically received at the plant (excluding concentrated milk received from another plant by agreement for other than Class I use) into ultra-pasteurized or aseptically-processed fluid milk products.
(c) A supply plant from which the quantity of bulk fluid milk products shipped to (and physically unloaded into) plants described in paragraph (c)(1) of this section is not less than 10 percent of the Grade A milk received from dairy farmers (except dairy farmers described in § 1051.12(b)) and handlers described in § 1000.9(c), including milk diverted pursuant to § 1051.13, subject to the following conditions:
(1) Qualifying shipments may be made to plants described in paragraphs (c)(1)(i) through (iv) of this section, except that whenever shipping requirements are increased pursuant to paragraph (g) of this section, only shipments to pool plants described in paragraphs (a), (b), and (d) of this section shall count as qualifying shipments for the purpose of meeting the increased shipments.
(i) Pool plants described in paragraphs (a), (b), and (d) of this section;
(ii) Plants of producer-handlers;
(iii) Partially regulated distributing plants, except that credit for such shipments shall be limited to the amount of such milk classified as Class I at the transferee plant; and
(iv) Distributing plants fully regulated under other Federal orders, except that credit for shipments to such plants shall be limited to the quantity shipped to (and physically unloaded into) pool distributing plants during the month and credits for shipments to other order plants shall not include any such shipments made on the basis of agreed-upon Class II, Class III, or Class IV utilization.
(2) Concentrated milk transferred from the supply plant to a distributing plant for an agreed-upon use other than Class I shall be excluded from the supply plant's shipments in computing the supply plant's shipping percentage.
(d) Two or more plants operated by the same handler and located in the marketing area may qualify for pool status as a unit by meeting the total and in-area route disposition requirements of a pool distributing plant specified in paragraph (a) of this section and subject to the following additional requirements:
(1) At least one of the plants in the unit must qualify as a pool plant pursuant to paragraph (a) of this section;

(2) Other plants in the unit must process Class I or Class II products, using 50 percent or more of the total Grade A fluid milk products received in bulk form at such plant or diverted therefrom by the plant operator in Class I or Class II products; and

(3) The operator of the unit has filed a written request with the market administrator prior to the first day of the month for which such status is desired to be effective. The unit shall continue from month-to-month thereafter without further notification. The handler shall notify the market administrator in writing prior to the first day of any month for which termination or any change of the unit is desired.

(e) A system of two or more supply plants operated by one or more handlers may qualify for pooling by meeting the shipping requirements of paragraph (c) of this section in the same manner as a single plant subject to the following additional requirements:

(1) Each plant in the system is located within the marketing area. Cooperative associations or other handlers may not use shipments pursuant to §1000.9(c) to qualify supply plants located outside the marketing area;

(2) The handler(s) establishing the system submits a written request to the market administrator on or before July 15 requesting that such plants qualify as a system for the period of August through July of the following year. Such request will contain a list of the plants participating in the system in the order, beginning with the last plant, in which the plants will be dropped from the system if the system fails to qualify. Each plant that qualifies as a pool plant within a system shall continue each month as a plant in the system through the following July unless the handler(s) establishing the system submits a written request to the market administrator that the plant be deleted from the system or that the system be discontinued. Any plant that has been so deleted from a system, or that has failed to qualify in any month, will not be part of any system for the remaining months through July. The handler(s) that have established a system may add a plant operated by such handler(s) to a system if such plant has been a pool plant each of the 6 prior months and would otherwise be eligible to be in a system, upon written request to the market administrator no later than the 15th day of the prior month. In the event of an ownership change or the business failure of a handler who is a participant in a system, the system may be reorganized to reflect such changes if a written request to file a new marketing agreement is submitted to the market administrator; and

(3) If a system fails to qualify under the requirements of this paragraph (e), the handler responsible for qualifying the system shall notify the market administrator which plant or plants will be deleted from the system so that the remaining plants may be pooled as a system. If the handler fails to do so, the market administrator shall exclude one or more plants, beginning at the bottom of the list of plants in the system and continuing up the list as necessary until the deliveries are sufficient to qualify the remaining plants in the system.

(f) Any distributing plant, located within the marketing area as described in §1051.2:

(1) From which there is route disposition and/or transfers of packaged fluid milk products in any non-federally regulated marketing area(s) located within one or more States that require handlers to pay minimum prices for raw milk, provided 25 percent or more of the total quantity of fluid milk products physically received at such plant (excluding concentrated milk received from another plant by agreement for other than Class I use) is disposed of as route disposition and/or is transferred in the form of packaged fluid milk products to other plants. At least 25 percent of such route disposition and/or transfers, in aggregate, are in any non-federally regulated marketing area(s) located within one or more States that require handlers to pay minimum prices for raw milk. Subject to the following exclusions:

(i) The plant is described in paragraph (a), (b), or (e) of this section;

(ii) The plant is subject to the pricing provisions of a State-operated milk pricing plan which provides for the payment of minimum class prices for raw milk;

(iii) The plant is described in §1000.8(a) or (e); or

(iv) A producer-handler described in §1051.10 with less than three million pounds during the month of route disposition and/or transfers of packaged fluid milk products to other plants.

(2) [Reserved]

(g) The applicable shipping percentages of paragraphs (c) and (e) of this section and §1051.13(d)(2) and (3) may be increased or decreased, for all or part of the marketing area, by the market administrator if the market administrator finds that such adjustment is necessary to encourage needed shipments or to prevent uneconomic shipments. Before making such a finding, the market administrator shall investigate the need for adjustment either on the market administrator’s own initiative or at the request of interested parties if the request is made in writing at least 15 days prior to the month for which the requested revision is desired effective. If the investigation shows that an adjustment of the shipping percentages might be appropriate, the market administrator shall issue a notice stating that an adjustment is being considered and invite data, views, and arguments. Any decision to revise an applicable shipping or diversion percentage must be issued in writing at least one day before the effective date.

(h) The term pool plant shall not apply to the following plants:

(1) A producer-handler as defined under any Federal order;

(2) An exempt plant as defined in §1000.8(e);

(3) A plant located within the marketing area and qualified pursuant to paragraph (a) of this section which meets the pooling requirements of another Federal order, and from which more than 50 percent of its route disposition has been in the other Federal order marketing area for 3 consecutive months;

(4) A plant located outside any Federal order marketing area and qualified pursuant to paragraph (a) of this section that meets the pooling requirements of another Federal order and has had greater route disposition in any non-Federal order marketing area for 3 consecutive months;

(5) A plant located in another Federal order marketing area and qualified pursuant to paragraph (a) of this section that meets the pooling requirements of such other Federal order and does not have a majority of its route disposition in this marketing area for 3 consecutive months, or if the plant is required to be regulated under such other Federal order without regard to its route disposition in any other Federal order marketing area;

(6) A plant qualified pursuant to paragraph (c) of this section which also meets the pooling requirements of another Federal order and from which greater qualifying shipments are made to plants regulated under the other Federal order than are made to plants regulated under the order in this part, or the plant has automatic pooling status under the other Federal order; and

(7) That portion of a regulated plant designated as a nonpool plant that is physically separate and operated separately from the pool portion of such plant. The designation of a portion of a regulated plant must
be requested in advance and in writing by the handler and must be approved by the market administrator. 

(i) Any plant that qualifies as a pool plant in each of the immediately preceding 3 months pursuant to paragraph (a) of this section or the shipping percentages in paragraph (c) of this section that is unable to meet such performance standards for the current month because of unavoidable circumstances determined by the market administrator to be beyond the control of the handler operating the plant, such as a natural disaster (ice storm, wind storm, flood, fire, earthquake, breakdown of equipment, or work stoppage, shall be considered to have met the minimum performance standards during the period of such unavoidable circumstances, but such relief shall not be granted for more than 2 consecutive months.

§ 1051.8 Nonpool plant.

See § 1000.8.

§ 1051.9 Handler.

See § 1000.9.

§ 1051.10 Producer-handler.

Producer-handler means a person who operates a dairy farm and a distributing plant from which there is route disposition in the marketing area, from which total route disposition and packaged sales of fluid milk products to other plants during the month does not exceed 3 million pounds, and who the market administrator has designated a producer-handler after determining that all of the requirements of this section have been met.

(a) Requirements for designation. Designation of any person as a producer-handler by the market administrator shall be contingent upon meeting the conditions set forth in paragraphs (a)(1) through (5) of this section. Following the cancellation of a previous producer-handler designation, a person seeking to have their producer-handler designation reinstated must demonstrate that these conditions have been met for the preceding month:

(1) The care and management of the dairy animals and the other resources and facilities designated in paragraph (b)(1) of this section necessary to produce all Class I milk handled (excluding receipts from handlers fully regulated under any Federal order) are under the complete and exclusive control, ownership, and management of the producer-handler and are operated as the producer-handler’s own enterprise at its sole risk.

(2) The plant operation designated in paragraph (b)(2) of this section at which the producer-handler processes and packages, and from which it distributes, its own milk production is under the complete and exclusive control, ownership, and management of the producer-handler and is operated as the producer-handler’s own enterprise and at its sole risk.

(3) The producer-handler neither receives at its designated milk production resources and facilities nor receives, handles, processes, or distributes at or through any of its designated milk handling, processing, or distributing resources and facilities other source milk products for reconstitution into fluid milk products or fluid milk products derived from any other source than:

(i) Its designated milk production resources and facilities (own farm production);

(ii) Pool handlers and plants regulated under any Federal order within the limitation specified in paragraph (c)(2) of this section; or

(iii) Nonfat milk solids which are used to fortify fluid milk products.

(4) The producer-handler is neither directly nor indirectly associated with the business control or management of, nor has a financial interest in, another handler’s operation; nor is any other handler so associated with the producer-handler’s operation.

(5) No milk produced by the herd(s) or on the farm(s) that supplies milk to the producer-handler’s plant operation is:

(i) Subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing program under the authority of a State government maintaining marketwide pooling of returns; or

(ii) Marketed in any part as Class I milk to the non-pool distributing plant of any other handler.

(b) Designation of resources and facilities. Designation of a person as a producer-handler shall include the determination of what shall constitute milk production, handling, processing, and distribution resources and facilities, all of which shall be considered an integrated operation, under the sole and exclusive ownership of the producer-handler.

(1) Milk production resources and facilities shall include all resources and facilities (milking herd(s), buildings housing such herd(s), and the land on which such buildings are located) used for the production of milk which are solely owned, operated, and which the producer-handler has designated as a source of milk supply for the producer-handler’s plant operation. However, for purposes of this paragraph (b)(1), any such milk production resources and facilities which do not constitute an actual or potential source of milk supply for the producer-handler’s operation shall not be considered a part of the producer-handler’s milk production resources and facilities.

(2) Milk handling, processing, and distribution resources and facilities shall include all resources and facilities (including store outlets) used for handling, processing, and distributing fluid milk products which are solely owned by, and directly operated or controlled by the producer-handler or in which the producer-handler in any way has an interest, including any contractual arrangement, or over which the producer-handler directly or indirectly exercises any degree of management control.

(3) All designations shall remain in effect until canceled pursuant to paragraph (c) of this section.

(c) Cancellation. The designation as a producer-handler shall be canceled upon determination by the market administrator that any of the requirements of paragraphs (a)(1) through (5) of this section are not continuing to be met, or under any of the conditions described in paragraph (c)(2), (3) of this section. Cancellation of a producer-handler’s status pursuant to this paragraph (c) shall be effective on the first day of the month following the month in which the requirements were not met or the conditions for cancellation occurred.

(1) Milk from the milk production resources and facilities of the producer-handler designated in paragraph (b)(1) of this section, is delivered in the name of another person as producer milk to another handler.

(2) The producer-handler handles fluid milk products derived from sources other than the milk production resources and facilities designated in paragraph (b)(1) of this section, except that it may receive at its plant, or acquire for route disposition, fluid milk products from fully regulated plants and handlers under any Federal order if such receipts do not exceed 150,000 pounds monthly. This limitation shall not apply if the producer-handler’s own-farm production is less than 150,000 pounds during the month.

(3) Milk from the milk production resources and facilities of the producer-handler is subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing plan operating under the authority of a State government.
(d) Public announcement. The market administrator shall publicly announce:
(1) The name, plant location(s), and farm location(s) of persons designated as producer-handlers;
(2) The names of those persons whose designations have been cancelled; and
(3) The effective dates of producer-handler status or loss of producer-handler status for each. Such announcements shall be controlling with respect to the accounting at plants of other handlers for fluid milk products received from any producer-handler.
(e) Burden of establishing and maintaining producer-handler status. The burden rests upon the handler who is designated as a producer-handler to establish through records required pursuant to §1000.27 that the requirements set forth in paragraph (a) of this section have been and are continuing to be met, and that the conditions set forth in paragraph (c) of this section for cancellation of the designation do not exist.
(f) Payments subject to Order 1131. Any producer-handler with Class I route dispositions and/or transfers of packaged fluid milk products in the marketing area described in §1131.2 of this chapter shall be subject to payments into the Order 1131 producer settlement fund on such dispositions pursuant to §1000.76(a) and payments into the Order 1131 administrative fund, provided such dispositions are less than three million pounds in the current month and such producer-handler had total Class I route dispositions and/or transfers of packaged fluid milk products from own farm production of three million pounds or more the previous month. If the producer-handler has Class I route dispositions and/or transfers of packaged fluid milk products into the marketing area described in §1131.2 of this chapter of three million pounds or more during the current month, such producer-handler shall be subject to the provisions described in §1131.7 of this chapter or §1000.76(a).
§1051.13 Producer milk.
Except as provided for in paragraphs (e) and (f) of this section, producer milk means the skim milk (or the skim equivalent of components of skim milk), including nonfat components, and butterfat in milk of a producer that is:
(a) Received by the operator of a pool plant directly from a producer or a handler described in §1000.9(c). All milk received pursuant to this paragraph (a) shall be priced at the location of the plant where it is first physically received;
(b) Received by a handler described in §1000.9(c) in excess of the quantity delivered to pool plants;
(c) Diverted by a pool plant operator to another pool plant. Milk so diverted shall be priced at the location of the plant to which diverted; or
(d) Diverted by the operator of a pool plant or a cooperative association, as described in §1000.9(c), to a nonpool plant located in the States of California, Arizona, Nevada, or Oregon, subject to the following conditions:
(1) Milk of a dairy farmer shall not be eligible for diversion unless at least one day’s production of such dairy farmer is physically received as producer milk at a pool plant during the first month the dairy farmer is a producer. If a dairy farmer loses producer status under the order in this part (except as a result of a temporary loss of Grade A approval or as a result of the handler of the dairy farmer’s milk failing to pool the milk under any order), the dairy farmer’s milk shall not be eligible for diversion unless at least one day’s production of the dairy farmer has been physically received as producer milk at a pool plant during the first month the dairy farmer is re-associated with the market;
(2) The quantity of milk diverted by a handler described in §1000.9(c) may not exceed 90 percent of the producer milk receipts reported by the handler pursuant to §1051.30(c) provided that not less than 10 percent of such receipts are delivered to plants described in §1051.7(c)(1) through (iii). These percentages are subject to any adjustments that may be made pursuant to §1051.7(g); and
(3) The quantity of milk diverted to nonpool plants by the operator of a pool plant described in §1051.7(a), (b) or (d) may not exceed 90 percent of the Grade A milk received from dairy farmers (except dairy farmers described in §1051.12(b)) including milk diverted pursuant to this section. These percentages are subject to any adjustments that may be made pursuant to §1051.7(g).
(4) Diverted milk shall be priced at the location of the plant to which diverted.
(e) Producer milk shall not include milk of a producer that is subject to inclusion and participation in a marketwide equalization pool under a milk classification and pricing program imposed under the authority of a State government maintaining marketwide pooling of returns.
(f) The quantity of milk reported by a handler pursuant to either §1051.30(a)(1) or (c)(1) for April through February may not exceed 125 percent, and for March may not exceed 135 percent, of the producer milk receipts pooled by the handler during the prior month. Milk diverted to nonpool plants reported in excess of this limit shall be removed from the pool. Milk in excess of this limit received at pool plants, other than pool distributing plants, shall be classified pursuant to §1000.44(a)(3)(v) and (b). The handler must designate, by producer pick-up, which milk is to be removed from the pool. If the handler fails to provide this information, the market administrator will make the determination. The following provisions apply:
(1) Milk shipped to and physically received at pool distributing plants in excess of the previous month’s pooled volume shall not be subject to the 125 or 135 percent limitation;
(2) Producer milk qualified pursuant to §1051.13 of any other Federal Order and continuously pooled in any...
Federal Order for the previous six months shall not be included in the computation of the 125 or 135 percent limitation;

(3) The market administrator may waive the 125 or 135 percent limitation:
   (i) For a new handler on the order, subject to the provisions of paragraph (f)(4) of this section; or
   (ii) For an existing handler with significantly changed milk supply conditions due to unusual circumstances; and

(4) A bloc of milk may be considered ineligible for pooling if the market administrator determines that handlers altered the reporting of such milk for the purpose of evading the provisions of this paragraph (f).

§ 1051.14 Other source milk.
See § 1000.14.

§ 1051.15 Fluid milk product.
See § 1000.15.

§ 1051.16 Fluid cream product.
See § 1000.16.

§ 1051.17 [Reserved]

§ 1051.18 Cooperative association.
See § 1000.18.

§ 1051.19 Commercial food processing establishment.
See § 1000.19.

Market Administrator, Continuing Obligations, and Handler Responsibilities

§ 1051.25 Market administrator.
See § 1000.25.

§ 1051.26 Continuity and separability of provisions.
See § 1000.26.

§ 1051.27 Handler responsibility for records and facilities.
See § 1000.27.

§ 1051.28 Termination of obligations.
See § 1000.28.

Handler Reports

§ 1051.30 Reports of receipts and utilization.
Each handler shall report monthly so that the market administrator’s office receives the report on or before the 9th day after the end of the month, in the detail and on the prescribed forms, as follows:

(a) Each handler that operates a pool plant shall report for each of its operations the following information:
   (1) Product pounds, pounds of butterfat, pounds of protein, and pounds of solids-not-fat other than protein
   (other solids) contained in or represented by:
   (i) Receipts of producer milk, including producer milk diverted by the reporting handler, from sources other than handlers described in § 1000.9(c); and
   (ii) Receipts of milk from handlers described in § 1000.9(c);
   (2) Product pounds and pounds of butterfat contained in:
   (i) Receipts of fluid milk products and bulk fluid cream products from other pool plants;
   (ii) Receipts of other source milk; and
   (iii) Inventories at the beginning and end of the month of fluid milk products and bulk fluid cream products;
   (3) The utilization or disposition of all milk and milk products required to be reported pursuant to this paragraph (a); and

(b) Such other information with respect to the receipts and utilization of skim milk, butterfat, milk protein, and other nonfat solids as the market administrator may prescribe.

(1) The product pounds, pounds of butterfat, pounds of protein, pounds of solids-not-fat other than protein (other solids) contained in receipts of milk

Subpart B—Milk Pricing

Classification of Milk

§ 1051.40 Classes of utilization.
See § 1000.40.

§ 1051.41 [Reserved]

§ 1051.42 Classification of transfers and diversions.
See § 1000.42.

§ 1051.43 General classification rules.
See § 1000.43.

§ 1051.44 Classification of producer milk.
See § 1000.44.

§ 1051.45 Market administrator’s reports and announcements concerning classification.
See § 1000.45.

Class Prices

§ 1051.50 Class prices, component prices, and advanced pricing factors.
See § 1000.50.

§ 1051.51 Class I differential and price.
The Class I differential shall be the differential established for Los Angeles County, California, which is reported in § 1000.52. The Class I price shall be the price computed pursuant to § 1000.50(a) for Los Angeles County, California.

§ 1051.52 Adjusted Class I differentials.
See § 1000.52.

§ 1051.53 Announcement of class prices, component prices, and advanced pricing factors.
See § 1000.53.

§ 1051.54 Equivalent price.
See § 1000.54.

Producer Price Differential

§ 1051.60 Handler’s value of milk.
For the purpose of computing a handler’s obligation for producer milk, the market administrator shall determine for each month the value of milk of each handler with respect to each of the handler’s pool plants and of
each handler described in §1000.9(c) with respect to milk that was not received at a pool plant by adding the amounts computed in paragraphs (a) through (h) of this section and subtracting from that total amount the values computed in paragraphs (i) and (j) of this section. Unless otherwise specified, the skim milk, butterfat, and the combined pounds of skim milk and butterfat referred to in this section shall result from the steps set forth in §1000.44(a), (b), and (c), respectively, and the nonfat components of producer milk in each class shall be based upon the proportion of such components in producer skim milk. Receipts of nonfluid milk products that are distributed as labeled reconstituted milk for which payments are made to the producer-settlement fund of another Federal order under §1000.76(a)(4) or (d) shall be excluded from pricing under this section.

(a) Class I value. (1) Multiply the hundredweight of skim milk in Class I by the Class I skim milk price; and
(2) Add an amount obtained by multiplying the pounds of butterfat in Class I by the Class I butterfat price; and
(b) Class II value. (1) Multiply the pounds of nonfat solids in Class II skim milk by the Class II nonfat solids price; and
(2) Add an amount obtained by multiplying the pounds of butterfat in Class II times the Class II butterfat price.
(c) Class III value. (1) Multiply the pounds of protein in Class III skim milk by the protein price; and
(2) Add an amount obtained by multiplying the pounds of other solids in Class III skim milk by the other solids price; and
(3) Add an amount obtained by multiplying the pounds of butterfat in Class III by the butterfat price.
(d) Class IV value. (1) Multiply the pounds of nonfat solids in Class IV skim milk by the nonfat solids price; and
(2) Add an amount obtained by multiplying the pounds of butterfat in Class IV by the butterfat price.
(1) Class III value.
(2) Class IV value.
(3) Add an amount equal to the minus location adjustments and subtract an amount equal to the plus location adjustments computed pursuant to §1051.75.
(b) Class III value.
(c) Class IV value.
(d) Add an amount equal to not less than one-half of the unobligated balance in the producer-settlement fund; and
(e) The statistical uniform price for unregulated milk.

On or before the 14th day after the end of each month, the market administrator shall announce publicly the following prices and information:
(a) The producer price differential; and
(b) The butterfat price; and
(c) The nonfat solids price; and
(d) The other solids price; and
(e) The butterfat price; and
(f) The average butterfat, nonfat solids, protein and other solids content of producer milk; and
(g) The statistical uniform price for milk containing 3.5 percent butterfat, computed by combining the Class III price and the producer price differential.

Subpart C—Payments for Milk

§1051.70 Producer-settlement fund.

See §1000.70.
§ 1051.71 Payments to the producer-settlement fund.

Each handler shall make payment to the producer-settlement fund in a manner that provides receipt of the funds by the market administrator no later than the 16th day after the end of the month (except as provided in § 1000.90). Payment shall be the amount, if any, by which the amount specified in paragraph (a) of this section exceeds the amount specified in paragraph (b) of this section:

(a) The total value of milk to the handler for the month as determined pursuant to § 1051.60.

(b) The sum of:

(1) An amount obtained by multiplying the total hundredweight of producer milk as determined pursuant to § 1000.44(c) by the producer price differential as adjusted pursuant to § 1051.75;

(2) An amount obtained by multiplying the total pounds of protein, other solids, and butterfat contained in producer milk by the protein, other solids, and butterfat prices respectively; and

(3) An amount obtained by multiplying the pounds of skim milk and butterfat for which a value was computed pursuant to § 1051.60(i) by the producer price differential as adjusted pursuant to § 1051.75 for the location of the plant from which received.

§ 1051.72 Payments from the producer-settlement fund.

No later than the 18th day after the end of each month (except as provided in § 1000.90), the market administrator shall pay to each handler the amount, if any, by which the amount computed pursuant to § 1051.71(b) exceeds the amount computed pursuant to § 1051.71(a). If, at such time, the balance in the producer-settlement fund is insufficient to make all payments pursuant to this section, the market administrator shall reduce uniformly such payments and shall complete the payments as soon as the funds are available.

§ 1051.73 Payments to producers and to cooperative associations.

(a) Handler payment responsibility. Each handler shall pay each producer for producer milk for which payment is not made to a cooperative association pursuant to paragraph (b) of this section, as follows:

(1) Partial payment. For each producer who has not discontinued shipments as of the date of this partial payment, payment shall be made so that it is received by each producer on or before the last day of the month (except as provided in § 1000.90) for milk received during the first 15 days of the month from the producer at not less than the lowest announced class price for the preceding month, less proper deductions authorized in writing by the producer.

(2) Final payment. For milk received during the month, payment shall be made so that it is received by each producer no later than the 19th day after the end of the month (except as provided in § 1000.90) in an amount not less than the sum of:

(i) The hundredweight of producer milk received times the producer price differential for the month as adjusted pursuant to § 1051.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month;

(v) Less any amount paid pursuant to paragraph (a)(1) of this section;

(vi) Less proper deductions authorized in writing by such producer, and

plus or minus adjustments for errors in previous payments to such producer subject to approval by the market administrator;

(vii) Less deductions for marketing services pursuant to § 1000.86; and

(viii) Less deductions authorized by CDFA for the California Quota Program pursuant to § 1051.11.

(b) Payments for milk received from cooperative association members. On or before the day prior to the dates specified in paragraphs (a)(1) and (2) of this section (except as provided in § 1000.90), each handler shall pay to a cooperative association for milk from producers who market their milk through the cooperative association and who have authorized the cooperative to collect such payments on their behalf an amount equal to the sum of the individual payments otherwise payable for such producer milk pursuant to paragraphs (a)(1) and (2) of this section.

(c) Payment for milk received from cooperative association pool plants or from cooperatives as handlers pursuant to § 1000.9(c). On or before the day prior to the dates specified in paragraphs (a)(1) and (2) of this section (except as provided in § 1000.90), each handler who receives fluid milk products at its plant from a cooperative association in its capacity as the operator of a pool plant or who receives milk from a cooperative association in its capacity as a handler pursuant to § 1000.9(c), including the milk of producers who are not members of such association and who the market administrator determines have authorized the cooperative association to collect payment for their milk, shall pay the cooperative for such milk as follows:

(1) For bulk fluid milk products and bulk fluid cream products received from a cooperative association in its capacity as the operator of a pool plant and for milk received from a cooperative association in its capacity as a handler pursuant to § 1000.9(c) during the first 15 days of the month, at not less than the lowest announced class prices per hundredweight for the preceding month;

(2) For the total quantity of bulk fluid milk products and bulk fluid cream products received from a cooperative association in its capacity as the operator of a pool plant, at not less than the total value of such products received from the association’s pool plants, as determined by multiplying the respective quantities assigned to each class under § 1000.44, as follows:

(i) The hundredweight of Class I skim milk times the Class I skim milk price for the month plus the pounds of Class I butterfat times the Class I butterfat price for the month.

(ii) The pounds of nonfat solids in Class II skim milk by the Class II nonfat solids price;

(iii) The pounds of butterfat in Class II times the Class II butterfat price;

(iv) The pounds of nonfat solids in Class IV times the nonfat solids price;

(v) The pounds of butterfat in Class III and Class IV milk times the butterfat price;

(vi) The pounds of protein in Class III milk times the protein price;

(vii) The pounds of other solids in Class III milk times the other solids price; and

(viii) Add together the amounts computed in paragraphs (c)(2)(i) through (vii) of this section and from that sum deduct any payment made pursuant to paragraph (c)(1) of this section.

(c) For the total quantity of milk received during the month from a cooperative association in its capacity as a handler under § 1000.9(c) as follows:

(i) The hundredweight of producer milk received times the producer price differential as adjusted pursuant to § 1051.75;

(ii) The pounds of butterfat received times the butterfat price for the month;

(iii) The pounds of protein received times the protein price for the month;

(iv) The pounds of other solids received times the other solids price for the month; and
(v) Add together the amounts computed in paragraphs (c)(3)(i) through (v) of this section and from that sum deduct any payment made pursuant to paragraph (c)(1) of this section.

(d) Handler underpayment proration. If a handler has not received full payment from the market administrator pursuant to § 1051.72 by the payment date specified in paragraph (a), (b), or (c) of this section, the handler may reduce pro rata its payments to producers or to the cooperative association (with respect to receipts described in paragraph (b) of this section, prorating the underpayment to the volume of milk received from the cooperative association in proportion to the total milk received from producers by the handler), but not by more than the amount of the underpayment. The payments shall be completed on the next scheduled payment date after receipt of the balance due from the market administrator.

(e) Payments to missing or deceased producers. If a handler claims that a required payment to a producer cannot be made because the producer is deceased or cannot be located, or because the cooperative association or its lawful successor or assignee is no longer in existence, the payment shall be made to the producer-settlement fund, and in the event that the handler subsequently locates and pays the producer or a lawful claimant, or in the event that the handler no longer exists and a lawful claim is later established, the market administrator shall make the required payment from the producer-settlement fund to the handler or to the lawful claimant, as the case may be.

(f) Producer payment record. In making payments to producers pursuant to this section, each handler shall furnish each producer, except a producer whose milk was received from a cooperative association handler described in § 1000.9(a) or (c), a supporting statement in a form that may be retained by the recipient which shall show:

1. The name, address, Grade A identifier assigned by a duly constituted regulatory agency, and payroll number of the producer;
2. The daily and total pounds, and the month and dates such milk was received from that producer;
3. The total pounds of butterfat, protein, and other solids contained in the producer’s milk;
4. The minimum rate or rates at which payment to the producer is required pursuant to the order in this part;
5. The rate used in making payment if the rate is other than the applicable minimum rate;
6. The amount, or rate per hundredweight, or rate per pound of component, and the nature of each deduction claimed by the handler; and
7. The net amount of payment to the producer or cooperative association.

§ 1051.74 [Reserved]

§ 1051.75 Plant location adjustments for producer milk and nonpool milk.

For purposes of making payments for producer milk and nonpool milk, a plant location adjustment shall be determined by subtracting the Class I price specified in § 1051.51 from the Class I price at the plant’s location. The difference, plus or minus as the case may be, shall be used to adjust the payments required pursuant to §§ 1051.73 and 1000.76.

§ 1051.76 Payments by a handler operating a partially regulated distributing plant.

See § 1000.76.

§ 1051.77 Adjustment of accounts.

See § 1000.77.

§ 1051.78 Charges on overdue accounts.

See § 1000.78.

Administrative Assessment and Marketing Service Deduction

§ 1051.85 Assessment for order administration.

On or before the payment receipt date specified under § 1051.71, each handler shall pay to the market administrator its pro rata share of the expense of administration of the order at a rate specified by the market administrator that is no more than 8 cents per hundredweight with respect to:

(a) Receipts of producer milk (including the handler’s own production) other than such receipts by a producer described in § 1000.9(c) that were delivered to pool plants of other handlers;
(b) Receipts from a handler described in § 1000.9(c); and
(c) Receipts of concentrated fluid milk products from unregulated supply plants and receipts of nonfluid milk products assigned to Class I use pursuant to § 1000.43(d) and other source milk allocated to Class I pursuant to § 1000.44(a)(3) and (8) and the corresponding steps of § 1000.44(b), except other source milk that is excluded from the computations pursuant to § 1051.60(h) and (i); and
(d) Receipts of the marketing area from a partially regulated distributing plant that exceeds the skim milk and butterfat subtracted pursuant to § 1000.76(a)(1)(i) and (ii).

§ 1051.86 Deduction for marketing services.

See § 1000.86.

Subpart D—Miscellaneous Provisions

§ 1051.90 Dates.

See § 1000.90.

Dated: June 4, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018–12245 Filed 6–7–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


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 cracks found in the rear spar web and lower chord on the left and right wings. This AD requires repetitive detailed inspections for cracking of the rear spar web and lower chord, and applicable on-condition actions. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 13, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 13, 2018.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airlines, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet https://www.myboeingfleet.com. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket
You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0074; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, 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:

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 September 14, 2017 (82 FR 57437). The NPRM was prompted by reports of cracks found in the rear spar web and lower chord on the left and right wings. The NPRM proposed to require repetitive detailed inspections for cracking of the rear spar web and lower chord, and applicable on-condition actions. We are issuing this AD to address cracks in the rear spar of the left and right wing between wing buttock line (WBL) 91 and WBL 155, which could lead to the inability of a principal structural element to sustain required flight loads and adversely affect the structural integrity of the airplane.

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.

Support for the NPRM
The Boeing Company stated its support for the NPRM.

Request To Require the Same Grace Period Regardless of Inspection Method
Southwest Airlines (Southwest), requested that we revise paragraph (h) of the proposed AD, which refers to the “Compliance” section of Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017, regarding the different compliance times for the two inspection methods given in Table 1 of the “Compliance” section for Group 2 airplanes. Southwest stated that the planned inspection method should have no bearing on the timing of the inspection, and therefore the compliance times should be the same for both options. They did not specify which of the two compliance times they would favor.

We acknowledge the commenter’s request. While the compliance times for inspections are not normally dependent on the planned inspection method, in this case, the initial compliance times were adjusted to account for differences in the probability of detection using a visual inspection versus an eddy current inspection. Because an eddy current inspection is more capable of detecting smaller cracks than a visual inspection, the initial compliance time was shortened for those airplanes that are inspected using the visual inspection option. We have not changed this AD in this regard.

Effect of Winglets on Accomplishment of the Proposed Actions
Aviation Partners Boeing stated that the installation of winglets using Supplemental Type Certificate (STC) ST01219SE does not affect the actions specified in the NPRM.

We agree with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC 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” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

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

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

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

Related Service Information Under 1 CFR Part 51
We reviewed Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017. This service information describes procedures for repetitive detailed or surface High Frequency Eddy Current (HFEC) inspections for cracking of the rear spar web and lower chord, and applicable on-condition actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance
We estimate that this AD affects 160 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspections ..........</td>
<td>Up to 22 work-hours × $85 per hour = up to $1,870 per inspection cycle.</td>
<td>$0</td>
<td>Up to $1,870 per inspection cycle.</td>
<td>Up to $299,200 per inspection cycle.</td>
</tr>
</tbody>
</table>

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

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

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:
(1) Is not a “significant regulatory action” under Executive Order 12866,
(2) Is not a “significant rule” under 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

§ 39.13 [Amended]
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):


(a) Effective Date
This AD is effective July 13, 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://rglj.faa.gov/Regulatory_and_Guidance_Library/rglsc.nsf/0/6bd1c0ce75a301293eb6257b30045557a?OpenDocument) 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 cracks found in the rear spar web and lower chord on the left and right wings. We are issuing this AD to detect and correct cracks in the rear spar of the left and right wing between wing buttock line (WBL) 91 and WBL 155, which could lead to the inability of a principal structural element to sustain required flight loads and adversely affect the structural integrity of the airplane.

(f) Compliance
Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions for Group 1 Airplanes

For airplanes identified as Group 1 in Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017:

Within 120 days after the effective date of this AD, inspect the airplane and do all applicable corrective actions using a method approved in accordance with the procedures specified in paragraph (j) of this AD.

(h) Required Actions for Group 2 Airplanes

For airplanes identified as Group 2 in Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017: Except as required by paragraph (i) of this AD, at the applicable times specified in the “Compliance” section of Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017.

Note 1 to paragraph (h) of this AD: Guidance for accomplishing the actions required by this AD is included in Boeing Alert Service Bulletin 737–57A1337, dated September 14, 2017, which is referred to in Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017.

(i) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017, uses the phrase “the original issue date of Requirements Bulletin 737–57A1337 RB,” this AD requires using “the effective date of this AD.”
(2) Where Boeing Alert Requirements Bulletin 737–57A1337 RB, dated September 14, 2017, specifies contacting Boeing, this AD requires repair using a method approved 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 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)(1) of this AD. Information may be emailed to: 9-ANM-LAACO-AMOC-Requests@faa.gov.
(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.
(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, 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.

(k) Related Information

(1) 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–
SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A318–111 and –112 airplanes; Model A319–111, –112, –113, –114, and –115 airplanes; Model A320–211, –212, –214, and –216 airplanes; and Model A321–111, –112, –211, –212, and –213 airplanes. This AD was prompted by a review of maintenance instructions for a blend repair of the snout diameter of the main beam assembly of the forward engine mount that would create an excessive gap between the bearing mono-ball and the snout. This AD requires modifying the main beam assembly of the forward engine mount. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 13, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 13, 2018.

ADDRESSES: For Airbus 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.airworthiness@airbus.com; internet: http://www.airbus.com. For Goodrich service information identified in this final rule, contact Goodrich Corporation, Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910–2098; phone: 619–691–2719; email: jan.lewis@goodrich.com; internet: http://www.goodrich.com/TechnicalPubs. You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on May 31, 2018.

Michael Kaszycki,
Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–12279 Filed 6–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39

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 all Airbus Model A318–111 and –112 airplanes; Model A319–111, –112, –113, –114, and –115 airplanes; Model A320–211, –212, –214, and –216 airplanes; and Model A321–111, –112, –211, –212, –214, and –213 airplanes. This AD was prompted by a review of maintenance instructions for a blend repair of the snout diameter of the main beam assembly of the forward engine mount that would create an excessive gap between the bearing mono-ball and the snout. This AD requires modifying the main beam assembly of the forward engine mount. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 13, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of July 13, 2018.

ADDRESSES: For Airbus 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.airworthies@airbus.com; internet: http://www.airbus.com. For Goodrich service information identified in this final rule, contact Goodrich Corporation, Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910–2098; phone: 619–691–2719; email: jan.lewis@goodrich.com; internet: http://www.goodrich.com/TechnicalPubs. You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on May 31, 2018.

Michael Kaszycki,
Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–12279 Filed 6–7–18; 8:45 am]

BILLING CODE 4910–13–P
Goodrich Aerospace issued SB RA32071–159, providing instructions for an in-shop inspection(s) for the main beam snout and, depending on findings, applicable corrective action(s) and re-identification.

Consequently, EASA issued AD 2017–0112, requiring replacement of the affected forward engine mount main beam assemblies. As the same main beam assemblies are certified for CFM56–5A engine installation, that [EASA] AD also applied to aeroplanes with that engine. Since that [EASA] AD was issued, it was determined that, for aeroplanes equipped with an affected forward engine mount main beam assembly, installation of an affected assembly can still be allowed until replacement, as required by this [EASA] AD.

For the reason described above, this [EASA] AD is revised accordingly.

Required actions include modifying the main beam assembly of the forward engine mount. The modification includes replacing, repairing, or reworking the main beam assembly. You may examine the MCAI in the AD docket on the internet at http://www.regulations.gov for locating Docket No. FAA–2017–1020.

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

Support for the NPRM
The Air Line Pilots Association, International (ALPA) and Jake Watson stated their support for the proposed AD. American Airlines (AAL) stated that it has no objection to the intent of the NPRM.

Request To Use Revised Vendor Service Information
AAL stated that the proposed AD should require Goodrich Aerospace Service Bulletin RA32071–159, Rev 1, dated July 25, 2017 ("SB RA32071–159 Rev 1"), which corrects part number references, revises illustrations, and clarifies the procedure. Alternatively, AAL asserted that the proposed AD should allow the use of RA32071–159 Rev 1, or later revisions. AAL stated that Goodrich Aerospace Service Bulletin RA32071–159, dated November 20, 2016, is not useable due to multiple issues.

We do not agree to require RA32071–159 Rev 1. Goodrich Aerospace Service Bulletin RA32071–159 is referenced as an additional source of guidance in Airbus Service Bulletin A320–71–1065, Revision 01, dated July 29, 2017, and Airbus Service Bulletin A320–71–1066, dated December 1, 2016; for inspecting and corrective actions. We acknowledge that RA32071–159 Rev 1 contains several improvements. Therefore, we recommend operators incorporate the latest approved service information. However, in paragraphs (g)(2)(ii) and (h) of this AD, we refer to “Goodrich Aerospace Service Bulletin RA32071–159” and not to any specific revision. Therefore, we have not changed this AD in this regard.

Request To Exclude Certain Actions
AAL stated that Goodrich Aerospace Service Bulletin RA32071–159 requires operators to “fully disassemble the engine mount assembly”, which is not necessary for the dimensional inspection of the snout. AAL noted that, as long as the mount is not installed on the engine, the bearing assembly can be removed to expose the snout, clean, and measure the snout. AAL added that if an operator is forced to fully disassemble the mount, it will drive the mount to an overhaul, which is time consuming and costly.

We infer that the commenter is asking that we exclude disassembly of the engine mount assembly from the inspection specified in paragraph (h) of the proposed AD. We do not agree. Neither Airbus nor the state of design authority, EASA, has informed the FAA that the snout diameter can be conclusively measured without full disassembly of the engine mount assembly. AAL did not provide any justification supported by approval from EASA; or Airbus’s EASA Design Organization Approval (DOA) to allow deviation from the required for compliance section of the service information. However, under the provisions of paragraph (n) of this AD, we will consider requests for approval of an alternative method of compliance if sufficient data are submitted to substantiate that a deviation would provide an acceptable level of safety. We have made no change to this AD in this regard.

Request To Specify Confirmation That a Certain Discrepant Repair Has Never Been Installed
Delta Airlines (Delta) asked that the proposed AD not specify a revision level for Goodrich Aerospace Service Bulletin RA32071–159. Delta added that, if one must be specified, all revisions published prior to the effective date of the AD should be acceptable methods of compliance.

We agree with the commenter’s request that the revision level of Goodrich Aerospace Service Bulletin RA32071–159 not be specified. As previously explained, this AD does not specify a revision level for Goodrich Aerospace Service Bulletin RA32071–159. Therefore, no change to this AD is necessary in this regard.

Request To Remove Revision Level for Vendor Service Information
Delta Airlines (Delta) asked that the proposed AD not specify a revision level for Goodrich Aerospace Service Bulletin RA32071–159. Delta added that, if one must be specified, all revisions published prior to the effective date of the AD should be acceptable methods of compliance.

We agree with the commenter’s request that the revision level of Goodrich Aerospace Service Bulletin RA32071–159 not be specified. As previously explained, this AD does not specify a revision level for Goodrich Aerospace Service Bulletin RA32071–159. Therefore, no change to this AD is necessary in this regard.

Request To Specify Confirmation That a Certain Discrepant Repair Has Never Been Installed
Delta requested that paragraph (g)(1) of the proposed AD be revised to specify that maintenance records must confirm that Repair 10 of Component Maintenance Manual (CMM) 71–21–08, Revisions 1 through 46, has never been performed. Delta stated that, based on the NPRM and service information, it is clear that the discrepant repair is Repair 10 of CMM 71–21–08, Revisions 1 through 46. Delta added that paragraph (g)(1) of the proposed AD does not specify that maintenance records must show only that forward mount main beams have not been repaired per the discrepant Repair 10 of CMM 71–21–08, Revisions 1 through 46, which would classify them as affected main beams.

We disagree with the commenter’s request; however, we provide the following clarification. The intent of paragraph (g)(1) of this AD is that if no maintenance record exists then there is a possibility that the main beam has been repaired using Repair 10 of CMM 71–21–08, Revisions 1 through 46, and, therefore, qualifies as an “affected main beam.” We have not changed this AD in this regard.
Request To Apply Exceptions to Parts Without Maintenance Records of Repair History

Delta asked that the exceptions in paragraphs (g)(2)(i) through (g)(2)(iii) of the proposed AD also apply to parts for which maintenance records are not available to confirm repair history. Delta stated that this will account for mounts that are not installed on-wing and future spare purchases. Delta added that paragraph (g)(2) of the proposed AD does not permit parts with unknown repair history to be excluded if the criteria in paragraphs (g)(2)(i) through (g)(2)(iii) of the proposed AD are met. Delta noted that paragraph (g)(1) of the proposed AD, parts with unknown repair history, are considered “affected main beams” and have the same compliance requirements as parts that have been repaired per discrepant Repair 10 of CMM 71–21–08, Revisions 1 through 46.

We do not agree with the commenter’s request. Exceptions in paragraphs (g)(2)(i) through (g)(2)(iii) of this AD are based on the fact that maintenance records exist. Therefore, these exceptions do not apply to parts with unknown repair history in paragraph (g)(1) of this AD. We have not changed this AD in this regard.

Requests To Use Later Revisions of CMM Repairs

Delta and Lufthansa Technik (Lufthansa) asked that we allow use of later revisions of the CMM repairs in paragraphs (g)(2)(ii) and (h) of the proposed AD. Delta noted that paragraph (g)(2)(ii) doesn’t specify that a repair per the corrected Repair 10 of CMM 71–21–08, Revision 47 (and later), or Repair 21 of CMM 71–21–06, Revision 59 (and later), excludes forward mount main beams from the effectiveness. Delta added that the dimensional requirements of corrected Repair 10 and Repair 21 are equivalent to the requirements of Goodrich Aerospace Service Bulletin RA32071–159, and ensure that any main beams repaired will meet the intent of the proposed AD.

Delta stated that paragraph (h) of the proposed AD doesn’t specify that a qualifying inspection can be done as specified in the instructions of the later revisions of CMMs 71–21–08 and 71–21–06 that introduced the corrected Repair 10 and Repair 21. Delta explained that CMM 71–21–08, Revision 48 (and later), and CMM 71–21–06, Revision 60 (and later), contain the correct snout diameters as specified in Repair 10 of CMM 71–21–08, Revision 47, and Repair 21 of CMM 71–21–06, Revision 59. Delta further noted that EASA AD 2017–0132R1, dated November 22, 2017, permits the use of later revisions of the CMMs with corrected Repairs 10 and 21.

We disagree with the commenters’ requests. We cannot use the phrase, “or later approved revisions,” in an AD when referring to the service document because doing so violates Office of the Federal Register (OFR) regulations for approval of materials “incorporated by reference” in rules. In general terms, we are required by these OFR regulations to either publish the service document contents as part of the actual AD language; or submit the service document to the OFR for approval as “referenced” material, in which case we may only refer to such material in the text of an AD. The AD may refer to the service document only if the OFR approved it for “incorporation by reference.” To allow operators to use later revisions of the referenced document (issued after publication of the AD), either we must revise the AD to reference specific later revisions, or operators must request approval to use later revisions as an alternative method of compliance (AMOC) with this AD under the provisions of paragraph (n) of this AD. We have not changed this AD in this regard.

Request To Define Airplane Group

Delta asked that paragraph (i) of the proposed AD clarify that airplanes on which the main beams have never been replaced are considered Group 2 airplanes. Delta stated that paragraph (j) of the proposed AD doesn’t specify that airplanes on which the main beams have never been replaced (and thus never repaired) since aircraft delivery should be considered Group 2 airplanes. Delta added that an airplane on which the forward mounts have never been replaced since aircraft delivery will not have the discrepant Repair 10 of CMM 71–21–08, Revisions 1 through 46.

We do not agree to revise paragraph (i) of this AD; however, we have clarified the airplane group as follows. Paragraph (i) of this AD specifies Group 2 airplanes are airplanes on which an affected main beam has not been installed as of the effective date of this AD. Therefore, airplanes with main beams that have never been replaced since aircraft delivery might be considered Group 2 airplanes, if the original main beam is not an affected main beam as defined in paragraph (g) of this AD. However, if for example, an airplane with main beams that have never been replaced does not have maintenance records to conclusively confirm the part has never been repaired, as specified in paragraph (g)(1) of this AD, then it is a Group 1 airplane. We have not changed this AD in this regard.

Request To Change “Modify” to “Inspect and Disposition”

Delta asked that the proposed AD use the language “inspect and disposition” instead of “modify” to describe the action required by paragraph (j) of the proposed AD. Additionally, Delta asked that the proposed AD specify that replacement of a forward mount assembly containing an affected main beam with a forward mount assembly that contains an AD-compliant main beam is an acceptable means of compliance. Delta stated that paragraph (j) of the proposed AD uses the term “modify” to describe compliance with the requirements of the inspection and repair of the mounts. Delta added that, based on the instructions in the service information, the intent of the work instructions is to inspect affected main beams and disposition based on inspection findings; the dispositions range from scrapping the main beam to blending, based on measured snout diameter. Delta noted that the replacement of a forward mount assembly that contains an affected main beam with a forward mount assembly with an AD-compliant main beam meets the intent of the proposed AD to remove affected main beams from service.

We partially agree. We do not agree to replace “modify” with “inspect and disposition,” because corrective action cannot be defined by the term “disposition,” which is open to interpretation. Operators must follow the instructions in the Airbus service information referenced in paragraph (j) of this AD for the applicable method of compliance. However, we acknowledge that, while the Accomplishment Instructions of Airbus Service Bulletin A320–71–1066, dated December 1, 2016, specify to do a “Modification of the FWD Engine Mount Assembly on Engine 1 and Engine 2,” the Accomplishment Instructions of Airbus Service Bulletin A320–71–1065, Revision 01, dated July 28, 2017, specify to do inspections and applicable corrective actions. Therefore, we have changed paragraph (j) of this AD to replace “modify” with “inspect, including doing all applicable inspections and corrective actions.”

Request To Include Goodrich Aerospace Service Bulletin for the Required Modification

Lufthansa requested that we include Goodrich Aerospace Service Bulletin
RA32071–159 in paragraph (j) of the proposed AD to “make it more clear.”

We do not agree. The commenter provided no explanation of what is unclear in paragraph (j) or how adding the Goodrich Aerospace service bulletin will clarify the requirements of paragraph (j). Therefore, we have not changed this AD in this regard.

Requests To Provide Credit for Previous Actions Done Using Other Service Information

Delta and Lufthansa asked that the proposed AD include credit for doing previous actions by accomplishing Goodrich Aerospace Service Bulletin RA32071–159; Repair 10 of CMM 71–21–08, Revision 47 (and later); or Repair 21 of CMM 71–21–06, Revision 59 (and later). Delta stated that paragraph (l) of the proposed AD includes credit for previous actions only for compliance with Airbus Service Bulletin A320–71–1065, Revision 01, dated July 28, 2017. Delta asserted that the intent of the proposed AD is met by the accomplishment of Goodrich Aerospace Service Bulletin RA32071–159; Repair 10 of CMM 71–21–08, Revision 47 (and later); or Repair 21 of CMM 71–21–06, Revision 59 (and later); due to the correction of the inspection and repair requirements.

We do not agree with the commenter’s request. Goodrich Aerospace Service Bulletin RA32071–159 is referenced in the airplane level Airbus service information as a secondary document; therefore, it is not an alternate for the instructions in the airplane level service information. All of the steps in paragraph 3.C. of Airbus Service Bulletin A320–71–1065, Revision 01, dated July 28, 2017, are required for compliance and must be done to comply with this AD. If not done before the effective date of this AD, paragraph (f) of this AD states that you must comply with the actions in the AD, “unless already done.”

Regarding future revisions of CMM repairs, we may not refer to any document that does not yet exist. To allow operators to use later revisions of a required document (issued after publication of the AD), either we must revise the AD to reference specific later revisions, or operators must request approval to use later revisions as an alternative method of compliance with the requirements of an AD under the provisions of the AMOC paragraph of the AD. However, as explained previously, the identified CMM repairs are not required for accomplishment of any action in this AD; therefore, no change to this AD is necessary in this regard.

Request To Change Parts Installation Prohibition

Delta asked that paragraph (m) of the proposed AD, “Parts Installation Prohibition,” be changed to permit the same allowance to install an affected main beam onto an aircraft equipped with an affected forward engine mount assembly within the windows defined in paragraph (j) of the proposed AD. Delta stated that paragraph (m) of the proposed AD prohibits the installation of an affected main beam on any airplane after the effective date of the AD. Delta further points out that the parallel EASA AD 2017–0132R1, dated November 22, 2017, permits the installation of an affected main beam onto an aircraft equipped with an affected forward engine mount assembly within the compliance times defined in paragraph (j) of the proposed AD.

We agree with the commenter’s request. After the NPRM was issued, EASA issued AD 2017–0132R1, dated November 22, 2017, which revised its parts installation requirement. We have revised paragraph (m) of this AD to match the EASA AD. In addition, we have revised this AD to refer to EASA AD 2017–0132R1, dated November 22, 2017.

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, with 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 Service Bulletin A320–71–1065, Revision 01, dated July 28, 2017. This service information describes procedures for modifying the main beam assembly of the forward engine mount. The modification includes, among other things, repair or replacement of the main beam assembly.

Airbus has also issued Service Bulletin A320–71–1066, dated December 1, 2016. This service information describes procedures for modifying the main beam assembly of the forward engine mount. The modification includes, among other things, rework of the main beam assembly.

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 500 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modification</td>
<td>Up to 76 work-hours × $85 per hour = $6,460</td>
<td>$778</td>
<td>Up to $7,238</td>
<td>Up to $3,619,000</td>
</tr>
</tbody>
</table>

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.
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):


(a) Effective Date

This AD is effective July 13, 2018.

(b) Affected ADs

None.
directly to the manager of the International Section, send it to the attention of the person identified in paragraph (o)(2) of this AD. Information may be emailed to: 9-AMN-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 required by paragraph (k) 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.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0132R1, dated November 22, 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–2017–1020.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198–6547; telephone 425–227–1405; fax 425–227–1149.

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

(4) Goodrich service information identified in this AD that is not incorporated by reference is available at Goodrich Corporation, Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910–2098; phone: 619–691–2719; email: jan.lewis@goodrich.com; internet: http://www.goodrich.com/TechPubs.

(p) 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 31.

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


(iii) For Airbus 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.

(iv) For Goodrich service information identified in this final rule, contact Goodrich Corporation, Aerostructures, 850 Lagoon Drive, Chula Vista, CA 91910–2098; phone: 619–691–2719; email: jan.lewis@goodrich.com; internet: http://www.goodrich.com/TechPubs.

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

(vi) 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 202–741–4000, or go to: http://www.archives.gov/federal-register/cfr/ibr-locations.html.

(vii) Issued in Des Moines, Washington, on May 29, 2018.

Jeffrey E. Duven,
Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–12268 Filed 6–7–18; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 777–300ER series airplanes. This AD requires replacing the water filter assembly in certain steam ovens. This AD was prompted by a report that water can enter the steam oven cavity and become heated and then released when the oven door is opened. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 25, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 25, 2018.

We must receive comments on this AD by July 23, 2018.

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

• Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
• Fax: 202–493–2251.

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

For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562 797 1717; internet https://www.myboeingfleet.com. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0507.

Examine the AD Docket

You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0507; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:
Stanley Chen, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3565; email: stanley.chen@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We have received a report that members of the cabincrew on a Model 787 airplane were injured when hot
water escaped during the opening of the steam oven door. The incident occurred with Jamco steam ovens, part number (P/N) ASN2001–1 and P/N ASN2001–12. Investigation revealed that the current water filter configuration allows foreign objects to enter the water system, which can prevent the solenoid valve from moving to a fully closed position and subsequently allow water to enter the steam oven cavity. Water in the steam oven cavity can be heated and then released when the door is opened. A new water filter assembly has been developed, which includes a larger screen to prevent foreign object debris from moving downstream to block the solenoid valve from moving to a fully closed position. This condition, if not addressed, could result in water becoming heated as it collects in the bottom of the oven during the cooking cycle, resulting in hot water escaping when the oven door is opened, and subsequent injury to the cabin crew.

The Jamco steam ovens installed on Model 777–300ER series airplanes have the same part numbers as those installed on the affected Model 787 airplane; therefore, Model 777–300ER series airplanes are subject to the same unsafe condition revealed on the Model 787 airplane. The unsafe condition on Model 787 airplanes has been addressed.

## Related Service Information Under 1 CFR Part 51

We reviewed Boeing Service Bulletin 777–25–0617, dated June 6, 2014. The service information describes procedures for replacing the water filter assembly in Jamco steam ovens, P/N ASN2001–1 and P/N ASN2001–12. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

## FAA’s Determination

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

## AD Requirements

This AD requires accomplishing the actions specified in the service information described previously.

## FAA’s Justification and Determination of the Effective Date

There are currently no domestic operators of this product. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

## ESTIMATED COSTS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replacement</td>
<td>1 work-hour × $85 per hour = $85 per steam oven .........................</td>
<td>$0</td>
<td>$85 per steam oven.</td>
</tr>
</tbody>
</table>

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

## Authority for This Rulemaking

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

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

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

## Regulatory Findings

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

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

1. Is not a “significant regulatory action” under Executive Order 12866,
2. Is not a “significant rule” under DOT Regulatory Policies and Procedures (49 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

§ 39.13 [Amended]
(a) The authority citation for part 39 continues to read as follows:
Authority: 49 U.S.C. 106(g), 40113, 44701.

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


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


(c) Applicability
This AD applies to The Boeing Company Model 777–300ER series airplanes, certificated in any category, as identified in Boeing Service Bulletin 777–25–0617, dated June 6, 2014.

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

(e) Unsafe Condition
This AD was prompted by a report that water can enter the steam oven cavity and become heated and then released when the oven door is opened. This condition, if not addressed, could result in injury to the cabin crew.

(f) Compliance
Comply with this AD within the compliance times specified, unless otherwise done.

(g) Replacement of Water Filter Assembly
Within 375 days after the effective date of this AD: Replace the water filter assembly for jamco steam ovens, part number (P/N) ASN2001–1 and P/N ASN2001–12, at the locations identified in, and in accordance with the Accomplishment Instructions of Boeing Service Bulletin 777–25–0617, dated June 6, 2014.


(h) Parts Installation Prohibition
As of the effective date of this AD, no person may install on any airplane, a Jamco steam oven having P/N ASN2001–1 or P/N ASN2001–12, unless the modification required by paragraph (g) of this AD is accomplished for that steam oven.

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

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

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

(j) Related Information
For more information about this AD, contact Stanley Chen, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3565; email: stanley.chen@faa.gov.

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

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


(ii) Reserved.


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

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

Issued in Des Moines, Washington, on May 29, 2018.

Michael Kaszyczki, Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–12270 Filed 6–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


RIN 2120–AA66

Establishment of Class E Airspace; Pago Pago, American Samoa

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Pago Pago International Airport, Pago Pago, American Samoa (AS), to accommodate new area navigation (RNAV) procedures at the airport. This action is necessary for the safety and management of instrument flight rules (IFR) operations within the National Airspace System.

DATES: Effective 0901 UTC, September 13, 2018.

The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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


SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the earth at Pago Pago International Airport, Pago Pago, American Samoa, to support IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the Federal Register for Docket No. FAA–2018–0082 (83 FR 12289; March 21, 2018). The NPRM proposed to establish Class E airspace extending upward from 700 feet above the earth at Pago Pago International Airport, Pago Pago, American Samoa. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment was received, supporting the proposal.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Pago Pago International Airport, Pago Pago, AS. This airspace is necessary to accommodate the redesign for IFR operations in standard instrument approach and departure procedures at the airport. Class E airspace is established within a 7-mile radius of Pago Pago International Airport and within 4 miles either side of the 071° bearing extending from the 7-mile radius to 10.6 miles northeast, and within 4 miles either side of the 240° bearing extending from the 7-mile radius to 10.4 miles southwest; and that airspace extending upward from 1,200 feet above the surface within a 20-mile radius of Pago Pago International Airport, excluding that airspace extending beyond 12 miles of the shoreline.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of establishing Class E airspace extending upward from 700 feet above the surface at Pago Pago International Airport, Pago Pago, American Samoa (AS) to accommodate new area navigation (RNAV) procedures at the airport qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, Paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to cause any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

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

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


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

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

AWP AS E5 Pago Pago, AS [New]

Pago Pago International Airport, American Samoa
(Lat. 14°19′54″N, Long. 170°42′41″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Pago Pago International Airport, and within 4 miles either side of the 071° bearing of the Pago Pago International Airport extending from the 7-mile radius to 10.6 miles northeast of the airport, and within 4 miles either side of the 240° bearing of the airport, and extending from 7-miles radius to 10.4 miles southwest of the Pago Pago
International Airport; and that airspace extending upward from 1,200 feet above the surface within a 20-mile radius of Pago Pago International Airport, excluding that airspace extending beyond 12 miles of the shoreline.

Issued in Washington, DC, on May 30, 2018.
Rodger A. Dean Jr.,
Manager, Airspace Policy Group.
[FR Doc. 2016–12295 Filed 6–7–18; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–0653; Airspace Docket No. 17–AWA–2]

RIN 2120–AA66

Amendment of Class B Airspace; San Francisco, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the San Francisco, CA, Class B airspace area to contain aircraft conducting instrument flight rules (IFR) instrument approach procedures to San Francisco International Airport (SFO), San Francisco, CA. The FAA is taking this action to improve the flow of air traffic, enhance safety, and reduce the potential for midair collision in the SFO Class B airspace area while accommodating the concerns of airspace users. Further, this effort supports the FAA’s national airspace redesign goal of optimizing terminal and enroute airspace to reduce aircraft delays and improve system capacity.

DATES: Effective date 0901 UTC, August 16, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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


SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the San Francisco, CA, Class B airspace area to improve the flow of air traffic and enhance safety within the National Airspace System (NAS).

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

History

The FAA published a notice of proposed rulemaking (NPRM) in the Federal Register for Docket No. FAA–2017–0653 (83 FR 2747; January 19, 2018). The NPRM proposed to modify the San Francisco, CA, Class B airspace area. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. Ten written comments were received in response to the NPRM. All comments received were considered before making a determination on the final rule.

Discussion of Comments

In the response to the NPRM, several individuals and three aviation groups: Airline Pilots Association, International (ALPA), Aircraft Owners and Pilot Association (AOPA), and Experimental Aircraft Association (EAA) submitted comments expressing support for the proposed design of the San Francisco Class B and provided substantive comments and recommendations to further the design. The comments were grouped in the following:

• Glider Operations
• Areas C and D
• Area B
• Area F
• Ceiling of class B at 10,000 feet
• ADS–B requirement

Having considered the issues and recommendations provided by the commenters, the FAA offers the following responses.

Glider Operations

One individual commenter stated glider operations are just outside of the current lateral limits of the airspace and expanding the airspace may cause issues for the operations that exist in those locations.

Prior to publishing the NPRM, the FAA formed an ad-hoc committee and held informal airspace meetings to present a pre-rulemaking outline of the revised Class B airspace. At that time, representatives from the glider community expressed concern that the changes to the airspace would have a negative impact on glider activity near Mount Diablo. Based on this input, the proposal put forth in the NPRM reflected changes to the Class B airspace over Mt. Diablo by eliminating some of the Class B airspace previously suggested during the pre-rulemaking phase and raising the floor in other areas to 7000 feet. The FAA is retaining these changes in the final rule to accommodate glider operations in the Mount Diablo area. In addition, the airspace over Pacifica was raised in the design proposal, accepted during the ad-hoc and thereby accommodating hang gliders.

Areas C and D

Four comments were received regarding the shape and altitudes associated with Area C and Area D. One
commenter expressed concern that the boundaries of Areas C and D are very close to one another and stated that general aviation pilots risk unintentionally violating lateral or vertical limits as they try to transition around the airspace. The commenter suggested that the cutouts exist due to the poor design of three departure procedures and recommended amending the departure procedures to allow for higher floors to the airspace and will enable the incorporation of Area C into Area D. Areas C and D were not designed to capture the Area Navigation (RNAV) departure procedures (DPs). These areas were designed to contain the instrument approaches to Runway (RWY) 10. Track data shows that the SNTNA DP, GNNRR DP and WESLA DPs do not enter Area C or D. All of these DPs have an initial climb gradient of at least 500 feet per nautical mile and standard aircraft performance places them above the C and D areas. The DPs were designed in compliance with the current RNAV DP design criteria in concert with industry and air traffic control standards. They were flown in simulators under varied wind conditions and have been utilized without incident since March 2015.

Three other comments were concerned that lowering the floor of Areas C and D would impede VFR transiting along the coast.

Area C is an arrival extension to Area A and was built to contain RNAV approaches to RWY10. Area D provides a longer arrival extension from the west and also contains the RWY10 arrival approaches and neither can be raised. The RNAV approach to RWY10L crosses NORMM (intermediate fix) which is located just outside of Area D at or above 3,500 feet descending on a 3-degree glide path to cross XATTU (final approach fix) at or above 1,800 feet descending. XATTU is located on the border of Area C and Area A. Area D is needed to contain this descent path. The RNAV approaches to RWY10R cross DOTNE (intermediate fix) at 3,500 feet descending on a 3-degree glide path to cross JULOS (final approach fix) at 1,900 feet descending. DOTNE is just outside of Area D and JULOS is in the center of Area C. Area D is needed to contain this descent path. Area C is needed to capture the descent through 1,900 feet to 1,600 on the approach.

Area B

Two individual commenters stated lowering Area B from 1500 to 1400 feet will almost certainly lead to inadvertent Class B airspace violations in pilots making a right crosswind departure from KSQ. RWY30. Additionally, they indicate that it will put a general aviation pilot at a disadvantage if flying over water. The FAA concurs and raised the floor of Area B to 1,500 feet.

Area F

Two aviation groups (AOPA and EAA) noted that the current floor is set at 1,900 feet descending. Area F was not designed to contain RNAV approaches and neither can be raised. The floor inside of Area F will be raised to 2,300 feet and VFR aircraft will have adequate maneuvering altitude with this design.

Ceiling of Class B at 10,000 Feet

AOPA and EAA requested justification for the establishment of a 10,000-foot ceiling to the Class B airspace. AOPA noted that the 10,000-foot ceiling will require general aviation pilots seeking to transit the Class B airspace to fly at a low altitude (less than 1,600 feet MSL) or a high altitude (over 10,000 feet MSL). AOPA states that the FAA should improve the opportunity for general aviation aircraft to overfly the coast at cruise altitudes more normally utilized, such as 7,500 and 8,500 feet MSL. AOPA recommended that the Class B areas west of the U.S. coast have a ceiling of 7,000 feet MSL to facilitate general aviation operations during instrument conditions and passenger enplanements. The configuration of each Class B airspace area is individually tailored and is designed to contain all published instrument procedures. The current Class B airspace between 8,000 and 10,000 feet at San Francisco International Airport is used to do much of the vectoring of aircraft to facilitate sequencing and provide for separation on final. The airspace around the Bay Area is very congested and the only airspace available for vectoring that facilitates the sequencing of arrivals and prevents conflict with other arrivals and departures is offshore. Fifty percent of the aircraft on the SERFR from the south are vectored. Aircraft from the east cannot be vectored without conflicting with multiple other arrival and departure routes. There are a significant number of arrivals from the west, northwest, and southwest offshore. The FAA is being asked by the public to perform more vectoring offshore to mitigate aircraft noise. Additionally,
new arrival procedures are being developed originating from offshore that will also utilize this airspace. For these reasons, AOPA’s recommendation to establish a ceiling of 7,000 feet MSL west of the U.S. coast is not feasible, as it will deteriorate the arrival rate of the SFO airport.

**ADSB Requirement**

One individual commenter stated, because the lateral boundaries of Class B airspace are being expanded, the Mode C veil will be extended as well. The commenter noted that this change will cause financial loss due to the equipment requirements (Mode C transponder/ADS–B Out) associated with this airspace expansion. Additionally, one individual commenter contends the expansion of the Class B airspace will have a negative financial burden to aircraft owners due to Automatic Dependent Surveillance-Broadcast (ADS–B) requirement in 14 CFR 91.225(d)(3)”, stating privately owned operators have to move their aircraft further away from the Class B airspace if they do not equip for ADS–B.

The FAA does not agree with the commenter who states the Mode C Veil will expand with the expansion of the Class B airspace. The Mode C veil was established by an independent 14 Code of Federal Regulation (CFR) rulemaking action under part 91.215 “ATC transponder and altitude reporting equipment and use.” Although the Class B airspace extends beyond 30 miles in certain areas around SFO, the Mode C veil does not extend with the Class B airspace and remains a 30-mile ring around SFO.

The FAA does not agree with the individual commenters that stated expansion beyond 30 miles for the Class B will expand the forthcoming ADS–B equipment mandate. The ADS–B requirement in 14 CFR 91.225 states ADS–B equipment is required in 1) Class B, 2) within 30 miles and up to 10,000 feet MSL of a Class B, 3) above the ceiling and within the lateral boundaries of a Class B upward to 10,000 feet MSL. In the three locations where SFO’s Class B extends beyond 30 miles all altitudes for those areas are 8,000 feet to 10,000 feet MSL.

Considering these areas are Class B (from 8,000 to 10,000 feet MSL) they require ADS–B equipment. There is no provision stating you must equip with ADS–B below the floor and within the boundaries of a Class B outside the 30-mile ring. Hence, aircraft that choose not to equip with the ADS–B mandate in the year 2020, will not have to extend beyond 30 miles to other airports because the SFO Class B expanded beyond 30 miles at higher altitudes.

**Differences From the NPRM**

In the NPRM, the FAA proposed lower floor altitudes for Areas B and F but have raised these altitudes in response to comments received to the NPRM. Initially, Area B was proposed at 1,400 feet MSL and has been changed to 1,500 feet MSL. Area F was proposed at 2,100 feet MSL and has been changed to 2,300 feet MSL.

Additionally, a charting error is being corrected to Area C. The initial geographic lat/long coordinate (lat. 37°41′25″ N. long. 122°30′33″ W) in Area C was duplicated at the end of the description in the NPRM. The FAA is removing the unnecessary secondary geographic lat/long coordinate to correct the charting error.

**The Rule**

The FAA is amending Title 14 of the Code of Federal Regulations (14 CFR) part 71 to modify the SFO Class B airspace area. This action (depicted on the attached graphic) moves away from the three concentric circle (upside down wedding cake) design configuration and is redrawn based on arrival and departure routes into and out of SFO. Using this design approach allows the FAA to minimize the Class B airspace necessary to contain instrument procedures within Class B airspace for aircraft arriving and departing SFO and to re-designate current Class B airspace as Class E or Class G to make it available for aircraft circumnavigating the Class B airspace area. Additionally, the proposed modifications would better segregate IFR aircraft arriving/departing SFO and VFR aircraft operating in the vicinity of the SFO Class B airspace area. The modifications to the SFO Class B airspace area are discussed below.

**Area A.** Area A is amended as proposed by moving the southern boundary northward to accommodate local hang glide operations and incorporating minor modifications to the northeast boundary by using geographic coordinates to define the surface area. Area A extends upward from the surface, to and including 10,000 feet MSL.

**Area B.** Area B is amended by incorporating portions of existing Area B and Area F and establishing a floor at 1,500 feet MSL. The existing Area B southern boundary is moved northward and eastern boundary is moved westward, and a small portion of existing Area F is added. The floor of the existing Area F portion is lowered from 2,100 feet MSL to 1,500 feet MSL. Area B extends upward from 1,500 feet MSL, to and including 10,000 feet MSL.

**Area C.** A new Area C is established, as proposed in the NPRM, west of SFO beyond Area A, by incorporating small portions of existing Area F and Area I and establishing a floor at 1,600 feet MSL. The floor of the existing Area F portion is lowered from 2,100 feet MSL to 1,600 feet MSL and the floor of the existing Area I portion is raised from 1,500 feet MSL to 1,600 feet MSL. Area C extends upward from 1,600 feet MSL, to and including 10,000 feet MSL.

**Area D.** A new Area D is established, as proposed in the NPRM, west of SFO beyond the new Area C, by incorporating small portions of existing Area F, Area G, and Area I. The floor of the existing Area F portion is retained at 2,100 feet MSL, the floor of the existing Area G portion is lowered from 3,000 feet MSL to 2,100 feet MSL, and the floor of the existing Area I portion is raised from 1,500 feet MSL to 2,100 feet MSL. Area D extends upward from 2,100 feet MSL to and including 10,000 feet MSL.

**Area E.** A new Area E is established, as proposed in the NPRM, northwest of SFO extending clockwise to the east of SFO beyond Area A, by incorporating a sliver of existing Area A and small portions of existing Area F and Area G. The floor of the existing Area A portion is raised from the surface to 2,100 feet MSL, the floor of the existing Area F portion is retained at 2,100 feet MSL, and the floor of the existing Area G portion is lowered from 3,000 feet MSL to 2,100 feet MSL. Area E extends upward from 2,100 feet MSL, to and including 10,000 feet MSL.

**Area F.** A new Area F is established, located southeast of SFO beyond the new Area B, by incorporating small portions of existing Area A, Area C, Area F, and Area G. The floor of the existing Area B portion is raised from 1,500 feet MSL to 2,300 feet MSL, the floor of the existing Area C portion is lowered from 2,500 feet MSL to 2,300 feet MSL and the existing Area G portion is lowered from 3,000 feet MSL to 2,300 feet MSL, and the floor of the existing Area F portion is retained at 2,300 feet MSL. Area F extends upward from 2,300 feet MSL, to and including 10,000 feet MSL.

**Area G.** A new Area G is established, as proposed in the NPRM, northwest of SFO beyond the new Area D and Area E, by incorporating small portions of existing Area A, Area F, Area G, Area H, and Area I. The floor of the existing Area A portion is raised from the surface to 3,000 feet MSL, the existing Area F portion is raised from 2,300 feet MSL to 3,000 feet MSL, and the existing Area I portion is raised from 1,500 feet.
MSL to 3,000 feet MSL; the floor of the existing Area G portion is raised from 3,000 feet MSL and the floor of the existing Area H portion is lowered from 4,000 feet MSL to 3,000 feet MSL. Additionally, a sliver of Class B airspace is established beyond the existing Area H external SFO Class B airspace boundary with a floor of 3,000 feet MSL. Area G extends upward from 3,000 feet MSL, to and including 10,000 feet MSL.

**Area H.** A new Area H is established, as proposed in the NPRM, southeast of SFO beyond the new Area E and Area F, by incorporating small portions of existing Area A, Area B, Area C, Area D, Area F, and Area G. The floor of the existing Area A portion is raised from the surface to 3,000 feet MSL, the existing Area B portion is raised from 1,500 feet MSL to 3,000 feet MSL, the existing Area C portion is raised from 2,500 feet MSL to 3,000 feet MSL, and the existing Area F portion is raised from 2,100 feet MSL to 3,000 feet MSL; the floor of the existing Area G portion is retained at 3,000 feet MSL; and the floor of the existing Area D portion is lowered from 6,000 feet MSL to 3,000 feet MSL. Area H extends upward from 3,000 feet MSL, to and including 10,000 feet MSL.

**Area I.** A new Area I is established, as proposed in the NPRM, north of SFO beyond the new Area A, Area G, and Area H, by incorporating small portions of the existing Area A, Area C, Area D, Area F, and Area G. The floor of the existing Area A portion is raised from the surface to 3,000 feet MSL, the existing Area B portion is raised from 1,500 feet MSL to 3,000 feet MSL, the existing Area C portion is raised from 2,500 feet MSL to 3,000 feet MSL, and the existing Area F portion is raised from 2,100 feet MSL to 3,000 feet MSL; the floor of the existing Area G portion is retained at 3,000 feet MSL; and the floor of the existing Area D portion is raised from 1,500 feet MSL to 4,000 feet MSL. The floor of the existing Area A, Area C, Area D, Area F, and Area G is established beyond the existing Area H, Area E, and Area F, by incorporating small portions of the existing Area D, Area E, and Area G, external SFO Class B boundary, with a floor of 6,000 feet MSL. Area I extends upward from 5,000 feet MSL, to and including 10,000 feet MSL.

**Area J.** A new Area J is established, as proposed in the NPRM, north of SFO beyond the new Area A, Area G, and Area H, by incorporating small portions of the existing Area D, Area E, Area G, and Area H. The floor of the existing Area G portion is raised from 3,000 feet MSL to 5,000 feet MSL and the existing Area D and Area H portions are raised from 4,000 feet MSL to 5,000 feet MSL, and the floor of the existing Area E portion is lowered from 6,000 feet MSL to 5,000 feet MSL. Additionally, a small portion of Class B airspace is established beyond the existing Area D, Area E, and Area G external SFO Class B airspace boundaries with a floor of 5,000 feet MSL. Area J extends upward from 5,000 feet MSL, to and including 10,000 feet MSL.

**Area K.** A new Area K is established, as proposed in the NPRM, north of SFO beyond the new Area I and Area L (described below), by incorporating small portions of the existing Area D and Area E. The floor of the existing Area D portion is raised from 4,000 feet MSL to 5,000 feet MSL and the floor of the existing Area E portion is retained at 6,000 feet MSL. Additionally, a sliver of Class B airspace is established beyond the existing Area E external SFO Class B boundary, with a floor of 6,000 feet MSL. Area K extends upward from 6,000 feet MSL, to and including 10,000 feet MSL.

**Area L.** A new area is established, as proposed in the NPRM, northeast of SFO beyond the new Area I, by incorporating small portions of the existing Area D and Area E. The floor of the existing Area D portion is raised from 4,000 feet MSL to 5,000 feet MSL and the floor of the existing Area E portion is raised from 6,000 feet MSL to 7,000 feet MSL. Additionally, a small portion of Class B airspace is established beyond the existing Area E external SFO Class B boundary, with a floor of 7,000 feet MSL. Area L extends upward from 7,000 feet MSL, to and including 10,000 feet MSL.

**Area M.** A new area is established, as proposed in the NPRM, south of SFO beyond the new Area I, by incorporating small portions of the existing Area D, Area E, Area G, Area J, and Area K. The floor of the existing Area D portion is raised from 4,000 feet MSL to 6,000 feet MSL and the floor of the existing Area E portion is raised from 6,000 feet MSL to 8,000 feet MSL and the floor of the existing Area J portion is retained at 8,000 feet MSL. Additionally, a portion of Class B airspace is established beyond the existing Area E external SFO Class B boundary, with a floor of 8,000 feet MSL. Area M extends upward from 8,000 feet MSL, to and including 10,000 feet MSL, to accommodate delay vectoring for runway 10 and 19 IFR arrival aircraft.

**Regulatory Notices and Analyses**

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a...
“significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of redesigning Class B airspace associated with the KSFO for the purpose of reducing the potential for midair collisions in airspace around airports with high-density air traffic, qualifies for categorical exclusion under the National Environmental Policy Act and its agency-specific implementing regulations in FAA Order 150.1F, “Environmets: Policies and Procedures” regarding categorical exclusions for procedural actions at paragraph 5-6.5.a, which categorically excludes from full environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points. This airspace action is an editorial change only and is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 150.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Paperwork Reduction Act

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

Regulatory Evaluation

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

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

It is appropriate to redesign SFO Class B airspace for reasons described earlier including the availability of new procedures such as the use of “Optimized Profile Descents,” advances in technology: migration to GPS from ground based navigation facilities and updated charting criteria.

This regulation will modify the San Francisco, CA, (SFO) Class B airspace area to improve the flow of air traffic, enhance safety and reduce the potential for midair collision in the SFO Class B airspace area while accommodating the concerns of airspace users. This effort supports the FAA’s national airspace redesign plan utilizing terminal and enroute airspace to reduce aircraft delays and improve system capacity.

The Class B airspace redesign may enhance opportunities for more fuel-efficient descent profiles.

Further, the SFO Class B airspace redesign will enhance safety by containing IFR traffic arriving and departing SFO within the confines of Class B airspace and will better segregate IFR and VFR aircraft.

Finally, the regulation will return current Class B airspace that is not being used for SFO airport arrivals or departures to the NAS. Because it will modify SFO Class B airspace to take advantage of more fuel efficient approaches and optimize terminal and enroute airspace to reduce delays and improve system capacity, the rule is expected to be a minimal cost rule with the potential to result in minor cost savings.

FAA has, therefore, determined that this final rule is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866, and is not “significant” as defined in DOT’s Regulatory Policies and Procedures.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.” To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. The RFA covers a wide-range of small entities, including small businesses, not-for profit organizations, and small governmental jurisdictions. Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The redesign of the SFO Class B airspace will not affect a substantial number of small entities because the redesign does not alter or amend any existing flight path at SFO. Any change to an existing flight path will be achieved through a separate action. Therefore, the expected outcome, if any, will be a minimal economic impact on small entities affected by this rulemaking action.

If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the
head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39, as amended by the Uruguay Round Agreements Act (Pub. L. 103–465)), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and determined that it will improve safety and is consistent with the Trade Agreements Act.

Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

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

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


§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 3000 Subpart B—Class B Airspace.

A WP CA B San Francisco, CA
San Francisco International Airport (Primary Airport) (Lat. 37°37′08″ N, long. 122°22′32″ W)

Boundaries.

Area A. That airspace extending upward from the surface to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°41′25″ N, long. 122°30′23″ W; to lat. 37°41′08″ N, long. 122°29′46″ W; to lat. 37°40′32″ N, long. 122°29′44″ W; to lat. 37°39′25″ N, long. 122°29′41″ W; to lat. 37°40′04″ N, long. 122°31′15″ W, thence to the point of beginning.

Area D. That airspace extending upward from 2,100 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°44′35″ N, long. 122°35′53″ W; to lat. 37°41′40″ N, long. 122°29′11″ W; to lat. 37°41′08″ N, long. 122°29′46″ W; to lat. 37°40′32″ N, long. 122°29′44″ W; to lat. 37°39′25″ N, long. 122°29′41″ W; to lat. 37°38′42″ N, long. 122°29′41″ W; to lat. 37°38′26″ N, long. 122°29′41″ W; to lat. 37°39′19″ N, long. 122°31′44″ W; to lat. 37°41′47″ N, long. 122°37′40″ W, thence to the point of beginning.

Area E. That airspace extending upward from 2,100 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°44′15″ N, long. 122°28′11″ W; to lat. 37°47′12″ N, long. 122°18′31″ W; to lat. 37°45′33″ N, long. 122°14′38″ W; to lat. 37°44′42″ N, long. 122°15′13″ W; to lat. 37°42′17″ N, long. 122°11′39″ W; to lat. 37°39′53″ N, long. 122°11′31″ W; to lat. 37°35′11″ N, long. 122°11′13″ W; to lat. 37°35′32″ N, long. 122°14′06″ W; to lat. 37°40′21″ N, long. 122°14′12″ W; to lat. 37°42′40″ N, long. 122°16′43″ W; to lat. 37°43′37″ N, long. 122°18′59″ W; to lat. 37°43′52″ N, long. 122°19′49″ W; to lat. 37°43′37″ N, long. 122°18′50″ W; to lat. 37°44′10″ N, long. 122°16′43″ W; to lat. 37°44′10″ N, long. 122°14′12″ W; to lat. 37°35′32″ N, long. 122°14′06″ W; to lat. 37°33′53″ N, long. 122°14′49″ W; to lat. 37°33′00″ N, long. 122°15′24″ W; to lat. 37°33′39″ N, long. 122°16′55″ W; to lat. 37°33′36″ N, long. 122°17′48″ W; to lat. 37°32′57″ N, long. 122°20′25″ W; to lat. 37°32′54″ N, long. 122°22′20″ W; to lat. 37°33′08″ N, long. 122°22′36″ W; to lat. 37°33′36″ N, long. 122°22′58″ W; to lat. 37°33′56″ N, long. 122°23′19″ W; to lat. 37°34′01″ N, long. 122°23′34″ W; to lat. 37°34′17″ N, long. 122°23′50″ W; to lat. 37°34′29″ N, long. 122°24′01″ W; to lat. 37°35′00″ N, long. 122°24′17″ W; to lat. 37°36′09″ N, long. 122°25′36″ W; to lat. 37°36′22″ N, long. 122°25′42″ W; to lat. 37°36′42″ N, long. 122°25′34″ W; to lat. 37°38′26″ N, long. 122°29′41″ W; to lat. 37°39′25″ N, long. 122°29′41″ W; to lat. 37°40′32″ N, long. 122°29′44″ W; to lat. 37°41′08″ N, long. 122°29′46″ W, thence to the point of beginning.

Area B. That airspace extending upward from 1,500 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°35′32″ N, long. 122°14′06″ W; to lat. 37°35′11″ N, long. 122°11′13″ W; to lat. 37°32′49″ N, long. 122°12′15″ W; to lat. 37°31′39″ N, long. 122°13′08″ W; to lat. 37°33′00″ N, long. 122°15′24″ W; to lat. 37°33′53″ N, long. 122°14′49″ W, thence to the point of beginning.

Area C. That airspace extending upward from 1,600 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°41′25″ N, long. 122°30′23″ W; to lat. 37°41′08″ N, long. 122°29′46″ W; to lat. 37°40′32″ N, long. 122°29′44″ W; to lat. 37°39′25″ N, long. 122°29′41″ W; to lat. 37°40′04″ N, long. 122°31′15″ W, thence to the point of beginning.
122°35′33″ W; to lat. 37°41′47″ N, long.
122°37′40″ W; to lat. 37°39′19″ N, long.
122°31′44″ W; to lat. 37°38′26″ N, long.
122°29′41″ W; to lat. 37°36′42″ N, long.
122°25′34″ W; to lat. 37°36′22″ N, long.
122°25′42″ W; to lat. 37°36′09″ N, long.
122°25′36″ W; to lat. 37°35′00″ N, long.
122°23′39″ W; to lat. 37°34′29″ N, long.
122°24′01″ W; to lat. 37°34′17″ N, long.
122°23′50″ W; to lat. 37°40′37″ N, long.
122°30′05″ W; to lat. 37°46′40″ N, long.
122°47′13″ W; thence to the point of beginning.

Area I. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°39′53″ N, long.

Area II. That airspace extending upward from 3,000 feet MSL to and including 10,000 feet MSL with the area bounded by a line beginning at lat. 37°39′53″ N, long.

Area III. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area IV. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area V. That airspace extending upward from 3,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area VI. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area VII. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area VIII. That airspace extending upward from 3,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°53′11″ N, long.

Area IX. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°39′36″ N, long.

Area X. That airspace extending upward from 4,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°39′36″ N, long.

Area XI. That airspace extending upward from 3,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°39′36″ N, long.

Area XII. That airspace extending upward from 5,000 feet MSL to and including 10,000 feet MSL within the area bounded by a line beginning at lat. 37°39′36″ N, long.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–1900]

Medical Devices; General and Plastic Surgery Devices; Classification of the Microneedling Device for Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the microneedling device for aesthetic use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the microneedling device for aesthetic use’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 8, 2018. The classification was applicable on March 1, 2018.


SUPPLEMENTARY INFORMATION:

I. Background

 Upon request, FDA has classified the microneedling device for aesthetic use as class II (special controls), which we
have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On July 5, 2016, Bellus Medical, LLC, submitted a request for De Novo classification of the SkinPen Precision System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 1, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4430. We have named the generic type of device microneedling device for aesthetic use, and it is identified as a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

### TABLE 1—MICRONEEDLING DEVICE FOR AESTHETIC USE RISKS AND MITIGATION MEASURES

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation and Labeling.</td>
</tr>
<tr>
<td>Cross-contamination and infection</td>
<td>Sterilization validation, Reprocessing validation, Non-clinical performance testing, Shelf life testing, and Labeling.</td>
</tr>
<tr>
<td>Electrical shock or electromagnetic interference with other devices</td>
<td>Electromagnetic compatibility testing, Electrical safety testing, and Labeling.</td>
</tr>
<tr>
<td>Damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to:</td>
<td>Non-clinical performance testing, Technological characteristics, Shelf life testing, Labeling, and Software verification, validation, and hazard analysis.</td>
</tr>
<tr>
<td>• Exceeding safe penetration depth</td>
<td></td>
</tr>
<tr>
<td>• Mechanical failure</td>
<td></td>
</tr>
<tr>
<td>• Software malfunction</td>
<td></td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final
order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:


2. Add § 878.4430 to subpart E to read as follows:

§ 878.4430 Microneedling device for aesthetic use.

(a) Identification. A microneedling device for aesthetic use is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) The technical specifications and needle characteristics must be identified, including needle length, geometry, maximum penetration depth, and puncture rate.

(2) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Accuracy of needle penetration depth and puncture rate;

(ii) Safety features built into the device to protect against cross-contamination, including fluid ingress protection; and

(iii) Identification of the maximum safe needle penetration depth for the device for the labeled indications for use.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

(5) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.

(6) Software verification, validation, and hazard analysis must be performed for all software components of the device.

(7) The patient-contacting components of the device must be demonstrated to be biocompatible.

(8) Performance data must validate the cleaning and disinfection instructions for reusable components of the device.

(9) Labeling must include the following:

(i) Information on how to operate the device and its components and the typical course of treatment;

(ii) A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;

(iii) Validated methods and instructions for reprocessing of any reusable components;

(iv) Disposal instructions; and

(v) A shelf life.

(10) Patient labeling must be provided and must include:

(i) Information on how the device operates and the typical course of treatment;

(ii) The probable risks and benefits associated with use of the device; and

(iii) Postoperative care instructions.

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the in vivo cured intramedullary fixation rod as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 8, 2018. The classification was applicable on December 19, 2017.

FOR FURTHER INFORMATION CONTACT:

Peter Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1512, Silver Spring, MD 20993–0002, 301–796–6402, Peter.Allen@fda.hhs.gov.
reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 28, 2016, IlluminOss Medical, Inc. submitted a request for De Novo classification of the IlluminOss Photodynamic Bone Stabilization System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 19, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 888.3023. We have named the generic type of device in vivo cured intramedullary fixation rod, and it is identified as a prescription implanted device consisting of a balloon that is inserted into the medullary canal of long bones for the fixation of fractures. The balloon is infused with, and completely encapsulates, a liquid monomer that is exposed to a curing agent that polymerizes the monomer within the balloon creating a hardened rigid structure.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

### TABLE 1—IN VIVO CURED INTRAMEDULLARY FIXATION ROD RISKS AND MITIGATION MEASURES

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse tissue reaction resulting from:</td>
<td>Biocompatibility evaluation and Labeling.</td>
</tr>
<tr>
<td>• Balloon leakage.</td>
<td></td>
</tr>
<tr>
<td>• Device materials.</td>
<td></td>
</tr>
<tr>
<td>Infection, including wound complications</td>
<td>Sterilization validation, Reprocessing validation, Shelf life testing, Pyrogenicity testing, and Labeling.</td>
</tr>
<tr>
<td>Bone fracture resulting from:</td>
<td>Non-clinical performance testing and Labeling.</td>
</tr>
<tr>
<td>• Device bending, cracking, or fracture.</td>
<td></td>
</tr>
<tr>
<td>• Device migration or instability, including initial inadequate fixation.</td>
<td></td>
</tr>
<tr>
<td>• Inability to properly deploy or remove device.</td>
<td></td>
</tr>
<tr>
<td>Soft tissue damage including transection or laceration of neural, vascular, or muscular structures.</td>
<td>Non-clinical performance testing and Labeling.</td>
</tr>
<tr>
<td>Pain and/or loss of function resulting from:</td>
<td></td>
</tr>
<tr>
<td>• Balloon leakage.</td>
<td></td>
</tr>
<tr>
<td>• Device bending, cracking, or fracture.</td>
<td></td>
</tr>
</tbody>
</table>
FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, in vivo cured intramedullary fixation rods are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

§ 888.3023 In vivo cured intramedullary fixation rod.

(a) Identification. An in vivo cured intramedullary fixation rod is a prescription implanted device consisting of a balloon that is inserted into the medullary canal of long bones for the fixation of fractures. The balloon is infused with, and completely encapsulates, a liquid monomer that is exposed to a curing agent which polymerizes the monomer within the balloon creating a hardened rigid structure.

(b) Classification. Class II (special controls). The special controls for this device are:

(i) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(1) Mechanical testing must be conducted on the final device to assess burst, abrasion, bending, and torsion in static and dynamic conditions.

(2) Mechanical testing must demonstrate the integrity of the balloon including testing for leaks, ruptures, and release of cured/uncured material.

(ii) Performance testing must demonstrate the ability, in the event of a leak, to remove the uncured material from its in vivo location.

(iii) Performance testing must demonstrate the reliability and accuracy of the curing method used.

(iv) Performance testing must be conducted to evaluate the temperature rise during curing.

(2) Electrical safety, electromagnetic compatibility (EMC) testing, and electromagnetic interference (EMI) testing must be conducted for all electrical components.

(i) All patient-contacting components must be demonstrated to be biocompatible.

(ii) Performance data must demonstrate the sterility and pyrogenicity of patient contacting components of the device that are provided sterile.

(iii) Performance data must validate the reprocessing instructions for any reusable components or instruments.

(iv) Performance data must support the shelf life of the system by demonstrating continued sterility, package integrity, and system functionality over the established shelf life.

(v) Technological characterization of the device must include materials, curing agents, and a description of the operating principles of the device, including the delivery system and devices which initiate the curing process.

(vi) Labeling must include the following:

(A) A detailed summary of the device technical parameters.

(B) Information describing all materials of the device.

(C) Information describing how to perform the procedure and use the device, including the delivery system and devices which initiate the curing process, as well as how to remove the device and any uncured materials.

(D) A shelf life.

(E) Validated methods and instructions for reprocessing any reusable components or instruments.

TABLE 1—IN VIVO CURED INTRAMEDULLARY FIXATION ROD RISKS AND MITIGATION MEASURES—Continued

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
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</thead>
<tbody>
<tr>
<td>Electric shock or interference with other electrical devices</td>
<td>Non-clinical performance testing and Labeling. Electrical safety testing, Electromagnetic compatibility testing, and Labeling.</td>
</tr>
<tr>
<td>Exothermic reaction leading to tissue injury</td>
<td>Non-clinical performance testing.</td>
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</tbody>
</table>
A notice of proposed rulemaking (REG–149518–03) withdrawing proposed regulations under section 337(d) published in 1992, and proposing new proposed regulations by cross-reference to the temporary regulations, was published in the Federal Register (80 FR 33451) on the same date as TD 9722. Additionally, on June 12, 2015, the Treasury Department and the IRS published proposed regulations (REG–138759–14) under section 732(f) in the Federal Register (80 FR 33452) (together with the 2015 proposed regulations under section 337(d), the 2015 regulations).

The Treasury Department and the IRS received one comment letter in response to the 2015 regulations. Except as described below, the commenter largely supported the 2015 regulations while recommending some minor modifications and clarifications to the 2015 regulations under both section 337(d) and section 732(f). The comment letter is discussed in detail in the Explanation of Provisions section of this preamble.

After considering this comment letter, this Treasury decision adopts as final regulations the rules set forth in the 2015 regulations under section 337(d) (with only minor, nonsubstantive clarifications in response to the commenter’s request for additional certainty regarding certain collateral effects) and section 732(f) (without any change). However, the Treasury Department and the IRS are considering publishing a new notice of proposed rulemaking to propose more substantive amendments to the final regulations under section 337(d) and to allow for additional public comment with respect to these more substantive proposals in response to the comment letter, further reflection by the Treasury Department and the IRS, and concerns raised by practitioners.

2. Regulations Under Section 337(d)

A. Background

In General Utilities & Operating Co. v. Helvering, 296 U.S. 200 (1935), the Supreme Court held that corporations generally could distribute appreciated property to their shareholders without the recognition of any corporate level gain (the General Utilities doctrine). Beginning with legislation in 1969 and culminating in the Tax Reform Act of 1986, Public Law 99–514 (100 Stat. 2085) (the Act), Congress repealed the General Utilities doctrine by enacting section 336(a) to apply gain and loss recognition to liquidating distributions. Under current law, sections 311(b) and 336(a) require a corporation that distributes appreciated property to its shareholders to recognize gain determined as if the property were sold to the shareholders for its fair market value. Additionally, section 631 of the Act added section 337(d) to permit the Secretary to prescribe regulations that are necessary or appropriate to carry out the purposes of the General Utilities doctrine. “Including regulations to ensure that [the repeal of the General Utilities doctrine] may not be circumvented through the use of any provision of law or regulation.”

After the enactment of sections 311(b) and 337(d), the Treasury Department and the IRS became aware of transactions in which taxpayers used a partnership to postpone or avoid completely gain generally required to be recognized under section 311(b). In one example of this transaction, a corporation entered into a partnership and contributed appreciated property. The partnership then acquired stock of that corporate partner, and later made a liquidating distribution of this stock to the corporate partner. Under section 731(a), the corporate partner did not recognize gain on the partnership’s distribution of its stock. By means of this transaction, the corporation had disposed of the appreciated property it formerly held and had acquired its own stock, permanently avoiding its gain in the appreciated property. If the corporation had directly exchanged the appreciated property for its own stock, section 311(b) would have required the corporation to recognize gain upon the exchange.

In response to these types of abusive transactions, the Treasury Department and the IRS issued Notice 89–37, 1989–1 CB 679, on March 9, 1989. Notice 89–37 announced that future regulations under section 337(d) would address the use of partnerships to avoid the repeal of the General Utilities doctrine.

On December 15, 1992, the Treasury Department and the IRS published a notice of proposed rulemaking under section 337(d) (PS–91–90, REG–208989–90, 1993–1 CB 919) in the Federal Register (57 FR 59324) addressing abusive partnership transactions involving stock of a corporate partner (the 1992 proposed regulations). The 1992 proposed regulations set forth a deemed redemption rule and a separate distribution rule to prevent a corporate partner from avoiding corporate-level gain through transactions with a partnership involving stock of the corporate partner, stock of the partner’s affiliate, and other equity interests in the corporate partner. The 1992 proposed regulations treated a corporation as an affiliate of a partner at
the time of a deemed redemption or distribution by the partnership if, immediately thereafter, the partner and corporation were members of an affiliated group as defined in section 1504(a) without regard to section 1504(b) (section 337(d) affiliation). On January 19, 1993, the Treasury Department and the IRS issued Notice 93–2, 1993–1 CB 292, which stated that the 1992 proposed regulations would be amended to limit the application of the regulations to transactions in which section 337(d) affiliation existed immediately before the deemed redemption or distribution. The Treasury Department and the IRS received comments on the 1992 proposed regulations, and adopted a number of these comments in the 2015 regulations.

B. The 2015 Regulations

The 2015 regulations under section 337(d) set forth a rule (the deemed redemption rule) that was aimed at protecting the repeal of the General Utilities doctrine. The 2015 regulations provided that certain transactions create the economic effect of an exchange of appreciated property for Stock of the Corporate Partner and, to tax such exchange appropriately, the deemed redemption rule provided that a Corporate Partner recognizes gain at the time of, and to the extent that, any transaction (or series of transactions) has the economic effect of an exchange by the partner of its interest in appreciated property for an interest in Stock of the Corporate Partner owned, acquired, or distributed by the partnership. (The terms Corporate Partner and Stock of the Corporate Partner are defined in section 1.B.i. of the Explanation of Provisions.)

The 2015 regulations did not adopt the separate distribution rule set forth in the 1992 proposed regulations. Instead, the 2015 regulations applied the deemed redemption rule to partnership distributions of Stock of the Corporate Partner to the Corporate Partner as though the partnership amended its agreement, immediately before the distribution, to allocate 100 percent of the distributed stock to the Corporate Partner. The 2015 regulations also set forth de minimis and inadvertence exceptions to the deemed redemption rule.

3. Regulations Under Section 732(f)

A. Section 732(f)

Section 538 of the Ticket to Work and Work Incentives Improvement Act of 1999, Public Law 106–170 (113 Stat. 1860) (December 17, 1999), added section 732(f) generally effective for distributions made after July 14, 1999. Section 732(f) provides that if (1) a corporate partner receives a distribution from a partnership of stock in another corporation (distributed corporation); (2) the corporate partner has control of the distributed corporation, defined as ownership of stock meeting the requirements of section 1504(a)(2), immediately after the distribution or at any time thereafter (control requirement); and (3) the partnership’s basis in the stock immediately before the distribution exceeded the corporate partner’s basis in the stock immediately after the distribution, then the basis of the distributed corporation’s property must be reduced by this excess. The amount of this reduction is limited to the amount by which the sum of the aggregate adjusted basis of property and the amount of money of the distributed corporation exceeds the corporate partner’s adjusted basis in the stock of the distributed corporation. The corporate partner must recognize gain to the extent that the basis of the distributed corporation’s property cannot be reduced.

Congress enacted section 732(f) due to concerns that a corporate partner could otherwise negate the effects of a basis step-down to distributed property required under section 732(b) by applying the step-down against the basis of the stock of the distributed corporation.

For example, assume a corporate partner has a partnership interest with zero basis and receives a partnership distribution of high-basis stock in a corporation. The corporate partner’s basis in the distributed corporation’s stock is reduced to zero under section 732(a) or section 732(b). If the partnership has elected under section 754, then the basis of other partnership property is increased by an equal amount under section 734(b). The section 732 basis decrease and the section 734(b) basis increase generally offset each other. However, if the corporate partner owned stock in the distributed corporation that satisfied the control requirement, the corporate partner could liquidate the distributed corporation under section 332, and section 334(b) would generally provide for a carryover basis in the distributed corporation’s property received by the corporate partner in the liquidation. Taken together, these rules could permit the partnership to increase the basis of its retained property without an equivalent basis reductio, allowing the liquidation of the distributed corporation. Section 732(f) generally precludes this result by requiring that either the distributed corporation must reduce the basis of its property or the corporate partner must recognize gain (to the extent the distributed corporation is unable to reduce the basis of its property). Thus, section 732(f) generally ensures that any basis increase under section 734(b) is offset.

Section 732(f)(8) grants the Secretary authority to prescribe regulations that may be necessary to carry out the purposes of this subsection, including regulations to avoid double counting and to prevent the abuse of such purposes.

B. The 2015 Regulations

In the preamble to the 2015 regulations under section 732(f), the Treasury Department and the IRS stated that the application of section 732(f) was too broad in some circumstances and too narrow in others. Specifically, the application was overbroad because section 732(f) could require basis reduction or gain recognition even though that basis reduction or gain recognition did not further the purposes of section 732(f). Alternatively, the application was too narrow because corporate partners could inappropriately avoid the purposes of section 732(f) by engaging in transactions that allow corporate partners to receive property held by a distributed corporation without reducing the basis of that property to account for basis reductions under section 732(b) made when the partnership distributed stock of the distributed corporation to the corporate partner.

To address these concerns, the 2015 regulations set forth specific rules governing the application of section 732(f) in two specific sets of circumstances. The first rule would permit consolidated group members to aggregate the bases of their respective interests in the same partnership, in certain circumstances, for section 732(f) purposes. The second rule would restrict corporate partners from entering into certain transactions or a series of transactions (gain elimination transactions), such as a distribution followed by a reorganization under section 368(a), that might eliminate gain in the stock of a distributed corporation while avoiding the effects of a basis step-down under section 732(f) because the control requirement would not be immediately satisfied.

In addition, the 2015 regulations under section 732(f) required taxpayers to apply those rules with respect to tiered partnerships in a manner consistent with the purpose of section 732(f).
Explanation of Provisions

1. Final Regulations Under Section 337(d)

A. Generally

The final regulations under section 337(d) provide that the purpose of the regulations is to prevent corporate taxpayers from using a partnership to circumvent gain required to be recognized under section 311(b) or section 336(a). These final regulations, including the rules governing the amount, timing, and character of recognized gain, must be applied in a manner consistent with, and which reasonably carries out, this purpose.

These final regulations apply when a partnership, either directly or indirectly, owns, acquires, or distributes Stock of the Corporate Partner (as defined in § 1.337(d)–3(c)(2) of these final regulations). Under these final regulations, a Corporate Partner (as defined at § 1.337(d)–3(c)(1) of these final regulations) may recognize gain when it is treated as acquiring or increasing its interest in Stock of the Corporate Partner held by a partnership in exchange for appreciated property in a manner that avoids gain recognition under section 311(b) or section 336(a). These final regulations also provide exceptions under which a Corporate Partner is not required to recognize gain.

B. Scope and Definitions

i. Corporate Partner and Stock of the Corporate Partner

The 2015 regulations defined a Corporate Partner as a person that holds or acquires an interest in a partnership and that is classified as a corporation for federal income tax purposes. The 2015 regulations defined Stock of the Corporate Partner expansively to include the Corporate Partner’s stock, or other equity interests, including options, warrants, and similar interests, in the Corporate Partner, or in a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply (referred to in this Explanation of Provisions as a Controlling Corporation). Stock of the Corporate Partner also included interests in any entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner.

The commenter asked whether an equity interest issued by a third party on a Corporate Partner’s stock, such as an option issued by a bank on the Corporate Partner’s stock, was considered Stock of the Corporate Partner. The Treasury Department and the IRS confirm that all options, warrants, and other similar interests issued by third parties on a Corporate Partner’s stock, a Controlling Corporation’s stock, or any interests in any entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner, are Stock of the Corporate Partner under both the temporary regulations and these final regulations. No inference is intended regarding whether options, warrants, and other similar interests are subject to section 1032 where they create an equity interest in the Stock of the Corporate Partner.

ii. Stock of the Corporate Partner: Controlling Corporations

The 2015 regulations provided that Stock of the Corporate Partner includes the stock (or other equity interests) in a Controlling Corporation. The commenter asked whether stock in a Controlling Corporation wholly constitutes Stock of the Corporate Partner or only constitutes Stock of the Corporate Partner to the extent the value of the Controlling Corporation’s stock is attributable to that corporation’s interest in the Corporate Partner. These final regulations clarify that it is intended that stock (or any other equity interest) in a Controlling Corporation will wholly constitute Stock of the Corporate Partner irrespective of the ratio of the Controlling Corporation’s interest in the Corporate Partner to the Controlling Corporation’s total assets. In response to this comment, the final regulations also include a new example to clearly illustrate this point. See Example 2 of § 1.337(d)–3(h) in these final regulations.

With respect to the rule that Stock of the Corporate Partner includes an interest in an entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner (Value Rule), the commenter asked that, in cases in which the entity is not controlled by the Corporate Partner and which is not a Controlling Corporation, that a limitation be added that the interest in the entity would not be treated as Stock of the Corporate Partner if less than 20 percent of the assets of the entity consisted of Stock of the Corporate Partner. The Treasury Department and the IRS agree with the commenter that the Value Rule in the 2015 regulations could be overbroad in certain situations but decline to adopt the commenter’s specific suggestion in these final regulations because such a rule would be too generous and could permit taxpayers to structure transactions that would contravene the purpose of section 337(d) and these regulations. However, the Treasury Department and the IRS are considering publishing new proposed regulations to limit the application of the Value Rule to entities that are not Controlling Corporations but which own, directly or indirectly, 5 percent or more of the stock, by vote or value, of the Corporate Partner and clarifying how taxpayers would determine what portion of the value of the interest in the entity is attributable to Stock of the Corporate Partner.

iii. Stock of the Corporate Partner: Attribution

The 2015 regulations defined Stock of the Corporate Partner to include stock in a Controlling Corporation. The 2015 regulations employed the section 304(c) definition of control, which generally requires the ownership of stock with either 50 percent of the voting power in the corporation or 50 percent of the value of the corporation. While section 304(c) incorporates the constructive ownership rules of section 318(a) with some modifications, the 2015 regulations excluded the application of sections 318(a)(1) and (3) from its definition of control.

The commenter agreed with excluding section 318(a)(3) attribution from the application of section 304(c) under the 2015 regulations, but noted that it may be inappropriate to exclude section 318(a)(1) family attribution. The commenter suggested that families could invoke this exclusion to structure partnerships in such a way to avoid these regulations but which would be transactions that should otherwise be subject to these final regulations. The Treasury Department and the IRS agree that excluding family attribution under section 318(a)(1) could produce inappropriate results. Additionally, the Treasury Department and the IRS have also determined that taxpayers could structure transactions designed to take advantage of the lack of section 318(a)(3) attribution. Therefore, the Treasury Department and the IRS are considering publishing new proposed regulations to further modify the definition of Stock of the Corporate Partner so that it would no longer exclude attribution under sections 318(a)(1) and (3) when determining whether an interest in an entity is Stock of the Corporate Partners under section 304(c), but which would limit the proposed expanded scope of section 304(c) control to entities that own, directly or indirectly, an interest in the Corporate Partner.
The 2015 regulations provided an exception from the definition of Stock of the Corporate Partner in the case of certain related-party partnerships. Under this exception, Stock of the Corporate Partner did not include any stock or other equity interests held or acquired by a partnership if all interests in the partnership’s capital and profits are held by members of an affiliated group defined in section 1504(a) that includes the Corporate Partner (Affiliated Group Exception).

The commenter suggested that the final regulations extend the Affiliated Group Exception to partnerships in which a high percentage, but not all, of its interests are owned by affiliated group members. The commenter asserted that, under these facts, there would be no reason to require gain recognition. The commenter also recommended that the final regulations extend the affiliated group exception to lower-tier partnerships owned by one or more upper-tier partnerships, if the upper-tier partnerships are entirely owned by members of an affiliated group that includes the Corporate Partner.

After further study of this issue, and in light of the other exceptions to the deemed redemption rule, the Treasury Department and the IRS decline to adopt these comments because even without such extensions the Affiliated Group Exception could permit inappropriate elimination of corporate level built-in gain. For example—

Assume that P, a corporation, owns all of the stock of S1, and S1 owns all of the stock of CP. P, S1, and CP are members of an affiliated group. P and CP form a 50–50 partnership, where CP contributes appreciated property to the partnership, and P contributes S1 stock with a basis equal to fair market value. After seven years, the partnership liquidates and distributes the S1 stock to CP and the appreciated asset to P. At that time, the asset may be sold outside of the group with an artificially increased basis. While the built-in gain that was in the asset now is preserved in the S1 stock held by CP, the group may permanently eliminate the gain without tax by causing CP to liquidate. CP would receive nonrecognition treatment on distribution of the S1 stock to S1 under section 332, and S1 would receive nonrecognition treatment on the receipt of its own stock under section 1032. Thus, the liquidation of CP permanently eliminates the built-in gain on the appreciated asset that attached to the hock stock CP held in S1 after the liquidation of the partnership.

Although these final regulations retain the Affiliated Group Exception, the Treasury Department and the IRS are considering publishing new proposed regulations to remove the Affiliated Group Exception because this exception can permit corporations to engage in transactions with partnerships to eliminate permanently the built-in gain on appreciated assets or otherwise to avoid the purposes of General Utilities repeal and these regulations.

C. Deemed Redemption Rule

i. Generally

The 2015 regulations provided that if a transaction is a Section 337(d) Transaction, a Corporate Partner must recognize gain under the deemed redemption rule. To determine the amount of gain, the Corporate Partner must first determine the amount of appreciated property (other than Stock of the Corporate Partner) effectively exchanged for Stock of the Corporate Partner (by value) and then calculate the amount of taxable gain recognized.

The deemed redemption rule applies only to the extent that the transaction has the effect of an exchange by the Corporate Partner of its interest in appreciated property for Stock of the Corporate Partner. Thus, this rule does not apply to the extent a transaction has the effect of an exchange by a Corporate Partner of non-appreciated property for Stock of the Corporate Partner or has the effect of an exchange by a Corporate Partner of appreciated property for property other than Stock of the Corporate Partner.

The 2015 regulations set forth general principles that apply in determining the amount of appreciated property effectively exchanged for Stock of the Corporate Partner. These general principles require that the Corporate Partner’s economic interest with respect to both Stock of the Corporate Partner and all other appreciated property of the partnership be determined based on all facts and circumstances, including the allocation and distribution rights set forth in the partnership agreement.

A Corporate Partner must recognize gain under the 2015 regulations even if the Section 337(d) Transaction would not otherwise change the Corporate Partner’s allocable share of gain under section 704(c). For example, if a Corporate Partner contributes
appreciated property to a newly-formed partnership and an individual contributes cash that the partnership subsequently uses to purchase Stock of the Corporate Partner, then the purchase of the stock is a Section 337(d) Transaction even though the Corporate Partner’s allocable share of gain in the appreciated property under section 704(c) is the same before and after the purchase. See Example 4 of § 1.337(d)–3(h) in these final regulations.

The Treasury Department and the IRS did not receive comments on this general deemed redemption rule. Therefore, these final regulations adopt the rule set forth in the 2015 regulations.

ii. Subsequent Transactions

Under the 2015 regulations, the deemed redemption rule did not apply to transactions involving stock that does not meet the definition of Stock of the Corporate Partner. The commenter asked whether, in cases in which the deemed redemption rule does not apply to an initial transaction because the definition of Stock of the Corporate Partner is not satisfied, if certain subsequent transactions would trigger gain recognition by treating those transactions as Section 337(d) Transactions. The Treasury Department and the IRS intend for certain subsequent transactions to trigger gain recognition as Section 337(d) Transactions. Therefore, in response to this comment, the Treasury Department and the IRS clarify that these final regulations apply to certain transactions involving related parties in which a first transaction does not constitute a Section 337(d) Transaction because the partnership does not own stock in either a Corporate Partner or in a Controlling Corporation, but the Corporate Partner in a later, separate transaction transfers its partnership interest to a related corporation whose stock the partnership owns. In these transactions, the deemed redemption rule will trigger gain as if the first transaction was a Section 337(d) Transaction with the result that the corporation or partner who is now itself a Corporate Partner will “step into the shoes” of the first Corporate Partner and will be subject to the deemed redemption rule to the extent of the first Corporate Partner’s remaining built-in gain in the appreciated asset immediately prior to the transfer.

iii. Prior Transactions

The 2015 regulations provided that, if the Corporate Partner has an existing interest in the Corporation’s Stock of the Corporate Partner prior to the Section 337(d) Transaction, the deemed redemption rule applies only with respect to the Corporate Partner’s incremental increase in the Stock of the Corporate Partner. For example, changing allocations to increase a Corporate Partner’s interest in the Stock of the Corporate Partner from 50 percent to 80 percent and to decrease the Corporate Partner’s interest in other appreciated property from 80 percent to 50 percent would have the effect of an exchange by the Corporate Partner of the 30-percent incremental decrease in its interest in the appreciated property for the 30-percent incremental increase in the Stock of the Corporate Partner. The Treasury Department and the IRS did not receive comments on this rule, and therefore, these final regulations adopt the rule set forth in the 2015 regulations.

iv. Special Rule for Determination of Corporate Partner’s Interest

For purposes of recognizing gain under the deemed redemption rule, the 2015 regulations provided that a Corporate Partner’s interest in an identified share of Stock of the Corporate Partner will never be less than the Corporate Partner’s largest interest (by value) in that share of Stock of the Corporate Partner that was taken into account when the partnership previously determined whether there had been a Section 337(d) Transaction (regardless of whether the Corporate Partner recognized gain in the earlier transaction). See Example 7 of § 1.337(d)–3(h) in these final regulations. This rule ensures that alternating increases and decreases in a Corporate Partner’s interest in Stock of the Corporate Partner do not cause duplicate gain recognition. This limitation does not apply if any reduction in the Corporate Partner’s interest in the identified share of Stock of the Corporate Partner occurred as part of a plan or arrangement to circumvent the purpose of these final regulations. See Example 8 of § 1.337(d)–3(h) in these final regulations.

The commenter raised a question regarding the numbers used in this Example 8 (which was numbered as Example 7 in the 2015 regulations under section 337(d)). The commenter pointed out that under the example’s facts, the two partners make initial contributions to the partnership in a 99 to 1 ratio, and make subsequent contributions in a 50 to 50 ratio. The commenter questioned why the example stated that the two partners are “equal partners” in all respects after the subsequent contributions. In response to this comment, the Treasury Department and the IRS clarify the example to provide that the subsequent contributions resulted in the partners’ total contributions as being in a 50 to 50 ratio, so that, after the partners make these subsequent contributions, the partners have equal interests in the partnership in all respects. The aim of the example is to illustrate the rule that partners cannot utilize this special rule for determining a Corporate Partner’s interest to circumvent the purpose of these final regulations. The Treasury Department and the IRS did not receive any other comments on this rule, and therefore, these final regulations adopt the rule set forth in the 2015 regulations.

v. Amount and Character of Gain

The 2015 regulations provided that, if a transaction is a Section 337(d) Transaction, the deemed redemption rule requires the Corporate Partner to recognize a percentage of the total gain in partnership appreciated property that is subject to the exchange equal to a fraction, the numerator of which is the Corporate Partner’s interest (by value) in appreciated property effectively exchanged for Stock of the Corporate Partner under the deemed redemption rule, and the denominator of which is the Corporate Partner’s interest (by value) in appreciated property immediately before the Section 337(d) Transaction. The 2015 regulations define this fraction as the Gain Percentage. The Corporate Partner’s gain under the deemed redemption rule equals the product of (i) the Corporate Partner’s Gain Percentage and (ii) the gain from the appreciated property that is the subject of the exchange that the Corporate Partner would recognize if, immediately before the Section 337(d) Transaction, all assets of the partnership and any assets contributed to the partnership in the Section 337(d) Transaction were sold in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)), reduced, but not below zero, by any gain the Corporate Partner is required to recognize with respect to the appreciated property in the Section 337(d) Transaction under any other section of the Code.

The gain from the hypothetical sale used to compute gain under the deemed redemption rule is determined by applying the principles of section 704(c), which generally requires the partnership to take into account variations between the adjusted tax basis and fair market value of partnership property it has contributed to the partnership and upon certain other events that allow or
require the value of partnership property to be redetermined under §1.704–1(b)(2)(iv)(f). See Examples 4 and 6 of §1.337(d)–3(h) in these final regulations. A partner’s share of gain under section 704(c) for this purpose includes any remedial allocations under §1.704–3(d) for a partnership that has elected under section 704(c) to report notional items of offsetting tax gain and loss to its partners to eliminate distortions that may arise when the partnership’s total tax gain or loss on the sale of partnership property is less than all partners’ aggregate share of gain or loss from the property. The Treasury Department and the IRS did not receive comments on this general rule governing the amount of gain from a Section 337(d) Transaction. These final regulations therefore adopt the rule set forth in the 2015 regulations. However, the commenter asked whether section 743(b) basis adjustments are taken into account when determining a Corporate Partner’s gain in a Section 337(d) Transaction. The Treasury Department and the IRS confirm that basis adjustments, including adjustments made pursuant to section 743(b), are taken into account when calculating this gain, so that the Corporate Partner would not be subject to a duplication of tax liability.

The commenter also noted that the 2015 regulations do not specify the character of the gain that a Corporate Partner recognizes in a Section 337(d) Transaction. In response to this comment, the final regulations clarify that the character of the gain that the Corporate Partner recognizes in a Section 337(d) Transaction is the same character of the gain that the Corporate Partner would have recognized if, immediately before the Section 337(d) Transaction, the Corporate Partner had disposed of the appreciated property in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)).

vi. Basis Rules

The 2015 regulations contained two rules related to the effect of the deemed redemption rule on partner and partnership basis. First, the 2015 regulations require the Corporate Partner to increase its basis in its partnership interest by an amount equal to the gain that the Corporate Partner recognizes in a Section 337(d) Transaction. This basis increase is necessary to prevent the Corporate Partner from recognizing gain a second time when the partnership liquidates (or, if property is distributed to the Corporate Partner, when that property is sold). Under the 2015 regulations, this basis increase applies regardless of whether the partnership has a Section 754 election in effect. The commenter suggested that the final regulations clarify how a basis increase is treated for basis-recovery purposes. The final regulations provide this clarification by specifying that this increase is treated as property that is placed in service by the partnership in the taxable year of the Section 337(d) Transaction.

Second, the 2015 regulations require the partnership to increase its adjusted tax basis in the appreciated property that is treated as the subject of a Section 337(d) Transaction by the amount of gain that the Corporate Partner recognized with respect to that property as a result of the Section 337(d) Transaction. The Treasury Department and the IRS did not receive comments on this basis increase rule and, accordingly, these final regulations adopt the rule set forth in the 2015 regulations.

D. Partnership Distributions of Stock of the Corporate Partner

i. General Rule Governing Distributions

The 2015 regulations extended the deemed redemption rule to certain distributions to the Corporate Partner of Stock of the Corporate Partner. These rules governing distributions applied only if the distributed stock had previously been the subject of a Section 337(d) Transaction or became the subject of a Section 337(d) Transaction as a result of the distribution (a section 337(d) distribution). The 2015 regulations did not apply to a distribution to the Corporate Partner of the Stock of the Corporate Partner to which section 732(f) applied at the time of the distribution.

If the deemed redemption rule applied to a distribution, the 2015 regulations deem the partnership to amend its agreement immediately before the distribution to allocate a 100 percent interest in that portion of the stock to the Corporate Partner that is distributed and to allocate an appropriately reduced interest in other partnership property away from the Corporate Partner. The 2015 regulations employ this deemed allocation solely for purposes of recognizing gain, and no inference is intended with regard to the treatment of such allocations generally.

The Treasury Department and the IRS did not receive comments on this general rule governing partnership distributions and, accordingly, these final regulations adopt the rule set forth in the 2015 regulations.

ii. Gain Recognition Rule

The 2015 regulations provided that if a distribution is a section 337(d) distribution, then in addition to any gain recognized under the deemed redemption rule upon the distribution of Stock of the Corporate Partner to the Corporate Partner, the 2015 regulations also would require the Corporate Partner to recognize gain to the extent that the partnership’s basis in the distributed Stock of the Corporate Partner exceeds the Corporate Partner’s basis in its partnership interest (as reduced by any cash distributed in the transaction) immediately before the distribution.

The commenter noted that the language used in this provision differs from the gain recognition provision of section 732(f)(1)(C), which evaluates whether the partnership’s adjusted basis in the distributed stock immediately before the distribution exceeded the Corporate Partner’s adjusted basis in that stock immediately after the distribution. The commenter asked whether these differences were intentional and, if so, for the explanation of the differences. The differences were not intentional and the Treasury Department and the IRS have determined that the provisions should be the same. Accordingly, the language of the gain recognition rule in these final regulations is modified to conform to the language used in the section 732(f) gain recognition provision.

iii. Basis Rules

The 2015 regulations set forth two rules under sections 337(d) and 732 to coordinate the effects of the rule requiring gain recognition when the basis of the Stock of the Corporate Partner is stepped down on a section 337(d) distribution with existing rules for determining the basis of property upon partnership distributions. The first rule applied for purposes of: (1) determining the basis of property distributed to the Corporate Partner (other than the basis of the Corporate Partner in its own stock); (2) determining the basis of the Corporate Partner’s remaining partnership interest; (3) determining the partnership’s basis in undistributed Stock of the Corporate Partner; and (4) computing gain on the distribution. For these purposes, the basis of Stock of the Corporate Partner distributed to the Corporate Partner equals the greater of (i) the partnership’s basis of that distributed Stock of the Corporate Partner immediately before the distribution, or (ii) the fair market value of that distributed Stock of the Corporate Partner immediately before
the distribution, less the Corporate Partner’s allocable share of gain from all of the Stock of the Corporate Partner, if the partnership sold all of its assets in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)) immediately before the distribution. See Examples 3 and 4 of § 1.337(d)–3(h) in these final regulations. This special rule is necessary to prevent basis from shifting away from distributed Stock of the Corporate Partner to other property. This basis shift could occur, for example, upon a distribution of less than all of the partnership’s Stock of the Corporate Partner to the Corporate Partner.

The commenter asked whether this basis rule applies solely to the Corporate Partner or whether it applies for all purposes and recommended expanding Example 4 of § 1.337(d)–3(h) to discuss the basis that AX partnership and partner A have in the X stock that is distributed to A.

The second rule applied when a Corporate Partner receives both Stock of the Corporate Partner and other property in a section 337(d) distribution. Under this rule, the basis to be allocated to the properties distributed under section 732(a) or (b) is allocated first to the Stock of the Corporate Partner before taking into account the distribution of any other property (other than cash). Therefore, before taking into account the distribution of other property, the Corporate Partner will reduce its basis in its partnership interest by the Corporate Partner’s basis in the distributed Stock of the Corporate Partner (but not below zero). The Corporate Partner will determine its basis in other distributed partnership property and in its remaining partnership interest after giving effect to this reduction. The 2015 regulations set forth this rule to ensure that the purposes of the repeal of the General Utilities doctrine are not circumvented through the use of any provision of law or regulations.

When a Corporate Partner receives a partnership distribution of its own stock, it is unclear under existing law whether the Corporate Partner has basis in that stock. (See, for example, Rev. Rul. 2006–2, 2006–1 CB 261.) The resolution of this question is beyond the scope of these final regulations. However, because the distribution to a Corporate Partner of its own stock affects the Corporate Partner’s basis in other distributed property and any retained partnership interest, these final regulations make clear that the partnership and the Corporate Partner must determine the basis of other distributed property and any retained partnership interest by reference to the partnership’s basis in the distributed Stock of the Corporate Partner. That is, the Corporate Partner determines its basis in other distributed property and in any retained partnership interest as though the distributed stock was stock other than Stock of the Corporate Partner. Similarly, the 2015 regulations computed any gain recognition on the distribution by comparing the Corporate Partner’s basis in its partnership interest to the basis of that Stock of the Corporate Partner in the hands of the partnership (without regard to whether the Corporate Partner can have basis in the distributed stock). No inference is intended with respect to the question of whether a corporation does or does not have basis in its own stock.

The commenter noted that duplication of gain under sections 337(d) and 732(f) may occur under the 2015 regulations. The commenter provided an example in which a Corporate Partner could potentially recognize gain first under section 337(d) from a partnership distribution to which section 732(f) does not apply, because its control requirement is not satisfied at the time of the distribution, but then later be subject to the 732(f) basis reduction if the control requirement is subsequently satisfied. The Treasury Department and the IRS agree with the commenter and therefore, these final regulations set forth a basis rule providing that, for purposes of determining the amount of the decrease to the basis of property held by a distributed corporation pursuant to section 732(f), the amount of this decrease is reduced by the amount of gain that a Corporate Partner has recognized under this section in a Section 337(d) Transaction, both in cases where section 732(f) applies at the time of the Section 337(d) Transaction and in cases where section 732(f) is subsequently triggered. This rule prevents the Corporate Partner from recognizing the same gain twice.

E. Exceptions

i. De Minimis Exception

The 2015 regulations set forth a de minimis rule providing that the 2015 regulations do not apply to a Corporate Partner if three conditions are satisfied. These conditions are tested upon the occurrence of a Section 337(d) Transaction and upon any subsequent revaluation event described in § 1.704–1(b)(2)(iv)(f).

The first condition requires that both the Corporate Partner and any persons related to the Corporate Partner under section 267(b) or section 707(b) own, in the aggregate, less than 5 percent of the partnership. The second condition requires that the partnership hold Stock of the Corporate Partner worth less than 2 percent of the value of the partnership’s gross assets, including Stock of the Corporate Partner. The third condition requires that the partnership has never, at any point in time, held more than $1,000,000 in Stock of the Corporate Partner or more than 2 percent of any particular class of Stock of the Corporate Partner.

The 2015 regulations provided a special rule that applies if the conditions of the de minimis rule are satisfied at the time of a Section 337(d) Transaction, but are not satisfied at the time of a subsequent Section 337(d) Transaction or revaluation event described in § 1.704–1(b)(2)(iv)(f). This rule provided that, solely for purposes of the deemed redemption rule, a Corporate Partner may determine its gain on the subsequent acquisition or revaluation event as if it had already recognized gain at the previous event. Accordingly, the Corporate Partner would only recognize gain with respect to appreciation arising between the earlier acquisition or revaluation event and the subsequent event. Neither the Corporate Partner nor the partnership increases its basis by the gain the Corporate Partner would have recognized if the de minimis rule did not apply to the prior acquisition or revaluation event.

The Treasury Department and the IRS are concerned that taxpayers could intentionally plan to combine entities, each meeting the de minimis limits, to avoid the purposes of these final regulations. To address this concern, in these final regulations, the Treasury Department and the IRS add a clarifying provision to the de minimis exception stating that the exception does not apply to Stock of the Corporate Partner that is acquired as part of a plan to circumvent the purpose of these final regulations.
ii. Exception for Certain Dispositions of Stock

The 2015 regulations set forth another exception titled the “inadvertence rule.” This exception provided that the 2015 regulations do not apply to Section 337(d) Transactions in which the partnership satisfies two requirements. First, the partnership must dispose of, by sale or distribution, the Stock of the Corporate Partner before the due date (including extensions) of its federal income tax return for the taxable year in which the partnership acquired the stock (or in which the Corporate Partner joined the partnership, if applicable). Second, the partnership must not have distributed the Stock of the Corporate Partner to the Corporate Partner or a person possessing section 304(c) control of the Corporate Partner.

The commenter asked, whether, notwithstanding the exception’s title, the dispositions needed to be inadvertent to qualify for the exception. In order to avoid any ambiguity or any assumption that these dispositions must be inadvertent, these final regulations rename the exception to state that the exception simply applies to “certain dispositions of stock” that qualify for the exception and that inadvertence is not a requirement.

The Treasury Department and the IRS also note that this exception requires that the stock at issue is not distributed to the Corporate Partner or a Controlling Corporation. As discussed in (1)(B) of this Explanation of Provisions with respect to the general definition of Stock of the Corporate Partner, the Treasury Department and the IRS are considering publishing new proposed regulations to modify the definition of Stock of the Corporate Partner to remove the exception for attribution under section 318(a)(1) and (3) from the scope of section 304(c) control.

F. Other Comments

The commenter requested that these final regulations provide examples on how to measure a Corporate Partner’s partnership interest in more complex partnership agreements, such as situations in which the agreement contains a distribution waterfall. Similarly, the commenter requested that these final regulations provide more detailed examples relating to tiered partnership structures. The Treasury Department and the IRS believe that the purpose of these final regulations is to set forth rules of general applicability to prevent a corporate partner from avoiding corporate level gain through transactions with a partnership. The Treasury Department and the IRS therefore believe that providing such detailed examples is beyond the scope of these final regulations.

2. Final Regulations Under Section 732(f)

These final regulations adopt the rules set forth in the 2015 regulations under section 732(f) without any change to conform the application of section 732(f) with Congress’ identified purposes for enacting sections 337(d), 732(f), and 1502 in certain situations.

A. Aggregation of Section 732(b) Basis Adjustments

As discussed in the Background, section 732(f) generally applies on a partner-by-partner basis. However, the Treasury Department and the IRS determined that, in certain circumstances, it is appropriate to aggregate the bases of consolidated group members in a partnership for purposes of applying section 732(f).

The 2015 regulations provided that corporate partners that are members of the same consolidated group (as defined in § 1.1502–1(h)(1)) could aggregate their bases in interests in the same partnership for purposes of section 732(f) when two conditions are met. First, two or more of the corporate partners receive a distribution of stock in a distributed corporation from the partnership. Second, the distributed corporation is or becomes a member of the distributee partners’ consolidated group following the distribution.

Under this rule, section 732(f) only applies to the extent that the partnership’s adjusted basis in the distributed stock immediately before the distribution exceeds the aggregate basis of the distributed stock in the hands of all members of the distributee corporate partners’ consolidated group immediately after the distribution. The 2015 regulations included the requirement that the distributed corporation be a member of the consolidated group in order to avoid unintended consequences that could result if that corporation were a controlled foreign corporation.

The commenter recommended that the final regulations extend this basis-aggregation rule to include a distributed corporation (including a controlled foreign corporation) that is owned by members of the distributee partners’ consolidated group following the distribution. The commenter stated that the distributed corporation need not be a member of the distributee partners consolidated group, and that the rule should apply to corporations like a controlled foreign corporation that cannot be a member of a consolidated group. The Treasury Department and the IRS decline to adopt the comment because there could be unanticipated consequences if the distributed corporation were a controlled foreign corporation.

B. Gain Elimination Transactions

The 2015 regulations also provided rules that restrict corporate partners from entering into transactions or a series of transactions (gain elimination transactions), such as a distribution followed by a reorganization under section 368(a), that might eliminate gain in the stock of a distributed corporation while avoiding the effects of a basis step-down in transactions, because the section 732(f) control requirement is not immediately satisfied.

Accordingly, the 2015 regulations provided that, in the event of a gain elimination transaction, section 732(f) shall apply as though the corporate partner acquired control (as defined in section 732(f)(5)) of the distributed corporation immediately before the gain elimination transaction.

The Treasury Department and the IRS did not receive comments on the proposed rule governing gain elimination transactions. These final regulations adopt the rules set forth in the 2015 regulations.

C. Tiered Partnerships

The 2015 regulations required taxpayers to apply its rules to tiered partnerships in a manner consistent with the purpose of section 732(f). These final regulations maintain this requirement. The commenter requested that these final regulations provide examples illustrating their application to tiered partnerships. The Treasury Department and the IRS decline to adopt this comment, because such examples are beyond the scope of these final regulations, which is to set forth rules of general applicability governing the application of section 732(f) to two specific sets of circumstances.

Applicability Date

These final regulations apply to transactions occurring on or after June 12, 2015.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

Further, pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is
Paragraph 1. The authority citation for part 1 is amended by removing the sectional authority for §1.337(d)–3T, adding a sectional authority for §1.337(d)(3) in numerical order, and revising the sectional authority for §1.732–3 to read as follows:

Authority: 26 U.S.C. 7805 * * *

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Section 1.337(d)–3 also issued under 26 U.S.C. 337(d).

* * * * * * *

Section 1.732–3 also issued under 26 U.S.C. 337(d), 732(f)(8), and 1502.

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Par. 2. Section 1.337(d)–3 is added to read as follows:

§1.337(d)–3 Gain recognition upon certain partnership transactions involving a partner’s stock.

(a) Purpose. The purpose of this section is to prevent corporate taxpayers from using a partnership to circumvent gain required to be recognized under section 311(b) or section 336(a). The rules of this section, including the determination of the amount of gain, must be applied in a manner that is consistent with and reasonably carries out this purpose.

(b) In general. This section applies when a partnership, either directly or indirectly, owns, acquires, or distributes Stock of the Corporate Partner (within the meaning of paragraph (c)(2) of this section). Under paragraphs (d) or (e) of this section, a Corporate Partner (within the meaning of paragraph (c)(1) of this section) is required to recognize gain when a transaction has the effect of the Corporate Partner acquiring or increasing an interest in its own stock in exchange for appreciated property in a manner that contravenes the purpose of this section as set forth in paragraph (a) of this section. Paragraph (f) of this section sets forth exceptions under which a Corporate Partner does not recognize gain.

(c) Definitions. The following definitions apply for purposes of this section:

(1) Corporate Partner. A Corporate Partner is a person that is classified as a corporation for federal income tax purposes and holds or acquires an interest in a partnership.

(2) Stock of the Corporate Partner—(i) In general. With respect to a Corporate Partner, Stock of the Corporate Partner includes the Corporate Partner’s stock, or other equity interests, including options, warrants, and similar interests, in the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c) (except that section 318(a)(1) and (3) shall not apply). Stock of the Corporate Partner also includes interests in any entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner.

(ii) Affiliated partner exception. Stock of the Corporate Partner does not include any stock or other equity interests held or acquired by a partnership if all interests in the partnership’s capital and profits are held by members of an affiliated group as defined in section 1504(a) that includes the Corporate Partner.

(3) Section 337(d) Transaction. A Section 337(d) Transaction is a transaction (or series of transactions) that has the effect of an exchange by a Corporate Partner of its interest in appreciated property for an interest in Stock of the Corporate Partner owned, acquired, or distributed by a partnership. For example, a Section 337(d) Transaction may occur when —

(i) A Corporate Partner contributes appreciated property to a partnership that owns Stock of the Corporate Partner;

(ii) A partnership acquires Stock of the Corporate Partner;

(iii) A partnership that owns Stock of the Corporate Partner distributes appreciated property to a partner other than a Corporate Partner;

(iv) A partnership distributes Stock of the Corporate Partner to the Corporate Partner; or

(v) A partnership agreement is amended in a manner that increases a Corporate Partner’s interest in Stock of the Corporate Partner (including in connection with a contribution to, or distribution from, a partnership).

(4) Gain Percentage. A Corporate Partner’s Gain Percentage equals a fraction, the numerator of which is the Corporate Partner’s interest (by value) in appreciated property effectively exchanged for Stock of the Corporate Partner under the test described in paragraphs (d)(1) and (2) of this section, and the denominator of which is the Corporate Partner’s interest (by value) in that appreciated property immediately before the Section 337(d) Transaction. Paragraph (d) of this section requires a partnership to multiply the Gain Percentage by the Corporate Partner’s aggregate gain in appreciated property to determine gain recognized under this section.

(d) Deemed redemption rule—(1) In general. A Corporate Partner in a partnership that engages in a Section 337(d) Transaction recognizes gain at the time, and to the extent, that the Corporate Partner’s interest in appreciated property (other than Stock of the Corporate Partner) is reduced in exchange for an increased interest in Stock of the Corporate Partner, as determined under paragraph (d)(2) of this section. This section does not apply to the extent a transaction has the effect of an exchange by a Corporate Partner of non-appreciated property for Stock of the Corporate Partner, or has the effect of an exchange by a Corporate Partner for property other than Stock of the Corporate Partner.

(2) Corporate Partner’s interest in partnership property. The Corporate Partner’s interest with respect to both Stock of the Corporate Partner and the appreciated property that is the subject
of the exchange is determined based on all facts and circumstances, including the allocation and distribution rights set forth in the partnership agreement. The Corporate Partner’s interest in an identified share of Stock of the Corporate Partner will never be less than the Corporate Partner’s largest interest (by value) in that share of Stock of the Corporate Partner that was taken into account when the partnership previously determined whether there had been a Section 337(d) Transaction with respect to such share (regardless of whether the Corporate Partner recognized gain in the earlier transaction). See Example 7 of paragraph (h) of this section. However, this limitation will not apply if any reduction in the Corporate Partner’s interest in the identified share of Stock of the Corporate Partner occurred as part of a plan or arrangement to circumvent the purpose of this section. See Example 8 of paragraph (h) of this section.

(3) Amount and character of gain recognized on the exchange—(i) Amount of gain. The amount of gain the Corporate Partner recognizes under paragraph (d)(1) of this section equals the product of the Corporate Partner’s Gain Percentage and the gain from the appreciated property that is the subject of the exchange that the Corporate Partner would recognize if, immediately before the Section 337(d) Transaction, all assets of the partnership and any assets contributed to the partnership in the Section 337(d) Transaction were sold in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)).

(4) Basis adjustments—(i) Corporate Partner’s basis in the partnership interest. The basis of the Corporate Partner’s interest in the partnership is increased by the amount of gain that the Corporate Partner recognizes under this paragraph (d).

(ii) Partnership’s basis in partnership property. The partnership’s adjusted tax basis in the appreciated property that is treated as the subject of the exchange under this paragraph (d) is increased by the amount of gain recognized with respect to that property by the Corporate Partner as a result of that exchange, regardless of whether the partnership has an election in effect under section 754. For basis recovery purposes, this basis increase is treated as property that is placed in service by the partnership in the taxable year of the Section 337(d) Transaction.

(e) Distribution of Stock of the Corporate Partner—(1) In general. This paragraph (e) applies to distributions to the Corporate Partner of Stock of the Corporate Partner to which section 732(f) does not apply and that have previously been the subject of a Section 337(d) Transaction or become the subject of a Section 337(d) Transaction as a result of the distribution. Upon the distribution of Stock of the Corporate Partner to the Corporate Partner, paragraph (d) of this section will apply as though immediately before the distribution the partners amended the partnership agreement to allocate to the Corporate Partner a 100 percent interest in that portion of the Stock of the Corporate Partner that is distributed, and to allocate an appropriately reduced interest in other partnership property away from the Corporate Partner.

(2) Basis rules—(i) Basis allocation on distributions of stock and other property. If, as part of the same transaction, a partnership distributes Stock of the Corporate Partner and other property (other than cash) to the Corporate Partner, see § 1.732–1(c)(1)(iii) for a rule allocating basis first to the Stock of the Corporate Partner before the distribution of the other property.

(ii) Computation of basis. For purposes of determining the basis of property distributed to a partner in a transaction that includes the distribution of Stock of the Corporate Partner (other than the basis of the Corporate Partner in its own stock), the basis of the partner’s remaining partnership interest, and the partnership’s basis in the distributed Stock of the Corporate Partner, and for purposes of computing gain under paragraph (e)(3) of this section, the partnership’s basis of Stock of the Corporate Partner distributed to the partner equals the greater of—

(A) The partnership’s basis of that distributed Stock of the Corporate Partner immediately before the distribution; or

(B) The fair market value of that distributed Stock of the Corporate Partner immediately before the distribution less the partner’s allocable share of gain from all of the Stock of the Corporate Partner if the partnership sold all of its assets in a fully taxable transaction for cash in an amount equal to the fair market value of such property (taking into account section 7701(g)) immediately before the distribution.

(iii) Section 732(f) basis reduction. For purposes of determining the amount of the decrease to the basis of property held by a distributed corporation pursuant to section 732(f), the amount of this decrease shall be reduced by the amount of gain that a Corporate Partner has recognized under this section in the same Section 337(d) Transaction or in a prior Section 337(d) Transaction involving the property.

(3) Gain recognition. The Corporate Partner will recognize gain on a distribution of Stock of the Corporate Partner to the Corporate Partner to the extent that the partnership’s adjusted basis in the distributed Stock of the Corporate Partner (as determined under paragraph (e)(2)(ii) of this section) immediately before the distribution exceeds the Corporate Partner’s adjusted basis in its partnership interest immediately after the distribution.

(f) Exceptions—(1) De minimis rule—(i) In general. Unless Stock of the Corporate Partner is acquired as part of a plan to circumvent the purpose of this section, this section does not apply to a Corporate Partner if at the time that the partnership acquires Stock of the Corporate Partner or at the time of a revaluation event as described in § 1.704–1(b)(2)(iv)(f) (without regard to whether or not the partnership revalues its assets)—

(A) The Corporate Partner and any persons related to the Corporate Partner under section 267(b) or section 707(b) own in the aggregate less than 5 percent of the partnership;

(B) The partnership holds Stock of the Corporate Partner with a value of less than 2 percent of the partnership’s gross assets (including the Stock of the Corporate Partner); and

(C) The partnership has never, at any point in time, held in the aggregate—

(1) Stock of the Corporate Partner with a fair market value greater than $1,000,000; or

(2) Stock of any entity that is 100 percent owned by the Corporate Partner.
(2) More than 2 percent of any particular class of Stock of the Corporate Partner.

(ii) De minimis rule ceases to apply. If a partnership satisfies the conditions of the de minimis rule of paragraph (f)(1) of this section upon an acquisition of Stock of the Corporate Partner or revaluation event as described in §1.704–1(b)(2)(iv)(f), but later fails to satisfy the conditions of the de minimis rule upon a subsequent acquisition or revaluation event, then solely for purposes of paragraph (d) of this section, the Corporate Partner may compute its gain on the subsequent acquisition or revaluation event as if it had already recognized gain at the previous event. Neither the Corporate Partner nor the partnership increases its basis by the gain the Corporate Partner would have recognized if the de minimis rule of paragraph (f)(1) of this section did not apply to the prior acquisition or revaluation event.

(2) Certain dispositions of stock.

Unless acquired as part of a plan to circumvent the purposes of this section, this section does not apply to Stock of the Corporate Partner that—

(i) Is disposed of (by sale or distribution) by the partnership before the due date (including extensions) of its federal income tax return for the taxable year during which the Stock of the Corporate Partner is acquired (or for the taxable year in which the Corporate Partner becomes a partner, whichever is applicable); and

(ii) Is not distributed to the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply.

(g) Tiered partnerships. The rules of this section shall apply to tiered partnerships in a manner that is consistent with the purpose set forth in paragraph (a) of this section.

(h) Examples. The following examples illustrate the principles of this section. All amounts in the following examples are reported in millions of dollars:

Example 1. Deemed redemption rule—contribution of Stock of the Corporate Partner. (i) In Year 1, X, a corporation, and A, an individual, form partnership AX as equal partners in all respects. X contributes Asset 1 with a fair market value of $100 and a basis of $20. A contributes stock in P, with a basis and fair market value of $100. P is the sole owner of X. P’s interest in X constitutes 10 percent of P’s total assets.

(ii) Because A and X are equal partners in AX in all respects, the partnership formation causes X’s interest in Stock of the Corporate Partner to decrease from $100 to $50 and its interest in Asset 1 to increase from $0 to $50 prior to the distribution of $100 to P. The partnership formation is a Section 337(d) Transaction because the formation has the effect of an exchange for X of $50 of Asset 1 for $50 of X stock.

(iii) X must recognize gain under paragraph (d) of this section with respect to Asset 1 to prevent the circumvention of section 311(b) principles. X’s gain equals the product of X’s Gain Percentage and the gain from Asset 1 that X would recognize (decreased, but not below zero) multiplied by 50 percent (the deemed redemption rule in paragraph (d) of this section). Under paragraph (d)(4)(i) of this section, X’s basis in its AX partnership interest increases from $20 to $60. Under paragraph (d)(4)(ii) of this section, AX’s basis in Asset 1 increases from $20 to $60 because Asset 1 is the appreciated property treated as the subject of the exchange.

Example 2. Deemed redemption rule—contribution of stock in a corporation that controls the Corporate Partner. (i) In Year 1, X, a corporation, and A, an individual, form partnership AX as equal partners in all respects. X contributes Asset 1 with a fair market value of $100 and a basis of $20. A contributes stock in P, with a basis and fair market value of $100. P is the sole owner of X. P’s interest in X constitutes 10 percent of P’s total assets.

(ii) Because P controls X within the meaning of section 304(c), stock in P is Stock of the Corporate Partner under paragraph (c)(2)(i) of this section.

(iii) X must recognize gain under paragraph (d) of this section with respect to Asset 1 to prevent the circumvention of section 311(b) principles. X’s gain equals the product of X’s Gain Percentage and the gain from Asset 1 that X would recognize (decreased, but not below zero, by any gain that X recognized with respect to Asset 1 in the Section 337(d) Transaction under any other provision of this chapter) if, immediately before the Section 337(d) Transaction, all assets were sold in a fully taxable transaction for cash in an amount equal to the fair market value of such property. If Asset 1 had been sold in a fully taxable transaction immediately before the formation of partnership AX, X’s allocable share of gain would have been $80. X’s Gain Percentage is 50 percent (equal to a fraction, the numerator of which is X’s $50 interest in Asset 1 effectively exchanged for Stock of the Corporate Partner, and the denominator of which is X’s $100 interest in Asset 1 immediately before the Section 337(d) Transaction). Thus, X recognizes $40 of gain ($80 multiplied by 50 percent) under the deemed redemption rule in paragraph (d) of this section.

Example 3. Distribution of Stock of the Corporate Partner—pro rata distribution. (i) The facts are the same as in Example 1(i) of this paragraph (h). AX liquidates in Year 9, when Asset 1 and the X stock each have a fair market value of $200. X and A each receive 50 percent of Asset 1 and 50 percent of the X stock in the liquidation. At the time AX liquidates, X’s basis in its AX partnership interest is $60 and A’s basis in its AX partnership interest is $100.

(ii) When AX liquidates, X’s interests in its stock and in Asset 1 do not change. Thus, the liquidation is not a Section 337(d) Transaction because it does not have the effect of an exchange of appreciated property for Stock of the Corporate Partner.

(iii) Paragraph (e) of this section applies because the distributed X stock was the subject of a previous Section 337(d) Transaction and because section 732(f) does not apply. Under §1.732–1(c)(1)(iii), the distribution to X of X stock is a pro rata distribution. Therefore, immediately before the distribution of 50 percent of Asset 1 to X for purposes of determining X’s basis in the distributed property, for purposes of determining X’s basis in Asset 1 and X’s gain on distribution, the basis of the distributed X stock is treated as $50, the greater of $50 (50 percent of the stock’s $100 basis in the hands of the partnership), or $50, the fair market value of that distributed X stock ($100) less X’s allocable share of gain from the distributed property. If AX had sold Asset 1 for $200 in a fully taxable transaction for cash in an amount equal to the fair market value of such property immediately before the distribution ($50), Thus, X reduces its basis in its partnership interest by $50 prior to the distribution of Asset 1. Accordingly, X’s basis in the distributed portion of Asset 1 is $10. Because AX’s basis in the distributed X stock immediately before the distribution ($50) does not exceed X’s basis in its AX partnership interest immediately before the distribution ($60), X recognizes no gain under paragraph (e)(3) of this section.

Example 4. Distribution of Stock of the Corporate Partner—non pro rata distribution. (i) The facts are the same as Example 3(i) of this paragraph (h), except that when AX liquidates, X receives 75 percent of the X stock and 25 percent of Asset 1 and A receives 25 percent of the X stock and 75 percent of Asset 1.

(ii) The liquidation of AX causes X’s interest in X stock to increase from $100 to $150 and its interest in Asset 1 to decrease from $100 to $50. Thus, AX’s liquidating distributions of X stock and Asset 1 to X are...
a Section 337(d) Transaction because the distributions have the effect of an exchange by X of $50 of Asset 1 for $50 of X stock.

(iii)(A) X must recognize gain with respect to Asset 1 to prevent the circumvention of section 311(b) principles. Under paragraph (e)(1) of this section, paragraph (d) of this section is applied as if X and A amended the AX partnership agreement to allocate to X a 100 percent interest in the distributed portion of the X stock. X must recognize gain equal to the product of X's Gain Percentage and the value of Asset 1 immediately before the distribution ($105), X recognizes this section ($100) does not exceed X's basis in the distributed X stock immediately before the distribution as computed for purposes of section 704(c) and 50 percent of the amount of gain recognized on the sale of X stock (here, $50). Therefore, X's basis in the distributed X stock ($105) less A's allocable share of gain if the partnership had sold X stock for $100 prior to the distribution for cash in an amount equal to its fair market value ($50). Thus, A will reduce its basis in its partnership interest by $25 prior to the distribution of Asset 1.

Accordingly, X's basis in the distributed Asset 1 is $75. Because AX's basis in the distributed X stock immediately before the distribution as computed for purposes of this section ($100) does not exceed A's basis in its AX partnership interest immediately before the distribution ($100), A recognizes no additional gain under paragraph (e)(3) of this section.

Example 5. Deemed redemption rule—subsequent purchase of Stock of the Corporate Partner. The facts are the same as Example 1(ii) of this paragraph (h), except (A) AX's basis in the distributed X stock is $25, (B) AX sells the X stock for $50 to a third party, and (C) AX now has a Section 337(d) Transaction because the amendment of the partnership agreement is not a Section 337(d) Transaction because the partnership agreement is not liquidated, and the AX partnership assets immediately before the distribution have not changed.

(ii) In Year 9, when the values of Asset 1 and the X stock have not changed, the partnership distributes $50 of cash and 50 percent of Asset 1 (valued at $50) to B in liquidation of B's interest. X and A are equal partners in all respects after the distribution.

Upon the liquidation of B's interest, X's interest in Asset 1 decreases from $33.33 to $25, and its interest in X stock increases from $33.33 to $50. AX's liquidation of B's interest has the effect of an exchange by X of its interest in Asset 1 for stock and by A of its interest in X stock for cash, and thus, is a Section 337(d) Transaction. X must recognize gain at the time, and to the extent, that X's share of appreciated property (other than X stock) is reduced in exchange for X stock. Thus, the consequences of the partnership's purchase of X stock are the same as those described in Example 4. Under paragraph (d)(3) of this paragraph (h), resulting in X recognizing $40 of gain.

Example 6. Change in allocation ratios—amendment of partnership agreement. (i) The facts are the same as Example 3(ii) of this paragraph (h), except that in Year 9, AX does not liquidate, and the AX partnership agreement is amended to allocate to X 80 percent of the income, gain, loss, and deduction from the X stock and to allocate to A 20 percent of the income, gain, loss, and deduction from Asset 1. If AX had sold the partnership assets immediately before the change to the partnership agreement, X would have been allocated $90 of gain from Asset 1 and $50 of gain from the X stock.

(ii) The amendment to the AX partnership agreement causes X's interest in its stock to increase from $100 (50 percent of the stock's $200 value immediately before the amendment of the agreement) to $160 (80 percent of stock value immediately following amendment of agreement) and its interest in Asset 1 to decrease from $100 to $40. Thus, the amendment of the partnership agreement is a Section 337(d) Transaction because the amendment has the effect of an exchange by X of $60 of Asset 1 for $60 of its stock.

(iii) X must recognize gain equal to the product of X's Gain Percentage and the gain from Asset 1 that X would have recognized (decreased) had the amendment taken effect by any gain recognized with respect to Asset 1 in the Section 337(d) Transaction under any other provision of this chapter) if, immediately before the Section 337(d) Transaction, AX had sold all of its assets in a fully taxable transaction for cash in an amount equal to the fair market value of such property.

Thus, X's interest in its stock is not considered to be increased, and X therefore recognizes no gain under paragraph (d) of
this section, provided that the transactions did not occur as part of a plan or arrangement to circumvent the purpose of this section.

**Example 8. Change in allocation ratios—plan to circumvent purpose of this section. (i)** In Year 1, X, a corporation, and A, an individual, sell Stock $99 and $1, respectively, to newly-formed partnership AX, with X receiving a 99 percent interest in AX and A receiving a 1 percent interest in AX. AX borrows $100,000 from a third-party lender and uses the proceeds to purchase X stock, which is Stock of the Corporate Partner. Later, as part of a plan or arrangement to circumvent the purposes of this section, A contributes $99,999 of cash, which AX uses to repay the loan, and X contributes Asset 1 with a fair market value of $99,901 and basis of $20,000. After these contributions, A and X are equal partners in AX in all respects.

(ii) Pursuant to paragraph (d)(2) of this section, X’s interest in X stock and other appreciated property held by the partnership is determined based on all facts and circumstances, including allocation and distribution rights in the partnership agreement. Generally, pursuant to paragraph (d)(2) of this section, X’s interest in X stock for purposes of paragraph (d) of this section will never be less than the Corporate Partner’s largest interest (by value) in those shares of Stock of the Corporate Partner taken into account when the partnership previously determined whether there had been a Section 337(d) Transaction (regardless of whether the Corporate Partner recognized gain in the earlier transaction). This limitation does not apply, however, if the reduction in X’s interest in X stock occurred as part of a plan or arrangement to circumvent the purpose of this section. Because the transactions described in this example are part of a plan or arrangement to circumvent the purpose of this section, the limitation in paragraph (d)(2) of this section does not apply. Accordingly, the deemed redemption rule under paragraph (d) of this section applies to the transactions with the consequences described in Example 1(ii) of this paragraph (h), resulting in X recognizing $39,990.50 of gain.

**Example 9. Tiered partnership. (i)** In Year 1, X, a corporation, and A, an individual, form partnership UTP. X contributes Asset 1 with a fair market value of $80 and a basis of $0 in exchange for an 80 percent interest in UTP. A contributes $20 of cash in exchange for a 20 percent interest in UTP. UTP and B, an individual, form partnership LTP as equal partners. UTP contributes Asset 1 and $20 of cash. B contributes X stock, which is Stock of the Corporate Partner, with a basis and fair market value of $100.

(ii) Pursuant to paragraph (g) of this section, the rules of this section shall apply to tiered partnerships in a manner that is consistent with the purpose set forth in paragraph (a) of this section. Pursuant to paragraph (d)(1) of this section, if X is in a partnership that engages in a Section 337(d) Transaction, X must recognize gain at the time, and to the extent, that X’s share of appreciated property is reduced in exchange for X stock. The formation of LTP causes X’s interest in X stock to increase from $0 to $40 and its interest in Asset 1 to decrease from $64 to $32. Thus, LTP’s formation is a Section 337(d) Transaction because the formation has the effect of an exchange by X of $32 of Asset 1 for $32 of X stock.

(iii) X must recognize gain with respect to Asset 1 to prevent the circumvention of section 311(b) principles. X must recognize gain equal to the product of X’s Gain Percentage and the gain from Asset 1 (decreased, but not below zero, by any gain X recognized with respect to Asset 1 in the Section 337(d) Transaction under any other provision of this chapter) that X would recognize if, immediately before the Section 337(d) Transaction, all assets were sold in a fully taxable transaction for cash in an amount equal to the fair market value of such property. If Asset 1 had been sold in a fully taxable transaction immediately before LTP’s formation, X’s allocable share of gain would have been $80 pursuant to section 704(c). X’s Gain Percentage is 50 percent (equal to a fraction, the numerator of which is X’s $32 interest in Asset 1 effectively exchanged for X stock, and the denominator of which is X’s $64 interest in Asset 1 immediately before the Section 337(d) Transaction). Thus, X recognizes $40 of gain ($80 multiplied by 50 percent) under the deemed redemption rule in paragraph (d) of this section. Under paragraphs (d)(4)(i) and (ii) of this section, X’s basis in its UTP partnership interest increases from $0 to $40, UTP’s basis in its LTP partnership interest increases from $20 to $60, and LTP’s basis in Asset 1 increases from $0 to $40 pursuant to paragraph (g) of this section.

(i) **Applicability date.** This section applies to transactions occurring on or after June 12, 2015.

### §1.337(d)–3T [Removed]

**Par. 3. Remove §1.337(d)–3T.**

**Par. 4. Section 1.732–1 is amended by revising paragraphs (c)(1) and (c)(5)(ii) to read as follows:**

#### §1.732–1 Basis of distributed property other than money.

* (c) * * *  (1) General rule—(i) Unrealized receivables and inventory items. Except as provided in paragraph (c)(1)(ii) of this section, the basis to be allocated to properties distributed to a partner under section 732(a)(2) or (b) is allocated first to any unrealized receivables (as defined in section 751(c)) and inventory items (as defined in section 751(d)(2)) in an amount equal to the adjusted basis of each such property to the partnership immediately before the distribution. If the basis to be allocated is less than the sum of the adjusted bases to the partnership of the distributed unrealized receivables and inventory items, the adjusted basis of the distributed property must be decreased in the manner provided in §1.732–1(c)(2)(i). See §1.460–4(k)(2)(iv)(D) for a rule determining the partnership’s basis in long-term contract accounted for under a long-term contract method of accounting.

(ii) **Other distributed property.** Any basis not allocated to unrealized receivables or inventory items under paragraph (c)(1)(i) of this section or to stock of persons that control the corporate partner or to the corporate partner’s stock under paragraph (c)(1)(iii) of this section is allocated to any other property distributed to the partner in the same transaction by assigning to each distributed property an amount equal to the adjusted basis of the property to the partnership immediately before the distribution. However, if the sum of the adjusted bases to the partnership of such other distributed property does not equal the basis to be allocated among the distributed property, any increase or decrease required to make the amounts equal is allocated among the distributed property as provided in §1.732–1(c)(2).

(iii) **Stock distributed to the corporate partner.** If a partnership makes a distribution described in §1.337(d)–3(e)(1), then for purposes of this section, the basis to be allocated to properties distributed under section 732(a)(2) or (b) is allocated first to the Stock of the Corporate Partner, as defined in §1.337(d)–3(c)(2), before the distribution of any other property (other than cash). The amount allocated to the Stock of the Corporate Partner is as provided in §1.337(d)–3(e)(2).

### §1.732–1T [Removed]

**Par. 5. Remove §1.732–1T.**

**Par. 6. Section 1.732–3 is revised to read as follows:**

#### §1.732–3 Corresponding adjustment to basis of assets of a distributed corporation controlled by a corporate partner.

(a) **Determination of control.** The determination of whether a corporate partner that is a member of a consolidated group has control of a distributed corporation for purposes of section 732(f) shall be made by applying the special aggregate stock ownership rules of §1.1502–34.
(b) Aggregation of basis within consolidated group. With respect to distributed stock of a corporation, if the following two conditions are met, then section 732(f) shall apply only to the extent that the partnership’s adjusted basis in the distributed stock immediately before the distribution exceeds the aggregate basis of the distributed stock of the corporation in the hands of corporate partners that are members of the same consolidated group (as defined in §1.1502–1(h)) immediately after the distribution:

(1) Two or more of the corporate partners receive a distribution of stock in another corporation; and

(2) The corporation, the stock of which was distributed by the partnership, is or becomes a member of the distributee partners’ consolidated group following the distribution.

c. Application of section 732(f) to Gain Elimination Transactions—(1) General rule. In the event of a Gain Elimination Transaction, section 732(f) shall apply as though the Corporate Partner immediately before the distribution eliminates the gain. The term “Gain Elimination Transaction” includes (without limitation) a reorganization under section 368(a) in which the Corporate Partner and the Distributed Corporation combine, and a distribution of the Distributed Stock by the Corporate Partner to which section 355(c)(1) or 361(c)(1) applies.

(2) Definitions. The following definitions apply for purposes of this paragraph (c):

(i) Corporate Partner. The term “Corporate Partner” means a person that is classified as a corporation for federal income tax purposes and that holds or acquires an interest in a partnership.

(ii) Stock. The term “Stock” includes other equity interests, including options, warrants, and similar interests.

(iii) Distributed Stock. The term “Distributed Stock” means Stock distributed by a partnership to a Corporate Partner, or Stock the basis of which is determined by reference to the basis of such Stock. Distributed Stock also includes Stock owned directly or indirectly by a Distributed Corporation if the basis of such Stock has been reduced pursuant to section 732(f).

(iv) Distributed Corporation. The term “Distributed Corporation” means the issuer of Distributed Stock (or, in the case of an option, the issuer of the Stock into which the option is exercisable).

(v) Gain Elimination Transaction. The term “Gain Elimination Transaction” means a transaction in which Distributed Stock is disposed of and less than all of the gain is recognized unless—

(A) The transferor of the Distributed Stock receives in exchange Stock or a partnership interest that is exchanged basis property (as defined in section 7701(a)(44)) with respect to the Distributed Stock; or

(B) A transferee corporation holds the Distributed Stock as transferred basis property (as defined in section 7701(a)(43)) with respect to the transferor corporation’s gain. A Gain Elimination Transaction includes (without limitation) a reorganization under section 368(a) in which the Corporate Partner and the Distributed Corporation combine, and a distribution of the Distributed Stock by the Corporate Partner to which section 355(c)(1) or 361(c)(1) applies.

(d) Tiered partnerships. The rules of this section shall apply to tiered partnerships in a manner that is consistent with the purposes of section 732(f).

(e) Applicability date. This section applies to transactions occurring on or after June 8, 2018.

Kirsten Wielobob,
Deputy Commissioner for Services and Enforcement.

David J. Kautter,
Assistant Secretary of the Treasury (Tax Policy).

SUPPLEMENTARY INFORMATION:

The Massachusetts Department of Transportation (Craigie) Bridge across Charles River, mile 1.0, at Boston, Massachusetts, has a vertical clearance of 12 feet at normal pool in the closed position. The existing drawbridge operating regulations are listed at 33 CFR 117.591(e).

The Massachusetts Department of Transportation requested a temporary deviation from the normal operating schedule. This temporary deviation will allow the bridge to remain closed from 11 p.m. on July 4, 2018 through 1 a.m. on July 5, 2018 to allow pedestrian traffic to exit the Boston Pops Fireworks Spectacular. The waterway is used extensively by recreational traffic during the fireworks display. A State Police Unit will be on-scene to direct vessel traffic. Vessels that can pass under the bridge in the closed position may do so at any time. The bridge will be able to open for emergencies. There is no alternate route for vessels to pass. The Coast Guard will inform users of the waterway of the change in operating schedule through our Local and Broadcast Notices to Mariners so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: June 4, 2018.

C.J. Bisignano,
Supervisory Bridge Management Specialist, First Coast Guard District.

ADDRESS: The docket for this deviation, USCG–2018–0516 is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH”. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Jeffrey Stieb, Bridge Management Specialist, First District Bridge Branch, U.S. Coast Guard; telephone 617–223–8364, email Jeffrey.D.Stieb@uscg.mil.

The Coast Guard has issued a Notice of deviation from 33 CFR 117.591(e).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0516]

Drawbridge Operation Regulation; Charles River, Boston, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Massachusetts Department of Transportation (Craigie) Bridge across Charles River, mile 1.0, at Boston, Massachusetts. This deviation is necessary to facilitate the Boston Pops Fireworks Spectacular on July 4, 2018, and allows the bridge to remain in the closed position for two hours.

DATES: This deviation is effective from 11 p.m. on July 4, 2018 through 1 a.m. on July 5, 2018.

BILLING CODE 4830–01–P

BILLING CODE 9110–04–P
DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Parts 1 and 4

[NPS–WASO–24719; PPWOPADU0/ PPMRLE1Y.Y00000]

RIN 1024–AE43

Technical and Clarifying Edits; Criminal Violations NPS Units Nationwide

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: This rule removes criminal penalty provisions that are outdated and unnecessary under federal statute. The rule also clarifies—consistent with recent decisions by the U.S. Supreme Court—that, absent exigent circumstances, a search warrant is necessary to require a motor vehicle operator to submit to a blood test (rather than a breath or urine test) to measure blood alcohol and drug content.

DATES: This rule is effective June 8, 2018.

FOR FURTHER INFORMATION CONTACT: Jay Calhoun, NPS Regulations Program Specialist, 1849 C Street NW, Washington, DC 20240, (202) 513–7112, john_calhoun@nps.gov.

SUPPLEMENTARY INFORMATION:

Background

Criminal Penalty Provisions

Paragraph (a) of 36 CFR 1.3 describes the penalties for violating a provision of NPS regulations contained in parts 1 through 7, part 9 subpart B, and parts 12 and 13 of chapter 1 of title 36. These penalties are payment of a fine as provided by law or imprisonment not exceeding six months, or both, and payment of the costs of all proceedings. The authority to impose these penalties is found in the NPS Organic Act (54 U.S.C. 100751) and 18 U.S.C. 1865. The NPS has the authority to impose these penalties for a violation of any regulation relating to the use and management of the units of the National Park System.

Paragraphs (b), (c), and (d) of 36 CFR 1.3 describe lesser penalties that apply to violations of NPS regulations that occur within units of the National Park System that originated as military parks or national historic sites. These additional provisions are superfluous because the NPS has the authority to impose greater penalties under the NPS Organic Act for violations of NPS regulations that occur in any unit of the National Park System, including those units referred to in paragraphs (b), (c), and (d). This rule removes these unnecessary provisions to reduce the chance of confusion and clarify that a uniform penalty structure applies to the entire National Park System.

Criminal Violations NPS Units

Existing NPS regulations at 36 CFR 4.23(c) state that a driver suspected of operating a motor vehicle while under the influence of alcohol or drugs must submit to a blood test (if requested) for the purpose of determining blood alcohol and drug content. This language could be misleading because it does not explicitly state that—absent exigent circumstances—a search warrant must be present in order to require a blood test. This is the Constitutional requirement under the Fourth Amendment following the U.S. Supreme Court decisions in Missouri v. McNeely (2013) and Birchfield v. North Dakota (2016). This rule revises section 4.23(c) to explicitly state this general requirement for a warrant for blood tests. Law enforcement officers will still have the regulatory authority to require an operator to submit to less intrusive tests such as the extraction of saliva, breath tests, or urine samples without a warrant. In practice, NPS law enforcement officers generally stopped requiring blood tests after the McNeely decision in 2013.

Consistent with McNeely and Birchfield, this rule deletes the requirement that a suspected operator submit to a blood test under 36 CFR 4.23(c)(1). This rule clarifies that 36 CFR 4.23(c)(2)'s prohibition on refusing tests applies to those tests allowed under (c)(1) (and would thus no longer apply to the refusal of a blood test, since blood tests have been deleted from that paragraph). This rule creates a new 36 CFR 4.23(c)(3) that provides that absent exigent circumstances, an operator cannot ordinarily be required to submit for a blood test unless it occurs through a search warrant. Existing paragraphs (c)(3) and (c)(4) are redesignated as paragraphs (c)(4) and (c)(5) but otherwise do not change.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review

Executive Order 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this rule in a manner consistent with these requirements.

Small Business Regulatory Enforcement Fairness Act

This rule is an E.O. 13771 deregulatory action because, once finalized, it will impose less than zero costs by removing unnecessary criminal penalty provisions and clarifying the current law regarding the valid use of blood tests to measure blood alcohol and drug content.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.
This rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. This rule only affects use of federally-administered lands and waters. It has no outside effects on other areas. A Federalism summary impact statement is not required.

Administrative Procedure Act (Notice of Proposed Rulemaking and Effective Date)

We recognize that under 5 U.S.C. 553(b) and (c), notice of proposed rules ordinarily must be published in the Federal Register and the agency must give interested parties an opportunity to submit their views and comments. We have determined under 5 U.S.C. 553(b) and 318 DM HB 5.3, however, that notice and public comment for this rule are not required. We find good cause to treat notice and comment as unnecessary. As discussed above, the penalty provisions being removed are superfluous and not used by the NPS. The clarification that the NPS must obtain a warrant to require a blood sample is settled law and comports with NPS practice since 2013. These regulatory changes will not benefit from public comment, and further delaying them is contrary to the public interest.

We also recognize that rules ordinarily do not become effective until at least 30 days after their publication in the Federal Register. We have determined, however, that good cause exists for this rule to be effective immediately upon publication for the reasons stated above.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. This rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. The NPS has evaluated this rule under the criteria in Executive Order 13175 and under the Department's tribal consultation policy and have determined that tribal consultation is not required because the rule will have no substantial direct effect on federally recognized Indian tribes.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. The NPS 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.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. We have determined the rule is categorically excluded under 43 CFR 46.210(i) because it is administrative, legal, and technical in nature. We also have determined the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects in not required.

List of Subjects

36 CFR Part 1

National parks, Penalties, Reporting and recordkeeping requirements, Signs and symbols.

36 CFR Part 4

National parks, Traffic regulations.

The National Park Service amends 36 CFR parts 1 and 4 as follows:
III. EPA Action

I. Proposed Action

On February 16, 2018 (83 FR 6996), the EPA proposed to approve the second 10-year maintenance plan for the Douglas, Arizona SO₂ maintenance area. Submitted by the Arizona Department of Environmental Quality on December 14, 2016, the Douglas second 10-year SO₂ maintenance plan ("plan") demonstrates maintenance of the 1971 SO₂ standards through 2030. We proposed to approve the plan because we determined that it complied with the relevant Clean Air Act (CAA or "Act") requirements. Our proposed action contains more information on the plan and our evaluation (83 FR 6996, February 16, 2018).

II. Public Comments and EPA Responses

The EPA’s proposed action provided for a 30-day public comment period. The EPA received eleven anonymous comment letters in response to the proposed action. All eleven comments concerned issues that are outside the scope of our proposed approval of the Douglas second 10-year SO₂ maintenance plan. The issues raised in those comments include, but are not limited to, air quality in China and India, natural gas, mining, electric vehicles, wind farms, and wind turbines.

III. EPA Action

The EPA is taking final rulemaking action to approve the Douglas second 10-year SO₂ maintenance plan under sections 110 and 175A of the CAA. As authorized in section 110(k)(3) of the Act, the EPA is approving the submitted SIP revision because it fulfills all relevant requirements.

IV. Statutory and Executive Order Reviews

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

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

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13176 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 7, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving the revision to the State of Arizona’s SIP may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52
Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

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

Deborah Jordan,
Acting Regional Administrator, EPA Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

2. In §52.120, table 1 in paragraph (e) is amended by adding the entry “Maintenance Plan Renewal, 1971 Sulfur Dioxide National Ambient Air Quality Standards, Douglas Maintenance Area” after the entry “Modeling and Emissions Inventory Supplement for the Douglas Sulfur Dioxide Nonattainment Area State Implementation and Maintenance Plan and Redesignation Request, dated September 2005” to read as follows:

§52.120 Identification of plan.

(e) * * *

Part D Elements and Plans (Other than for the Metropolitan Phoenix or Tucson Areas)

* * *


December 14, 2016

June 8, 2018, [insert Federal Register citation].

Adopted by the Arizona Department of Environmental Quality on December 14, 2016. Fulfills requirements for second 10-year maintenance plan.

* * *

Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * *

[FR Doc. 2018–12300 Filed 6–7–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of adequacy.

SUMMARY: In this document, the Environmental Protection Agency ("EPA" or "Agency") is notifying the public that the Agency has found that the 2017 motor vehicle emissions budgets ("budgets") for volatile organic compounds ("VOCs") and nitrogen oxides ("NOx") submitted by the New York State Department of Environmental Conservation for the 2008 national ambient air quality standard ("NAAQS") for ozone are adequate for transportation conformity purposes for the New York portions of the New York-Northern New Jersey-Long Island, NY–NJ–CT 8-hour ozone nonattainment area. The transportation conformity rule requires that the EPA
conduct a public process and make an affirmative decision on the adequacy of these budgets before they can be used by metropolitan planning organizations in conformity determinations. As a result of this finding, upon the effective date of this notification of adequacy, the New York Metropolitan Transportation Council must use these budgets in future transportation conformity determinations. The budgets are contained in New York’s November 10, 2017, state implementation plan submittal for the 2008 ozone NAAQS and are associated with the reasonable further progress milestone demonstration.

DATES: This finding is effective June 22, 2018.

FOR FURTHER INFORMATION CONTACT: Hannah Greenberg, Environmental Protection Agency Region 2, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007-1866; (212) 637-3829, greenberg.hannah@epa.gov.

SUPPLEMENTARY INFORMATION:
Throughout this document, whenever “we,” “us,” or “our” is used, we mean the EPA.

This document is simply an announcement of a finding that we have already made. EPA Region 2 sent a letter to the New York State Department of Environmental Conservation on April 19, 2018, stating that the 2017 motor vehicle emissions budgets (“budgets”) in the submitted state implementation plan (“SIP”) for the 2008 national ambient air quality standard for ozone for the New York portion of the New York-Northern New Jersey-Long Island 8-hour ozone nonattainment area are adequate for transportation conformity purposes. These budgets are associated with the SIP’s reasonable further progress milestone demonstration and must apply to future transportation conformity determinations conducted by the New York Metropolitan Transportation Council (“NYMTC”).

On November 10, 2017, the New York State Department of Environmental Conservation submitted a SIP revision for the New York portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT, 2008 8-hour ozone nonattainment area. This revision to the SIP included 2017 summer day volatile organic compound (“VOC”) and nitrogen oxides (“NOx”) motor vehicle emissions budgets associated with the SIP’s reasonable further progress demonstration. We announced availability of the plan and related budgets on the EPA’s transportation conformity website on December 6, 2017, requesting comments by January 5, 2018. We received no comments in response to the adequacy review posting.

This finding will also be available at the EPA’s conformity website: https://www.epa.gov/state-and-local-transportation/conformity-adequacy-review-region-2.

The motor vehicle emissions budgets are provided in Table 1 below.

### Table 1—2017 Motor Vehicle Emissions Budgets for NYMTC

<table>
<thead>
<tr>
<th>Year</th>
<th>VOC</th>
<th>NOx</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>65.69</td>
<td>117.21</td>
</tr>
</tbody>
</table>

Transportation conformity is required by Clean Air Act section 176(c). The EPA’s conformity rule requires that long-range transportation plans, transportation improvement programs, and transportation projects conform to a state’s air quality SIP and establishes the criteria and procedures for determining whether or not they conform. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay attainment of the NAAQS. The criteria the EPA uses to determine whether a SIP’s motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). We have further described our process for determining the adequacy of submitted SIP budgets in 40 CFR 93.118(f), and we followed this rule in making our adequacy determination. Please note that an adequacy review is separate from the EPA’s completeness review and should not be used to prejudge the EPA’s ultimate action on the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

Pursuant to 40 CFR 93.104(e), within 2 years of the effective date of this document, NYMTC and the U.S. Department of Transportation will need to demonstrate conformity to the new budgets. For demonstrating conformity to the budgets in this plan, the on-road motor vehicle emissions from implementation of the long-range transportation plan should be projected consistently with the budgets in this plan.

**Authority:** 42 U.S.C. 7401–7671 q.

**Dated:** April 30, 2018.

Peter D. Lopez,
Regional Administrator, Region 2.

[FR Doc. 2018-12303 Filed 6–7–18; 8:45 am]

BILLING CODE 6560-50-P

Environmental Protection Agency

40 CFR Part 52

Adequacy Determination for the St. Louis Area 2008 8-Hour Ozone Redesignation Request and Maintenance State Implementation Plan, Motor Vehicle Emissions Budgets for Transportation Conformity Purposes; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of adequacy determination.

SUMMARY: In this document, the EPA is notifying the public that the St. Louis area 2008 8-hour ozone redesignation request and maintenance plan motor vehicle emission budgets (MVEBs) for volatile organic compounds (VOCs) and nitrogen oxides (NOx) are adequate for transportation conformity purposes. As a result, these budgets must be used by the State of Missouri for future transportation conformity determinations for the St. Louis area.

DATES: This finding is effective June 22, 2018.

FOR FURTHER INFORMATION CONTACT: Heather Hamilton, at (913) 551–7039, by email at Hamilton.heather@epa.gov, or by mail at U.S. Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

SUPPLEMENTARY INFORMATION: Throughout this document “we,” “us,” or “our” refer to EPA. The word “budget(s)” refers to the motor vehicle emission budgets (MVEBs) for volatile organic compounds and nitrogen oxides. For the purposes of this document, “SIP” refers to the St. Louis Area 2008 8-Hour Ozone Redesignation Request and Maintenance State Implementation Plan, submitted by Missouri Department of Natural Resources to EPA as a SIP revision on September 12, 2016. The Plan was revised on February 16, 2018.

This document is an announcement of a finding that EPA has already made. EPA Region 7 sent a letter to Missouri Department of Natural Resources on May 15, 2018, stating that the MVEBs contained in the Redesignation Request and Maintenance Plan are adequate for transportation conformity purposes. As a result of EPA’s finding, the State of Missouri must use the MVEBs from the February 16, 2018, Redesignation Request and Maintenance Plan for

...
future transportation conformity determinations for the St. Louis area. The finding is available at EPA’s conformity website: https://www.epa.gov/state-and-local-transportation.

Transportation conformity is required by section 176(c) of the Clean Air Act, as amended in 1990. EPA’s conformity rule requires that transportation plans, programs and projects conform to state air quality implementation plans and establishes the criteria and procedure for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP’s motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA’s completeness review, and it should not be used to prejudge EPA’s ultimate approval of the SIP. EPA plans to take action on the SIP at a later date. We have described our process for determining the adequacy of submitted SIP budgets in 40 CFR 93.118(f), and have followed this rule in making our adequacy determination.

Authority: 42 U.S.C. 7401–7671q.


James B. Gulliford,
Regional Administrator, Region 7.

[FR Doc. 2018–12388 Filed 6–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52, 62, and 70


State of Iowa: Approval and Promulgation of the State Implementation Plan, the 111(d) Plan and the Operating Permits Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Iowa State Implementation Plan (SIP), the 111(d) plan, and the Operating Permits Program. These revisions update and clarify rules and make minor revisions and corrections. Approval of these revisions will ensure consistency between the state and federally-approved rules, and ensure Federal enforceability of the state’s revised air program rules.

DATES: This final rule is effective on July 9, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2017–0470. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through https://www.regulations.gov or please contact the person identified in the FOR FURTHER INFORMATION CONTACT section for additional information.

FOR FURTHER INFORMATION CONTACT: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7039, or by email at hamilton.heather@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document “we,” “us,” and “our” refer to EPA. This section provides additional information by addressing the following:

I. Background
II. What is being addressed in this document?
III. Have the requirements for approval of the SIP, 111(d) Plan, and Operating Permit Plan Revisions been met?
IV. EPA’s Response to Comments
V. What action is EPA taking?
VI. Incorporation by Reference
VII. Statutory and Executive Order Reviews

I. Background

On September 15, 2017, EPA proposed to approve revisions to the Iowa State Implementation Plan (SIP), the 111(d) plan, and the Operating Permits Program. See 82 FR 43315. In conjunction with the September 15, 2017 notice of proposed rulemaking (NPR), EPA issued a direct final rule (DFR) approving revisions to the Iowa SIP, the 111(d) plan, and the Operating Permits Program. See 82 FR 43303. In the DFR, EPA stated that if adverse comments were submitted to EPA by October 16, 2017, the action would be withdrawn and not take effect.

EPA received three comments prior to the close of the comment period; one in support of the rule revisions and two of which were adverse. EPA withdrew the DFR on November 14, 2017. See 82 FR 52667. This action is a final rule based on the NPR. A detailed discussion of Iowa’s SIP revisions, the 111(d) plan revision, and the Operating Permits Program revisions were provided in the DFR and will not be restated here, except to the extent relevant to our response to the public comment we received.

II. What is being addressed in this document?

EPA is taking final action to approve revisions to the Iowa SIP, the 111(d) plan, and the Operating Permits Program. These revisions update and clarify rules and make minor revisions and corrections. Approval of these revisions will ensure consistency between the state and federally-approved rules, and ensure Federal enforceability of the state’s revised air program rules. Chapters with revisions are as follows:

• Chapter 20—Scope of Title-Definitions
• Chapter 21—Compliance
• Chapter 22—Controlling Pollution *
• Chapter 23—Emission Standards for Contaminants
• Chapter 25—Measurement of Emissions
• Chapter 26—Prevention of Emergency Pollution Episodes
• Chapter 27—Certificate of Acceptance
• Chapter 28—Ambient Air Quality Standards
• Chapter 31—Nonattainment Areas
• Chapter 33—Special Regulations and Construction Permit Requirements for Major Stationary Sources—Prevention of Significant Deterioration (PSD) of Air Quality
* Title V Operating Permit Program rules are included in chapter 22 starting at 22.100.

III. Have the requirements for approval of the SIP, 111(d) Plan, and Operating Permit Plan Revisions been met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the TSD which is part of this docket, these revisions meet the substantive SIP requirements of the CAA, including section 110 and implementing regulations. These revisions are also consistent with applicable EPA requirements of the 111(d) plan submission and Title V of the CAA and 40 CFR part 70.
IV. EPA’s Response to Comments

The public comment period for EPA’s proposed rule opened September 15, 2017, the date of its publication in the Federal Register, and closed on October 16, 2017. During this period, EPA received three comments; one in favor of the rule revision, and two with adverse comments.

Below are adverse comments from the first commenter with EPA’s responses:

First commenter, comment 1: The commenter stated that EPA must disapprove 567 Iowa Administrative Code (IAC) 22.1(2), “Exemptions” as applied to construction permits for existing stationary sources, because existing sources already subject to PSD cannot use a plantwide applicability limit (PAL) to avoid PSD requirements. The commenter also stated that EPA must disapprove this provision because it does not ensure that the minor sources exemptions will not cause or contribute to a violation of a NAAQS or increment.

EPA’s response: Under 40 CFR 52.21(aa)(1), existing major stationary sources may be issued an “actuals PAL”. As stated in the New Source Review (NSR) Reform Final Rule (67 FR 80185), sources subject to an actuals PAL that maintain their emissions below a plantwide actual emissions cap (that is, an actuals PAL), may use the PAL process instead of the major NSR permitting process when modifications are made to the facility or individual emissions units to determine PSD applicability. Iowa’s PAL program was approved by EPA on May 4, 2007. See 72 FR 27056.

While compliance with an actuals PAL may allow a source to avoid PSD applicability, it does not necessarily exempt a source from compliance with a state’s minor NSR program. Therefore, a source with an actuals PAL in Iowa may still need obtain a permit when there is a physical change or change in method of operation under Iowa’s minor NSR program in 567 IAC 22.1. The exclusion of PAL sources from the list of sources that cannot use the exemptions from 567 IAC 22.1 simply allows those PAL sources to use the same exemptions as other sources in order to avoid the permitting requirements of 567 IAC 22.1(1).

Furthermore, allowing PAL sources to use the exemptions in 567 IAC 22.1(2) does not require EPA to disapprove the SIP. The state performs technical reviews of construction permit exemptions to insure the minor sources will not cause or contribute to a violation of a NAAQS or increment. For example, on October 25, 2013, EPA approved a construction permit exemption for certain temporary diesel engines used in periodic testing and maintenance of natural gas pipelines in 567 IAC 22.1(2) paragraph “oo”. See 78 FR 63887. As demonstrated in the docket for that action, Iowa conducted an air quality assessment and determined that the exemption was appropriate and included conditions in the exemption that insured that the engine emissions would not exceed the emission limits allowed under the small unit exemption in 567 IAC 22.1(2), paragraph “w”. As an additional safeguard, 567 IAC 22.1(2) specifies that permitting exemptions do not relieve the owner or operator of any source from any obligations to comply with any other applicable requirements, including Title V requirements and PSD requirements.

First commenter, comment 2: The commenter stated that EPA must disapprove 567 IAC 22.1(3) (as applicable to construction permits for animal feeding operations) because it allows animal operations to be exempt from air pollution permitting, and because it only requires animal feeding operations to obtain a permit under Iowa’s chapter 65 regulations that do not approved into the SIP. Finally, the commenter stated that 567 IAC 22.1(3) illegally allows a source category to be exempt from air pollution regulation.

EPA’s response: The modification to 567 IAC 22.1(3) clarifies that a new or modified anaerobic lagoon for an animal feeding operation shall apply for a construction permit as provided in 567 IAC chapter 65. It does not exempt animal feeding operations from air pollution permitting, and solely applies to anaerobic lagoons at animal feeding operations.

On October 9, 2002, EPA approved modifications to 567 IAC 22.1(3), 567 IAC 22.1(3), paragraph “c”, subparagraph (3), and 567 IAC 22.3(2) to include new air construction permitting requirements for anaerobic lagoons at animal feeding operations. See 67 FR 62889. EPA notes that 567 IAC 22.1(3), paragraph “c”, which is enforceable by the state and EPA as it is approved as part of Iowa’s SIP, contains air construction permit requirements that specifically apply to persons constructing anaerobic lagoons at animal feeding operations. 567 IAC 22.1(3), which is also enforceable by the state and EPA as it is approved as part of Iowa’s SIP, also contains air construction permitting requirements for anaerobic lagoons at animal feeding operations. In addition, the EPA notes that anaerobic lagoons for animal feeding operations are not exempt from air construction permitting requirements under 567 IAC 22.1(2), which contains exemptions from air construction permitting requirements for certain sources.

Concerning the comment that Iowa’s Chapter 65 regulations are not approved as part of the SIP, the EPA notes that in its October 9, 2002 approval of the modifications to 567 IAC 22.1(3), 567 IAC 22.1(3), paragraph “c”, subparagraph (3), and 567 IAC 22.3(2), the EPA stated that chapter 65 requirements have not been requested by Iowa to be approved into the SIP because chapter 65 includes requirements (for example, odor controls) not pertaining to the requirements of section 110 of the CAA.

First commenter, comment 3: The commenter stated that EPA should make clear that the current New Source Performance Standards (NSPS) apply to sources in Iowa, even if the NSPS was subject to a legal challenge and even if Iowa has not adopted the current NSPS.

EPA’s response: While the state included revisions to its adoption of the NSPS in the submittal dated April 13, 2017, the state specifically requested that EPA not act on the revisions, and therefore this comment is outside of the scope of this action. The EPA notes that the NSPS is applicable to sources in Iowa regardless of whether Iowa has adopted the NSPS. Iowa adopts the NSPS in order to obtain concurrent enforcement authority of the NSPS with the EPA.

First commenter, comment 4: The commenter stated that 567 IAC 25.1(9), “Methods and Procedures” should be disapproved as the rule claims that the Department can authorize the use of alternative methodologies for testing and monitoring. The commenter further stated that the state does not have authority to alter stack test and monitoring methodologies for NSPS and NESHAP standards.

EPA’s response: 567 IAC 25.1, paragraph “[a]” was revised in order for the state rules to be consistent with the most current Federal rules. In addition to provisions within each NSPS and NESHAP that preserve EPA’s authority to approve certain alternative methodologies for testing and monitoring, EPA also retains this authority in accordance with sections 111(h)(3) and 112(e)(3) of the CAA, 40 CFR 60.8(b)(2) and (3), 61.14, and part 63, subpart E.

First commenter, comment 5: The commenter stated that EPA must disapprove 567 IAC 26.2(2) because it is missing PM2.5 thresholds for air
pollution alerts and air pollution warnings.

**EPA’s response:** Iowa revised 567 IAC 26.2 in order to be consistent with 40 CFR part 51, appendix L, which addresses example regulations for prevention of air pollution emergency episodes that would cause imminent and substantial endangerment to the health of persons. States are required under 40 CFR part 51, subpart H, to develop emergency contingency plans that are classified as Priority 1 regions where ambient concentrations of a pollutant exceed specific thresholds. In accordance with 40 CFR 51.151, each plan for a Priority 1 region must include a contingency plan that provides for taking action necessary to prevent ambient pollutant concentrations at any such area in the region from reaching a significant harm threshold.

To date, EPA has not promulgated a significant harm threshold for Priority 1 areas for PM$_{2.5}$. However, EPA has recommended PM$_{2.5}$ priority levels through guidance, and has recommended that states develop emergency episode contingency plans for any area that has monitored and recorded 24-hour PM$_{2.5}$ levels greater than 140.4 μg/m$^3$ since 2006. If a state has monitored and recorded PM$_{2.5}$ levels greater than 140.4 μg/m$^3$, the EPA also recommends that the state develop emergency action levels and a significant harm level for PM$_{2.5}$ in accordance with EPA guidance and consistent with the requirements of 40 CFR 51.150 through 51.153.

Because Iowa has not monitored and recorded 24-hour PM$_{2.5}$ levels greater than 140.4 μg/m$^3$ since 2006, Iowa is not required to develop an emergency action plan nor establish emergency action levels and a significant harm level for PM$_{2.5}$.

**First commenter, comment 6:** The commenter stated that EPA must disapprove paragraph 27.2(4)“c” as this paragraph implies that local air agencies have authority to grant variances for emission limits and other applicable requirements. In addition, the commenter stated that Iowa Code 455B–133, 134, and 143 must be disapproved due to director’s variance provisions.

**EPA’s response:** The EPA has interpreted this as a comment on EPA’s proposed approval of 567 IAC 27.3(4), paragraph “c”. The current local air pollution control agencies in Iowa do not have federally approved variance procedures. See 40 CFR 52.820(c).

**First commenter, comment 7:** The commenter stated that Iowa removed the title “Significant Impact Levels (SILs)” of the table in 567 IAC 33.3(20) but left the SILs in place. The commenter stated that removing the title does not fix the problem of SILs not being authorized by the Clean Air Act. The commenter stated that therefore the last sentence of 567 IAC 33.3(20) and the table must be disapproved and expressed further reasons to disapprove the SILs.

**EPA’s response:** As acknowledged by the commenter, the only change to the title in 567 IAC 33.3(20) was the removal of the title’s title. The title was removed by the state to be consistent with the text of 40 CFR 51.165(b)(2), which also does not have a title. Because the state only removed the title of the table, and did not otherwise revise the text or table of 567 IAC 33.3(20), the comments concerning the last sentence of the 567 IAC 33.3(2) and the table are outside the scope of this action. In addition, the referenced sentence and table are consistent with the text and table of 40 CFR 51.165(b)(2).

**First commenter, comment 8:** The commenter stated that EPA must disapprove 567 IAC 33.3(22) in its entirety as the Clean Air Act does not allow for the rescission of PSD permits.

**EPA’s response:** 40 CFR part 52 implements the PSD provisions of the CAA. PSD permits may be rescinded in accordance with 40 CFR 52.21(w).

**Second commenter:** A second commenter stated that EPA cannot rescind 567 IAC 21.1(4) unless the Clean Air Interstate Rule (CAIR) is removed from the Iowa SIP.

**EPA’s response:** 567 IAC 21.1(4) specifies emissions inventory requirements for Iowa’s implementation of CAIR. Iowa’s CAIR regulations are found in 567 IAC chapter 34 and remain a part of the approved SIP. The Federal CAIR regulations have been phased out and replaced by the Cross-State Air Pollution Rule (CSAPR). (See 76 FR 48208). Because the emissions inventory requirements of 567 IAC 21.1(4) were implemented in Iowa in order to comply with CAIR and are not relied upon for any other provision of Iowa’s SIP, and because CAIR has been replaced by the CSAPR, EPA is approving Iowa’s request to remove 567 IAC 21.1(4) from Iowa’s SIP.

**V. What action is EPA taking?**

EPA is taking final action to approve revisions to the Iowa State Implementation Plan, the 111(d) plan, and the Operating Permits Program. These revisions update and clarify rules and makes minor revisions and corrections. Approval of these revisions will ensure consistency between the state and federally-approved rules, and ensure Federal enforceability of the state’s revised air program rules.

**VI. Incorporation by Reference**

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Iowa Regulations described in the final amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 7 Office (please contact the person identified in the FOR FURTHER INFORMATION CONTACT section of this preamble for more information).

Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.

**VII. Statutory and Executive Order Reviews**

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.

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1 See EPA Memorandum entitled “Guidance on Sip Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle (PM$_{2.5}$) National Ambient Air Quality Standards (NAAQS), William T. Harrison, September 25, 2009.

2 62 FR 27968 (May 22, 1997).
• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
• Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 7, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects
40 CFR Part 52
Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone,
Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 62
Environmental protection, Air pollution control, Administrative practice and procedure, Reporting and recordkeeping requirements.

40 CFR Part 70
Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

James B. Gulliford,
Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR parts 52, 62, and 70 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart Q—Iowa


§ 52.820 Identification of plan. 
(c) * * *
## EPA-APPROVED IOWA REGULATIONS—Continued

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<td>In 22.1(3) the following sentence regarding electronic submission is not SIP approved. The sentence is: “Alternatively, the owner or operator may apply for a construction permit for a new or modified stationary source through the electronic submittal format specified by the department.”</td>
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EPA-APPROVED IOWA REGULATIONS—Continued

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<td>Special Construction Permit Requirements for Major Stationary Sources in Areas Designated Attainment or Unclassified (PSD).</td>
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<td>Provisions of the 2010 PM2.5 PSD—Increments, SIs and SMCs rule (published October 20, 2010) relating to SIs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved. Iowa’s rule incorporating EPA’s 2007 revision of the definition of “chemical processing plants” (the “Ethanol Rule,” (published May 1, 2007) or EPA’s 2008 “fugitive emissions rule,” (published December 19, 2008) are not SIP-approved.</td>
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PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

3. The authority citation for part 62 continues to read as follows:

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

Subpart Q—Iowa

4. Amend §62.3913 by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 62.3913 Identification of plan.

(d) Amended plan, submitted September 19, 2001. Clarifying revisions to the plan with regard to design capacity reports for control of air emissions from municipal solid waste landfills submitted by the Iowa Department of Natural Resources on September 19, 2001. The amended plan was effective February 11, 2002.

(e) Amended plan, submitted April 13, 2017. Grammatical revision to the plan for the control of air emissions from municipal solid waste landfills submitted by the Iowa Department of Natural Resources, on April 13, 2017. The state effective date of the revision was March 22, 2017. The effective date of the amended plan is August 7, 2018.

PART 70—STATE OPERATING PERMIT PROGRAMS

5. The authority citation for part 70 continues to read as follows:

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

6. Amend appendix A to part 70 by adding paragraph (r) under the heading “Iowa” to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

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(r) The Iowa Department of Natural Resources submitted for program approval revisions to rules 567–22.100, 567–22.103, 567–22.105, and 567–22.108. The state effective date was March 22, 2017. This revision is effective August 7, 2018.

[FR Doc. 2018–12166 Filed 6–7–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5524–F2]

RIN 0938–AT16

Medicare Program; Changes to the Comprehensive Care for Joint Replacement Payment Model (CJR): Extreme and Uncontrollable Circumstances Policy for the CJR Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes a policy that provides flexibility in the determination of episode spending for Comprehensive Care for Joint Replacement Payment Model (CJR) participant hospitals located in areas impacted by extreme and uncontrollable circumstances for performance years 3 through 5.

DATES: Effective July 9, 2018.

FOR FURTHER INFORMATION CONTACT: Heather Holsey, (410) 786–0028. For questions related to the CJR model:

CJR@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model: Extreme and Uncontrollable Circumstances Policy for the Comprehensive Care for Joint Replacement Payment Model final rule and interim final rule with comment period published on December 1, 2017 (82 FR 57066 through 57104), we issued an interim final rule with comment period in conjunction with the final rule in order to address the need for a policy to provide some flexibility in the determination of episode costs for providers located in areas impacted by extreme and uncontrollable circumstances. Specifically, we finalized an extreme and uncontrollable events policy for the performance years 2 through 5 reconciliation and sought comment on potential refinements we might make to this policy for future performance year reconciliations after performance year 2. The 30-day comment period for that rule closed on January 30, 2018. We received 3 comments on our comment solicitation on potential refinements we might make to the extreme and uncontrollable circumstances policy for future performance year reconciliations after performance year 2. Those 3 comments and our responses are discussed in the following paragraphs. We also received 4 comments that did not relate to the extreme and uncontrollable circumstances policy comment solicitation.

* * * * *
II. Provisions of the Interim Final Rule With Comment Period and Analysis of and Response to Public Comments

A. Overview and Background

In the interim final rule with comment period published on December 1, 2017, we established an extreme and uncontrollable circumstances policy for CJR performance years 2 through 5 to provide some flexibility in determining episode spending for CJR participant hospitals located in areas impacted by extreme and uncontrollable circumstances. While this policy most notably addressed Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires of August, September, and October 2017, we noted that this policy could also include other similar events that occur within a given performance year, including performance year 2, if those events meet the requirements we set forth in this policy. While Hurricane Maria, which also occurred in the same timeframe, had and, as of the writing of this final rule, continues to have a significant and crippling effect on Puerto Rico and the U.S. Virgin Islands, Hurricane Maria was not part of the interim final rule with comment period as the CJR model is not in operation in the areas impacted by Hurricane Maria, and, therefore there are no CJR participant hospitals that have been impacted by Hurricane Maria. Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires of August, September, and October of 2017 affected large regions of the United States where the CJR model operates, leading to widespread destruction of infrastructure that impacted residents’ ability to continue normal functions afterwards.

As we stated in the interim final rule with comment period, at least 101 CJR participant hospitals are located in the areas affected by Hurricane Irma and Hurricane Harvey, at least 22 CJR participant hospitals are located in areas impacted by the California wildfires and approximately 12 are in the areas affected by Hurricane Nate. Based on a review of news articles focusing on the hurricanes, at least 35 hospitals evacuated for Hurricane Irma and several hospitals evacuated at least partially for Hurricane Harvey. In Florida, at least two CJR participant hospitals in Miami, (Anne Bates Leach Eye Hospital and University of Miami Hospital) and one CJR participant hospital in Miami Beach—Mount Sinai Medical Center—had to close because of Hurricane Irma. Tampa General Hospital, a CJR participant hospital in Tampa, evacuated all patients except for those too ill to move. In response to Hurricane Irma, on September 9, 2017, Tampa Community Hospital, a CJR participant hospital, suspended all services and evacuated all patients to two other CJR participant hospitals, Brandon Regional Hospital and Medical Center of Trinity. In Texas, Baptist Beaumont Hospital, a CJR participant hospital in Beaumont, Texas, had to shut down and evacuate on August 31, 2017. On the same day, Christus Southeast Texas St. Elizabeth, another CJR participant hospital in Beaumont, Texas, left only the emergency and trauma center of the hospital open in order to ensure it had enough water for the patients still at the hospital. Patients seeking care at the Medical Center of Southeast Texas, a CJR participant hospital in Port Arthur, Texas, had to be taken by dump truck through the submerged hospital parking lot to the perimeter of the property, where a boat would take them to the hospital. An additional review of news related to California wildfires also shows that the fires caused various hospitals to evacuate patients. On November 16, 2017, five counties in Alabama were declared as major disaster areas due to the destruction of structures, power and bridges caused by Hurricane Nate. Although we did not yet have enough data to evaluate these event-specific effects on CJR episodes at the time of the publication of the interim final rule with comment period, we stated that we anticipated that at least some CJR participant hospitals might have experienced episode cost escalation as a result of hurricane or fire damage and subsequent emergency evacuations.

Under §510.305(e), as of performance year 2, CJR participant hospitals who have episode costs as calculated under §510.305(e)(1)(iii) (for example, episode costs that exceed the target price for the performance year) will owe CMS 5 percent of the loss. While the intent of this loss repayment policy is to incentivize providers to manage costs while improving the quality of CJR patient care, we noted in the interim final rule with comment period that in extreme and uncontrollable circumstances, prudent patient care management might involve potentially expensive air ambulance transport or prolonged inpatient stays when other alternatives are not practical due, for example, to state and local mandatory evacuation orders or compromised infrastructure. In addition to the news reports of disaster conditions that impacted several CJR participant hospitals, a number of research studies on natural disasters and rushed evacuations for hospitals supported our assumption that costs can rise during disaster situations.

Prior to January 1, 2018, the effective date of the interim final rule with comment period, CJR regulations at §510.210 did not allow cancellation of episodes for extreme and uncontrollable circumstances. The CJR regulations at §510.305 also did not permit an adjustment to account for episode spending that may have escalated significantly due to events driven by extreme and uncontrollable circumstances.

B. Identifying Participant Hospitals Affected by Extreme and Uncontrollable Circumstances

As discussed in the interim final rule with comment period, for purposes of developing a policy to identify hospitals affected by extreme and uncontrollable circumstances, we consulted section 1135 of the Social Security Act (the Act). That section allows the Secretary to temporarily waive or modify certain Medicare requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and emergency period. It also allows the Secretary to temporarily waive or modify certain Medicare requirements to ensure that providers who provide

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such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). The Secretary has invoked this authority in response to significant natural disasters such as Hurricane Katrina in 2005 and Superstorm Sandy in 2012. Though the section 1135 waiver authority enables us to take actions that give healthcare providers and suppliers greater flexibility, it does not allow for payment adjustment for participant hospitals in the CJR model. However, as we noted in the interim final rule with comment period, the extreme and uncontrollable circumstance policy should only apply when a disaster is widespread and extreme. A section 1135 waiver identifies the “emergency area” and “emergency period,” as defined in section 1135(g) of Act, for which waivers are available. As we stated in the interim final rule with comment period, we believe it is appropriate to establish an extreme and uncontrollable circumstance policy that applies only when and where the magnitude of the event calls for the use of special waiver authority to help providers respond to the emergency and continue providing care.

In the interim final rule with comment period, we noted that the extreme and uncontrollable circumstance policy also should be tailored to the specific areas experiencing the extreme and uncontrollable circumstance. Section 1135 waivers typically are authorized for a geographic area that may encompass a greater region (that is, an entire state) than is directly and immediately affected by the relevant emergency. In addition, section 1135(g) of the Act defines the emergency area as that area covered by both a Secretarial and a Presidential declaration; consequently, the scope of the emergency area is not entirely in the Secretary’s control. For purposes of this policy, we stated that a narrower geographic scope, rather than the full emergency area, would ensure that the payment policy adjustment is focused on the specific areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and is not applied to areas sustaining little or no adverse effects. Therefore, to narrow the scope of this policy to ensure it is applied to those providers most likely to have experienced the greatest adverse effects, we also required that the area be declared as a major disaster area under the Stafford Act. Once an area is declared as a major disaster area under the Stafford Act, the specific counties, municipalities, parishes, territories, and tribunals that are part of the major disaster area are identified and can be located on the Federal Emergency Management Agency (FEMA) website at www.FEMA.gov/disasters.

For this policy, only major disaster declarations under the Stafford Act in combination with issued section 1135 waivers are used to identify the specific counties, municipalities, parishes, territories, and tribunals where the extreme and uncontrollable circumstance took place. Using the major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy will apply only when the event is extreme, meriting the use of special authority, and targeting the specific area affected by the extreme and uncontrollable circumstance. As we noted in the interim final rule with comment period, we are not including emergency declarations under the Stafford Act or national emergency declarations under the National Emergencies Act in this policy, even if such a declaration serves as a basis for the Secretary’s invoking the section 1135 waiver authority. This is because we believe it is appropriate for our extreme and uncontrollable circumstance policy to apply only in the narrow circumstance where the circumstance constitutes a major disaster, which are more catastrophic in nature and tend to have significant impacts to infrastructure, rather than the broader grounds for which an emergency could be declared.

In the policy we established to define extreme and uncontrollable circumstances for the CJR model, an area is identified as having experienced ‘extreme and uncontrollable circumstances,’ if it is within an “emergency area” and “emergency period” as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act.

As we stated in the interim final rule with comment period, we believe Hurricanes Harvey, Irma, and Nate and the California wildfires in August, September, and October of 2017 triggered the automatic extreme and uncontrollable circumstance policy we adopted in the interim final rule with comment period. For the performance year 2 reconciliation conducted in March 2018, this extreme and uncontrollable circumstance policy applies to those CJR participant hospitals whose CMS Certification Number (CCN) has a primary address located in a state, U.S. territory, or tribal government that is within an “emergency area” and “emergency period,” as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act and that is designated in a major disaster declaration under the Stafford Act. The states and territories for which section 1135 waivers were issued in response to Hurricanes Harvey, Irma, Nate, and the California wildfires (during the fall of 2017) are Alabama, California, Florida, Georgia, South Carolina, Texas, Louisiana, and Mississippi. Section 1135 waivers also were issued for Puerto Rico and the Virgin Islands as a result of Hurricane Maria, but, as we noted in the interim final rule with comment period, there are no CJR participant hospitals with CCNs with a primary address in either of these areas. To view the 1135 waiver documents and for additional information on section 1135 waivers see: https://www.cms.gov/About-CMS/Agency-Information/ Emergency/. The major disaster declarations are located on FEMA website at https://www.fema.gov/disasters. When locating the counties, municipalities, parishes, tribunals, and territories for the major disaster declaration, FEMA designates these locations as ‘designated areas’ for that specific state, or tribal. All counties, municipalities, parishes, tribunals, and territories identified as designated areas on the disaster declaration are included.

The counties, parishes, and tribal governments that met the criteria for the CJR policy on extreme and uncontrollable circumstances in performance year 2 are as follows: 9

- The following counties in Alabama: Autauga, Baldwin, Choctaw, Clarke, Dallas, Macon, Mobile, and Washington.
- The following counties in California: Butte, Lake, Mendocino, Napa, Nevada, Orange, Sonoma, and Yuba. 11
- All 67 counties 12 and Big Cypress Indian Reservation, Brighton Indian Reservation, Fort Pierce Indian

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9 The Secretary issued Mississippi a waiver under section 1135 for Hurricane Nate. However the President did not issue a major disaster declaration (An emergency disaster declaration was issued,), so under this policy Mississippi is not included on this list.
10 https://www.fema.gov/disaster/4349/designated-areas.
11 https://www.fema.gov/disaster/4344/designated-areas.
12 https://www.fema.gov/disaster/4337/designated-areas.
Reservation, Hollywood Indian Reservation, Immokalee Indian Reservation, and Tampa Reservation in Florida.  
- All 159 counties in Georgia.  
- All 46 counties, and the Catawba Indian Reservation in South Carolina.  
Using these criteria, in the interim final rule with comment period, we stated that we were able to identify at least 101 CJR participant hospitals located in the areas affected by Hurricanes Harvey and Hurricane Irma, approximately 12 CJR participant hospitals in the areas affected by Hurricane Nate, and at least 22 CJR participant hospitals in areas impacted by the California wildfires. As there are no CJR model areas in Puerto Rico or the U.S. Virgin Islands, we again noted that no CJR participant hospitals were impacted by Hurricane Maria. CJR participant hospitals for whom this extreme and uncontrollable circumstances policy applies for performance year 2 (and subsequent performance years if and when the policy is invoked) receive notification via the initial reconciliation reports CMS delivers to providers upon completion of the reconciliation calculations, which under § 510.305(d) are initiated beginning 2 months after the close of the performance year.  
Though the Hurricanes and California wildfires were the driving force for developing the extreme and uncontrollable circumstance policy, in the interim final rule with comment period, we stated that this policy is being implemented for the duration of the CJR model, and that we are amending the CJR regulations accordingly, as further outlined later in this final rule.

C. Provisions for Adjusting Episode Spending Due to Extreme and Uncontrollable Circumstances

In the interim final rule with comment period, we noted that without a policy to provide CJR participant hospitals some flexibility in extreme and uncontrollable circumstances, we might inadvertently create an incentive to place cost considerations above patient safety, especially in the later years of the CJR model when the downside risk percentage increases. In considering policy alternatives to help ensure beneficiary protections by mitigating participant hospitals’ financial liability for costs resulting from extreme and uncontrollable circumstances, we considered and rejected a blanket cancellation of all episodes occurring during the relevant period. As we stated in the interim final rule with comment period, we do not believe that a blanket cancellation would be in either beneficiaries’ or CJR participant hospitals’ best interests, as it is possible that hospitals can manage costs and earn a reconciliation payment despite these extreme and uncontrollable circumstances.

Furthermore, we would not want CJR participant hospitals to limit case management services for beneficiaries in CJR episodes during extreme and uncontrollable circumstances, when prudent care management could potentially involve using significantly more expensive transport or care settings. Therefore, we determined that capping the actual episode spending at the target amounts for those episodes would be the best way to protect beneficiaries from potential care stunting and hospitals from escalating costs. As we stated in the interim final rule with comment period, this will also ensure that those hospitals that are still able to earn reconciliation payments on those eligible episodes where the disaster did not have a noticeable impact on cost.

In determining the start date of episodes to which this extreme and uncontrollable circumstances policy will apply, we determined that a window of 30 days prior to and including the date that the emergency period (as defined in section 1135(g) of the Act) begins should reasonably capture those beneficiaries whose high CJR episode costs could be attributed to extreme and uncontrollable circumstances. As we stated in the interim final rule with comment period, we believe this 30-day window is particularly appropriate due to the 90-day CJR model episode length. Including all episodes that begin within 30 days before the date the emergency period begins should enable us to include the majority of beneficiaries still in institutional settings and who are still within the first third of their episodes when the extreme and uncontrollable circumstance arises. We note that the average length of stay for DRG 469 is between 5 and 6 days and the average length of stay for DRG 470 is between 2 and 3 days (see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Payments/2018Hospital-Payment-Fcode-Table-5.zip).

Under § 510.300(a)(1), we differentiated fracture and non-fracture CJR episodes and pricing, noting that lower extremity joint replacement procedures performed as a result of a hip fracture are typically emergent procedures. Fracture episodes typically occur for beneficiaries with more complex health issues and can involve higher episode spending. As we stated in the interim final rule with comment period, we do not expect a high volume of CJR non-fracture episodes to be initiated once extreme and uncontrollable circumstances arise, given that it is not prudent to conduct non-fracture major joint replacement surgeries, which generally are elective and non-emergent, until conditions stabilize and infrastructure is reasonably restored. Therefore, for non-fracture episodes, the extreme and uncontrollable circumstances policy we established in the interim final rule with comment period only applies to dates of admission to anchor hospitalization that occur between 30 days before and up to the date on which the emergency period (as defined in section 1135(g) of the Act) begins. We believe this policy empowers hospitals to decide whether they can safely and appropriately perform non-fracture THA and TKA procedures after the commencement of the emergency period and whether or not performing these procedures would subject their organization to undue financial risk resulting from increased costs that are beyond the organization’s control.

However, for CJR fracture episodes, the extreme and uncontrollable circumstances policy we established in the interim final rule with comment period applies to dates of admission to the anchor hospitalization that occur within 30 days before, on, or up to 30 days after the date the emergency period (as defined in section 1135(g) of the Act) begins. As we stated in the interim final
rule with comment period, we recognize that fracture cases in CJR are often emergent and unplanned, and it may not be prudent to postpone major joint surgical procedures in many of those CJR fracture cases. Therefore, fracture episodes with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins are subject to this extreme and uncontrollable circumstances policy. As we stated in the interim final rule with comment period, for which the 30-day window before and after the emergency period should ensure that hospitals caring for CJR fracture patients during extreme and uncontrollable circumstances are adequately protected from episode costs beyond their control.

In the interim final rule with comment period, we established that, for performance years 2 through 5, for participant hospitals that are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act, and in a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, the following conditions apply. For a non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300. For a fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300. We codified this new extreme and uncontrollable circumstance policy at § 510.305(k). We sought comment on potential refinements to this policy for future performance year reconciliations after performance year 2.

Comment: All of the comments we received in response to our comment solicitation expressed support for an extreme and uncontrollable circumstances policy for the CJR model. All commenters supported the application of the policy to episodes with anchor stays beginning on or within 30 days before the date of the emergency period. A commenter supported the policy as established in the interim final rule with comment period and stated that it should apply to future performance years beyond performance year 2. Another commenter, who also supported the policy, noted that due to the substantial disruptions in the post-acute care market from significant infrastructure damage, the policy could be significantly improved if CMS capped payments for both fracture and non-fracture episodes with an anchor hospitalization within 30 days before or after the date that the emergency period begins. A different commenter, who also supported the policy, urged CMS to expand it to include more episodes by developing specific, recovery-focused criteria, such as the number of patients remaining displaced from their homes, the proportion of health care services remaining unavailable and distance to comparable services for rural areas to determine the end date for episodes.

Response: We appreciate the support expressed by commenters for our extreme and uncontrollable circumstances policy and agree with commenters that it is appropriate for the policy to cover both fracture and non-fracture episodes with anchor stays occurring on or within 30 days before the date of the emergency period. In response to the commenter who stated that our extreme and uncontrollable circumstances policy should apply to future performance years, we can confirm that it does. While we note that recovery efforts from major disasters can take extensive time and resources, as we stated in the interim final rule with comment period, we continue to believe that it is not prudent to conduct non-fracture major joint replacement surgeries, which generally are elective and non-emergent, until conditions stabilize and infrastructure is reasonably restored. Although we acknowledge that joint replacements can have a substantial impact on quality of life for beneficiaries, we are not persuaded by commenters that it is appropriate to extend the extreme and uncontrollable events policy to non-fracture CJR episodes beginning on or within the 30 days after the onset of an emergency period. If lasting infrastructure damage has severely crippled post-acute care access and limited offerings in a community, we are not convinced that elective surgeries should resume, especially for beneficiaries likely to need institutional post-acute care, until there is some assurance that that care will be available.

When we originally finalized the CJR target amounts in the November 24, 2015 final rule (80 FR 73273), we distinguished between hip fracture and non-fracture CJR episodes and pricing in response to comments. Commenters on that rule noted that lower extremity joint replacement procedures performed as a result of a hip fracture are typically emergent procedures (80 FR 73301), which can be more clinically complex in nature and more costly to treat due to their emergent nature. Therefore, as we stated in the interim final rule with comment period, given the frequent emergent nature of fractures, we acknowledge that it may not be prudent to postpone major joint surgical procedures in many of those CJR cases. Consequently, we believe it is appropriate, as was established in the interim final rule with comment period, to extend coverage under the extreme and uncontrollable circumstances policy to fracture cases occurring on or within 30 days after the date of the disaster, and we thank the commenters for their support of this policy that covers fracture cases on or within 30 days of the emergency period in the extreme and uncontrollable events policy.

In considering the commenter’s suggestion that we develop ongoing specific, recovery-focused criteria, such as the number of patients remaining displaced from their homes, the proportion of health care services remaining unavailable and distance to comparable services for rural areas to determine the end date for episodes we note that it would be extremely difficult to establish general criteria that would apply broadly to all emergency periods that might trigger the extreme and uncontrollable circumstances policy; this type of criteria would likely need to be specific to each individual emergency period and would therefore be more subjective and less predictable.
for providers in the CJR model. We believe the time-based criteria we established for this policy are more straightforward and create clear guidelines for CJR participant hospitals that may need an advanced, predictable understanding of which episodes will be subject to the extreme and uncontrollable circumstances policy. We established this policy to limit financial liability under the CJR model for participant hospitals caring for CJR fracture patients during extreme and uncontrollable circumstances where costs can escalate beyond their control. While we acknowledge that disaster recovery efforts can be prolonged beyond 30-day periods, we believe that care management planning is even more essential when communities are recovering from major disasters.

However, we do not believe that altering the post emergency window from 30 to 90 days, as suggested by a commenter, would be appropriate, as a longer post emergency window might incentivize providers to disengage from the care management the CJR model is focused on improving.

We note a technical correction to the preamble of the interim final rule with comment period. In several places we described our extreme and uncontrollable circumstances policy as applying when a major disaster declaration served as the condition precedent to an section 1135 waiver. However, this was incorrect, as in several of the events to which our policy applies, an emergency declaration under the Stafford Act was the condition precedent for the Secretary’s exercise of the section 1135 waiver authority. For example, the section 1135 waiver for Hurricane Nate was based on an emergency declaration under the Stafford Act, but a major disaster declaration under the Stafford Act subsequently was made. The regulation text at 42 CFR 510.35(k), which we are finalizing without modification, accurately reflects the policy.

III. Provisions of the Final Regulations

This final rule incorporates the provisions of the interim final rule with comment period without changes. Therefore, this extreme and uncontrollable circumstances policy, as codified at 42 CFR 510.35(k) will apply to CJR participant hospitals that are both located in an emergency area during an emergency period (as those terms are defined in section 1135(g) of the Act) for which the Secretary has issued a waiver under section 1135; and that are also located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

IV. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated cost burden associated with the information collection requirements in section V. (Regulatory Impact Statement) of this final rule.

V. Regulatory Impact Statement


Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will 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 an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2018, that threshold is approximately $150 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

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 regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this final rule is not a “significant regulatory action” and thus does not trigger the aforementioned requirements of Executive Order 13771.

In the December 1, 2017 interim final rule with comment period, we utilized 2016 CJR episode level data to approximate the impact to projected CJR model savings resulting from the extreme and uncontrollable circumstances policy for performance year 2 (82 FR 37096). Specifically, we first identified the CJR participant hospitals located in Alabama, California, Florida, Georgia, South Carolina, Mississippi, Texas, and Louisiana (those states for which 1135 waivers were issued) that were also located in the counties listed in section...
II.B. of this final rule and listed on www.FEMA.gov/disasters as having a major disaster declaration. To approximate the date of the emergency, we used the date of the disasters as listed on the FEMA website from 2017 (resetting the year to 2016 to align with the claim dates of service) and selected all CJR episodes for these providers that initiated in the month preceding (that is, 30 days prior) the date of the disaster. Date of disaster declaration dates were matched to the CJR participant hospitals based on the hospitals’ state addresses. For non-fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization was on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins. For fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization was on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins. Our analyses indicated that the impact of capping the actual episode payments at the episode target prices based on the 2017 extreme and uncontrollable circumstances policy could result in a decrease to the CJR model estimated savings ranging between $1.5 to $5.0 million for performance year 2, quantifying the dollar impact for that year based on a point estimate of $2 million. We also noted that this performance year 2 projected impact was mitigated by the 5 percent stop-loss/stop-gain levels applicable to performance year 2 and added that if these disasters had occurred in a future performance year with higher stop-loss/stop-gain levels then we would expect the projected impact to increase. The performance year 2 savings estimates did not assume any change in spending or volume due to these extreme and uncontrollable circumstances, neither before nor after the date of the disaster as listed on the FEMA website.

For purposes of assessing the impact of finalizing this policy for performance years 3 through 5, we note that we are unable to accurately or reasonably model an impact due to our inability to predict future disaster events. It is entirely possible future years could be completely free of major disasters and emergencies that might qualify as triggering events for the extreme and uncontrollable circumstances policy. Likewise, it is entirely possible that future years could have many more significant disaster events that might qualify as triggering events for the extreme and uncontrollable circumstances policy. In the absence of any future knowledge of potential disasters that might qualify as events that would invoke the extreme and uncontrollable circumstances policy, we are assuming that the performance year 2 extreme and uncontrollable circumstances $1.5 to $5 million range estimate, quantified using a 2 million dollar point estimate, can be extrapolated across the remaining 3 performance years of the CJR model since we modeled this using knowledge of actual 2017 events. Extrapolating the $2 million per year across performance years 3 through 5 results in an estimated cost of $6 million which could potentially net against savings predicted for the CJR model. We note that extrapolating the range estimate could make the impact of this policy for the remaining 3 years of the model as low as $4.5 million or as high as $15 million. However, we again reiterate that this assumption may be inaccurate as this $2 million per year figure was based on an estimate of known events in 2017 on modeled payments for performance year 2. Specifically, future years could be disaster free or could experience more frequent and destructive disasters, either of which could render this impact estimate incorrect. However, in absence of future knowledge we believe this extrapolation estimate can be used to approximate an impact for this extreme and uncontrollable circumstances policy for performance years 3 through 5 of the CJR model.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 510

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the interim final rule published in the December 1, 2017 Federal Register (82 FR 57066), is adopted as final without change.


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.


Alex M. Azar II,
Secretary, Department of Health and Human Services.

[FR Doc. 2018–12379 Filed 6–7–18; 8:45 am]
This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

[NRC–2018–0113]

Clarification of Export Reporting Requirements for Nuclear Facilities, Equipment, and Non-Nuclear Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory issue summary; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is seeking public comment on a draft regulatory issue summary (RIS) to clarify the reporting requirements for certain exports of nuclear facilities, equipment, and non-nuclear materials.

DATES: Submit comments by August 7, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

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

• Federal Rulemaking website: Go to http://www.regulations.gov and search for Docket ID NRC–2018–0113. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

• Mail comments to: May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.


SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0113 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:


• 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.

B. Submitting Comments

Please include Docket ID NRC–2018–0113 in your comment submission. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

The RIS is intended for all persons that are required to report exports of nuclear materials, equipment, and non-nuclear materials under part 110 of title 10 of the Code of Federal Regulations (10 CFR), “Export and Import of Nuclear Equipment and Material.” Specifically, the RIS is intended to clarify the reporting requirements under 10 CFR 110.54(a)(1). The regulation in 10 CFR 110.54(a)(1) states, in part, that licensees exporting nuclear facilities, equipment, and certain non-nuclear materials under a general or specific license during the previous quarter must submit reports by January 15, April 15, July 15, and October 15 of each year on DOC/NRC Forms AP–M or AP–13, and associated forms. The draft RIS includes information relating to this reporting requirement and clarifies that the quarterly reporting requirement is in addition to, and not obviated by, the separate NRC annual reporting requirement in 10 CFR 110.54(c).

The NRC issues RISs to communicate with stakeholders on a broad range of matters. This may include communicating and clarifying NRC technical or policy positions on regulatory matters that have not been communicated to, or are not broadly understood by, the nuclear industry. As noted in 83 FR 20858 (May 8, 2018), this document is being published in the Proposed Rules section of the Federal Register to comply with publication requirements under 1 CFR chapter I.

Proposed Action

The NRC is requesting public comments on the draft RIS. All comments that are to receive consideration in the final RIS must still be submitted electronically or in writing as indicated in the ADDRESSES section of this document. The NRC staff will make a final determination regarding issuance of the RIS after it considers any public comments received in response to this request.
## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**14 CFR Part 71**

[Docket No. FAA–2018–0437; Airspace Docket No. 18–ASO–5]

**RIN 2120–AA66**

**Proposed Establishment and Modification of Area Navigation Routes, Florida Metroplex Project; Southeastern United States**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish 16 high altitude area navigation (RNAV) routes (Q-routes), and modify 7 existing Q-routes, in support of the Florida Metroplex Project. The proposed routes were developed to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems that cause system inefficiencies due to their limitations.

**DATES:** Comments must be received on or before July 9, 2018.


**FOR FURTHER INFORMATION CONTACT:** Paul Gallant, Airspace Policy Group, Office of Airspace Services. Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

**Authority for This Rulemaking**

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of area navigation routes in the NAS, increase airspace capacity, and reduce complexity in high air traffic volume areas.

**Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers (FAA Docket No. FAA–2018–0437; Airspace Docket No. 18–ASO–5) and be submitted in triplicate to the Docket Management Facility (see ADDRESSES section for address and phone number). You may also submit comments through the internet at http://www.regulations.gov.

**Availability and Summary of Documents for Incorporation by Reference**

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this proposed rule. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**Background**

The Florida Metroplex Project developed Performance Based Navigation (PBN) routes involving Jacksonville Air Route Traffic Control Center (ARTCC), Miami ARTCC, and San Juan Center Radar Approach...
Control (CERAP). The proposed new and amended Q-routes would support the strategy to transition the NAS from a ground-based navigation and radar-based system to a satellite-based PBN system. Additionally, the routes would connect to Caribbean Air Traffic Service routes to provide efficient direct routings to and from Caribbean locations.

Taking advantage of the capabilities of the advanced flight management systems in modern aircraft, these Q-routes would serve to reduce air traffic control (ATC) sector complexity, increase NAS capacity, reduce pilot-to-air traffic controller communications, and allow aircraft to be cleared to their cruising altitude and flight planned route more expeditiously.

Comment Period

This NPRM includes a 30-day public comment period instead of the 45-day period generally provided for area navigation route proposals. The proposed Q-routes would support the FAA’s Next Generation Air Transportation System (NextGen) efforts to modernize the NAS. The routes would be a critical part of that effort to improve NAS efficiency by increasing airspace capacity and reducing complexity in high air traffic volume areas. The 30-day comment period would provide the opportunity for public input on the proposal as well as an option for FAA to consider the possibility of synchronizing the implementation of the routes with other scheduled NextGen programs and equipment upgrades.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to establish 16 new Q-routes, and amend 7 existing Q-routes, in the southeastern United States in support of the Florida Metropolex Project. The proposed new routes would be designated Q–75, Q–77, Q–79, Q–81, Q–83, Q–85, Q–87, Q–89, Q–93, Q–97, Q–99, Q–109, Q–113, Q–115, Q–135, Q–172, and Q–409. In addition, amendments are proposed to the descriptions of Q–65, Q–69, Q–103, Q–104, Q–110, Q–116, and Q–118. The proposed new and amended route end points are listed below. Full route descriptions are in “The Proposed Amendment” section of this notice.

The proposed new Q-routes are as follows:

Q–75: Q–75 would extend between the ENEME, GA, WP (in southeast GA) and the MCLAW, FL, WP (near the Florida Keys) and the Atlanta, GA, VORTAC. This would provide linkage to routes going to the Caribbean area.

Q–81: Q–81 would extend between the TUNSL, FL, WP (near the FL Keys) and the HONDID, GA, WP (in southwest GA).

Q–83: Q–83 would extend between the JEVED, GA, WP (off the southeast GA coast) and the SLOJO, SC, WP (in northern SC).

Q–85: Q–85 would extend between the LPERD, FL, WP (off the northeast FL coast) and the SMPRR, NC, WP (in southern NC).

Q–87: Q–87 would extend between the PEAKY, FL, WP (near Marathon, FL) and the LCAPE, SC, WP (near the SC–NC line).

Q–89: Q–89 would extend between the MANLE, FL, WP (off the central Florida coast) and the Atlanta, GA, VORTAC.

Q–92: Q–93 would extend between the MCLAW, FL, WP (near the Florida Keys) and the QUIWE, SC, WP (in southwest SC).

Q–97: Q–97 would extend between the TOVAR, FL, WP (along the southeast Florida coast) and the ELLDE, NC, WP (in southern NC).

Q–99: Q–99 would extend between the DOFFY, FL, WP (in northern Florida) and the POLYY, NC, WP (near the SC–NC line).

Q–109: Q–109 would extend between the DOFFY, FL, WP (in northern Florida) and the LAANA, NC, WP (in southern NC).

Q–110: Q–113 would extend between the RAYCO, SC, WP (in east central SC) and the SARKY, SC, WP (near the SC–NC line).

Q–135: Q–135 would extend between the JROSS, SC, WP (north of Beaufort, SC) and the RAPZZ, NC, WP (in southern NC).

Q–172: Q–172 would extend between the YUTEE, SC, WP (in western SC) and the RAPZZ, NC, WP (in southern NC).

Q–409: Q–409 would extend between the ENMEME, GA, WP (in southeast GA) and the MRPIT, NC, WP (in southern NC).

The proposed amended Q-routes are as follows:


Q–69: Q–69 currently extends between the BLAAN, SC, WP and the RICCS, WV, WP. The route would be extended approximately 210 NM to the south of the BLAAN, SC, WP to the VIYAP, GA, Fix (located near Brunswick, GA). The extended route segments would consist of the VIYAP, GA, fix; OLBEC, GA, WP; ISUZO, GA, WP; and the GURGE, SC, WP. The EMGET, SC, WP would be inserted between the BLAAN, SC, WP and the RYCKI, NC, WP.

Q–103: Q–103 currently extends between the Pulaski, VA, VORTAC and the ABRA, PA, WP. The route would be extended to the south of the Pulaski, VA, VORTAC to the CYNTA, GA, WP (in southeastern GA). The extended segments would consist of the CYNTA, GA, WP; PUPPY, GA, WP; RIELE, SC, WP; EMCET, SC, WP; and the SLOJO, SC, WP.

Q–104: Q–104 currently extends between the DEFUN, FL, fix, and the Cypress, FL, VOR/DME. The route would be amended by removing the DEFUN, FL, fix; and the Cypress, FL, VOR/DME from the route. The ACORI, AL, WP, and the CABLO, GA, WP, would be added prior to the HEVYN, FL, fix. The ENDEW, FL, WP would be added between the SWABE, FL, fix and the St. Petersburg, FL, VORTAC.

Q–110: Q–110 currently extends between the BLANS, IL, WP, and the THNDR, FL, Fix. The amended route would be the same as currently charted between the BLANS, IL, WP and the JYROD, AL, WP. Beyond that point, the route would be realigned to terminate at the new OCTAL, FL, WP (on the southeast FL coast). The FEONA, GA; GULFR, FL; BRUTS, FL; KPASA, FL; RVERO, FL, WP’s, and the THNDR, FL, fix, would be removed. The DAWWN, GA; JOKKY, FL; AMORY, FL; SMELZ, FL; and SHEEK, FL waypoints would be inserted between the JYROD, AL, WP and the JAYMC, FL, WP. After JAYMC, the route would proceed to the OCTAL, FL, WP.

Q–116: Q–116 currently extends between the KPASA, FL, WP, and the CEEYA, GA, WP. The current KPASA, FL; BRUTS, FL; GULFR, FL; and CEEYA, GA, waypoints would be removed. The route would be expanded and realigned to extend between the Vulcan, AL, VORTAC and the OCTAL, FL, WP (on the southeast FL coast). The following waypoints would be added between the Vulcan, AL, VORTAC and the OCTAL, FL, WP: DEEDA, GA; JAWJA, FL; MICES, FL; PATOY, FL;
SMELZ, FL; SHEEK, FL; and JAYMC, FL.

Q–118: Q–118 currently extends between the Marion, IN, VOR/DME and the KPASA, FL, WP. The amended route would add the Atlanta, GA, VORTAC between the KAILL, GA, WP and the JOHNN, GA, WP; add the JAMIZ, FL, WP between the JOHNN, GA, and BRUTS, FL, WPs; and add the JINOS, FL, WP between the BRUTS, FL, WP and the PEAKY, FL, WP. The route be extended to the south of the KPASA, FL, WP to the PEAKY, FL, WP (near Marathon in the Florida Keys). The SHEEK, FL, WP; CHRRI, FL, fix; FEMID, FL, WP and BRIES, FL, WP would be added between the KPASA, FL, WP and the PEAKY, FL, WP. Q–118 would provide linkage to routes from the Caribbean area.

Note: In the regulatory text, below, some route descriptions include waypoints located over international waters. In those route descriptions, in place of a two-letter state abbreviation, either “OA,” meaning “Offshore Atlantic,” or “OG,” meaning “Offshore Gulf of Mexico,” is used.

RNAV routes are published in paragraph 2006 of FAA Order 7400.11B dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document would be subsequently published in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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


§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, is amended as follows:


* * * * *
HONID, GA
Q-83 JEVED, GA to SLOJO, SC [New]
JEVED, GA
ROYCO, GA
TAALN, GA
KONEY, SC
WURLF, SC
EFFAY, SC
SLOJO, SC

Q-85 LPERD, FL to SMPRK, NC [New]
LPERD, FL
GIPPL, GA
ROYCO, GA
IGARY, SC
PELIE, SC
BUMMA, SC
SMPRK, NC

Q-87 PEAKY, FL to LCAPE, SC [New]
PEAKY, FL
COPEY, FL
GRIDS, FL
TRICO, FL
MATLK, FL
ONEWY, FL
ZERFO, FL
DEUCEN, FL
FEMON, FL
VIYAP, GA
TAAHN, CA
JROSS, SC
RAYVO, SC
HINTZ, SC
REDPH, SC
LCAPE, SC

Q-89 MANLE, FL to Atlanta, GA (ATL) [New]
MANLE, FL
WAKUP, FL
PRMUS, FL
YANTI, GA
Atlanta, GA (ATL) VORTAC

Q-93 MCLAW, FL to QUIWE, SC [New]
MCLAW, FL
VAULT, FL
LINEY, FL
FORIN, FL
EBAYY, FL
MALET, FL
DEHRL, FL
KENLI, FL
PRMUS, FL
WOPN, OA
GIPPL, GA
ISUZO, GA
FISHO, SC
QUIWE, SC

Q-97 TOVAR, FL to ELLDE, NC [New]
TOVAR, FL
EBAYY, FL
MALET, FL
DEHRL, FL
KENLI, FL
PRMUS, FL
WOPN, OA
JEVED, GA
Caket, SC
ELMSZ, SC
YURCK, NC
ELLDE, NC

Q99 DOFFY, FL to POLYY, NC [New]
DOFFY, FL
CAMJO, FL
HEPAR, GA
TREEM, GA
HLAAN, SC
BWAGS, SC
EFFAY, SC
WNGUI, SC
POLYY, NC

Q-109 DOFFY, FL to LAAN, NC [New]
Q–113 RAYVO, SC to SARKY, SC [New]

RAYVO, SC WP (Lat. 33°38’44.12” N, long. 080°04’00.84” W)

CEELY, SC WP (Lat. 34°12’54.72” N, long. 079°27’57.01” W)

SARKY, SC WP (Lat. 34°25’41.43” N, long. 079°14’17.50” W)

Q–135 JROSS, SC to RAPZZ, NC [New]

JROSS, SC WP (Lat. 32°42’40.00” N, long. 080°37’38.00” W)

PELIE, SC WP (Lat. 31°21’23.88” N, long. 079°44’43.43” W)

ELMSZ, SC WP (Lat. 31°40’36.61” N, long. 079°17’59.56” W)

RAPZZ, NC WP (Lat. 34°15’03.34” N, long. 078°29’17.58” W)

Q–172 YUTEE, SC to RAPZZ, NC [New]

YUTEE, SC WP (Lat. 33°47’28.54” N, long. 081°33’19.15” W)

BWAGS, SC WP (Lat. 34°08’03.77” N, long. 080°45’12.36” W)

HINTZ, SC WP (Lat. 34°10’11.02” N, long. 079°44’48.12” W)

CEELY, SC WP (Lat. 34°12’54.72” N, long. 079°27’57.01” W)

OKNEE, SC WP (Lat. 34°15’39.92” N, long. 078°59’42.38” W)

RAPZZ, NC WP (Lat. 34°15’03.34” N, long. 078°29’17.58” W)

Q–409 ENEME, GA to MRPIT, NC [New]

ENEME, GA WP (Lat. 30°42’12.09” N, long. 082°26’09.31” W)

PUPPY, GA WP (Lat. 31°24’35.58” N, long. 081°49’06.19” W)

ISUZO, GA WP (Lat. 31°57’47.85” N, long. 081°14’44.79” W)

KONITY, NC WP (Lat. 32°17’01.62” N, long. 080°01’23.79” W)

JROSS, NC WP (Lat. 32°42’40.00” N, long. 080°37’38.00” W)

SUESU, GA WP (Lat. 31°52’02.58” N, long. 079°33’51.88” W)

OKNEE, SC WP (Lat. 34°15’39.92” N, long. 078°10’40.68” W)

MRPIT, NC WP (Lat. 34°26’05.99” N, long. 079°01’45.10” W)

Q–65 KPSASA, FL to Rosewood, OH (ROD) [Amended]

KPASA, FL WP (Lat. 28°10’34.00” N, long. 081°54’27.00” W)

DOFFY, FL WP (Lat. 29°15’22.73” N, long. 082°31’38.10” W)

FETAL, FL WP (Lat. 30°30’32.00” N, long. 082°41’11.00” W)

ENEME, GA WP (Lat. 30°42’12.09” N, long. 082°26’09.31” W)

JEOPI, GA WP (Lat. 31°35’37.02” N, long. 082°31’18.38” W)

TRASY, GA WP (Lat. 31°55’25.92” N, long. 082°35’50.51” W)

CESKI, GA WP (Lat. 32°16’21.27” N, long. 082°40’38.96” W)

DAREE, GA WP (Lat. 34°37’35.72” N, long. 083°51’35.03” W)

LORNN, TN WP (Lat. 35°21’16.33” N, long. 084°14’19.35” W)

SOGE, TN WP (Lat. 36°31’50.64” N, long. 084°11’35.39” W)

ENGRA, KY WP (Lat. 37°29’02.34” N, long. 084°15’02.15” W)

OCASE, KY WP (Lat. 38°23’59.05” N, long. 084°11’03.22” W)

Rosewood, OH (ROD) VORTAC (Lat. 40°17’16.08” N, long. 084°02’35.15” W)

Q–69 VIYAP, GA to RICCS, WV [Amended]

VIYAP, GA FIX (Lat. 31°15’08.15” N, long. 081°26’08.18” W)

OLBEC, GA WP (Lat. 31°28’32.85” N, long. 081°26’17.61” W)

ISUZO, GA WP (Lat. 31°57’47.85” N, long. 081°14’44.79” W)

CURGE, SC WP (Lat. 32°29’02.26” N, long. 081°12’41.48” W)

HLAAN, NC WP (Lat. 33°51’09.38” N, long. 080°53’32.78” W)

EMCET, SC WP (Lat. 34°09’41.99” N, long. 080°50’12.51” W)

RYCKI, NC WP (Lat. 36°24’43.05” N, long. 080°25’07.50” W)

LUNDD, VA WP (Lat. 36°44’22.38” N, long. 080°21’07.41” W)

ILLSA, VA WP (Lat. 37°38’55.85” N, long. 080°11’38.44” W)

EWESS, WV WP (Lat. 38°21’50.31” N, long. 080°06’52.03” W)

RICKS, WV WP (Lat. 38°55’14.65” N, long. 080°05’01.68” W)

Q–103 CYNTA, GA to AIRRA, PA [Amended]

CYNTA, GA WP (Lat. 30°36’27.06” N, long. 082°05’35.45” W)

PUPPY, GA WP (Lat. 31°24’35.58” N, long. 081°49’06.19” W)

RILEE, SC WP (Lat. 32°37’27.14” N, long. 081°23’34.97” W)

EMCET, SC WP (Lat. 34°09’41.99” N, long. 080°50’12.51” W)

SLOJO, SC WP (Lat. 34°38’46.31” N, long. 080°39’25.63” W)

Pulaski, VA (PSK) VORTAC (Lat. 37°05’15.74” N, long. 080°42’46.44” W)

ASBURI, WV FIX (Lat. 37°49’24.41” N, long. 080°27’51.44” W)

OAKLE, WV FIX (Lat. 38°07’13.80” N, long. 080°21’44.84” W)

PERRI, WV FIX (Lat. 38°17’50.49” N, long. 080°18’05.11” W)

PERKS, WV FIX (Lat. 38°39’40.84” N, long. 080°10’29.36” W)

RICCS, WV WP (Lat. 38°55’14.65” N, long. 080°05’01.68” W)

EMNEM, WV WP (Lat. 39°31’27.12” N, long. 080°04’28.21” W)

AIRRA, PA WP (Lat. 41°06’16.48” N, long. 080°03’48.73” W)

Q–104 ACORI, AL to St. Petersburg, FL (PIE) [Amended]

ACORI, AL WP (Lat. 31°46’23.36” N, long. 085°51’29.51” W)

CABLO, GA WP (Lat. 30°46’29.00” N, long. 084°50’24.00” W)
ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of March 26, 2018. In the ANPRM, FDA requested comments, data, research results, or other information that may inform regulatory actions FDA might take with respect to premium cigars. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ANPRM published on March 26, 2018 (83 FR 12901). Submit either electronic or written comments by July 25, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 25, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 25, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- **For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”**

Instructions: All submissions received must include the Docket No. FDA–2017–N–6107 for “Regulation of Premium Cigars.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Deidre Jurand or Nate Mease, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1–877–287–1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 26, 2018, FDA published an ANPRM with a 90-day comment period to obtain information related to the regulation of premium cigars under the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, and regulations regarding the sale and distribution of tobacco products. FDA is seeking comments, data, research results, or other information that may inform regulatory actions FDA might take with respect to premium cigars. Specifically, FDA is seeking information related to the following topics: Definition of premium cigars, use patterns of premium cigars, and public health considerations associated with premium cigars.

The Agency has received requests for a 90-day extension of the comment period for the ANPRM. FDA has considered the requests and is extending the comment period for the ANPRM for 30 days, until July 25, 2018. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action on these important issues.

Dated: June 5, 2018.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–12367 Filed 6–7–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2017–N–6565]

RIN 0910–AH60

Regulation of Flavors in Tobacco Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of March 21, 2018. In the ANPRM, FDA requested information related to the role that flavors play in tobacco products. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ANPRM published on March 21, 2018 (83 FR 12294). Submit either electronic or written comments by July 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 19, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:
- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–6565 for “Regulation of Flavors in Tobacco Products.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, 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: Laura Rich or Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1–877–287–1373, AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 21, 2018, FDA published an ANPRM with a 90-day comment period to obtain information related to the role that flavors play in tobacco products. Specifically, the ANPRM is seeking comments, data, research results, or other information about, among other things, how flavors attract youth to tobacco products.

The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments. DATES: FDA is extending the comment period on the ANPRM published on March 16, 2018 (83 FR 11818). Submit either electronic or written comments by July 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service is extending the comment period for the ANPRM for 30 days, until July 19, 2018. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action on these important issues.

Dated: June 5, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–12369 Filed 6–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1130

[Docket No. FDA–2017–N–6189]

RIN 0910–AH86

Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the advance notice of proposed rulemaking (ANPRM) that appeared in the Federal Register of March 16, 2018. In the ANPRM, FDA requested information for consideration in developing a tobacco product standard to set a maximum nicotine level in combusted cigarettes so that they are minimally addictive or nonaddictive. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the ANPRM published on March 16, 2018 (83 FR 11818). Submit either electronic or written comments by July 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 16, 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 in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–6189 for “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT Contains CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts.

FOR FURTHER INFORMATION CONTACT:
Gerie Voss, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1–877–CTP–1373, AskCTP@fda.hhs.gov.
SUPPLEMENTARY INFORMATION: In the Federal Register of March 16, 2018, FDA published an ANPRM with a 90-day comment period to obtain information for consideration in developing a tobacco product standard to set a maximum nicotine level in combusted cigarettes.

The Agency has received a number of requests for a 90-day extension of the comment period for the ANPRM and one request for a 120-day extension. FDA has considered the requests and is extending the comment period for the ANPRM for an additional 30 days, until July 16, 2018. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential regulatory action on these important issues.

Dated: June 5, 2018.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–12368 Filed 6–7–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR
National Indian Gaming Commission
25 CFR Part 543
Minimum Internal Control Standards
AGENCY: National Indian Gaming Commission, Department of the Interior.
ACTION: Notice of proposed rulemaking.
SUMMARY: The National Indian Gaming Commission (NIGC) proposes to amend its minimum internal control standards for Class II gaming under the Indian Gaming Regulatory Act to correct an erroneous deletion of the key control standards and to make other minor edits and additions for clarity.
DATES: Written comments on this proposed rule must be received on or before July 9, 2018.
ADDRESSES: You may submit comments by any one of the following methods, however, please note that comments sent by electronic mail are strongly encouraged.
• Email comments to: 543_comments@nigc.gov.
• Mail comments to: National Indian Gaming Commission, 1849 C Street NW, MS 1621, Washington, DC 20240.
• Fax comments to: National Indian Gaming Commission at 202–632–0045.

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

SUPPLEMENTARY INFORMATION:
I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25
The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandates Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

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

Civil Justice Reform

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

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, et seq., and assigned OMB Control Number 3141-0009. The OMB control number expires on November 30, 2018.

Tribal Consultation

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

The key control language proposed here is the most substantive of all the changes and was the subject of extensive consultation in 2012 (77 FR 58708). The language proposed here has not changed since initially adopted. It was inadvertently written over with the addition of kiosk controls in 2013. The remaining changes are all technical in nature, correcting numbering and adding minor clarifications.

List of Subjects in 25 CFR Part 543

Accounting, Administrative practice and procedure, Gambling, Indian—tribal consultation policy, Gaming on Indian lands, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Commission proposes to amend 25 CFR part 543 as follows:

PART 543—MINIMUM INTERNAL CONTROL STANDARDS FOR CLASS II GAMING

I. Authority


II. Development of the Rule

On September 21, 2012, the Commission concluded nearly two years of consultation and drafting with the publication of comprehensive amendments, additions, and updates to Part 543, the minimum internal control standards (MICS) for Class II gaming operations (77 FR 58708). The regulations require tribes to establish controls and implement procedures at least as stringent as those described in Part 543. The key control language proposed here is the most substantive of all the changes and was the subject of extensive consultation in 2012 (77 FR 58708). The language proposed here has not changed since initially adopted. It was inadvertently written over with the addition of kiosk controls in 2013. The remaining changes are all technical in nature, correcting numbering and adding minor clarifications.

List of Subjects in 25 CFR Part 543

Accounting, Administrative practice and procedure, Gambling, Indian—Indian Tribal Consultation, Gaming on Indian lands, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Commission proposes to amend 25 CFR part 543 as follows:

PART 543—MINIMUM INTERNAL CONTROL STANDARDS FOR CLASS II GAMING

1. The authority for part 543 continues to read as follows:


2. Amend §543.10 by revising paragraph (e) to read as follows:

§543.10 What are the minimum internal control standards for card games?

(e) Standards for reconciliation of card room bank. Two agents—one of whom must be a supervisory agent—must independently count the main card room bank and table inventory at the end of each shift and record the following information:

1. Date;
2. Shift;
3. Table number (if applicable);
4. Amount by denomination;
5. Amount in total; and
6. Signatures of both agents.

3. Amend §543.17 by revising paragraphs (d), (i)(4)(i), and (j) to read as follows:

§543.17 What are the minimum internal control standards for drop and count?

* * * * *

The rule was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (“NIGC” or “Commission”) and set out a comprehensive framework for the regulation of gaming on Indian lands. On January 5, 1999, the NIGC published a final rule in the Federal Register called Minimum Internal Control Standards. 64 FR 590. The rule added a new part to the Commission’s regulations establishing Minimum Internal Control Standards (MICS) to reduce the risk of loss because of customer or employee access to cash and cash equivalents within a casino. The rule contains standards and procedures that govern cash handling, documentation, game integrity, auditing, surveillance, and variances, as well as other areas.

The Commission recognized from their inception that the MICS would require periodic review and updates to keep pace with technology and has substantially amended them numerous times, most recently in late 2013 (78 FR 63873).

II. Development of the Rule

On September 21, 2012, the Commission concluded nearly two years of consultation and drafting with the publication of comprehensive amendments, additions, and updates to Part 543, the minimum internal control standards (MICS) for Class II gaming operations (77 FR 58708). The regulations require tribes to establish controls and implement procedures at least as stringent as those described in this part to maintain the integrity of the gaming operation. In late 2013, the Commission published a new rule, adding kiosk drop, count, fill, and surveillance standards to Part 543 (78 FR 63873).

Now, the Commission proposes additional revisions, largely technical in nature, that are meant to correct earlier editing oversights and to better clarify the intent of the provisions.

III. Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandates Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

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

Civil Justice Reform

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

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, et seq.

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by 44 U.S.C. 3501, et seq., and assigned OMB Control Number 3141–0009. The OMB control number expires on November 30, 2018.

Tribal Consultation

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

The key control language proposed here is the most substantive of all the changes and was the subject of extensive consultation in 2012 (77 FR 58708). The language proposed here has not changed since initially adopted. It was inadvertently written over with the addition of kiosk controls in 2013. The remaining changes are all technical in nature, correcting numbering and adding minor clarifications.

List of Subjects in 25 CFR Part 543

Accounting, Administrative practice and procedure, Gambling, Indian—Indian Tribal Consultation, Gaming on Indian lands, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Commission proposes to amend 25 CFR part 543 as follows:

PART 543—MINIMUM INTERNAL CONTROL STANDARDS FOR CLASS II GAMING

1. The authority for part 543 continues to read as follows:


2. Amend §543.10 by revising paragraph (e) to read as follows:

§543.10 What are the minimum internal control standards for card games?

(e) Standards for reconciliation of card room bank. Two agents—one of whom must be a supervisory agent—must independently count the main card room bank and table inventory at the end of each shift and record the following information:

1. Date;
2. Shift;
3. Table number (if applicable);
4. Amount by denomination;
5. Amount in total; and
6. Signatures of both agents.

3. Amend §543.17 by revising paragraphs (d), (i)(4)(i), and (j) to read as follows:

§543.17 What are the minimum internal control standards for drop and count?

* * * * *
(d) Card game drop standards. Controls must be established and procedures implemented to ensure security of the drop process. Such controls must include the following:

(1) Surveillance must be notified when the drop is to begin so that surveillance may monitor the activities.

(2) At least two agents must be involved in the removal of the drop box, at least one of whom is independent of the card games department.

(3) Once the drop is started, it must continue until finished.

(4) All drop boxes may be removed only at the time previously designated by the gaming operation and reported to the TGRA. If an emergency drop is required, surveillance must be notified before the drop is conducted and the TGRA must be informed within a timeframe approved by the TGRA.

(5) At the end of each shift:
   (i) All locked card game drop boxes must be removed from the tables by an agent independent of the card game shift being dropped;
   (ii) For any tables opened during the shift, a separate drop box must be placed on each table, or a gaming operation may utilize a single drop box with separate openings and compartments for each shift; and
   (iii) Card game drop boxes must be transported directly to the count room or other equivalently secure area by a minimum of two agents, at least one of whom is independent of the card game shift being dropped, until the count takes place.

(6) All tables that were not open during a shift and therefore not part of the drop must be documented.

(7) All card game drop boxes must be posted with a number corresponding to a permanent number on the gaming table and marked to indicate game, table number, and shift, if applicable.

* * * * *

(i) The count of each box must be recorded in ink or other permanent form of recordation.

* * * * *

(j) Controlled keys. Controls must be established and procedures implemented to safeguard the use, access, and security of keys in accordance with the following:

(1) Each of the following requires a separate and unique key lock or alternative secure access method:
   (i) Drop cabinet;
   (ii) Drop box release;
   (iii) Drop box content; and
   (iv) Storage racks and carts used for the drop.

(2) Access to and return of keys or equivalents must be documented with the date, time, and signature or other unique identifier of the agent accessing or returning the key(s).

(i) For Tier A and B operations, at least two (2) drop team agents are required to be present to access and return keys. For Tier C operations, at least three (3) drop team agents are required to be present to access and return keys.

(ii) For Tier A and B operations, at least two (2) count team agents are required to be present at the time count room and other count keys are issued for the count. For Tier C operations, at least three (two for card game drop box keys in operations with three tables or fewer) count team agents are required to be present at the time count room and other count keys are issued for the count.

(3) Documentation of all keys, including duplicates, must be maintained, including:
   (i) Unique identifier for each individual key;
   (ii) Key storage location;
   (iii) Number of keys made, duplicated, and destroyed; and
   (iv) Authorization and access.

(4) Custody of all keys involved in the drop and count must be maintained by a department independent of the count and the drop agents as well as those departments being dropped and counted.

(5) Other than the count team, no agent may have access to the drop box content keys while in possession of storage rack keys and/or release keys. Other than the count team, only agents authorized to remove drop boxes are allowed access to drop box release keys.

(6) The use of keys at times other than the scheduled drop and count must be properly authorized and documented.

(8) Emergency manual keys, such as an override key, for computerized, electronic, and alternative key systems must be maintained in accordance with the following:

   (i) Access to the emergency manual key(s) used to access the box containing the player interface drop and count keys requires the physical involvement of at least three agents from separate departments, including management. The date, time, and reason for access, must be documented with the signatures of all participating persons signing out/in the emergency manual key(s);

   (ii) The custody of the emergency manual keys requires the presence of two agents from separate departments from the time of their issuance until the time of their return; and

(iii) Routine physical maintenance that requires access to the emergency manual key(s), and does not involve accessing the player interface drop and count keys, only requires the presence of two agents from separate departments. The date, time, and reason for access must be documented with the signatures of all participating agents signing out/in the emergency manual key(s).

(9) Controls must be established and procedures implemented to safeguard the use, access, and security of keys for kiosks.

* * * * *

4. Amend §543.18 by revising paragraph (d)(6)(v) to read as follows:

§543.18 What are the minimum internal control standards for the cage, vault, kiosk, cash and cash equivalents?

* * * * *

(d) * * *

(v) Dollar amount per financial instrument redeemed;

* * * * *

5. Amend 543.23 by revising paragraph (c)(1)(viii) to read as follows:

§543.23 What are the minimum internal control standards for audit and accounting?

* * * * *

(c) * * *

(viii) Drop and count standards, including supervision, count room access, count team, card game drop standards, player interface financial instrument drop standards, card game count standards, player interface financial instrument count standards, collecting currency cassettes and financial instrument storage components from kiosks, kiosk count standards, and controlled keys;

* * * * *

6. Amend 543.24 by revising paragraphs (a) and (d)(5) to read as follows:

§543.24 What are the minimum internal control standards for auditing revenue?

(a) Supervision. Supervision must be provided as needed for revenue audit by an agent(s) with authority equal to or greater than those being supervised.

* * * * *

(d) * * *

(5) Complimentary services or items. At least monthly, review the reports required in §543.13(c). These reports must be made available to those entities authorized by the TGRA or by tribal law or ordinance.

* * * * *

Dated: May 1, 2018, Washington, DC.
Endangered and Threatened Wildlife and Plants; Removing Oenothera coloradensis (Colorado Butterfly Plant) From the Federal List of Endangered and Threatened Plants

AGENCY: Fish and Wildlife Service.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to remove the Colorado butterfly plant (Oenothera coloradensis, currently listed as Gaura neomexicana ssp. coloradensis) from the Federal List of Endangered and Threatened Plants (List) due to recovery. This determination is based on a thorough review of the best available scientific and commercial data, which indicate that the threats to the Colorado butterfly plant have been eliminated or reduced to the point that it has recovered, and that this plant is no longer likely to become endangered in the foreseeable future and, therefore, no longer meets the definition of a threatened species under the Endangered Species Act of 1973, as amended (Act). This proposed rule, if made final, would also remove the currently designated critical habitat for the Colorado butterfly plant. We are seeking information, data, and comments from the public on the proposed rule to remove the Colorado butterfly plant from the List (i.e., “delist” the species). In addition, we are also seeking input on considerations for post-delisting monitoring of the Colorado butterfly plant.

DATES: We will accept comments received or postmarked on or before August 7, 2018. Comments submitted electronically using the Federal eRulemaking Portal (see ADDRESSES, below), must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in FOR FURTHER INFORMATION CONTACT by July 23, 2018.

ADDRESSES: Written comments: You may submit written comments by one of the following methods:

1. Electronically: Go to the Federal eRulemaking Portal: http://www.regulations.gov. In the Search box, enter Docket No. FWS–R6–ES–2018–0008, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, 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 the blue “Comment Now!” box. If your comments will fit in the provided comment box, please use this feature of http://www.regulations.gov, as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.


We request that you submit written comments only by the methods described above. We will post all comments on http://www.regulations.gov. This generally means that we will post any personal information you provide us (see Public Comments, below, for more details).

Document availability: This proposed rule and supporting documents, including a copy of the draft post-delisting monitoring plan referenced in this document, are available on http://www.regulations.gov at Docket No. FWS–R6–ES–2018–0008. In addition, the supporting file for this proposed rule will be available for public inspection, by appointment, during normal business hours at the Wyoming Ecological Services Field Office; 5353 Yellowstone Road, Suite 308A, Cheyenne, WY 82009; telephone: 307–772–2374. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

FOR FURTHER INFORMATION CONTACT: Tylor A. Abbott, Field Supervisor, telephone: 307–772–2374. Direct all questions or requests for additional information to: COLORADO BUTTERFLY PLANT QUESTIONS, U.S. Fish and Wildlife Service; Wyoming Ecological Services Field Office; 5353 Yellowstone Road, Suite 308A, Cheyenne, WY 82009. Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 800–877–8339.
You may submit your comments and materials concerning the proposed rule by one of the methods listed in

ADDRESS. Comments must be submitted to http://www.regulations.gov before 11:59 p.m. (Eastern Time) on the date specified in DATES. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in DATES.

We will post your entire comment— including your personal identifying information—on http://www.regulations.gov. If you provide personal identifying information in your comment, 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.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on http://www.regulations.gov, or by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Wyoming Ecological Services Field Office (see Document availability under ADDRESSES, above).

Public Hearing

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the Federal Register (see DATES, above). Such requests must be sent to the address shown in FOR FURTHER INFORMATION CONTACT. We will schedule a public hearing on this proposal, if any is requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the Federal Register and local newspapers at least 15 days before the hearing.

Peer Review

In accordance with our policy, “Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities,” published on July 1, 1994 (59 FR 34270), we will seek the expert opinion of at least three appropriate and independent specialists regarding scientific data and interpretations contained in this proposed rule. We will send copies of this proposed rule to the peer reviewers immediately following its publication in the Federal Register. We will ensure that the opinions of peer reviewers are objective and unbiased by following the guidance set forth in the Director’s Memo that updates and clarifies Service policy on peer review (USFWS 2016a).

The purpose of such review is to ensure that our decisions are based on scientifically sound data, assumptions, and analysis. Accordingly, our final decision may differ from that described in this proposal.

Previous Federal Actions

On October 18, 2000, we published a rule in the Federal Register (65 FR 62302) listing the Colorado butterfly plant, with the scientific name Gaura neomexicana, as a Endangered species set forth in the Director’s policy and an objective and unbiased by following the guidelines set forth in the Director’s Memo that updates and clarifies Service policy on peer review (USFWS 2016a). We summarize relevant information below.

The Colorado butterfly plant is a short-lived perennial herb that is monocarpic or semelparous, meaning that it flowers once, sets seed, and then dies. Flowering plants may, on rare occasions, flower a second year or become vegetative the year after flowering (Floyd 1995, pp. 10–15, 32). Pollinators for related species of Gaura and Colyphus (Onagraceae, tribe Onagreae) consist of noctuid moths (Noctuidae) and halictid bees (Lasioglossum: Clinebell et al. 2004, p. 378); both moths and bees have been identified visiting Colorado butterfly plant flowers during annual surveys (USFWS 2016c, entire). Additionally, one study found that the Colorado butterfly plant does not exhibit a bimodal (day and night) pollination system that is seen in other Gaura species, since the majority of pollination occurs at night by noctuid moths (Krakos et al. 2013, entire).

The Colorado butterfly plant is self-compatible; plants produce flowers capable of forming viable seed with pollen from the same plant (Floyd 1995, p. 4). During dispersal, many seeds fall to the ground around parent plants (Floyd and Ranker 1998, p. 854). Because the seed floats, it also may be dispersed downstream. Livestock and native ungulates could provide an important dispersal mechanism as well, through ingestion of the seeds (USFWS 2012, p. 27). Populations of this species show evidence of a seedbank, an adaptation that enables the species to take advantage of favorable growing seasons, particularly in flood-prone areas (Holzel and Otte 2004, p. 279).

The number of individuals in a population of Colorado butterfly plants appears to be influenced by rates of seedling establishment and survival of vegetative rosettes to reproductive maturity. These factors may be influenced by summer precipitation (Floyd and Ranker 1998, p. 858; Fertig 2000, p. 13). The combination of cool and moist spring months is important in germination, and germination levels influence the outcome of flowering plant population census in subsequent years. Additionally, summer conditions, and temperature in particular, appear to be an important mortality factor rather than influencing germination (Laursen and Heidel 2003, p. 6). Differences in soil moisture and vegetation cover may also influence recruitment success (Munk et al. 2002, p. 123).

The vegetative rosette within a population may provide an important
and particularly resilient stage of the life history of this species. Individual vegetative rosettes appear to be capable of surviving adverse stochastic events such as flooding (Mountain West Environmental Services 1985, pp. 2–3) and adverse climatic years when new seedling establishment is low. Therefore, episodic establishment of large seedling recruitment classes may be important for the long-term growth, replenishment, and survival of populations (Floyd and Ranker 1998, entire).

**Taxonomy**

The Colorado butterfly plant, a member of the evening primrose family (Onagraceae), was listed as *Gaura neomexicana ssp. coloradensis* in 2000 (65 FR 62302; October 18, 2000). Molecular studies by Hoggard et al. (2004, p. 143) and Levin et al. (2004, pp. 151–152) and subsequent revisions of the classification of the family Onagraceae (Wagner et al. 2007, p. 211) transferred the taxon previously known as *Gaura neomexicana* Wooton to *Oenothera* as *Oenothera coloradensis* ssp. *neomexicana* (Wooton) W.L. Wagner & Hoch. More recent analyses showed that there are no infraspecific entities (any taxa below the rank of species) within the taxon; the listed entity is now recognized as *Oenothera coloradensis* (Wagner et al. 2013, p. 67). A more detailed assessment of the taxonomy of the Colorado butterfly plant is available in the species Biological Report (USFWS 2017a, pp. 4–6). The taxonomic and nomenclatural changes do not alter the description, range, or threat status of the listed entity.

Throughout this proposed rule, we will use the current scientific name and rank, *Oenothera coloradensis*, for the Colorado butterfly plant. We acknowledge, however, that the listing of the Colorado butterfly plant in the Code of Federal Regulations (CFR) will continue to be identified as *Gaura neomexicana ssp. coloradensis* until such time as we publish a correction or a final delisting rule in the *Federal Register*.

**Species Abundance, Habitat, and Distribution**

The Colorado butterfly plant is a regional endemic riparian species known from 34 12-digit hydrologic unit code watersheds (watersheds) (28 extant and 6 extirpated), found from Boulder, Douglas, Larimer, and Weld Counties in Colorado, Laramie and Platte Counties in Wyoming, and western Kimball County in Nebraska (see figure below). Prior to 1984, few extensive searches for the plant had been conducted, and data taken from herbarium specimens were the primary basis of understanding the extent of the species’ historical distribution. At that time, the plant was known from a few historical and presumably extirpated locations in southeastern Wyoming and several locations in northern Colorado, as well as from three extant occurrences in Laramie County in Wyoming and Weld County in Colorado. Prior to listing, extensive surveys were conducted in 1998, to document the status of the known occurrences, and all still contained Colorado butterfly plants (Fertig 1998a, entire).
Habitat Description

The Colorado butterfly plant occurs on subirrigated (water reaches plant root zone from below the soil surface), alluvial soils derived from conglomerates, sandstones, and tuffaceous mudstones and siltstones of the Tertiary White River, Arikaree, and Oglalla Formations (Love and Christiansen 1985 in Fertig 2000, p. 6) on level or slightly sloping floodplains and drainage bottoms at elevations of 1,524–1,951 meters (m) (5,000–6,400 feet (ft)). Populations are typically found in habitats created and maintained by streams active within their floodplains, with vegetation that is relatively open and not overly dense or overgrown (65 FR 62302; October 18, 2000). Populations occur in a range of ecological settings, including streamside, outside of the stream channel but within the floodplain, and spring-fed wet meadows. The plant is often found in but not restricted to early- to mid-succession riparian habitat. Historically, flooding was probably the main cause of disturbances in the plant’s habitat, although wildfire and grazing by native herbivores also may have been important. Although flowering and fructifying stems may exhibit increased dieback because of the abovementioned events, vegetative rosettes appear to be little affected (Mountain West Environmental Services 1985, pp. 2–3).

It commonly occurs in communities dominated by nonnative and disturbance-tolerant native species including: Agrostis stolonifera (creeping bentgrass), Poa pratensis (Kentucky bluegrass), Glycyrrhiza lepidota (American licorice), Cirsium flodmanii (Flodman’s thistle), Grindelia squarrosa (curlytop gumweed), and Equisetum laevigatum (smooth scouring rush). Its habitat on Warren Air Force Base (AFB) includes wet meadow zones dominated by Panicum virgatum (switchgrass), Muhlenbergia richardsonis (mat muhly), Schizachyrium scoparium (little bluestem), Spartina pectinata (prairie cordgrass), and other native grasses. All of these habitat types are usually intermediate in moisture ranging from wet, streamside communities dominated by sedges, rushes, and cattails to dry, upland prairie habitats (Fertig 1998a, pp. 2–4).

Typically, Colorado butterfly plant habitat is open, without dense or woody vegetation. The establishment and survival of seedlings appears to be enhanced at sites where tall and dense vegetation has been removed by some form of disturbance. In the absence of occasional disturbance, the plant’s habitat can become choked by dense growth of willows, grasses, and exotic plants (Fertig 1996, p. 12). This prevents new seedlings from becoming established and replacing plants that have died (Fertig 1996, pp. 12–14).

For the purposes of this analysis, we consider all occurrences of the Colorado
butterfly plant within the same watershed to be one population. There are no data (e.g., genetic relatedness) available to more precisely define populations, and although distance of 1 km (0.6 mi) or greater may exceed the distance traveled by pollinators, it is possible that seeds may disperse over much greater distances (Heidel 2016, pers. comm.). Therefore, because these gaps are probably too small to prevent the dispersal of pollinators and/or seeds between subpopulations, colonies along the same stream reach should be considered part of the same population. This varies from the characterization of populations in both the listing decision (65 FR 62302; October 18, 2000) and critical habitat designation (70 FR 1940; January 11, 2005), where populations were defined by landowner and/or proximity within a drainage. We find organizing populations by watershed more accurately describes components of population ecology (genetic exchange within a geographic area), and stressors affecting the species tend to vary by watershed. Because of this new organization of population structure, some populations considered distinct and separate during the 2000 listing decision are now combined and vice versa, although many populations are the same in this proposed rule as they were presented in the 2000 listing rule.

Population Abundance and Trends

The Colorado butterfly plant occurred historically and persists in various ecological settings described above under Habitat Description including wet meadows, stream channels, stream floodplains, and spring-fed wetlands. A detailed summary of the status of the species between 1979 and 2016 is provided in the species’ Biological Report (USFWS 2017a, pp. 13–22). In 1998 and 1999, in preparation for listing the species, the rangewide census of flowering individuals was estimated at 47,300 to 50,300, with the majority of these occurring in Wyoming (Fertig 1998a, p. 5; Fertig 2000, pp. 8–13). However, a population was discovered in Colorado in 2005 that had a peak census of 26,000 plants in 2011, bringing the total rangewide population to approximately 73,300 to 76,300 plants over time. Another population was discovered upstream of known populations on Horse Creek in Laramie County, Wyoming, in 2016 with only 17 individuals, although the area had just been hayed and was likely an incomplete representation of the total number of plants in this population (USFWS 2016c, entire).

Average numbers may be a more appropriate way to represent populations than the minimum and maximum values, although all provide insight into the population’s resiliency, or the ability to withstand stochastic events. The number of reproductive individuals in a population is somewhat driven by environmental factors and varies considerably, so understanding the variability in the number of individuals present in any given year is meaningful in assessing population resiliency. Population numbers have fluctuated five-fold over the course of the longest-running monitoring study (28 years) conducted on Warren AFB. There, the population peaked at over 11,000 flowering plants in 1999 and 2011, making it one of the largest populations rangewide, and then dropped to 1,916 plants in 2008 (Heidel et al. 2016, p. 1). The Warren AFB population numbers provide some indication of how population numbers can vary in landscapes not managed for agricultural purposes, and it is likely that numbers vary even more dramatically on managed landscapes. If this fluctuation was applied to the rangewide population estimates above, then total rangewide numbers for average years might be less than 50 percent of rangewide estimates in favorable years (Handwerk 2016, pers. comm.; Heidel 2016, pers. comm.). The final listing rule (65 FR 62302; October 18, 2000) defined large populations as those containing more than 3,000 reproductive individuals; moderate populations as those containing 500 to 2,500 reproductive individuals; and small populations having fewer than 500 reproductive individuals. At the time, the species was represented by 10 stable or increasing populations, 4 extant but declining populations, 3 likely small populations, and 9 likely extirpated populations.

However, after monitoring roughly half the known populations annually for the past 13 years, we understand that population size fluctuates significantly from year to year; therefore, population size in any given year is not a good indicator of resiliency. Our estimates are now based on averages of population censuses over multiple years and trends of populations in response to management and stressors. Based on this, we now have 15 highly resilient populations, 2 moderately resilient populations, 6 low resiliency populations, 2 populations with unknown resiliency, 3 introduced populations, and records of 6 extirpated populations.

Colorado

In 2005, when critical habitat was designated for the Colorado butterfly plant, only a single population was known from Colorado. That population was not designated as critical habitat because it was protected under a WEA. Currently, the species is known to occur in Adams, Boulder, Douglas, Jefferson, Larimer, and Weld Counties in northern Colorado, spanning 12 watersheds (see figure above). Six historical occurrences have not been documented since 1984, and are presumed extirpated. Three of the eight records in Colorado are introduced and do not represent indigenous populations, and are either seeded into the wild or into a garden. These introduced sites were not designed specifically for species’ conservation, and therefore are not the focus of this species status evaluation in Colorado.

The majority of Colorado butterfly plants in Colorado are located on lands managed by the City of Fort Collins Natural Areas Department (Ft. Collins or CFCNAD) in Weld and Larimer Counties. The plants are distributed among three distinct habitats on either side of Interstate 25 and have numbered between 3 to more than 26,000 reproductive individuals. These areas are being managed to maintain suitable habitat for the species (CFCNAD 2008, p. 1; CFCNAD 2010, p. 1; CFCNAD 2011a, entire; CFCNAD 2011b, entire; CFCNAD 2014, entire). Annual census information on flowering individuals at the Meadow Springs Ranch in Weld County indicates that the large fluctuations in population numbers are actually around a stable mean (434 flowering plant average, median of 205, range of 45 – 1,432 flowering plants). Other populations in Colorado have not been routinely monitored; consequently, no trend information is available (USFWS 2016c, entire). In summary, the species is represented in Colorado by two highly resilient, three low resiliency, and three introduced populations.

Nebraska

Populations of the Colorado butterfly plant in Nebraska are considered at the edge of the species’ range and exist at higher elevations than we knew at the time we listed the species. Surveys conducted in 1985, along Lodgepole Creek near the Nebraska/Wyoming border in Kimball County, found just over 2,000 flowering plants (Rabbe 2016, pers. comm). A survey in 1992 found two populations of Colorado butterfly plant: One population (547 plants) along Lodgepole Creek and one population (43 plants) at Oliver Reservoir State Recreation Area (SRA) in the southwest panhandle of Nebraska in Kimball County (Fertig 2000a, p. 12).
Survey results from 2004 suggested the species was extirpated from the State. In 2005, no critical habitat was designated in Nebraska. However, a 2008 survey along historically occupied habitat and the Oliver Reservoir SRA, located 12 plants in four locations on private lands along Lodgepole Creek: 5 plants in areas where the species had been located before and 7 plants in areas newly watered by a landowner piping water into Lodgepole Creek from a cattle stock tank. No plants were found at the Oliver Reservoir SRA (Wooten 2008, p. 4). These areas have not been surveyed since 2008. Outside of these occurrences, no other populations of the species are known to occur in Nebraska (Rabbe 2016, pers. comm.).

**Wyoming**

Extant populations of Colorado butterfly plant in Wyoming occur throughout most of Laramie County and extend northward into Platte County (USFWS 2012, pp. 11–21), spanning 17 watersheds (see figure above). Over 90 percent of known occurrences in Wyoming are on private lands, with parts of two occurrences on State school trust lands, one occurrence on State lands, and one occurrence on Federal lands. Populations in Wyoming that are found partly or fully on State school trust lands are managed for agricultural uses. The population on Federal lands occurs on Warren AFB located adjacent to Cheyenne, provides information on species trends as it may have occurred prior to human settlement of the area (with wild grazers and natural streamflow), and represents the level of hydrological complexity of three different sizes of streams. The highest census numbers at Warren AFB totaled over 11,000 plants in 1998 and 2011, and the mean census numbers for all other years have remained at or above 50 percent of that peak, based on 1988–2016 numbers (Heidel et al. 2016, pp. 11–14).

In terms of genetic representation, a study conducted on Colorado butterfly plants occupying three drainages at Warren AFB found that one of the drainages was genetically unique and more diverse than the other two drainages (Floyd 1995, pp. 73–81). Another study at Warren AFB found that plants in one of the drainages contained unique alleles, sharing genetic composition with only a small number of individuals from the second and no individuals of the third drainage, indicating fine-scale genetic variability within that portion of the species’ range (Tuthill and Brown 2003, p. 251).

Assuming similar genetic structure across the species’ range, this result suggests a high degree of genetic representation at the species’ level. This genetic information, however, does not provide sufficient strength in terms of sample size in discerning populations from each other.

The Service has agreements with 11 private landowners within six watersheds in Laramie County, Wyoming, and one watershed in Weld County, Colorado (described in detail under Conservation Efforts, below), since 2004 to conduct annual monitoring of the Colorado butterfly plant. We also provide management recommendations to help landowners maintain habitat for the species. Many of the landowners graze cattle or horses where the species occurs; others use the areas for haying operations. Populations at these locations may fluctuate by as much as 100-fold annually (USFWS 2012, pp. 11–21; USFWS 2016c, entire). For example, one population was heavily grazed for over a decade, leading to counts of fewer than 30 reproductive individuals for several years, but when the grazing pressure was relieved, the population rebounded within 1 year to more than 600 reproductive individuals (USFWS 2016c, entire). This may indicate that either a robust seedbank was present or vegetative rosettes avoided the intense grazing pressure and bolted after grazing diminished. The total number of plants counted in Wyoming under these agreements has varied from approximately 1,000 to over 21,000 reproductive individuals since 2004. Combining annual census numbers from all monitored populations in Wyoming, we have observed small to extreme population fluctuations (USFWS 2012, pp. 11–21; USFWS 2016c, entire).

Wyoming is represented by 13 highly resilient populations, 2 moderately resilient populations, and 2 populations with unknown resiliency due to lack of information.

**Conservation Efforts**

The Service has worked with partners to protect existing populations. Much of this work has been accomplished through voluntary cooperative agreements. For example, beginning in 2004, the Service has entered into 11 WEAs with private landowners, representing six watersheds, to manage riparian habitat for Colorado butterfly plant (70 FR 1940; January 11, 2005). These 15-year WEAs cover a total of 1,038 hectares (ha) (2,564 acres (ac)) of the species’ habitat along 59 km (37 mi) of stream. These agreements represent approximately one-third of the known populations of Colorado butterfly plant in Wyoming and Colorado, including some of the largest populations on private lands. All of the landowners have agreed to the following:

1. Allow Service representatives or their designee access to the property for monitoring or fence installation;
2. Coordinate hay cutting activities in areas managed primarily for hay production to consider the Colorado butterfly plant’s seed production needs;
3. Prevent application of herbicides closer than 30.5 m (100 ft) from known subpopulations of the Colorado butterfly plant; and
4. Manage livestock grazing activities in conjunction with conservation needs of the Colorado butterfly plant.

One of the landowners signed a 10-year agreement instead of a 15-year agreement that was renewed for an additional 10 years in 2015. The remaining agreements expire in late 2019. We anticipate that participating landowners will continue to support the work being performed under the WEAs and will seek renewal of these agreements if the species remains listed under the Act. Based on the ongoing relationship that the Service has with these participating landowners, we anticipate that they would support the inclusions of their properties under the
post-delisting monitoring program should the Colorado butterfly plant be delisted.

One of the benefits of the WEAs for both the Service and private landowners is that we can review the population numbers annually and together develop management recommendations to improve growing conditions for the species. Populations occurring within designated critical habitat (see figure, above) have not been surveyed since 2004, and their trends, threats, and viabilities are uncertain. However, no projects potentially impacting critical habitat for this species have occurred. Additionally, we reviewed aerial imagery of the critical habitat units and found only two minimal changes between 2004 and 2015 (reflecting habitat conditions at the time of designation and the most recent aerial imagery available) throughout all critical habitat units; these changes affect only a few acres of designated critical habitat (USFWS 2017b, entire). Consequently, we determine that activities occurring on critical habitat are likely the same as they were at the time of designation. Furthermore, because many of the private lands included in the critical habitat designation are adjacent to lands under WEAs, we determine that the populations occurring within designated critical habitat are likely stable, and fluctuating similarly to populations on lands that we monitor under WEAs. We have no reason to believe that populations occurring on designated critical habitat are responding to stressors differently than those populations we monitor. Therefore, populations throughout the species’ range on private, local, and Federal lands either have been observed to be, or are highly likely to be, fluctuating around a stable population size.

The Service and the U.S. Air Force signed a memorandum of agreement (MOA) on January 18, 1982 (updated in 1999 and 2004) to facilitate the preservation, conservation, and management of the Colorado butterfly plant (USFWS 1982, entire; USFWS 1999, entire; USFWS 2004, entire). In 2004, Warren AFB developed a conservation and management plan for the species (Warren AFB 2004, entire) that was added to their integrated natural resources management plan in 2014 (Warren AFB 2014, entire). Through these plans, the Service partners with the U.S. Air Force and Wyoming Natural Diversity Database to monitor, protect the population of the Colorado butterfly plant on the Warren AFB. This includes annual monitoring: nonnative, invasive species control and eradication; and maintenance of appropriate floodplain characteristics for the species. Based on 29 years of monitoring and management, the population of the Colorado butterfly plant on the Warren AFB is doing well, with some areas declining while others are increasing (Heidel et al. 2016, entire).

Three populations in Larimer and Weld Counties, Colorado, occur on properties owned by the City of Fort Collins, and two are among the largest across the species’ range. The City of Fort Collins developed a 10-year master plan for the Natural Areas Department in 2014, which provides a framework for the conservation and preservation of natural areas, including the populations of the Colorado butterfly plant. The master plan prescribes conservation actions that allow for the persistence of the Colorado butterfly plant on the landscape (CFCNAD 2016a, entire), including prescribed burns to eliminate competition, managed grazing, and improved security of water flow to the species’ habitat.

In summary, these agreements and plans have provided useful data, facilitated good management of nine of the largest and most resilient populations, and resulted in stable or increasing population trends. Because of the information we obtained through these agreements and plans, we are able to understand the resilience of individual plants and populations, the representation of the species within its ecological settings, and the redundancy of the plant population’s numbers and potential for connectivity.

Summary of Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. “Species” is defined by the Act as including any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Determining whether the status of a species has improved to the point that it can be downlisted (i.e., reclassified from endangered to threatened) or delisted requires consideration of whether the species meets the definitions of either an endangered species or threatened species contained in the Act. For species that are already listed as endangered species or threatened species, this analysis of threats is an evaluation of both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following the delisting or downlisting and the removal or reduction of the Act’s protections.

A species is an “endangered species” for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range and is a “threatened species” if it is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The word “range” in the significant portion of its range phrase refers to the range in which the species currently exists, and the word “significant” refers to the value of that portion of the range being considered to the conservation of the species. We consider “foreseeable future” as that period of time within which a reliable prediction can be reasonably relied upon in making a determination about the future conservation status of a species, as described in the Solicitor’s opinion dated January 16, 2009. We consider 15 to 20 years to be a reasonable period of time within which reliable predictions can be made for the Colorado butterfly plant. This time period includes at least five generations of the species, coincides with the duration of one renewal of the WEAs expiring in 2019, and aligns with the timeframes for predictions regarding municipal development and growth in the area. For the purposes of this analysis, we first evaluate the status of the species throughout all of its range, then consider whether the species is in danger of extinction or likely to become so in any significant portion of its range.

In considering what factors might constitute threats, we must look beyond the exposure of the species to a particular factor to evaluate whether the species may respond to the factor in a way that causes actual impacts to the species. If there is exposure to a factor, but no response, or only a positive response, that factor is not a threat. If there is exposure to a factor and the species responds negatively, the factor
may be a threat, and we attempt to determine how significant a threat it is. If the threat is significant it may drive, or contribute to, the risk of extinction of the species such that the species warrants listing as an endangered species or a threatened species as those terms are defined by the Act. This does not necessarily require empirical proof of a threat. The combination of exposure and some corroborating evidence of how the species is likely impacted could suffice. The mere identification of factors that could impact a species negatively is not sufficient to compel a finding that listing is appropriate; we require evidence that these factors individually or cumulatively are operative threats that act on the species to the point that the species meets the definition of an endangered species or threatened species under the Act.

The Colorado butterfly plant is federally listed as threatened. Below, we present a summary of threats affecting the species and its habitats in the past, present, and predicted into the future. A detailed evaluation of factors affecting the species at the time of listing can be found in the listing determination (65 FR 62302; October 18, 2000) and designation of critical habitat (70 FR 1940; January 11, 2005). An evaluation of factors affecting the species after 2005 can be found in the 2012 5-year review (USFWS 2012, entire). The primary threats to the species identified at the time of listing include overgrazing by cattle or horses, haying or mowing at inappropriate times of the year, habitat degradation resulting from vegetation succession or urbanization of the habitat, habitat conversion to cropland or subdivision, water development, herbicide spraying, and competition with exotic plants (Marriott 1987, pp. 26–27; Fertig 1994, pp. 39–41). Fertig (2000a, pp. 16–17). Since the time of listing, oil and gas development and the effects of climate change have become potential threats to this species and are analyzed under Factor A and Factor E, respectively, below.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Residential, Urban, and Energy Development

At the time of listing (65 FR 62302; October 18, 2000), residential and urban development around the cities of Cheyenne and Fort Collins were identified as past causes of habitat conversion and habitat loss to the Colorado butterfly plant; these types of development were not a concern in Nebraska at the time of listing nor are they now. Although difficult to quantify because land conversion was not tracked during the settlement of the West, likely a few hundred acres of formerly suitable habitat were converted to residential and urban sites, contributing to loss of habitat (Fertig 1994, p. 38; Fertig 2000a, pp. 16–17). Much of the species’ range occurs along the northern Front Range of the Rocky Mountains in Colorado and Wyoming, which has experienced dramatic growth in the recent past and is predicted to grow considerably in the future (Regional Plan Association 2016, entire), particularly in Larimer and Weld Counties in Colorado (University of Colorado Boulder 2015, pp. 119–120). The demand that urban development places on water resources also has the ability to dewater the streams and lower groundwater levels required by the species to maintain self-sustaining populations, and is explored below. The two large populations of the Colorado butterfly plant in Larimer and Weld Counties, Colorado, occur on lands managed as open space by Fort Collins, and are not directly subject to residential or urban development. Consequently, despite projected increases in human density and urban development along the northern Front Range, these lands are managed to allow for the persistence of these populations, with managed grazing or burning (CFCNAD 2016b, entire). Fort Collins does not own all mineral rights on these lands; therefore, sensitive areas within these boundaries may be impacted by mineral development. However, in light of this potential threat, the city completed a planning process in which they highlighted areas to be avoided by mineral development (The Nature Conservancy 2013, entire). While oil and gas development has increased in northern Colorado and southeastern Wyoming since the time of listing, no oil or gas wells have been proposed or likely will be proposed in areas that will directly or indirectly impact populations of the Colorado butterfly plant in Colorado or in Wyoming, particularly the species’ occurrence in riparian and wetland habitats. Because the plant occurs in riparian and wetland habitats that routinely flood, it is likely that oil and gas wells will be sited outside of population boundaries. While there is potential for indirect effects through spills or sedimentation, we have no specific information about those effects on the species to date.

According to publicly available information, there are no current proposals for urban or residential development on lands containing populations of Colorado butterfly plant in Wyoming. Monitoring of lands under agreement (CFCNAD, WEAs, and Warren AFB) has also shown that neither urbanization nor conversion to intensive agricultural activities has occurred as predicted in the final listing rule (65 FR 62302, October 18, 2000; USFWS 2012, pp. 11–22; USFWS 2016c, entire). Populations at WAFB remained stable over the past 29 years without being managed for agricultural purposes, although numbers of reproductive individuals fluctuate during any given year (Heidel et al. 2016, pp. 14–18). Since the time of listing, the Service has received few requests for consultation under section 7 of the Act for projects that may adversely affect this species. Informal consultations have been limited to grazing, power lines, pipelines, road development, and drainage crossings projects, and avoidance and minimization of potential impacts has been readily achieved (USFWS 2017c, entire).

Furthermore, chapters 3 and 4 of the Laramie County Land Use Regulations address floodplain management and require specific provisions and permits for construction within floodplains (Laramie County 2011, pp. 165–185), which encompass all Colorado butterfly plant habitat within the county; these regulations, therefore, extend some level of protection to the species and its habitat. These regulations are in place to “promote public health, safety, and general welfare and to minimize public and private losses due to flood conditions” (Laramie County 2011, p. 165), and protect many resources, including the Colorado butterfly plant and its habitat, by limiting development in the floodplains. These regulations are discussed in detail under Factor D, below.

The threats of residential and urban development, once considered significant threats to the Colorado butterfly plant, have been largely avoided because most development has occurred outside of the habitat in which this species occurs. Annual monitoring conducted by the Service since 2004 indicates that populations are stable and unaffected by any development that has occurred within the species’ range. While human population growth and development are predicted for the Front Range of the Rocky Mountains in Colorado into the future, these areas are outside of the species’ occupied habitat, and we do not anticipate development in the protected areas under management of Fort Collins, and do not anticipate development due to continued restrictions against
development within the floodplain. Additionally, increases in oil and gas development in northern Colorado and southeastern Wyoming have not directly or indirectly impacted populations of the Colorado butterfly plant. Current ownership and management by Fort Collins and Warren AFB of lands containing a majority of large populations of the Colorado butterfly plant protect the species from current and future impacts due to residential, urban, and energy development.

Agricultural Practices

At the time of listing (65 FR 62302; October 18, 2000), conversion of grassland to farmlands, mowing grasslands, and grazing were considered threats to the Colorado butterfly plant. Prior to listing, the conversion of moist, native grasslands to commercial croplands was widespread throughout much of southeastern Wyoming and northeastern Colorado (Compton and Hugie 1993, p. 22), as well as in Nebraska. However, conversion from native grassland to cropland has slowed throughout the species’ range since the time of listing, with no lands converted in Laramie County and just 12 ha (30 ac) converted in Platte County between 2011 and 2012 (FSA 2013, entire).

Mowing areas for hay production that are occupied by the Colorado butterfly plant was identified as a threat at the time of listing, if conducted at an inappropriate time of year (prior to seed maturation) (Fertig 1994, p. 40; USFWS 1997, p. 8). However, monitoring over the past 13 years indicates that mowing prior to seed maturation occurs infrequently. Even in areas where early season mowing has occurred, annual monitoring has shown high numbers of reproductive plants present in subsequent years, suggesting that mowing for hay production is not a threat to the species (USFWS 2016c, entire).

The agricultural practices of grazing and herbicide application threatened the Colorado butterfly plant at the time of listing. However, since then, the Service has made significant efforts to cooperatively landowners on agricultural management that fosters resiliency in populations of the species. We believe that these measures have decreased the severity of these stressors. We also anticipate that landowners will continue their current agricultural practices into the future, based on the data we have collected from WEAs (USFWS 2016c, entire) and analysis of aerial imagery of designated critical habitat (USFWS 2017b, entire).

Through these agreements, we also learned that the species is highly adapted to withstand stochastic events. The assessment that the species is highly resilient is based on the information obtained through the WEAs; we do not rely on the implementation of the WEAs to ensure that the species remains highly resilient. Instead, we believe the plant will continue to thrive even if protections are removed. Grazing is further explored under Factor C, below, and herbicide spraying is further explored under Factor E, below.

Water Management

At the time of listing (65 FR 62302; October 18, 2000), water management (actions that moved water to croplands, such as irrigation canals, diversions, and center pivot irrigation development) was considered a threat that would remove moisture from Colorado butterfly plant habitat. The management of water resources for livestock production and domestic and commercial human consumption, coupled with increasing conversion of lands for agricultural production, often led to channelization and isolation of water resources; changes in seasonality of flow; and fragmentation, realignment, and reduction of riparian and moist lowland habitat (Compton and Hugie 1993, p. 22). All of these actions could negatively impact suitable habitat for the species.

Dewatering portions of Lodgepole Creek in Kimball County, Nebraska, has led to the extirpation of some of the species’ known historical populations there, and low likelihood of long-term resiliency for the two extant populations last monitored in 2008 (Rabbe 2016, pers. comm.). Extant populations in Nebraska continue to experience dewatering and overgrazing on private land. However, when water was reintroduced to formerly occupied habitat after being absent for more than 10 years, a population was rediscovered (Wooten 2008, p. 4). While rediscovery of this population indicates persistence of a viable seedbank for at least 10 years, numbers of plants within the population declined from over 600 plants (Fertig 2000a, p. 12) to 12 plants (Wooten 2008, p. 4), and the application of water that allowed plants to grow was temporary, which suggests the population has a low likelihood of long-term resiliency.

In 2016, the Colorado Water Conservation Board on behalf of Fort Collins filed an instream flow right on Graves Creek, the stream that feeds the population of Colorado butterfly plants in Soapstone Prairie (CFCNAD 2016b, entire). While the water right has not yet been granted, we believe that this instream flow right will protect and maintain subirrigation of this large and important population through ensuring adequate water availability to the species throughout the year.

The entire range of the Colorado butterfly plant occurs within the Platte River Basin. Water usage in the Platte River system is managed collaboratively by the States of Colorado, Wyoming, and Nebraska, and the Department of the Interior, through the Platte River Recovery Implementation Program (PRRIP). The PRRIP, which began in 1997, provides a mechanism for existing and new water users and water development activities in the Platte River Basin to operate in regulatory compliance with the Act regarding potential impacts to the five Platte River “target species” in Nebraska: Grus americana (whooping crane), Sturna (Sturnula) antillarum (interior least tern), Charadrius melodus (northern Great Plains population of piping plover), Scaphirhynchus albus (pallid sturgeon), and Platanthera praeclara (western prairie fringed orchid). Because the PRRIP ensures that shortages to the target flows in the central Platte River will be substantially reduced by keeping water within the basin more consistently throughout the year (PRRIP 2016), the hydrological component of habitat for the Colorado butterfly plant will be better maintained as well.

In summary, water management can directly and indirectly impact the Colorado butterfly plant. While management of water resources has negatively impacted the species on a localized scale in the past, there is no indication that water management throughout the majority of the species’ range poses a current threat to the species because programs and policies currently in place, such as the PRRIP and Graves Creek instream flow right, provide substantial assurances that the hydrological component of currently occupied habitat will remain protected over the long term.

Natural Succession and Competition With Nonnative, Invasive Species

In the absence of periodic disturbance, natural succession of the plant community in areas occupied by the Colorado butterfly plant moves from open habitats to dense coverage of grasses and forbs, and then to willows and other woody species. The semi-open habitats preferred by this species can become choked by tall and dense growth of willows; grasses; and nonnative, invasive species (Fertig 1994, 1997; Fertig 2000a, b). Physical disturbances such as flooding, fire, and native ungulate grazing were sufficient...
in the past to create favorable habitat conditions for the species. However, the natural flooding regime within the species’ floodplain habitat has been altered by construction of flood control structures and by irrigation and channelization practices (Compton and Hugie 1993, p. 23; Fertig 1994, pp. 39–40). Consequently, the species relies on an altered flood regime and other sources of disturbance to maintain its habitat.

In the absence of natural disturbances today, managed disturbance may be necessary to maintain and create areas of suitable habitat (Fertig 1994, p. 22; Fertig 1996, pp. 12–14; Fertig 2000a, p. 15). However, populations can persist without natural disturbances such as fire and flooding through natural dieback of woody vegetation and native ungulate grazing (Heid et al., 2016, pp. 2–5). Additionally, some Federal programs, such as those administered by the U.S. Department of Agriculture’s Natural Resources Conservation Service, focus on enhancing or protecting riparian areas by increasing vegetation cover and pushing the habitat into later successional stages, which removes the types of disturbance the Colorado butterfly plant needs (65 FR 62302; October 18, 2000, p. 62307). However, these programs are implemented in only a small portion of the species’ range. The Service learned from monitoring the 11 WEA properties that the typical approach of managing for livestock grazing, coupled with an altered flood regime, appears to provide the correct timing and intensity of disturbance to maintain suitable habitat for the species (USFWS 2012, pp. 9–21; USFWS 2016c, entire). There has been no noticeable change in general management practices or change in the natural succession rate in either the WEA properties or the designated critical habitat since the agreements were signed or the critical habitat was designated, and we have no reason to believe that these practices or rates will change in the foreseeable future. Therefore, through the information we have gathered since the time of listing, it appears that natural succession is not occurring at the level previously considered to threaten this species.

The final listing rule (65 FR 62302; October 18, 2000) included competition with exotic plants and noxious weeds as a threat to the Colorado butterfly plant. Competition with exotic plants and noxious weeds, here referred to as nonnative, invasive species, may pose a threat to the Colorado butterfly plant, particularly given the species’ adaptation to more open habitats. In areas of suitable habitat for Colorado butterfly plant, the following plants may become dominant: The native Salix exigua (coyote willow); nonnative, invasive Cirsium arvense (Canada thistle); and nonnative, invasive Euphorbia esula (leafy spurge). Salix in particular increases in the absence of grazing or mowing. These species can outcompete and displace the Colorado butterfly plant, presumably until another disturbance removes competing vegetation and creates openings for Colorado butterfly plant seedlings to germinate (Fertig 1990b, p. 17). Since 2004, we have monitored populations of the Colorado butterfly plant that have slowly decreased in numbers or disappeared following the invasion and establishment of these other plant species, only to see Colorado butterfly plants return to the area following disturbance (USFWS 2016c, entire). Additionally, at least one population has moved to an uninvaded area downstream of its former invaded habitat (Handwerk 2016, pers. comm.), suggesting that populations can move to find more suitable habitat nearby.

Prior to listing, biological control agents were used to control nonnative, invasive species at Warren AFB and may have depressed numbers and extent of Canada thistle and leafy spurge. Introduced gall-forming flies have slowly become established on Warren AFB and have reduced the vigor, height, and reproductive ability of small patches of Canada thistle (Fertig 1997, p. 15), at least in some years (Heid et al., 2016, p. 16). Also on the Warren campus, a biocontrol agent for leafy spurge, a different flea beetle than infests the Colorado butterfly plant, was observed in 1997 (Fertig 1999b, p. 18). While the effects of biocontrol agents on nonnative, invasive species appear promising, we do not have current information on the status of biocontrol of these agents.

Natural succession was considered a threat to the Colorado butterfly plant at the time of listing. However, we now understand that the altered flood regime of today, coupled with disturbance from fire and grazing, is sufficient to maintain suitable habitat throughout much of the species’ range. Competition with nonnative, invasive species is an ongoing stressor for portions of populations, although these invasive species tend not to survive the regular disturbances that create habitat for the Colorado butterfly plant. Therefore, while individuals or populations may be out-competed by native or nonnative, invasive species at higher succession levels, periodic disturbance maintains or creates new habitats for the Colorado butterfly plant.

Summary of Factor A

The following stressors warranted consideration as possible current or future threats to the Colorado butterfly plant habitat under Factor A: (1) Residential, urban, and energy development; (2) agricultural practices; (3) water management; and (4) natural succession and competition with nonnative, invasive species. However, these stressors are either being adequately managed, have not occurred to the extent anticipated at the time of listing, or new information indicates that the species is tolerant of the stressor as described above. While these stressors may be responsible for loss of historical populations (they have negatively affected population redundancy), and are currently negatively affecting the populations in Nebraska, we do not anticipate a rangewide increase in these stressors in the future, although they will continue at some level.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Factor B was not considered a threat to the species at the time of listing (65 FR 62302; October 18, 2000). We are aware of three unpermitted collections of seeds of the Colorado butterfly plant for scientific and/or commercial purposes since the publication of the final listing rule. These three collections were limited events that occurred at an introduction site in Colorado and from a large, robust population in Wyoming. Based on recent population data, these unpermitted collection events had no apparent impact on the number and distribution of plants within these populations or the species’ habitat (based on Heid et al., 2016, p. 13; USFWS 2016c, entire). Other than these collections, we are not aware of any attempts to use the Colorado butterfly plant for commercial, recreational, scientific, or educational purposes. In the future, we do not anticipate this species will be collected due to its lack of showiness for much of the year and because it occurs in generally inaccessible areas.

Summary of Factor B

At the time of listing, Factor B was not considered a threat to the Colorado butterfly plant. We are aware of only three unpermitted collections of the seeds of the species since listing. These collection events had no apparent effect on the number and distribution of plants from which they were taken. Based on available information, we do not consider there to be threats now or
in the future related to overutilization for commercial, recreational, scientific, or educational purposes.

C. Disease or Predation

The listing of the Colorado butterfly plant (65 FR 62302; October 18, 2000) did not include threats from disease or predation, although livestock grazing was described as a potential threat if grazing pressures were high. No diseases are known to affect this species. In 2000, a precipitous decline in plant numbers was observed in many populations monitored in Colorado and Wyoming. The exact cause of the decline was not positively identified, but weather and insect herbivory were two potential contributing factors. Weather-related impacts included an early start to the growing season, lower than normal spring precipitation levels (which were magnitudes lower than in all previous years), and higher mean temperatures in late summer. Insect herbivory also was suspected, as virtually all reproductive plants were riddled with holes, flowering and fruit production was curtailed or greatly reduced on all plants, and some bolted plants died before flowering. Interestingly, no vegetative (i.e., non-reproductive) plants showed similar evidence of herbivory (Heidel et al., 2011, pp. 284–285). Flowering plant numbers remained low or declined further in 2008. Surveyors identified one or more flea beetle species that may have been responsible for the herbivory. The likely flea beetle species (Altica foliacea) is a native species, and its numbers are not known to be affected by human causes.

Insect herbivory may not be a severe or immediate threat to Colorado or Wyoming populations as the above-referenced impacted populations rebounded to pre-infestation numbers in 2009 and 2010 (Heidel et al., 2011, p. 286). However, insect herbivory may be episodic and potentially tied to climate; preliminary tests have been conducted on its potential impact on population resiliency (Heidel et al., 2011, p. 286). For example, in 2014, intense herbivory from flea beetles at Soapstone Prairie and Meadow Springs Ranch resulted in high mortality and a reduction in bolting of vegetative rosettes (Strouse 2017, pers. comm.), and numbers of reproductive individuals in those populations were low in 2015 and 2016. We found that these populations rebounded in 2017 to record numbers, in the same way populations rebounded after the 2007 flea-beetle-caused decline. This variability has not been reported for the Nebraska populations, although it is possible that similar insect herbivory influenced 2008 survey results in Nebraska.

Colorado butterfly plant is highly palatable to a variety of insect and mammalian herbivores including Gaura moth (Schinia gaura), cattle, horses, and pronghorn (Antilocapra americana), but the plant appears to have some capacity to compensate for herbivory by increasing branch and fruit production (Fertig 1994, p. 6; Fertig 2000a, p. 17). Livestock grazing can be a threat at some sites if grazing pressures are high or if use is concentrated during the summer flowering and fruiting period. Additionally, plants may be occasionally uprooted or trampled by livestock and wildlife. In at least two locations where a population was divided by a fence, the heavily grazed side of the fence had few or no Colorado butterfly plants, while the ungrazed side had many (Marriott 1987, p. 27; USFWS 2016c, entire).

Heavy grazing at key times of the year during the life cycle of the Colorado butterfly plant may be detrimental to populations by temporarily removing reproductive individuals and eliminating seed production for that year. However, even after many years of intensive grazing, populations rebounded upon relief (USFWS 2012, pp. 11–21; USFWS 2016c, entire). This response is likely due to survival of non-reproductive individuals and recruitment from the seedbank. Moderate grazing acts as a disturbance that keeps the habitat in an open or semi-open state suitable for this species, and light to medium grazing can provide benefits by reducing the competing vegetative cover and allowing seedlings to become established (USFWS 1997, p. 8).

Summary of Factor C

In general, while disease or predation has had an occasional negative impact on individuals and localities, most of these impacts do not appear to affect entire populations, nor do these impacts persist for any extended period of time. Individuals are resilient to damage; vegetative plants (basal rosettes) appear to be resistant to damage from grazing activities and are capable of withstanding stochastic events, and reproductive plants send out additional flowering branches upon injury. Also, the lack of any known diseases affecting the species and the species’ redundancy of many populations distributed across most of the historical range would likely provide a buffer to any type of catastrophic disease outbreak.

D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine whether the stressors identified within the other factors may be ameliorated or exacerbated by an existing regulatory mechanism. Section 4(b)(1)(A) of the Act requires the Service to take into account “those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species.” In relation to Factor D under the Act, we interpret this language to require the Service to consider relevant Federal, State, and Tribal laws, regulations, and other such binding legal mechanisms that may ameliorate or exacerbate any of the threats we describe in threats analyses under the other four factors, or otherwise enhance conservation of the species. Our consideration of these mechanisms is described in detail within our analysis of each of the factors (see discussion under each of the other factors).

For currently listed species, we consider the adequacy of existing regulatory mechanisms to address threats to the species absent the protections of the Act. Therefore, we examine whether other regulatory mechanisms would remain in place if the species were delisted, and the extent to which those mechanisms will continue to help ensure that future threats will be reduced or minimized.

In our discussion under Factors A, B, C, and E, we evaluate the significance of threats as mitigated by any conservation efforts and existing regulatory mechanisms. Where threats exist, we analyze the extent to which conservation measures and existing regulatory mechanisms address the specific threats to the species. Regulatory mechanisms, if they exist, may reduce or eliminate the impacts from one or more identified threats. Presently, the Colorado butterfly plant is a Tier 1 species in the Plants of Greatest Conservation Need in Colorado (Colorado SWAP 2015, entire), and the species is listed on the State endangered species list for Nebraska, and will continue to be so designated due to the species’ extreme rarity in Nebraska (Wooten 2008, p. 1).

When we listed the Colorado butterfly plant in 2000 (65 FR 62302; October 18, 2000), the majority of known populations occurred on private lands managed primarily for agriculture, with one population at Warren AFB, and a few other populations throughout the species’ range under various local jurisdictions. The listing decision described the species’ status as
Sensitive by the U.S. Forest Service, although no populations occurred on Forest Service lands at the time. The listing decision also described the lack of protection extended to the Colorado butterfly plant through the Federal threatened status of _Zapus hudsonius preblei_ (Preble's meadow jumping mouse) that occurs in the same range of habitats due to the two species' use of differing successional stages of riparian habitats (65 FR 62302; October 18, 2000). 

Today, the population on Warren AFB represents one of the largest and most highly resilient populations of the species, is managed under an integrated natural resources management plan (Warren AFB 2014, entire) and a conservation and management plan under Air Force Information 32–7064 (Warren AFB 2004, entire). These plans call for annual monitoring, protection and maintenance, and research on threats and genetic variability of the population located there. Additionally, a Service employee stationed at Warren AFB manages its natural resources, including management of the Colorado butterfly plant and its habitat, such as directing the application of herbicide in the vicinity of the species' habitat. These plans would remain post-delisting. The population of the Colorado butterfly plant at Warren AFB has been monitored since before listing to determine population trends, detect any changes in its habitat, pursue viability assessment, and assess population response to different hydrological conditions. The results indicate that plant numbers fluctuate depending on climate and hydrology, and seem to be capable of rebounding after extreme stochastic events such as the flea beetle infestation of 2007 (Heidel _et al._, 2016, pp. 15–17). Should the protections of the Act be removed from this species upon delisting, the aforementioned plans would remain in place, at least until the next plan revisions, which have yet to be scheduled.

Discovery and subsequent protection of large populations of the Colorado butterfly plant on lands owned and managed by Fort Collins are an important addition to conservation of the species after it was listed in 2000. The regulatory protections that these two populations receive from occurring on municipal natural areas lands include indefinite protections of land and water and restoring and rehabilitating land and natural systems to build ecological diversity and permanence (City of Fort Collins 2014, pp. 1–2). Populations managed by Fort Collins are afforded protection from oil and gas development (The Nature Conservancy 2013, entire) and from water withdrawals (CFCCNAD 2016b, entire), as discussed above under Factor A. Also, as mentioned in “Residential, Urban, and Energy Development” under Factor A, the Laramie County Land Use Regulations address floodplain management and require specific provisions and permits for construction within floodplains (Laramie County 2011, pp. 165–185), which encompass all Colorado butterfly plant habitat within the county; therefore, these regulations extend some level of protection to the species and its habitat. While protecting riparian and wetland species is not the intent of these regulations, plants growing within the floodplain receive the habitat protections outlined as part of the floodplain construction avoidance provisions.

 Lands without specific regulatory mechanisms contain most populations of the Colorado butterfly plant. Over a decade of monitoring 11 occurrences on private lands in Wyoming has documented fluctuations in population size about a stable mean, apparently driven by changes in precipitation and disturbance regime (USFWS 2012, pp. 11–22; USFWS 2016c, entire). Management of lands under WEAs is discussed in Conservation Efforts, above.

Populations of Colorado butterfly plant are not known to occur on lands managed by the Bureau of Land Management (BLM) at this time, although there is potential for populations to be discovered on BLM lands in the future. Because of this possibility, the Service and BLM in Wyoming have developed conservation measures under a Statewide programmatic consultation under section 7 of the Act for the Colorado butterfly plant. These conservation measures are incorporated into BLM’s 2008 Record of Decision and Approved Rawlins Resource Management Plan (RMP; BLM 2008, entire) and include, but are not limited to: (1) Buffering individuals and populations by 800 m (0.5 mi); (2) implementing standards for healthy rangelands and guidelines for livestock grazing management for the public lands administered by BLM in the State of Wyoming; (3) limiting the number of grazing animals within the permit area; and (4) protecting surface water through prohibiting surface development in the following areas: Within 400 m (0.25 mi) of the North Platte River; within 152 m (500 ft) of live streams, lakes, reservoirs, and canals and associated riparian habitat; and within 152 m (500 ft) of water wells, springs, or artesian and flowing wells (BLM 2005, pp. 4–2 through 4–4). The newly discovered population on Wild Horse Creek (WY–23) occurs within the agreement area that BLM developed with the landowners, and so the conservation measures included in the Rawlins RMP are applied to this population.

 Water use is managed under the PRRIP, as described above under Factor A, which ensures that water use in the Platte River is conducted in a way to maintain volume at certain times of the year in the central and lower reaches of the Platte River in Nebraska. Because all of the watersheds in which the Colorado butterfly plant is found occur within the PRRIP, the water on which the species depends is managed under this program (PRRIP 2006). The water that this species requires would continue to be included under the PRRIP even if the Colorado butterfly plant is removed from the List of Threatened and Endangered Plants.

**Summary of Factor D**

At the time of listing (65 FR 62302; October 18, 2000), no Federal or State laws or regulations specifically protected populations of the Colorado butterfly plant and its habitat. However, two of the three largest populations occur on Warren AFB and lands owned and managed for the species by Fort Collins where regulatory mechanisms now exist. Additionally, 13 years of annual monitoring of 11 survey areas on private lands under WEAs that has occurred since the species was listed has shown that land used for agricultural purposes can be compatible with the resilience of the species, even without any regulatory mechanism in place (see discussions under Factors A, C, and E). Consequently, we find that existing regulatory mechanisms, as discussed above, will continue to address stressors to the Colorado butterfly plant absent protections under the Act.

**E. Other Natural or Manmade Factors Affecting Its Continued Existence**

Factor E requires the Service to consider any other factors that may be affecting the Colorado butterfly plant. Under this factor, we discuss small population size and restricted range, herbicide spraying, and effects of climate change.

**Small Population Size and Restricted Range**

The final listing decision (65 FR 62302; October 18, 2000) included the limited range and the small population size of many populations to be a threat
to the Colorado butterfly plant. However, small population size and a restricted range is not a threat in and of itself. Historically, Colorado butterfly plant populations occurred from Castle Rock, Colorado, north to Chugwater, Wyoming, and east into a small portion of southwest Nebraska. The extent of its range was approximately 6,880 ha (17,000 ac). Most of this range is still occupied, although some small and/or peripheral populations in Nebraska and Colorado have been extirpated since intensive survey efforts began. Despite the loss of these populations, the species continues to maintain multiple resilient, representative, and redundant populations throughout nearly all of its range known at the time of listing (see figure, above).

We have evidence that populations throughout the range have persisted despite stochastic events that may have caused short-term declines in number of individuals. For example, a 100-year flood in August 1983 on the Warren AFB inundated the Crow Creek portion of the population, knocking down some plants and surrounding vegetation, and depositing sediments (Rocky Mountain Heritage Task Force 1987, as cited in Heidel et al., 2016, p. 2). Instead of being extirpated, these populations rebounded in 1986 and continue to persist (summarized in Heidel et al., 2016, pp. 2–18). Additionally, based on annual monitoring of populations on private property in Wyoming, stochastic events such as floods and hail storms have reduced population numbers during the event year, then populations rebounded in following years (USFWS 2012, pp. 11–22; USFWS 2016c, entire). Individual plants may be vulnerable to random events such as fires, insect or disease outbreaks, or other unpredictable events. However, this species is adapted to disturbance, and rather than being extirpated, the seedbank can provide opportunity for populations to rebound after such events.

The historical range included populations farther south into Larimer and Weld Counties in Colorado that were lost prior to the listing of the species in 2000. No populations in Larimer and Weld Counties in Colorado have been extirpated since the species was listed, and we do not think that further range restriction has occurred in this portion of the species’ range. In the future, species range restriction may occur through loss of peripheral populations in Nebraska where dewatering has removed formerly suitable habitat (USFWS 2016c, entire). However, these populations are downstream of highly viable populations in Wyoming, and do not constitute a removal of the species from this drainage entirely. The resiliency and redundancy of populations across much of the species’ range indicate that further range restriction is not likely.

Herbicide Spraying

At the time of listing (65 FR 62302; October 18, 2000), the non-selective use of broadleaf herbicides to control Canada thistle, leafy spurge, and other nonnative, invasive plants was considered a threat to the Colorado butterfly plant. Non-selective spraying has had negative effects on some Colorado butterfly plant populations (Fertig 2000a, p. 16). For example, in 1983, which was prior to listing, nearly one-half of the mapped population on Warren AFB was inadvertently destroyed when sprayed with Tordon®, a persistent herbicide (Miller 1987, as cited in 65 FR 62302, October 18, 2000, p. 62307). The status of that portion of the population is unknown due to a subsequent lack of clear record-keeping at that time, prior to a Service biologist being employed on site; all plant locations have been tracked in the time after the Service biologist and Wyoming Natural Diversity Database began working at Warren AFB. Herbicide use along road crossings in and adjacent to plant populations was also noted (65 FR 62302, October 18, 2000, p. 62307).

After the 2000 listing of the Colorado butterfly plant, the Service worked with Warren AFB and private landowners under WEAs to develop best management practices for applying herbicides within the vicinity of known occurrences to remove nonnative, invasive species while minimizing adverse effects to individual Colorado butterfly plants. For example, the WEAs require an herbicide-application buffer of 30.5 m (100 ft) from known locations of the Colorado butterfly plant. However, at one property, the landowner inadvertently sprayed individual plants in spring 2016. During subsequent monitoring, Service staff observed reddened plants with shriveled leaves, which likely reduced the vigor of those individuals (USFWS 2016c, entire). We presume that there will be no long-term effects on the population, and in fact, we found vigorous Colorado butterfly plants growing in this area during surveys in 2017. Furthermore, if the species is delisted, we anticipate that landowners will continue to maintain this buffer in accordance with requirements under the WEAs and that Warren AFB will continue to apply the herbicide in the vicinity of the species’ habitat as stipulated in their integrated natural resources management plan and conservation and management plan.

While herbicide application may continue to occasionally occur within Colorado butterfly habitat, we know that unsprayed individuals persist in the population and can repopulate Colorado butterfly plants in areas where plants were killed. The seedbank can play an additional role in restoring Colorado butterfly plants to areas that have been sprayed. Based on our records, herbicide application is a management tool used in conjunction with nonnative, invasive species removal in only four of the known occurrences of the species, and these are among our largest and most resilient populations of the species. Our records indicate that, in general, application of buffers has been successful at reducing the presence of invasive species and competition near the Colorado butterfly plant (USFWS 2012, pp. 24–25; USFWS 2016c, entire), and when conducted appropriately, herbicide application can help improve habitat for the Colorado butterfly plant by eliminating competition.

Effects of Climate Change

Impacts from climate change were not considered in the final rule to list the species (65 FR 62302; October 18, 2000) or in the critical habitat designation (70 FR 1940; January 11, 2005). Our current analyses under the Act include consideration of ongoing and projected changes in climate. The terms “climate” and “climate change” are defined by the Intergovernmental Panel on Climate Change (IPCC). “Climate” refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007, p. 78). The term “climate change” thus refers to a change in the mean or variability of one or more measures of climate (e.g., temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2007, p. 78). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (e.g., habitat fragmentation) (IPCC 2007, pp. 8–14, 18–19). In our analyses, we use our expert judgment to weight relevant information including uncertainty, in our consideration of various aspects of climate change.
According to IPCC, “most plant species cannot naturally shift their geographical ranges sufficiently fast to keep up with current and high projected rates of climate change on most landscapes” (IPCC 2014, p. 13). Plant species with restricted ranges may experience population declines as a result of the effects of climate change.

The concept of changing climate can be meaningfully assessed both by looking into the future and reviewing past changes. A review of Wyoming climate since 1895 indicates that there has been a significant increase in the frequency of warmer-than-normal years, an increase in temperatures throughout all regions of the State, and a decline in the frequency of “wet” winters (Shumann 2011). Data from the Cheyenne area over the past 30 years indicate a rise in spring temperatures (Heidel et al. 2016). The current climate in Colorado butterfly plant habitat is quite variable, with annual precipitation ranging from 25–50 cm (10–20 in) of rain and 81–275 cm (32–108 in) of snow per year near the center of the species’ range at Cheyenne Municipal Airport (NOAA 2016, entire). The years 2000 through 2006 appeared to have lower than average precipitation (NOAA 2016, entire), which may have affected the ability of plants to withstand flea beetle outbreaks in 2007 (Heidel et al. 2011, p. 286). The Colorado butterfly plant is semelparous (individual plants are first vegetative, then flower and fruit, and then die). Therefore, individuals are likely capable of remaining in a vegetative state under some conditions and duration until suitable flowering conditions exist, suggesting that the species is adapted to variability in the amount and timing of precipitation.

Climate change may affect the timing and amount of precipitation as well as other factors linked to habitat conditions for the Colorado butterfly plant. For example, climate models predict that by 2050, watersheds containing the species will become warmer for all four seasons, precipitation will increase in the winter, and remain about the same in spring, summer, and fall (USGS 2016, pp. 1–3). Snow water equivalent will decrease in winter and spring, and soil water storage will decrease in all four seasons (USGS 2016, pp. 4–5). Modeling predicts an increase in winter precipitation, but decreases in soil water storage will mean less water for subirrigation of the species’ habitat. This may mean a shorter window for seed germination, lower seed production, and potentially increased years at the rosette stage to obtain sufficient resources to bolt and flower. However, we also understand that C₃ plants (plants which combine water, sugar, and carbon dioxide in carbon fixation), including this species, have a 41 percent proportional increase in growth resulting from a 100 percent increase in carbon dioxide (Poorter 1993, p. 77). This increase in growth rate due to higher carbon dioxide may counteract the need to spend more time in the vegetative portion of the life cycle in response to climate change.

Additionally, monitoring indicates that populations are able to withstand several consecutive years of poor growing conditions, and still rebound with suitable conditions (USFWS 2012, pp. 11–22; USFWS 2016c, entire). Climate change has the potential to affect the species and its habitat if flea beetle outbreaks are fostered or if flowering levels are suppressed. Although we lack scientific certainty regarding what those changes may ultimately mean for the species, we expect that the species’ current adaptations to cope with climate variability will mitigate the impact on population persistence.

Summary of Factor E

Under this factor, we discussed the Colorado butterfly plant’s small population size and restricted range, herbicide spraying, and climate change. In 2000, when we listed the species, the stochastic extirpation of individual populations suggested that the range of the species might be declining. Despite the fact that some populations in Colorado, Wyoming, and Nebraska were extirpated prior to listing, and others in Nebraska were extirpated after listing, four additional populations have been discovered, two of which are protected, and there are still representative and redundant populations occurring throughout the range of the species. Further, individuals and populations are resilient to a single herbicide application, and have been shown to survive or bounce back from such events. Education of landowners has greatly reduced the indiscriminate application of herbicides near populations of the Colorado butterfly plant. Finally, while climate change presents a largely unknown potential stressor to the species, individual plants are capable of deferring the reproductive stage until suitable conditions are available, populations are made up of individuals found in a range of microhabitats, and populations are located within various ecological settings within the species’ range. This indicates that the resiliency, redundancy, and representation of populations will maintain the species in the face of climate change.

Combination of Factors

Many of the stressors discussed in this analysis could work in concert with each other and result in a cumulative adverse effect to the Colorado butterfly plant, e.g., one stressor may make the species more vulnerable to other threats. For example, stressors discussed under Factor A that individually do not rise to the level of a threat could together result in habitat loss. Similarly, small population size and a restricted range in combination with stressors discussed under Factor A could present a potential concern. However, most of the potential stressors we identified either have not occurred to the extent originally anticipated at the time of listing or are adequately managed as described in this proposal to delist the species. Furthermore, those stressors that are evident, such as climate change and grazing, appear well-tolerated by the species. In addition, for the reasons discussed in this proposed rule, we do not anticipate stressors to increase on lands that afford protections to the species (Warren AFB and CF CNAD lands) where many of the largest populations occur. Furthermore, the increases documented in the number and size of many populations since the species was listed do not indicate that cumulative effects of various activities and stressors are affecting the viability of the species at this time or into the future.

Proposed Determination of Species Status

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for determining whether a species is an endangered species or threatened species and should be included on the Federal Lists of Endangered and Threatened Wildlife and Plants (listed). The Act defines an endangered species as any species that is “in danger of extinction throughout all or a significant portion of its range” and a threatened species as any species that is “likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” We may delist a species according to 50 CFR 424.11(d) if the best available scientific and commercial data indicate that the species is neither endangered or threatened for the following reasons: (1) The species is extinct; (2) the species has recovered and is no longer endangered or threatened; and/or (3) the original scientific data used at the time the species was classified were in error.
Determination of Status Throughout All of the Colorado Butterfly Plant’s Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Colorado butterfly plant. We examined the status of the species based on the 2010 Colorado butterfly plant recovery outline (USFWS 2010, entire). We also consulted with species experts and land management staff with Fort Collins and Warren AFB who are actively managing for the conservation of the Colorado butterfly plant.

The 2010 Colorado butterfly plant recovery outline presented a recovery vision for the species in which the primary focus was protection of existing populations, threats abatement, and research (USFWS 2010, entire). The initial action plan focused on protection of existing populations through partnerships with Warren AFB, Fort Collins, and private landowners, followed by developing a recovery plan that would contain objective, measurable recovery criteria which, when met, would indicate that the species could be removed from the Federal List of Endangered and Threatened Plants. In 2016, the Service’s Wyoming Ecological Services Field Office began development of a recovery plan for the Colorado butterfly plant. In reviewing information regarding population numbers and trends, as well as threats, it appeared that most monitored extant populations were doing well. Threats named at the time of listing were either affecting the species at low levels, likely due to management actions to recover the species, or not affecting the species at all, as was observed in preparing the 2012 5-year status review (USFWS 2012, entire). Therefore, the Service conducted an assessment of the status of the species and whether it should remain on the List of Endangered and Threatened Plants under the Act.

We carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Colorado butterfly plant. We considered all of the stressors identified at the time of listing in 2000, as well as newly identified potential stressors such as oil and gas energy development and the effects of climate change. The stressors considered in our five-factor analysis (discussed in detail above under Summary of Factors Affecting the Species) fall into one or more of the following categories:

- **Minimized or mitigated:** The following stressors are adequately managed, and existing information indicates that this will not change in the future: Residential, urban, and energy development; agricultural practices; water management; overutilization; and herbicide spraying.
- **Avoided:** The following stressor has not occurred to the extent anticipated at the time of listing, and existing information indicates that this will not change in the future: Restricted range.
- **Tolerated:** The species is tolerant of the following stressors, and existing information indicates that this will not change in the future: Natural succession and competition with nonnative, invasive species; disease and predation; and climate change.

These conclusions are supported by the available information regarding the species’ abundance, distribution, and trends, and are in agreement with conclusions presented in our 2010 recovery outline (USFWS 2010, entire) and in our 5-year review (USFWS 2012, entire). Thus, after assessing the best available information, we conclude that the Colorado butterfly plant is not in danger of extinction, nor is it likely to become so in the foreseeable future.

Determination of Status Throughout a Significant Portion of the Colorado Butterfly Plant’s Range

Under the Act and our implementing regulations, a species may warrant listing if it is an endangered or threatened species throughout all or a significant portion of its range. The Act defines “endangered species” as any species which is “in danger of extinction throughout all or a significant portion of its range,” and “threatened species” as any species which is “likely to become an endangered species within the foreseeable future through all or a significant portion of its range.” The term “species” includes “any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature.” We published a final policy interpreting the phrase “Significant Portion of its Range” (SPR) (79 FR 37578). The final policy states that (1) if a species is found to be an endangered or threatened species throughout a significant portion of its range, the entire species is listed as an endangered or a threatened species, respectively, and the Act’s protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is “significant” if the species is not currently an endangered or a threatened species throughout all of its range, but the portion’s contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time FWS or NMFS makes any particular status determination; and (4) if a vertebrate species is an endangered or a threatened species throughout an SPR, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies.

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. If the species is neither an endangered nor a threatened species throughout all of its range, we determine whether the species is an endangered or a threatened species throughout a significant portion of its range. If it is, we list the species as an endangered or a threatened species, respectively; if it is not, we conclude that listing the species is not warranted.

When we conduct an SPR analysis, we first identify any portions of the species’ range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and either an endangered or a threatened species. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is an endangered or a threatened species throughout a significant portion of its range—rather, it is a step in determining whether a more detailed analysis of the issue is
required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of “significant” (i.e., the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is an endangered or a threatened species. We must go through a separate analysis to determine whether the species is an endangered or a threatened species in the SPR. To determine whether a species is an endangered or a threatened species throughout an SPR, we will use the same standards and methodology that we use to determine if a species is an endangered or a threatened species throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the “significant” question first, or the status question first. Thus, if we determine that the portion of the range is not “significant,” we do not need to determine whether the species is an endangered or a threatened species there; if we determine that the species is not an endangered or a threatened species in a portion of its range, we do not need to determine if that portion is “significant.”

We evaluated the range of the Colorado butterfly plant to determine if any area could be considered a significant portion of its range. The only portion of the range where threats are geographically concentrated are the three populations in Nebraska. Grazing and water management, particularly the dewatering of Lodgepole Creek downstream of the Wyoming/Nebraska border in the three populations in Nebraska, has proven to impact populations in that portion of the range. Grazing geographically concentrated are the significant portion of its range. The only area could be considered a "significant."'' (i.e., the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is an endangered or a threatened species. We must go through a separate analysis to determine whether the species is an endangered or a threatened species in the SPR. To determine whether a species is an endangered or a threatened species throughout an SPR, we will use the same standards and methodology that we use to determine if a species is an endangered or a threatened species throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the “significant” question first, or the status question first. Thus, if we determine that the portion of the range is not “significant,” we do not need to determine whether the species is an endangered or a threatened species there; if we determine that the species is not an endangered or a threatened species in a portion of its range, we do not need to determine if that portion is “significant.”

We evaluated the range of the Colorado butterfly plant to determine if any area could be considered a significant portion of its range. The only portion of the range where threats are geographically concentrated are the three populations in Nebraska. Grazing and water management, particularly the dewatering of Lodgepole Creek downstream of the Wyoming/Nebraska border in the three populations in Nebraska, has proven to impact populations in that portion of the species’ range. This stressor has affected these populations to a level that the populations were presumed extirpated at the time we designated critical habitat for this species (FR 1940; January 11, 2005). However, after water was reintroduced to the creek by a landowner, Colorado butterfly plants were again observed in Lodgepole Creek (Wooten 2008, p. 4). It is possible that the species only occurs in this portion of its range during times of adequate subirrigation and surface flows, and that seeds either remain dormant at this location for several years or are transported from neighboring populations located upstream on Lodgepole Creek in Wyoming. Nevertheless, the removal of water from Lodgepole Creek impacts populations of the Colorado butterfly plant within this portion of the species’ range.

Because we identified an area on the periphery of the species’ current range as warranting further consideration due to the geographic concentration of threats from water management, we then evaluated whether this area may be significant to the Colorado butterfly plant such that, without the members in that portion, the entire species would be in danger of extinction, or likely to become so in the foreseeable future, through all of its range. We can accomplish this by considering the viability of the remainder of the range without the portion and the biological or conservation importance of the portion. The viability of the remainder of the range, should the three populations in Nebraska be lost, will remain high: All of the highly and moderately resilient populations occur in the remainder of the range, which is comprised of more than 20 populations distributed through a geographically connected area, and which contains all of the ecological settings this species is known to inhabit.

Additionally, to determine significance of this threatened portion of the range, we examined its contribution to the species’ viability in terms of its resiliency, redundancy, and representation. Regarding redundancy, the populations within this portion of the range occur on the eastern extreme of the historical range of the species and represent a very small component of the total distribution of the species occurring downstream of several highly viable populations. Therefore, these populations do not substantially increase redundancy at the species level. Regarding resiliency, individual plants in this portion of the range may be resilient to dewatering or other stressors, but populations contain few individuals and are, therefore, threatened by stochastic events. Regarding representation, we understand that there may be connectivity among the populations occurring downstream of Lodgepole Creek in Wyoming. However, this connectivity is likely only through limited pollinator movement among the few flowering plants at any location, and through seed dispersal downstream from Wyoming to Nebraska, considering the distance is too great (>1 km/0.6 mi) for most pollinators to travel (Heidel 2016, pers. comm.). Consequently, the populations in Nebraska are likely not contributing any genetic information upstream. We do not have genetic information on these populations, but we understand that the populations in this portion of the species’ range do not occupy unique ecological settings, have unique morphology, or have differing phenology than other populations of the species on Lodgepole Creek or in the rest of the species’ range.

After careful examination of the Colorado butterfly plant population in the context of our definition of “significant portion of its range,” we determine an area on the periphery of the range warranted further consideration because threats are geographically concentrated there. After identifying this area, we evaluate whether it is significant and determine that it is not significant because, even without Colorado butterfly plants in this area, the species would not be in danger of extinction, or likely to become so in the foreseeable future. This is because the remainder of the species is characterized by high levels of resiliency, redundancy, and representation; the remainder of the species contains all of the highly and moderately resilient populations (high resiliency), is comprised of more than 20 populations distributed through a geographically connected area (high redundancy), and includes all of the ecological settings this species is known to inhabit (high representation).

Therefore, we did not need to determine if the species is in danger of extinction or likely to become so in the foreseeable future in this peripheral area in Nebraska.

Determination of Status for the Colorado Butterfly Plant

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the Colorado butterfly plant. The threats that led to the species being listed under the Act (primarily loss of the species’ habitat (Factor A) and small population size, restricted range, and herbicide spraying (Factor E)) have not occurred to the extent anticipated at the time of listing, or are being appropriately managed by the actions of multiple conservation partners over the past 18 years. These actions include habitat management,
monitoring, and research. Given commitments shown by private landowners, local governments, cooperating agencies, and other partners as discussed under Factor D, we expect conservation efforts will continue to support a healthy, viable population of the species post-delisting and into the foreseeable future. Furthermore, there is no information to conclude that at any time over the next 20 years (as we define the foreseeable future for this species) the species will be in danger of extinction. Because the species is not in danger of extinction now or within the foreseeable future throughout all or any significant portion of its range, the species does not meet the definition of an endangered species or threatened species. We therefore propose to remove the Colorado butterfly plant from the Federal List of Endangered and Threatened Wildlife at 5 CFR 17.11(h) due to recovery. Because the species is neither in danger of extinction now nor likely to become so in the foreseeable future throughout all or any significant portion of its range, the species does not meet the definition of an endangered species or a threatened species under the Act.

Effects of the Rule

This proposal, if made final, would revise 50 CFR 17.12(h) to remove the Colorado butterfly plant from the Federal List of Endangered and Threatened Plants. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, would no longer apply to this species. Federal agencies would no longer be required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect the Colorado butterfly plant or its designated critical habitat. This proposal, if made final, would also remove the designation of critical habitat for the Colorado butterfly plant in Wyoming (codified at 50 CFR 17.96(a)).

Post-Delisting Monitoring

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been delisted due to recovery. The purpose of this requirement is to develop a program that detects the failure of any delisted species to sustain itself without the protective measures provided by the Act. If, at any time during the monitoring period, data indicate that protective status under the Act should be restated, we can initiate listing procedures, including, if appropriate, emergency listing.

We are proposing delisting for the Colorado butterfly plant based on recovery actions taken and new information we have received. Since delisting would be due in part to recovery actions taken by Warren AFB, Fort Collins, and BLM, we have prepared a draft post-delisting monitoring plan for the Colorado butterfly plant. The plan has been developed with input from these and other partners.

It is our intent to work with our partners towards maintaining the recovered status of the Colorado butterfly plant. While not required, we intend to seek peer review comments on the draft post-delisting monitoring plan (PDM plan), including its objectives and procedures. A copy of the draft PDM plan is available at http://www.regulations.gov under Docket No. FWS–R6–ES–2018–0008. You can submit your comments on the draft PDM plan by one of the methods listed above under ADDRESSES.

Required Determinations

Clarity of This Proposed Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1996, 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.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), need not be prepared in connection with regulations pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the Federal Register on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President’s memorandum of April 29, 1994, Government-to-Government Relations with Native American Tribal Governments (59 FR 22951), E.O. 13175, and the Department of the Interior’s manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribes will be affected by this rule.

References Cited

A complete list of all references cited in this proposed rule is available at http://www.regulations.gov at Docket No. FWS–R6–ES–2018–0008, or upon request from the Wyoming Ecological Services Field Office (see ADDRESSES).

Authors

The primary authors of this proposed rule are staff members of the Wyoming Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we hereby propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

§ 17.12 [Amended]

■ 2. Amend § 17.12(h) by removing the entry “Gaura neomexicana ssp. coloradensis” under “FLOWERING PLANTS” from the List of Endangered and Threatened Plants.
§ 17.96 [Amended]

3. Amend § 17.96(a) by removing the entry “Family Onagraceae: Gaura neomexicana ssp. coloradensis (Colorado butterfly plant)”. Dated: May 15, 2018.

James W. Kurth,
Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, for the U.S. Fish and Wildlife Service.

[FR Doc. 2018–12409 Filed 6–7–18; 8:45 am]
BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 660

RIN 0648–XE456

Pacific Fisheries Management Council;
Notice of Intent To Withdraw an Environmental Impact Statement for Gear Rule Changes for the Pacific Coast Groundfish Fishery Trawl Catch Share Program

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

ACTION: Withdrawal of notice of intent to prepare an environmental impact statement.

SUMMARY: NMFS is issuing this notice to advise Federal, state, and local government agencies and the public that it is withdrawing its Notice of Intent (NOI) to prepare a draft Environmental Impact Statement (EIS) for the proposed action to revise regulations regarding the use and configuration of groundfish bottom trawl and midwater trawl gear in the Pacific Coast Groundfish Fishery's Trawl Catch Share Program, also called the Trawl Rationalization Program. After completion of the analysis, NMFS determined the impacts associated with this action would not reach a level necessitating an EIS, and is instead preparing an Environmental Assessment (EA).

DATES: The environmental impact statement for the proposed regulations is withdrawn as of June 8, 2018.

FOR FURTHER INFORMATION CONTACT: Colin Sayre, NMFS West Coast Regional Office, telephone: (206) 526–4656, or email: colin.sayre@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS published a NOI in the Federal Register on March 3, 2016 (81 FR 11189) to prepare an EIS in accordance with the National Environmental Policy Act (NEPA) to analyze the impacts on the human environment resulting from changes to gear requirements for groundfish bottom trawl and midwater trawl gear in the Trawl Rationalization Program. Additional details about the range of alternatives considered in this action are included in the March 3, 2016, NOI, and are not repeated here. NMFS solicited public input on the scope of the analysis through a public comment on the NOI from March 3, 2016, to April 4, 2016.

Upon completion of the analysis for the proposed action, NMFS determined that the impacts associated with the implementation of the proposed action would not be significant and, therefore, there is no need to complete the EIS. Instead, NMFS is completing an EA, in compliance with NEPA, for the proposed action. Therefore, NMFS is withdrawing the NOI to prepare an EIS. NMFS plans to circulate the draft EA for public review and comment concurrent with publication of the proposed rule for this action.


Dated: June 1, 2018.

Jennifer M. Wallace,
 Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–12165 Filed 6–7–18; 8:45 am]
BILLING CODE 3510–22–P
DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 5, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by July 9, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Mechanically Tenderized Beef Products.
OMB Control Number: 0583–0160.
Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.). This statute mandate that FSIS protect the public by ensuring that meat products are safe, wholesome, unadulterated, and properly labeled and packaged.

Need and Use of the Information: FSIS requires the use of the descriptive designation “mechanically tenderized” on the labels of raw or partially cooked needle or blade tenderized beef products, including beef products injected with marinade or solution, unless such products are destined to be fully cooked at an official establishment. Beef products that have been needle or blade tenderized are referred to as “mechanically tenderized” products. Consumers use the information added to the labels of raw or partially cooked mechanically tenderized beef products to ensure that they thoroughly cook these products.

Description of Respondents: Business or other-for profit.
Number of Respondents: 555.
Frequency of Responses: Reporting: One time.
Total Burden Hours: 19,719.

Ruth Brown,
Departmental Information Collection Clearance Officer.
[FR Doc. 2018–12353 Filed 6–7–18; 8:45 am]
BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection: Wild Food Collecting in Atlanta’s Browns Mill Community

AGENCY: Forest Service, USDA.
ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the USDA Forest Service is seeking comments from all interested individuals and organizations on the information collection, Wild Food Collecting in Atlanta’s Browns Mill Community, under the approved Forest Service Generic Information Collection on Non-Timber Forest Products.

DATES: Comments must be received in writing on or before July 9, 2018 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Cassandra Johnson Gaither, Forestry Sciences Lab, 320 Green St., Athens, GA 30602. Comments also may be submitted via facsimile to (706) 559–4266 or by email to: cjohnsont09@fs.fed.us. The public may inspect comments received at Forestry Sciences Lab, 320 Green St., Athens, GA 30602 during normal business hours. Visitors are encouraged to call ahead to (706) 559–4264 to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Cassandra Johnson Gaither, USDA Forest Service, Southern Research Station, 706–559–4270. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 twenty-four hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:
Title: Wild Food Collecting in Atlanta’s Browns Mill Community.
OMB Number: 0596–0243.
Expiration Date of Approval: October 31, 2020.
Type of Request: Individual Information Collection under Approved Generic Information Collection.

Abstract: This information collection gathers data on the social acceptability of urban foraging in Atlanta’s Browns Mill community, and is an individual information collection under the Forest Service generic collection on non-timber forest products (Office of Management and Budget approval # 0596–0243, approved through October 31, 2020). This 30-day Federal Register Notice provides an opportunity for public comment on this individual information collection taking place under the generic collection approval.
There is growing literature on urban foraging in the United States that...
concentrates on the Northeast, Pacific Northwest, and Pacific Southwest regions of the country. No studies have undertaken this investigation in the South, despite the fact that the South has a climate very conducive to both the growing and harvesting of wild foods. The City of Atlanta is cooperating with the Browns Mill community in southeast Atlanta to establish a Food Forest. This effort is being undertaken to help address the relative dearth of fresh produce sources in this part of the city, areas considered “food deserts”. The success of this effort for the Browns Mill community will hinge on residents’ views and ultimate engagement with the resource. This study aims to capture that information.

The data are intended to provide information on both urban foraging practices and the social acceptability of foraging by an urban minority group that is underserved from the perspective of having nearby, fresh produce sources. The survey will be conducted face-to-face at the household using paper copies of a survey instrument. Attempts will be made to conduct the survey face-to-face, but if that is not convenient for the householder, the survey will be left at the respondent’s home and picked up at an agreed upon time. Trained neighborhood residents will help to administer the survey. Attempts will be made to have survey administrators from the Browns Mill or a nearby community. This is expected to increase response rates because of the familiarity of administrators with this part of the city. All administrators will receive training in appropriate data collection techniques from the USDA Forest Service or one of its partners.

Type of Respondents: Browns Mill community residents.
Estimated Annual Number of Respondents: 400.
Estimated Annual Number of Responses per Respondent: 1.
Estimated Amount of Time to Complete Survey Respondent: 1.67 hours.
Estimated Total Annual Burden on Respondents: 66.8 hours.
Comment is Invited:
Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency’s estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Carlos Rodriguez-Franco,
Deputy Chief, Research & Development.

[FR Doc. 2018–12311 Filed 6–7–18; 8:45 am]
BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE
Forest Service

Bend-Fort Rock Ranger District; Deschutes National Forest; Deschutes County Oregon; Twin Vegetation Management and Restoration Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA Forest Service will prepare an environmental impact statement (EIS) on a proposed action to promote more resilient forest conditions closer to their historic range of variability, which would contribute to desirable recreation experiences, conserve and enhance wildlife habitat, and reduce impacts to streams and aquatic habitat within the 40,000 acres Twin project area. The project area is located south and southwest of Bend, Oregon and includes the areas surrounding Wickipup and Crane Prairie Reservoirs, North and South Twin Lakes, Browns Mountain and Round Mountain Late Successional Reserves. An analysis has been initiated that takes a landscape approach to managing the vegetation to meet objectives for resilient forests.

DATES: Comments concerning the scope of the analysis must be received by July 9, 2018. The draft EIS is expected September 2019 and the final EIS is expected August 2020.

ADDRESSES: Send written comments to Kevin Larkin, District Ranger, Bend-Fort Rock Ranger District, 63095 Deschutes Market Road, Bend, OR 97701. Comments may also be sent via email to comments-pacificnorthwest-deschutes@fs.fed.us, or via facsimile to 541–383–4700, or submitted in person during regular business hours, Monday–Friday, 8:00 a.m.–4:30 p.m. at the address listed above.

FOR FURTHER INFORMATION CONTACT: Alicia Underhill, Environmental Coordinator, Bend-Fort Rock Ranger District, 63095 Deschutes Market Road, Bend, OR 97701, phone 541–383–4012, between the hours of 8:00 a.m. and 4:30 p.m., Pacific Time, Monday through Friday or by email at alicia@derschutes@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:
Purpose and Need for Action

There is a need to manage stand structure and composition to tolerate primary disturbance agents (i.e., fire, insect and disease) on a landscape scale and to improve fire management opportunities in anticipation of future wildfire events. There is a need to address impacts to shorelines, streambanks, and riparian vegetation due to recreational use. There is a need to restore wetland and stream function. There is a need to manage recreation impacts and a need to address trees showing signs of future failure within developed recreation sites. There is a need to establish an appropriate buffer between developed and dispersed campsites to minimize conflicts. There is a need to manage system and non-system roads to reduce negative impacts to natural resources.

In summary, the Twin project intends to create more resilient forest conditions closer to their historic range of variability, which would contribute to desirable recreation experiences, conserve and enhance wildlife habitat, and reduce impacts to streams and aquatic habitat from high severity fires.

Proposed Action

The Bend-Fort Rock Ranger District proposes the following actions to meet the purpose and need of the project area. Silviculture treatments (e.g., thinning) will focus on restoration treatments in ponderosa and dry mixed conifer plant association groups and stand healthy and age class diversity in lodgepole pine plant association groups. Commercial treatments on 4,894 acres will focus on reducing stocking levels and re-establishing stand structure and species composition to reflect historic stand conditions found in fire adapted ecosystems. Commercial treatments on 2,855 acres focus on improving overall stand health and diversity of age...
classes across the landscape which would decrease the susceptibility of large scale mountain pine beetle outbreaks. Treatments proposed within the Browns Mountain Late Successional Reserve (LSR) are designed to accelerate the development of large trees and reduce stand densities which would reduce the risk of a stand to fire, insects and disease. No commercial treatments are proposed in Northern spotted owl (NSO) high quality habitat nor within activity centers or within high value habitat within LSR. Ladder fuel reduction treatments proposed in high value NSO habitat (approximately 920 acres) would affect the lowest canopy layer and stands would remain overstocked and above the upper management zone density.

To meet the need to improve fire management opportunities and provide for public and firefighter safety, this project proposes to treat approximately 16,800 acres of treatment to meet hazardous fuels reduction objectives.

The Twin projects also proposes to:
(a) Rehab dispersed sites that are causing resource damage; (b) enhance spawning gravel, address boat ramp erosion and improve accessible trails; (c) establish a buffer between developed and dispersed campsites; (d) remove trees showing signs of future failure within developed sites; and (e) close and decommissioning system roads and decommission user-created roads.

Responsible Official

The responsible official will be Kevin Larkin, District Ranger, Bend-Fort Rock Ranger District.

Nature of Decision To Be Made

The responsible official will consider how the proposed action meets the project’s purpose and need, how public comments have been considered, and what the short and long term effects and benefits are to other resource areas.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the EIS. Public comments regarding this proposal are requested in order to assist in identifying issues and opportunities associated with the proposal, how to best manage resources, and to focus the analysis. Those wishing to object must meet the requirements at 36 CFR 218.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency’s preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer’s concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

Dated: May 9, 2018.
Chris French,
Associate Deputy Chief, National Forest System.

SUPPLEMENTARY INFORMATION: This notice initiates the Scoping Process.

I. Purpose and Need

A. Project Description

The Twin Ranger District proposal to decommission user-created roads and decommissioning system roads and areas within developed sites; and (e) close and decommissioning system roads and decommission user-created roads.

B. Project Purpose

1. Benefits to the Environment

2. Benefits to Other Resource Areas

III. Responsible Official

The responsible official will be Kevin Larkin, District Ranger, Bend-Fort Rock Ranger District.

IV. Nature of Decision To Be Made

The responsible official will consider how the proposed action meets the project’s purpose and need, how public comments have been considered, and what the short and long term effects and benefits are to other resource areas.

V. Scoping Process

This notice of intent initiates the scoping process, which guides the development of the EIS. Public comments regarding this proposal are requested in order to assist in identifying issues and opportunities associated with the proposal, how to best manage resources, and to focus the analysis. Those wishing to object must meet the requirements at 36 CFR 218.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency’s preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer’s concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered.

Dated: May 9, 2018.
Chris French,
Associate Deputy Chief, National Forest System.
This clearance request covers the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, federally affiliated persons overseas, and the Island Areas of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the United States Virgin Islands. The methods of data collection for the Federally Affiliated Count Overseas and the Island Areas Censuses are different from the data collections described throughout this document and will be described separately in sections specific to those operations.

In compliance with Public Law 94–171, the Census Bureau will tabulate for each state the total population counts by race and Hispanic origin. The Census Bureau will tabulate these counts for the total population and for the population of 18 years of age and over. The Census Bureau intends to work with the National Conference of State Legislatures and other stakeholders to solicit feedback as to how the states would prefer to receive tabulations of citizenship data. If stakeholders such as the National Conference of State Legislatures elect to receive tabulations of citizenship data, the Census Bureau will make require a design change to include citizenship as part of the Public Law 94–171 Redistricting Data File. That new design plan would then be published in the Federal Register after the 2020 Census final design is completed in the summer of 2019. For the prototype and for the 2020 Census, the Census Bureau will provide these tabulations for a variety of standard census geographic areas including state, county, place, tract, and tabulation block. If states provide their congressional, legislative, and voting districts through the Redistricting Data Program, the Census Bureau will also provide the tabulations for these areas. The Census Bureau also will tabulate housing unit counts by occupancy status (occupied or vacant) and provide total population counts for group quarters by group quarters type for a select set of geography, including tabulation block by congressional, legislative, and voting districts will be available for the 50 states; equivalent tallies will be available for the District of Columbia and the Commonwealth of Puerto Rico. Tallies for state, county, and place will be available for the Island Areas.

The Census Bureau plans to conduct the most automated, modern, and dynamic decennial census in history. The 2020 Census includes design changes in four key areas:

1. New methodologies to conduct the Address Canvassing operation.
2. Innovative ways of optimizing self-response.
3. The use of administrative records and third-party data to reduce the Nonresponse Followup (NRFU) operation workload.
4. The use of technology to reduce the manual effort and improve the productivity of field operations, while decreasing the amount of physical space required to perform the field operations. To the extent that these innovations influence the collection of data from respondents in the 2020 Census, these innovations will be described below.

1. Reengineering Address Canvassing

A complete and accurate address list is the cornerstone of a successful census. In order to conduct the decennial census and enumerate in the census all people at a location, the Census Bureau needs the address and physical location of each place where someone is, or could be, living. In other words, all living quarters need to be identified. The Census Bureau maintains an address list and spatial data for the United States and Puerto Rico in its Master Address File (MAF)/Topologically Integrated Geographic Encoding and Referencing (TIGER) System database. This database was created using the address files from the 1990 Census and has been subsequently and regularly updated using:

- Information collected from decennial census operation updates, including address and spatial updates.
- The Delivery Sequence File of addresses from the United States Postal Service (USPS).
- Input from tribal, state, and local governments and third parties, including address and boundary updates.
- Information collected in other Census Bureau programs, such as the American Community Survey.

Type of Enumeration Areas

Prior to the census, it is necessary to delineate all geographic areas included in the 2020 Census into Type of Enumeration Areas (TEAs). These TEAs describe what methodology will be used for census material delivery and household enumeration in order to use the most cost-effective enumeration approach for achieving maximum accuracy and completeness. For the United States and Puerto Rico, TEAs are delineated at the block level based on the address and spatial data in the MAF/TIGER database. The MAF/TIGER does not contain data for the Island Areas, so a separate TEA is designated for these areas. The
TEAs designated for the 2020 Census are:

- **TEA 1 = Self-Response.**
- **TEA 2 = Update Enumerate.**
- **TEA 3 = Island Areas.**
- **TEA 4 = Remote Alaska.**
- **TEA 5 = Military.**
- **TEA 6 = Update Leave.**

The most common enumeration method by percentage of households is self-response (TEA 1), where materials will be delivered to each address through the mail, and enumeration data is expected to be returned or submitted by a respondent. After the initial self-response phase, nonresponding households will be enumerated in the NRFU operation. Puerto Rico is designated as entirely Update Leave. These TEAs, programs, and operations will be described throughout this notice.

### Address Canvassing

Address Canvassing is the process of validating and updating addresses in the MAF and spatial data in TIGER before the census in order to create the initial list of addresses to be enumerated in the census. All housing units, group quarters, and transitory locations need to be identified and located correctly on the map as recorded in TIGER. Group quarters are living quarters where people who are typically unrelated have group living arrangements and frequently are receiving some type of service. College/university student housing and nursing/skilled-nursing facilities are examples of group quarters. Transitory locations include recreational vehicle parks, campgrounds, racetracks, circuses, carnivals, marinas, hotels, and motels. People residing at transitory locations during the census are recorded as living in housing units located at transitory locations. Address Canvassing will not occur in Island Areas.

For the 2020 Census, the Census Bureau is using In-Office Address Canvassing for the first time, in addition to In-Field Address Canvassing. This innovation involves the use of electronic sources for much of the validation and updating of MAF/TIGER. Since 2015, the Census Bureau has used analysis of satellite imagery to identify areas of the United States and Puerto Rico where changes in living quarters have occurred. In-Office Address Canvassing is the process of using empirical geographic evidence (e.g., imagery and comparison of the Census Bureau’s address list to partner-provided lists) to assess the current address list. This process detects and identifies change using high-quality imagery, administrative data, and third-party sources to review and update the address list.

However, the Census Bureau will still need to conduct In-Field Address Canvassing in order to update the address and spatial data for an estimated 30 percent of housing units in TEA 1. The Census Bureau will make a final determination on which areas will be canvassed using In-Field Address Canvassing by March 2019. Some In-Office Address Canvassing activities will continue improving the address list until March 2020. In-Field Address Canvassing is the only stage of Address Canvassing that involves collecting information from the general public. The associated response burden is detailed later in this notice.

#### (2) Optimizing Self-Response

The goal of this innovation area is to communicate the importance of the 2020 Census to the entire population of the 50 states, the District of Columbia, and Puerto Rico in order to generate the largest possible self-response. Self-response reduces the need to conduct in-person follow-up operations to complete the enumeration. To that end, the Census Bureau will motivate people to respond, as well as make it easy for people to respond, from any location at any time.

### Internet Self-Response

One major means of making it easier for people to respond is by providing an internet questionnaire and using mailings, questionnaire delivery, advertising, and publicity to tell the public about this option. Internet response represents a substantial innovation for the enterprise. The internet was not a response option in the 2010 Census. The internet response option has been included in multiple tests leading up to the 2020 Census: The 2014 Census Test; all three census tests performed in 2015; the 2016 Census Test; the 2017 Census Test; and the 2018 End-to-End Census Test. Based on results from these tests, response rates from prior censuses, and data from the American Community Survey and other surveys, the Census Bureau estimates that 45 percent of U.S. households in areas that receive mailouts of materials from the Census Bureau will respond via the internet before the initial NRFU workload is created. At the same time, the Census Bureau recognizes the need for alternate response modes to allow respondents to complete their 2020 Census questionnaire, including paper questionnaires as used in the past. Details about the contact strategy for mailed materials in TEA 1 will be discussed below. The Census Questionnaire Assistance operation, also described below, will provide the third mode of self-response. Overall, the Census Bureau estimates that 60.5 percent of households that receive mailouts or hand delivery of materials from the Census Bureau will self-respond in one of these three modes (i.e., internet, paper, telephone) prior to the beginning of NRFU activities.

For the 2020 Census, “administrative records” and “third-party data” are terms used to describe micro data records contained in files collected and maintained by Federal, state, and local government agencies (“administrative records”) and commercial entities (“third-party data”) for administering programs and providing services. For many decades, the Census Bureau has successfully and securely used administrative records and third-party data for statistical purposes. For the 2020 Census, the Census Bureau intends to use administrative records from both internal sources, such as data from prior decennial censuses and the American Community Survey, and from a range of other Federal agencies, including the Internal Revenue Service (IRS), the Social Security Administration, the Centers for Medicare and Medicaid Services, the Department of Housing and Urban Development, the Indian Health Service, the Selective Service, and the U.S. Postal Service. The Census Bureau is also working to acquire state government administrative records from enrollment in Federal block grant programs, such as the U.S. Department of Agriculture’s Supplemental Nutrition Assistance Program and the Special Supplemental Nutrition Program for Women, Infants, and Children. Finally, the Census Bureau is also utilizing commercial third-party data from organizations such as CoreLogic and the Veterans Service Group of Illinois.

Throughout the decade, the Census Bureau continuously conducted analyses and assessments to verify that the proposed uses of administrative records and third-party data sources in the 2020 Census were appropriate in each instance. Based on this research, testing, and analyses, the Census Bureau announced its plans in November 2015 to utilize administrative records and third-party data in the 2020 Census. The 2020 Census Operational Plan calls for employing this information for the following purposes:

1. Consistent with previous decennial censuses, the Census Bureau will utilize administrative records from federal and
state government agencies and third-party data to refine contact strategies and build and update the residential address list.

2. Also consistent with previous decennial censuses, the Census Bureau will utilize federal and state administrative records to edit or impute invalid, inconsistent, or missing responses.

3. The new use of administrative records for the 2020 Census is to use data exclusively from federal administrative records to improve the accuracy and efficiency of NRFU operations by:

   a. Removing vacant housing units and nonresidential addresses from the NRFU workload.
   b. Enumerating households that do not self-respond and whom we were unable to contact after six mailings and one in-person field visit.

   For each of the purposes listed in items 2, 3a, and 3b, the Census Bureau uses or plans to use administrative data only when it can confirm empirically across multiple sources that the data are consistent, of high quality, and can be accurately applied to the addresses and households in question. The Census Bureau plans to enumerate households utilizing administrative records only from Federal government agencies, such as the Internal Revenue Service. Each of the nonresponding addresses will be evaluated under a strict set of Census Bureau rules throughout the process to ensure completeness and accuracy.

   Based on the research and tests conducted, the Census Bureau estimates that under the current operational plan Federal administrative records will be used to enumerate up to 6.5 million households of the projected total of approximately 60 million addresses that are expected to be the NRFU workload for the 2020 Census. These 6.5 million households represent less than five percent of the approximately 145 million addresses in the Census master address file. Where the Census Bureau does not have confidence in the data, such as when the data are inconsistent or missing in the Federal administrative records, the household will remain in the NRFU workload.

(4) Reengineering Field Operations

The final innovation area, “Reengineering Field Operations,” has a goal of using technology to manage the 2020 Census fieldwork efficiently and effectively, and as a result, reduce the staffing, infrastructure, and brick and mortar footprint for the 2020 Census. These changes to census field operations will not be apparent to respondents to any of the data collection operations.

The 2020 Census Operations

The set of 35 operations that constitute all processes that will occur in the course of the 2020 Census is described in the 2020 Census Operational Plan. In addition to the public-facing data collection operations, there are operations in the categories of support, Information Technology, infrastructure, data publication, and testing and evaluation. The sections below outline data collection operations in the 2020 Census along with some operations that directly support these data collection operations by producing materials for the 2020 Census.

Some data collection operations that are included in the 2020 Census Operational Plan are not described in this notice. These were or will be described in separate notices because of timing, type of work, or other considerations: Local Update of Census Addresses (Federal Register Notices: 81 FR 42686; 81 FR 78109), Redistricting Data Program (Federal Register Notices: 80 FR 40993; 80 FR 62015), Integrated Partnership and Communications (Federal Register Notice: 82 FR 38875), Evaluations and Experiments, and Count Question Resolution. In addition, all Coverage Measurement field operations, which result in an independent estimate of the coverage of the census, will be handled through separate Federal Register Notices.

Final plans for each of these operations could receive minor updates or other changes as a result of lessons learned during the 2018 End-to-End Census Test, further systems testing, or other input received from stakeholders after the date of this posting. Consistent with the Paperwork Reduction Act of 1995 procedures, shortly after the 60-day comment period for this Notice ends, a 30-day Federal Register Notice of a pending information collection will provide the latest information on plans for every data collection operation in the 2020 Census and provide an additional opportunity for the public to comment.

The Content and Forms Design and the Language Services operations for the 2020 Census are essential to data collection because they involve the development and translation of materials used with respondents. These two operations are described below to set the stage for the discussion of the remaining 2020 Census data collection operations.

(A) Content and Forms Design

The Census Bureau submitted the subjects planned for the 2020 Census to Congress on March 28, 2017, and the questions planned for the 2020 Census on March 29, 2018. The proposed questions for the 2020 Census questionnaire include age, citizenship, Hispanic origin, race, relationship, sex, and tenure.

(B) Language Services

Individuals of Limited English Proficiency require language assistance in order to complete their census questionnaires. The Census Bureau has identified the largest Limited English Proficiency populations in the United States using American Community Survey data and has established a program for providing non-English materials for the decennial census. Internet Self-Response and Census Questionnaire Assistance will be available in 12 non-English languages. Paper questionnaires, mailing materials, field data collection instruments, and field data collection materials will be available in English and Spanish. There will be additional support materials in 59 non-English languages.

(C) Address Canvassing

The purpose of address canvassing is (1) to deliver a complete and accurate address list and spatial database for enumeration and tabulation, and (2) to determine the type and address characteristics for each living quarter. Address canvassing consists of two major components: In-Office Address Canvassing and In-Field Address Canvassing. Only the latter component involves collection of information from residents at their living quarters.

For the 2010 Census, the Address Canvassing field staff, referred to as listers, traversed almost every block in the nation to compare what they observed on the ground with the contents of the Census Bureau’s address list. Listers verified or corrected addresses that were on the list, added new addresses to the list, and deleted addresses that no longer existed. Listers also collected map spot locations (i.e., Global Positioning System coordinates) for each structure and added new streets.

The Census Bureau has determined that for the 2020 Census there will be a full Address Canvassing that will consist of In-Office Address Canvassing complemented with In-Field Address Canvassing. In-Office Address Canvassing is the process of using empirical geographic evidence (e.g., imagery, comparison of the Census
### Internet Self-Response Instrument

The internet self-response instrument and all related support systems will be designed to handle the volume of responses that are expected to be received by internet in the 2020 Census. It is imperative that the application and systems service the scale of the operation in order to ensure that users do not experience delays while completing the survey or unavailability of the application. In addition, the internet application and other associated systems will be developed to adhere to the highest standards of data security in order to ensure that all respondent data are secure and confidential.

### Mailing materials

<table>
<thead>
<tr>
<th>Mailing materials treatment</th>
<th>Mailing 1</th>
<th>Mailing 2</th>
<th>Mailing 3 *</th>
<th>Mailing 4 *</th>
<th>Mailing 5 *</th>
</tr>
</thead>
</table>

* Targeted only to nonrespondents.

### Types of contact strategies include

- invitation letters, postcards, and questionnaires mailed to households.

A primary objective of the 2020 Census is for a majority of self-respondents to complete their census questionnaire online. To that end, the Census Bureau will use an approach called “Internet First,” in which the first mailing includes an invitation to respond to the census online.

In areas with low internet coverage or connectivity or other characteristics that may make it less likely that respondents will complete the census questionnaire online, the Census Bureau will employ an “internet Choice” contact strategy. In this approach, the first mailing includes both an invitation to complete the census online and a paper questionnaire. The Census Bureau anticipates about 20 percent of the households in TEA 1 will receive the internet Choice treatment. While all nonresponding households in the internet First areas will eventually receive a paper questionnaire—in the fourth mailing—households in internet Choice areas will receive a paper questionnaire in the first mailing, and again in the fourth mailing if they have not yet responded. Both mailing strategies have the objective of maximizing self-response to the 2020 Census, thereby minimizing NRFU.

The contact strategies for mailing materials in TEA 1 are outlined in table form:

### (D) Forms Printing and Distribution

The Forms Printing and Distribution operation involves the printing and distribution of the following paper forms:

- internet invitation letters.
- Reminder cards and letters.
- Questionnaire mailing packages.
- Materials for other special operations, as required.

Every address record will be identified by an ID, which will be printed on questionnaires and letters and used for tracking for responses. Paper questionnaires and responses from field operations will be linked to the ID in data capture. Internet and telephone respondents will be requested but not required to provide the ID. When an ID is not provided, these will be considered Non-ID responses. The Non-ID operation is discussed below.

### (E) Internet Self-Response

The internet Self-Response operation performs the following functions:

- Maximize online response to the 2020 Census through contact strategies and improved access for respondents.
- Collect response data through the internet to reduce paper and the NRFU universe.

Contact Strategies for Mailing Materials

“Contact strategies for mailing materials” refers to all attempts by the Census Bureau to make direct contact with individual households by mail.

### (F) Census Questionnaire Assistance

The Census Questionnaire Assistance operation has three primary functions:

- Answer respondent questions about specific items on the census questionnaire or other frequently asked questions about the census.
- Provide an option for respondents to complete a census interview over the telephone.
- Provide outbound calling in support of NRFU Reinterview and Coverage Improvement (discussed in the NRFU section below).

Respondents using the internet instrument will have the ability to contact Census Questionnaire Assistance by telephone when web-based self-service help tools cannot answer their questions. Each of the 13 supported languages, including English, will have its own toll-free number for callers. Respondents calling the English and Spanish language lines are presented with a self-service Interactive Voice Response system, offering an assortment of automated responses to Frequently Asked Questions information. At any time, respondents may opt to transfer to a customer service representative, who is prepared to further assist and enumerate them. All callers who need assistance in other languages will be connected directly to an appropriately-skilled Customer Service Representative fluent in the language, based on the toll-free number called.
(G) Update Leave

The Update Leave operation is designed to occur in areas where the majority of housing units either do not have mail delivered to the physical location of the housing unit or the mail delivery information for the housing unit cannot be verified. Update Leave can occur in geographic areas that:
- Do not have city-style addresses.
- Do not receive mail through city-style addresses.
- Receive mail at post office boxes.
- Have been affected by major disasters.

These areas will not be included in the In-Field Address Canvassing but will be worked within the In-Office Address Canvassing. The purpose of the Update Leave operation is to update the address and feature data for the area addressed and to leave an internet Choice questionnaire package at every housing unit identified to allow the household to self-respond. Enumerators do not attempt to enumerate the household in person when they leave the questionnaire.

Occupants can respond online, using the ID printed on the questionnaire, or they can fill out and mail back the paper questionnaire. If they have questions or wish to respond on the telephone, they can call Census Questionnaire Assistance, using the contact information provided in the package.

The Update Leave operation includes mailing a reminder letter and a reminder postcard to addresses that are capable of receiving mail within the areas designated for Update Leave. These mailed materials include the ID for the given address and the website address for the household to use in order to respond online. As in TEA 1, any households that do not self-respond will be contacted during the NRFU operation.

Finally, the Update Leave operation performs a check on the quality of the address listing work (quality control [QC]) on approximately 5 percent of the production workload.

(H) Update Enumerate

The Update Enumerate operation is designated to occur in areas where the initial visit requires enumerating at the living quarters while updating the address list. The majority of the operation will occur in remote geographic areas that have unique challenges associated with accessibility. Update Enumerate can occur in the following geographic areas:
- Remote Alaska.
- Areas that were a part of the 2010 Census Remote Update Enumerate operation, such as northern parts of Maine and southeast Alaska.
- Select American Indian areas that request to be enumerated in person during the initial visit.

Note that the areas included in the 2010 Census Remote Update Enumerate operation might be delineated into TEA 1 or TEA 6 for the 2020 Census, based on changes in address type or mailability.

In the Update Enumerate operation, field staff update the address and feature data and enumerate respondents in person. The address and feature data are updated on paper address registers and paper maps. The enumeration is collected on paper questionnaires. Field staff conducting Update Enumerate follow a specific contact strategy for the remote locations and conduct any needed follow-up. The Update Enumerate operation performs a check on the quality of the address work (listing QC) on approximately 10 percent of the living workload and a check on the quality of the enumeration data through a telephone reinterview on approximately 5 percent of the enumeration workload.

All completed questionnaires, address registers, and maps are delivered or shipped back to the area census office and then sent to a processing center for data capture, keying, and digitizing.

(I) Paper Data Capture

The Paper Data Capture operation captures and converts data from 2020 Census paper questionnaires. Core workloads for the Paper Data Capture operation include self-response questionnaires mailed back by respondents and Group Quarters Individual Census Reports. The Census Bureau's in-house Integrated Computer Assisted Data Entry system is used to capture paper responses from questionnaires. Each write-in and checkbox data field is data-captured, and Optical Character Recognition and Optical Mark Recognition are performed. If Key From Image is needed for forms that cannot be processed through Optical Character Recognition or Optical Mark Recognition, staff are presented the image of the page and are able to clarify, correct, or add to what was captured. The Census Bureau maintains the data, images of the forms, and the paper forms themselves until confirmation that the data have been correctly captured, at which point the paper forms are sent to destruction while the data and images are retained. The Census Bureau maintains the images for archiving purposes until such time as the National Archiving and Records Administration takes possession of the images for permanent archiving.

(j) Non-ID Processing

For the 2020 Census, respondents will be encouraged, but not required, to use the Census Bureau’s preassigned ID for the living quarters. Within the internet instrument, and, consequently, within Census Questionnaire Assistance, it will be possible for respondents to submit the census response without the preassigned ID. Non-ID Processing is the effort to associate census responses that lack a Census ID with records included on the Census Bureau’s 2020 Census address frame. This processing can occur through automated or clerical procedures. With the internet Self-Response instrument collecting the response and address data, it will be possible to perform automated processing to determine whether the address was already included on the address frame and extracted from the MAF. For those Non-ID responses not matched during automated processing, a clerical operation will make a further attempt to match the address to the 2020 Census address frame and validate nonmatching addresses. Some of the clerical work may require contacting the respondent to help determine a match or to verify the existence and location of the address; this is known as Non-ID Processing Phone Followup. Any nonmatching address whose existence and location cannot be verified by the clerical Non-ID operation will become a Field Verification assignment, handled as a component of the NRFU operation. Notably, Field Verification is only an address verification effort and does not include collection of the census questionnaire data.

(K) Nonresponse Followup

The 2020 Census NRFU operation will be different from the NRFU operation conducted in the 2010 Census. The Census Bureau will implement a NRFU operational design that utilizes a combination of the following:
- Administrative records and third-party data usage to reduce the workload.
- Reengineering of staffing and management of field operations.
- A Best-Time-to-Contact model to increase the likelihood of making contact attempts when an enumerator will find people at home.
- Automation to facilitate data collection.

The NRFU workload is comprised of addresses from a number of sources, including:
- Nonresponding addresses in the self-response and Update Leave TEAs.
Blank mail returns or mail returns otherwise deemed to be too incomplete.

Addresses considered to represent recently completed housing identified from the spring 2020 USPS Delivery Sequence File and other special efforts undertaken to identify new housing around the time of the census known as New Construction and Housing Unit Count Review; addresses upheld in the Local Update of Census Addresses appeals process; potentially other addresses determined to require follow-up after the initial enumeration universe is established.

Addresses with a vacant status reported from internet Self-Response.

Field Verification cases.

Coverage Improvement cases (described below).

Response Re-collect cases (described below).

After giving the population in the United States and Puerto Rico an opportunity to self-respond to the 2020 Census, the Census Bureau will use the most cost-effective strategy for contacting and counting people to ensure an accurate count. Once the households that did not respond through internet, telephone, or paper are known, administrative records will be used to identify vacant addresses and addresses that do not exist in order to reduce the workload of addresses that NRFU enumerators will visit.

Undeliverable-as-Addressed information from the USPS will provide the primary administrative records source for the identification of vacant addresses and addresses that do not exist.

During the NRFU operation, enumerators will visit each housing unit designated for follow-up, determine the occupancy status of the unit on April 1, 2020, and complete an interview using an automated application on a smartphone. Various techniques will be used during NRFU to make the data collection as efficient as possible. The number of allowed attempts to contact is controlled within the automated instrument, and best-time-to-contact modeling is used in the creation of the daily assignments. Every case in the NRFU workload will have a maximum of six unique contact days and 12 proxy attempts. After a third attempt to contact a household does not yield a respondent, a case will become proxy-eligible. A proxy is a neighbor, landlord, real estate agent, or other knowledgeable person who can provide information about the unit and the people who live there. An enumerator should attempt three proxies after each noninterview for a proxy-eligible case. Addresses will also be removed from the workload throughout the course of the NRFU operation as self-responses are received.

Administrative Records

If the initial in-person contact attempt is unsuccessful, the Census Bureau will use administrative records as the household response data when it: (1) Believes that the address is occupied, and (2) has high-quality administrative records. These include records such as from the Internal Revenue Service, the Social Security Administration, and the Centers for Medicare and Medicaid Services, as well as prior censuses and the American Community Survey.

Addresses found to be “administrative records vacant” or “administrative records nonexistent” will be removed from the NRFU workload and will immediately be mailed a final postcard that encourages occupants to self-respond to the 2020 Census. Addresses that are determined to be “administrative records occupied,” and for which enumeration is incomplete after one in-person visit attempt will be mailed a final postcard encouraging self-response after seven days.

NRFU Reinterview program

The NRFU Reinterview program will check the quality of the work done by enumerators in NRFU. A sample of approximately 5 percent of NRFU interviews will be selected for verification through NRFU Reinterview. All cases that are sampled for the program and have a valid phone number will initially be subject to a reinterview attempt by a Census Questionnaire Assistance customer service representative to verify that an enumerator conducted the interview and followed procedures. NRFU Reinterview cases that cannot be completed via telephone will be sent to the field for personal visit reinterviews. The customer service representative or enumerator working a NRFU Reinterview case always attempts to contact the respondent from the original interview, which may be a household member, neighbor, or some other proxy. If the original respondent confirms that he/she was contacted and an enumerator conducted the original interview, the customer service representative or enumerator conducts a full interview with the respondent.

Manager Visit

During the early weeks of NRFU, enumerators will conduct interviews with multiunit structure managers to determine the occupancy status of nonresponding units within the multiunit structure. This Manager Visit allows enumerators to identify several units as vacant or delete without having to attempt each unit individually. Enumerators have a maximum of two unique contact days to complete the Manager Visit cases. The Manager Visit Reinterview program will check the quality of work done by enumerators during the Manager Visit and will target enumerators with high numbers of vacant and delete unit statuses. During this Manager Visit Reinterview check, the enumerator will ask to speak to the manager from the original Manager Visit interview. If the respondent confirms that he/she was contacted and an enumerator conducted the original interview, the Manager Visit Reinterview enumerator asks about a subset of the list checked during the Manager Visit. If the respondent was not contacted or does not know if an enumerator conducted the original interview, the enumerator conducts a full interview and review the entire list of nonresponding units within the multiunit structure.

Field Verification

The NRFU universe also includes cases from Non-ID Processing that were not able to be matched to the address frame. As discussed in the Non-ID section, these are Field Verification cases, where the enumerators attempt to locate the address in question and collect its Global Positioning System (GPS) coordinates. A sample of the Field Verification cases is selected for verification through Field Verification Quality Control. Since Field Verification cases only require an enumerator to determine the existence of an address and will not require an interview with a respondent, this Field Verification Quality Control program will consist of an independent check of the production enumerator’s work in the field. The Field Verification Quality Control enumerator will conduct the same procedures as the Field Verification enumerator. Field Verification cases, along with their quality control component, have a maximum of one field contact day.

Coverage Improvement

The Coverage Improvement operation improves the enumeration count by resolving categories of erroneous enumerations (people counted in the
wrong place or counted more than once) and omissions (people who were missed) identified through collected enumeration data. The Coverage Improvement operation will attempt to resolve these issues identified from both self-response and NRFU questionnaires. The issues identified for the Coverage Improvement operation will be: Where a household enumeration shows a difference between the answer for the number of people within the household and the number of people enumerated, and answers to coverage questions in the initial enumeration that reflect potential coverage errors. Both of these types of cases could result in either erroneous enumerations or omissions. Automation and the internet self-response option will use various edit checks when these inconsistencies arise, which should reduce the prevalence of these types of respondent errors compared to the 2010 Census, which was completed almost entirely on paper questionnaires. All cases that are selected for Coverage Improvement with a valid phone number will be subject to an interview attempt by a Census Questionnaire Assistance customer service representative. Response-re-collect cases are generated as part of the quality assurance efforts for self-response and will be worked within NRFU.

(L) Group Quarters

The 2020 Census Group Quarters operation will enumerate people living or staying in group quarters and provide an opportunity for people experiencing homelessness and receiving service at a service-based location, such as a soup kitchen, to be counted in the census. The 2020 Census Group Quarters operation consists of the following components:

- In-Office Group Quarters Advance Contact.
- Group Quarters Enumeration.
- Service-Based Enumeration.
- Military Enumeration.
- Maritime Vessel (Shipboard) Enumeration.

The In-Office Group Quarters Advance Contact is an in-office activity conducted in the area census offices in which the group quarters name, address, contact name, and phone number from the address list that results from Address Canvassing will be verified. Preferred dates, times, methods of enumeration, and expected population on Census Day will be collected as well. Special instructions or concerns related to privacy, confidentiality, and security will also be addressed.

The Group Quarters enumeration will cover all 50 states, the District of Columbia, and Puerto Rico. This enumeration at group quarters occurs in approximately the same timeframe as the household enumeration operations. An additional late group quarters enumeration phase allows for the stakeholder identification and enumeration of group quarters that may have been missed during the earlier timeframe. The primary method of conducting in-person enumeration of people residing in group quarters will be by using the Individual Census Questionnaire as the paper data collection instrument. In-person interviewing is planned for all group quarter types that are part of the field enumeration workload.

Group Quarters Enumeration—eResponse Data Transfer

eResponse uses electronic data transfer from group quarter administrators to the Census Bureau. Client-level data from systems maintained by group quarter administrators can be transferred to a standardized Census Bureau system that will accept electronically submitted data in a standardized template. These data will be accepted in lieu of use of the Individual Census Questionnaire if data are deemed to be of sufficiently high quality and completeness.

Service-Based Enumeration

The Service-Based Enumeration is specifically designed to approach people using service facilities because they may be missed during the traditional enumeration of housing units and group quarters. These service locations and outdoor locations include the following:

- Shelters: Shelters with sleeping facilities for people experiencing homelessness; shelters for children who are runaways, neglected, or experiencing homelessness.
- Soup kitchens.
- Regularly-scheduled mobile food vans: Stops where regularly scheduled mobile food vans distribute meals.
- Targeted non-sheltered outdoor locations.

For the 2020 Census, Service-Based Enumeration will be conducted over the three-day period that ends on April 1, 2020, Census Day. Service providers for shelters, soup kitchens, and regularly-scheduled mobile food vans will be given the flexibility for their facility to be enumerated on any one of the three days. Targeted non-sheltered outdoor locations will be enumerated April 1, 2020.

Domestic Violence Shelters

Domestic Violence Shelters are facilities for those seeking safety from domestic violence. As in previous censuses, the enumeration of individuals at Domestic Violence Shelters will be handled by personnel specially trained to protect the safety and security of respondents being enumerated at these locations.

Military Enumeration

Military Enumeration involves enumeration of people living in group quarters (or barracks) on domestic military installations or military vessels. Military installations are fenced, secured areas used for military purposes. An important feature of the military enumeration operation is that it includes both group quarters and housing units. Privatized housing on military installations will be enumerated as part of the housing unit data collection operations rather than through Military Enumeration. A military vessel is defined as a United States Navy or United States Coast Guard vessel assigned to a home port in the United States. In order to support the military’s security requirements, military Group Quarters Enumeration will occur by means of electronic data transfer from the Defense Manpower Data Center to the Census Bureau.

(M) Enumeration at Transitory Locations

The 2020 Census Enumeration at Transitory Locations operation enumerates those individuals in occupied units at transitory locations who do not have a usual home elsewhere. This operation will:

- Use automation, where possible, to facilitate data collection and streamline operations such as advance contact. However, data collection will be done using paper.
- Use reengineered staffing and management of the field operation.
- Use in-person enumeration as the primary mode of data collection.

(N) Federally Affiliated Count Overseas

The Federally Affiliated Count Overseas operation obtains counts by home state of United States military and federal civilian employees who are stationed or assigned overseas and their dependents living with them. For the 2020 Census, overseas is defined as anywhere outside the 50 states, the District of Columbia, Puerto Rico, and the Island Areas: American Samoa, Commonwealth of the Northern Mariana Islands, Guam, and the United States Virgin Islands. Counts are submitted from Federal agencies and the
II. Method of Collection

Data collection operations result in respondent burden from: (1) Contacts during the address frame-building process, and (2) contacts during enumeration for the 2020 Census.

The frame-building operation in the field that can result in respondent burden is In-Field Address Canvassing. In-Field Address Canvassing is the process of having listers visit specific geographic areas to identify every place where people could live or stay and compare what they see on the ground with the existing census address list and either verify or correct the address and location information. Listers will knock on doors at every structure in the assignment in an attempt to locate living quarters. The Census Bureau expects that listers will make contact with residents (i.e., someone is at home) approximately 25 percent of the time, based on previous address list development field operations.

The second component of respondent burden is the census enumeration operations. This consists of multiple operations that in combination serve the purpose of reaching all residents for the purposes of the enumeration in the census. All attempts by the Census Bureau to make direct contact in TEAs 1 and 6 with individual households by mail for enumeration are referred to as “contact strategies for mailing materials.” Types of contact strategies for mailing materials include invitation letters, postcards, and questionnaires mailed to households.

The “Internet First” approach was developed to encourage respondents to use the internet. Currently, this model includes the mailing of a letter inviting respondents to complete the questionnaire online, two follow-up reminders and, if necessary, a mailed paper questionnaire followed by a final reminder (or two reminders to certain Administrative Records cases). All correspondence will contain a telephone number that respondents may use to complete the questionnaire over the telephone.

The “Internet Choice” contact strategy will be used for the estimated 20 percent of households that have low internet coverage or connectivity or other characteristics that may make it less likely the respondents will complete the census questionnaire online. This strategy includes both an invitation to complete the census online and a paper questionnaire as part of the first mailing.

For mobile housing unit addresses in TEAs 1 and 6 for which no self-response is received, the NRFU operation will be used to collect the household data. NRFU will use an automated instrument during data collection. Additional follow-up activities to improve and check quality will be included within the Census Questionnaire Assistance call center and NRFU workloads. All cases that are sampled for NRFU reinterview with a valid phone number will initially be subject to a reinterview attempt by a Census Questionnaire Assistance customer service representative. NRFU reinterview cases that cannot be completed via telephone will be sent to the field for personal visit reinterviews.

The NRFU reinterview program will check the quality of the work done by enumerators in NRFU. The NRFU reinterview program involves conducting an independent reinterview for selected cases to verify that an enumerator conducted the interview and followed procedures, as described above. During the early weeks of NRFU, enumerators will conduct interviews with multiunit structure managers to determine the occupancy status of nonresponding units within the multiunit structure, as described above. The NRFU universe also includes cases from Non-ID Processing that were not able to be matched to the address frame. As discussed above, these are Field Verification cases, where the enumerators attempt to locate the address in question and collect its GPS coordinates.

The Coverage Improvement operation resolves categories of erroneous enumerations (people counted in the wrong place or counted more than once) and omissions (people who were missed) identified through collected enumeration data. The Coverage Improvement operation will attempt to resolve these issues from both self-response and NRFU questionnaires.

In summary, a census address list is the basis for the census enumeration. Some of the work to create the address list will occur in In-Field Address Canvassing, which will incur respondent burden. Using a post-Address Canvassing extract of the MAF, census materials will be provided to or for all living quarters according the TEA designated for the area and the operation designated for the living quarters type. Self-response modes for housing units include internet, paper questionnaires, and telephone. Response modes for group quarters include paper questionnaires and electronic file transfers. Special operations will be implemented to collect data at identified transitory units and service-based locations. The various follow-up, QC, and coverage
improvement operations will also incur respondent burden. In addition, the Island Areas Censuses and Federally Affiliated Count Overseas operations enumerate the populations covered by those definitions, through the processes described above.

### III. Data

**OMB Control Number:** 0607–XXXX

**Form Number(s):**
- D–LF1
- D–LF1(E/S)
- D–Q
- D–Q(E/S)
- D–Q–UL
- D–Q–UL(E/S)
- D–Q–TL
- D–Q–TL(S)
- D–CQ–TL

**Type of Review:** Regular submission.

**Affected Public:** Households/Individuals.

**Estimated Number of Respondents:**
- 178,202,534.

**Estimated Time per Response:** 6.77 minutes.

### 2020 Census

<table>
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<th>Operation or category</th>
<th>Estimated number of respondents</th>
<th>Estimated time per response (minutes)</th>
<th>Total burden hours</th>
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</thead>
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<td>Geographic Areas Focused on Self-Response (this includes Mailout and Update Leave):</td>
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<td>Internet/Telephone/Paper</td>
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<td>GQ Advance Contact (facility)</td>
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<td>10,291</td>
<td>30</td>
<td>5,146</td>
</tr>
<tr>
<td>Federally Affiliated Count Overseas</td>
<td>82</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>178,202,534</td>
<td>6.77</td>
<td>26,306,103</td>
</tr>
</tbody>
</table>

*Estimated Total Annual Burden Hours:* 26,306,103 hours.

*Estimated Total Annual Cost to Public:* $0 (This is not the cost of respondents’ time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

*Respondent’s Obligation:* Mandatory.

*Legal Authority:* Title 13 U.S.C. Section 141.

### IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden...
SUPPLEMENTARY INFORMATION: In an effort to improve the measurement of business dynamics in the United States, the Census Bureau, with support from the National Science Foundation (NSF), plans to conduct the Annual Business Survey (ABS). The ABS is a new survey designed to combine Census Bureau firm-level survey collections to reduce respondent burden and simultaneously increase data quality and operational efficiencies. The ABS replaces the following collections: The five-year Survey of Business Owners (SBO) (Office of Management and Budget (OMB) control number 0607–0943) for employer businesses; the Annual Survey of Entrepreneurs (ASE) (OMB control number 0607–0968); and the Business Research and Development and Innovation for Microbusinesses (BRDI–M) form, a component of the Business Research and Development and Innovation Survey, BRDI–S (OMB control number 0607–0912). The ABS also replaces the innovation questions, formerly asked in the BRDI–S.

ABS estimates will include the number of employer firms and their sales/receipts, annual payroll, and employment by gender, ethnicity, race, and veteran status as well as research and development and innovation and various other relevant topics. The ABS will be conducted jointly by the Census Bureau and the National Center for Science and Engineering Statistics within the NSF. It is planned for five reference years (2017–2021). Title 13, United States Code (U.S.C.), Sections 8(b), 131, and 182, Title 42, U.S.C., Sections 1861–1875 (National Science Foundation Act of 1950, as amended), and Section 505 of the America COMPETES Reauthorization Act of 2010 (42 U.S.C. 1862p) authorize this collection. Sections 224 and 225 of Title 13, U.S.C., require responses from sampled firms.

The ABS covers all domestic nonfarm employer businesses filing Internal Revenue Service tax forms as individual proprietorships, partnerships, or any type of corporation, and with receipts of $1,000 or more. The ABS will sample approximately 850,000 employer businesses for the benchmark survey year 2017, with data collection taking place in 2018. Annually for survey years 2018 to 2021, the survey sample will be reduced to approximately 300,000 employer businesses to reduce the burden on the respondents. The Census Bureau will use administrative data to estimate the owner demographics such that each firm is placed into one of nine frames for sampling: American Indian, Asian, Black or African American, Hispanic, Non-Hispanic White Men, Native Hawaiian and Other Pacific Islander, Some Other Race, Publicly Owned Businesses, and Women Owned Businesses. The sample would be stratified by state, industry, and frame. The Census Bureau will select companies with certainty based on volume of sales, payroll, number of paid employees or industry classification. All certainty cases are sure to be selected and represent only themselves.

The ABS will provide continuing and timely national statistical data for the period between economic censuses. The data collected will be within the general scope and nature of those inquiries covered in the economic census. The next economic census is being conducted currently for the reference year 2017. Government program officials, industry organization leaders, economic and social analysts, business entrepreneurs, and domestic and foreign researcher in academia, business, and government will use statistics from the new ABS. More details on expected uses of the statistics from the new ABS are found in the Notice of Consideration for the ABS published in the Federal Register on October 24, 2017 (82 FR 49175).

Public Comments

The Census Bureau published a Notice of Consideration for the ABS in the Federal Register on October 24, 2017 (82 FR 49175). We received one comment. The commenter suggested that the Census Bureau take the following actions:

(1) Determine the cost and benefits of the survey and consider whether the benefits outweigh the costs;

(2) If the benefits outweigh the cost, consider how to minimize the cost imposed on the businesses participating in the survey;

(3) If, after conducting the cost-benefit analysis and examining the means for minimizing the cost imposed on survey participants, the Census Bureau nevertheless wishes to proceed with the survey, publish a revised notice that includes a cost-benefit analysis and an explanation of steps taken to minimize the costs on businesses forced to participate in the survey; and

(4) Eliminate the survey discrimination based on gender, ethnicity, race, and age.

Census Bureau Response to the Public Comment

The Census Bureau agrees that costs and benefits should be analyzed and weighed, and has already carried out
Based upon the foregoing, I have directed that the current mandatory business surveys be conducted for the purpose of collecting these data.


Ron S. Jarmin,
Associate Director for Economic Programs, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

[FR Doc. 2018–12356 Filed 6–7–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–010]

Crystalline Silicon Photovoltaic Products From the People’s Republic of China: Notice of Court Decision Not in Harmony With Final Determination of the Less Than Fair Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 25, 2018, the United States Court of International Trade (the Court) entered final judgment sustaining the final results of the second remand redetermination by the Department of Commerce (Commerce) pertaining to the antidumping duty (AD) investigation of certain crystalline silicon photovoltaic products from the People’s Republic of China (China). Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce’s final determination in the AD investigation of certain crystalline silicon photovoltaic products from China.


SUPPLEMENTAL INFORMATION:

Background

Subsequent to the December 23, 2014, publication of the Final Determination in the AD investigation of certain crystalline silicon photovoltaic products from China,2 and the February 18, 2015 publication of the AD order,2


2 See Certain Crystalline Silicon Photovoltaic Products from the People’s Republic of China: SolarWorld Americas, Inc. (SolarWorld), the petitioner, filed a complaint with the Court challenging, among other things, Commerce’s determination that South African import data under subheading 8548.10, of the United States Harmonized Tariff Schedule (HTS), constituted the best available information for valuing Changzhou Trina Solar Energy Co., Ltd.’s (Trina) byproduct offset for scrapped solar modules.3

In Jinko Solar I, the Court remanded Commerce’s use of South African import data under HTS subheading 8548.10, to value Trina’s byproduct offset for scrapped solar modules when calculating normal value. The Court found that Commerce did not adequately explain how its decision was reasonable in light of the record as a whole.4 Further, the Court found that two arguments made before the Court constituted post hoc rationalizations and directed Commerce to make those rationalizations explicit and identify supporting evidence for them, if either of the rationalizations informed Commerce’s decision to rely on HTS subheading 8548.10 to value Trina’s byproduct offset for scrapped solar modules.5

On August 2, 2017, Commerce issued its First Remand Results, in which it determined that it would continue to value Trina’s byproduct offset for scrapped solar modules with South African import data under HTS 8548.10 and explained its decision to do so.6 The Court, in Jinko Solar II, held that Commerce’s determination remained unsupported by substantial evidence and that Commerce did not explain how its selected surrogate value was a representative surrogate value for the scrapped modules.7 The Court directed Commerce to reconsider or further explain its decision to use South African import data under HTS subheading 8548.10 to value the byproduct offset for scrapped solar

3 See SolarWorld’s Complaint, No. 15–00086, ECF No. 10 (CIT April 17, 2015).
5 See Final Results of Redetermination Pursuant to Court Remand, Jinko Solar Co., Ltd. v. United States, Court No. 15–00080, Slip Op. 17–42 (Court of International Trade May 18, 2017) (August 2, 2017) (First Remand Results).
modules when calculating normal value.\(^8\)

On March 12, 2018, Commerce issued its Second Remand Results, wherein, considering the Court’s order, and under respectful protest, Commerce selected Thai import data under HTS category 2804.69 to value Trina’s byproduct offset for scrapped solar modules for purposes of its normal value calculations.\(^9\)

On May 25, 2018, the Court issued its decision in *Jinko Solar III* sustaining Commerce’s Second Remand Results.\(^10\)

**Timken Notice**

In its decision in *Timken*,\(^11\) as clarified by *Diamond Sawblades*,\(^12\) the United States Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not “in harmony” with a Commerce determination and must suspend liquidation of entries pending a “conclusive” court decision. The Court’s May 25, 2018, final judgment sustaining Commerce’s Second Remand Redetermination constitutes a final decision of the Court that is not in harmony with Commerce’s *Final Determination*. This notice is published in fulfillment of the publication requirements of *Timken*. Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal, or if appealed, pending a final and conclusive court decision. We have not amended the *Final Determination* because valuing Trina’s scrapped solar modules using Thai import data under HTS category 2804.69 rather than South African import data under HTS subheading 8548.10 did not result in a change to the weighted average dumping margin calculated for Trina in the *Final Determination*.

**Notification to Interested Parties**

This notice is issued and published in accordance with section 516A(e)(1) of the Act.

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\(^8\) *Id.* at 1264.


\(^12\) See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010).
enforcement vessel or aircraft. The vessel’s identification number must be in block Arabic numerals permanently affixed to or painted on the vessel in contrasting color to the background, and must be at least 18 inches (45.7 cm) in height for vessels over 65 ft (19.8 m) in length; at least 10 inches (25.4 cm) in height for all other vessels over 25 ft (7.6 m) in length; and at least 3 inches (7.6 cm) in height for vessels 25 ft (7.6 m) in length or less.

Furthermore, the owner or operator of a vessel for which a permit has been issued under § 635.4 and that uses handline, buoy gear, harpoon, longline, or gillnet, must display the vessel’s name, registration number or Atlantic Tunas, Atlantic HMS Angling, or Atlantic HMS Charter/Headboat permit number on each float attached to a handline, buoy gear, or harpoon, and on the terminal floats and high-flyers (if applicable) on a longline or gillnet used by the vessel. The vessel’s name or number must be at least 1 inch (2.5 cm) in height in block letters or Arabic numerals in a color that contrasts with the background color of the float or high-flyer.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually.

Respondent’s Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA Submission@omb.eop.gov or fax to (202) 395–5806.

Dated: June 5, 2018.

Sarah Brabson,
NOAA PRA Clearance Officer.

[FR Doc. 2018–12345 Filed 6–7–18; 8:45 am]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).


Title: U.S. Caribbean Commercial Fishermen Census.

OMB Control Number: 0648–0716.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 1,500.

Average Hours per Response: 30 minutes.

Burden Hours: 750.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

The National Marine Fisheries Service (NMFS) proposes to conduct a census of small-scale fishermen operating in the United States (U.S.) Caribbean. The extension for the data collection applies only to the Commonwealth of Puerto Rico because the data collection was completed in the U.S. Virgin Islands. The proposed socio-economic study will collect information on demographics, capital investment in fishing gear and vessels, fishing and marketing practices, economic performance, and miscellaneous attitudinal questions. The data gathered will be used for the development of amendments to fishery management plans, which require descriptions of the human and economic environment and socio-economic analyses of regulatory proposals. The information collected will also be used to strengthen fishery management decision-making and satisfy various legal mandates under the Magnuson-Stevens Fishery Conservation and Management Act (U.S.C. 1801 et seq.), Executive Order 12866, Regulatory Flexibility Act, Endangered Species Act, and National Environmental Policy Act, and other pertinent statutes.

Affected Public: Business or other for-profit organizations.

Frequency: One time.

Respondent’s Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA Submission@omb.eop.gov or fax to (202) 395–5806.

Dated: June 5, 2018.

Sarah Brabson,
NOAA PRA Clearance Officer.

[FR Doc. 2018–12344 Filed 6–7–18; 8:45 am]
bass, conservation equivalency rollover for summer flounder, Block Island Sound transit provisions, and slot limits in the recreational fisheries for all three species.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: June 4, 2018.

Tracey L. Thompson,
Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

FOR FURTHER INFORMATION CONTACT:

Date deleted from the Procurement List: July 8, 2018.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) and service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) and service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

<table>
<thead>
<tr>
<th>NSN(1)</th>
<th>Product Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>8415–01–605–7311</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XXSM</td>
</tr>
<tr>
<td>8415–01–605–7315</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XSM</td>
</tr>
<tr>
<td>8415–01–605–7316</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, MED</td>
</tr>
<tr>
<td>8415–01–605–7317</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, LG</td>
</tr>
<tr>
<td>8415–01–605–7319</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XLG</td>
</tr>
<tr>
<td>8415–01–605–7321</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XXLG</td>
</tr>
</tbody>
</table>

Mandatory for: 100% of the requirement for the U.S. Army Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC Contracting Activity: Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division Distribution: C-List Services

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Medical Procurement, Integration, and Warehousing Service</th>
</tr>
</thead>
</table>


COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add product(s) and service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: July 8, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) and service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) and service(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

<table>
<thead>
<tr>
<th>NSN(1)</th>
<th>Product Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>8415–01–605–7311</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XXSM</td>
</tr>
<tr>
<td>8415–01–605–7315</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XSM</td>
</tr>
<tr>
<td>8415–01–605–7316</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, MED</td>
</tr>
<tr>
<td>8415–01–605–7317</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, LG</td>
</tr>
<tr>
<td>8415–01–605–7319</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XLG</td>
</tr>
<tr>
<td>8415–01–605–7321</td>
<td>Coverall, Fuel Handlers, Type II, Class III, Coyote, XXLG</td>
</tr>
</tbody>
</table>

Mandatory for: 100% of the requirement for the U.S. Army Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC Contracting Activity: Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division Distribution: C-List Services

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Medical Procurement, Integration, and Warehousing Service</th>
</tr>
</thead>
</table>


COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) from the Procurement List that were previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Date deleted from the Procurement List: July 8, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION: Deletions

On 5/4/2018 (83 FR 87), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the
product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O’Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

<table>
<thead>
<tr>
<th>Product(s)</th>
<th>Service Type</th>
<th>Contracting Activity</th>
<th>Mandatory Source of Supply</th>
<th>Mandatory for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSN(s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Products

<table>
<thead>
<tr>
<th>NSN(s)</th>
<th>Product Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>8415-00-NSH-0687</td>
<td>Pants, Level 1, PCU, Army, Brown, M</td>
</tr>
<tr>
<td>8415-01-519-7444</td>
<td>Pants, Level 1, PCU, Army, Brown, M</td>
</tr>
</tbody>
</table>

Mandatory Source of Supply: Southeastern Kentucky Rehabilitation Industries, Inc., Corbin, KY

Contracting Activity: W96QACC–APG NATICK, NATICK, MA

Services

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Product Name(s):</th>
</tr>
</thead>
</table>

Service Type: Switchboard Operation Service

Mandatory for: 4th Communication Squadron; 1695 Wright Brothers Avenue, Seymour Johnson AFB, NC

Mandatory Source of Supply: Coastal Enterprises of Jacksonville, Inc., Jacksonville, NC

Contracting Activity: Dept. of the Air Force, FA0002 4TH CONS SQDN CC

Service Type: Janitorial/Custodial Service

Mandatory for: Indiana Air National Guard, 181st Fighter Wing: Hulman Regional Airport, 800 South Petercheff, Terre Haute, IN

Mandatory Source of Supply: Child-Adult Resource Services, Inc., Rockville, IN

Contracting Activity: Dept. of the Air Force, FA7014 AFDW PK

Service Type: Custodial Service

Mandatory for: David W. Dyer Federal Building-Courthouse, 300 NE First Ave, Miami, FL

Mandatory Source of Supply: Goodwill Industries of South Florida, Inc., Miami, FL

Contracting Activity: Public Buildings Service, Acquisition Division/Services Branch

Service Type: Janitorial/Custodial Service

Mandatory for: 183rd Fighter Wing Air National Guard Capitol Airport, 3101 J. David Jones Parkway, Springfield, IL

Mandatory Source of Supply: United Cerebral Palsy of the Land of Lincoln, Springfield, IL

Contracting Activity: Dept of the Army, W7M6 USFPO Activity IL ARNG

Service Type: Laundry Service

Mandatory for: Air National Guard-Sioux City, 2920 Headquarters Avenue, Sioux City, IA

Mandatory Source of Supply: Genesis Development, Jefferson, IA

Contracting Activity: Dept. of the Air Force, FA7014 AFDW PK

Service Type: Food Service

Mandatory for: Volk Field Air National Guard, 100 Independence Drive, Camp Douglas, WI

Mandatory Source of Supply: Challenge Unlimited, Inc., Alton, IL

Contracting Activity: Dept. of the Air Force, FA7014 AFDW PK

Service Type: Grounds Maintenance Service

Mandatory for: 130th Airlift Squadron, 1679 Coonskin Dr., Unit #36, Charleston, WV

Mandatory Source of Supply: Goodwill Industries of Kanawha Valley, Charleston, WV

Contracting Activity: Dept. of the Army, W7M7 USFPO Activity WV ARNG

Service Type: Grounds Maintenance Service

Mandatory for: Admiral Bakerfield Army Reserve Center, San Diego, CA

Mandatory Source of Supply: Job Options, Inc., San Diego, CA

Contracting Activity: Dept. of the Navy, U.S. Fleet Forces Command

Amy Jensen, Director, Business Operations.

[FR Doc. 2018-12386 Filed 6-7-18; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the Procurement List.

SUMMARY: This action adds a service to the Procurement List that will be provided by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Date added to the Procurement List: June 17, 2018.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–6055, or email CMTEFedReg@abilityOne.gov

SUPPLEMENTARY INFORMATION:

Addition

On 3/16/2018 (83 FR 52), the Committee for Purchase From People Who Are Blind or Severely Disabled published a notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the service and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will provide the service to the Government.

2. The action will result in authorizing small entities to provide the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O’Day Act (41 U.S.C. 8501–8506) in connection with the service proposed for addition to the Procurement List.

The Committee finds good cause to dispense with the 30-day delay in the effective date normally required by the Administrative Procedure Act. See 5 U.S.C. 553(d). This addition to the Committee’s Procurement List is effectuated because of the expiration of the U.S. Navy NAVSUP Fleet Logistics Center Norfolk Warehouse Support Service contract. The Federal customer contacted, and has worked diligently with the AbilityOne Program to fulfill this service need under the AbilityOne Program. To avoid performance disruption, and the possibility that the U.S. Navy will refer its business elsewhere, this addition must be effective on June 17, 2018, ensuring timely execution for a June 18, 2018 start date while still allowing 8 days for comments. Pursuant to its own regulation 41 CFR 51–2.4, the Committee has been in contact with one of the affected parties, the incumbent of the expiring contract since May 2017, and determined that no severe adverse impact exists. The Committee also published a notice of proposed Procurement List addition in the Federal Register on March 16, 2018, and did receive comments from the incumbent contractor. The Committee has addressed those comments which are provided in this notice. This addition will not create a public hardship and has limited effect on the public at large, but, rather, will create new jobs for other affected parties—people with significant disabilities in the AbilityOne Program who otherwise face challenges locating employment. Moreover, this addition will enable Federal customer operations to continue without interruption.
End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type: Warehouse Support Service

Mandatory for: NAVSUP Fleet Logistics Center Norfolk, NDW, Supply Management Division, NAVSUP Warehouse, Building 234, 234 Halligan Rd., Annapolis, MD

Mandatory Source of Supply: Richmond Area Supply Warehouse, Annapolis, MD

Contracting Activity: Dept. of the Navy, NAVSUP FLL Log CTR Norfolk

The U.S. AbilityOne Commission, whose mission is to provide employment opportunities for individuals who are blind or have significant disabilities in the manufacture and delivery of products and services to the Federal Government, received comments from one party with interests in the proposed addition to the Procurement List.

The Commenter objected to the addition of warehouse support service requirements at Navy Supply Warehouse, Annapolis, MD to the Procurement List for three reasons: suitability of the work for the AbilityOne Program, inability of a nonprofit agency to maintain the mandatory overall direct labor hour ratio while performing the warehouse support services requirement, and financial and business impact to the small business incumbent.

The Commenter questioned whether warehouse support services tasks, including inspecting, receiving and processing materials; utilizing material handling equipment (i.e., box truck, fork lifts, etc.); maintaining accurate records; and cleaning the warehouse are tasks suitable for people with significant disabilities. Pursuant to 41 CFR 51–2.4, the Commission conducts a suitability analysis prior to each Procurement List addition. Similar warehouse support service requirements are currently on the Procurement List, and the Commission has historically considered this type of work requirement suitable for the employment of individuals with significant disabilities. The Commission notes several nonprofit agencies currently perform warehouse support services requirements like the Navy Supply Warehouse, Annapolis, MD, in full compliance with the requirements of the AbilityOne Program.

The Commenter also questioned whether a nonprofit agency will be able to maintain the overall direct labor hour ratio requirement of performing 75% of the direct labor hours by people who are blind or significantly disabled. Pursuant to 41 U.S.C. 8501(6), a nonprofit agency in the AbilityOne Program must employ blind or significantly disabled individuals at a level no less than 75% of the agency’s overall direct labor hour ratio. The Commission notes that several nonprofit agencies currently perform warehouse support service requirements, like Navy Supply Warehouse, Annapolis, MD, and maintain compliance with the overall 75% direct labor hour requirement.

Finally, the Commenter asserted adverse financial and business impact to its operations should the work requirement be added to the Procurement List. The Commission conducted an analysis of a possible severe adverse impact on the Commenter, the incumbent contractor, in accordance with 41 CFR 51–2.4(a)(4) and concluded there was no severe adverse impact.

Amy Jensen,
Director, Business Operations.

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2018–0006; OMB Control Number 0704–0397]

Submission for OMB Review; Comment Request

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice; correction.

SUMMARY: DoD is making a correction to the notice published at 83 FR 19549 on May 3, 2018, which advised that the Defense Acquisition Regulations System submitted to OMB for clearance, a proposal for collection of information under the provisions of the Paperwork Reduction Act. The document contained an incorrect docket number.


FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION: In the notice published at 83 FR 19549 on May 3, 2018, in the first column, the following correction is made to this notice. The docket number cited, DARS–2018–0003, is corrected to read DARS–2018–0006.

Amy G. Williams,
Deputy, Defense Acquisition Regulations System.

[FR Doc. 2018–12357 Filed 6–7–18; 8:45 am]
BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2017–OS–0057]

Notice of Availability for Finding of No Significant Impact for the Environmental Assessment Addressing Construction and Operation of a Disposition Services Complex at DLA Disposition Services Red River, Texas

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of availability (NOA).

SUMMARY: On October 19, 2017, DLA published a NOA in the Federal Register announcing the publication of an Environmental Assessment (EA) Addressing Construction and Operation of a Disposition Services Complex at DLA Disposition Services Red River, Texas. The EA was available for a 30-day public comment period that ended November 20, 2017. The EA was prepared as required under the National Environmental Policy Act (NEPA) of 1969.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 571–767–0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EDT) or by email: ira.silverberg@dlamil.dla.mil.

SUPPLEMENTARY INFORMATION: DLA completed an EA to address the potential environmental consequences associated with the Proposed Action at DLA Disposition Services Red River, which is on Red River Army Depot (RRAD). This FONSI incorporates the EA by reference, summarizes the results of the analyses in the EA, and documents DLA’s decision to construct and operate the Disposition Services Complex at the installation. DLA has determined that the Proposed Action is not a major federal action that significantly affects the quality of the human environment within the context of NEPA, and that no significant impacts on the human environment are associated with this decision.

No public comments were received during the EA public comment period. Red River Army Depot (RRAD), the host installation, consulted with the Texas

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2017–OS–0057]

Notice of Availability for Finding of No Significant Impact for the Environmental Assessment Addressing Construction and Operation of a Disposition Services Complex at DLA Disposition Services Red River, Texas

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of availability (NOA).

SUMMARY: On October 19, 2017, DLA published a NOA in the Federal Register announcing the publication of an Environmental Assessment (EA) Addressing Construction and Operation of a Disposition Services Complex at DLA Disposition Services Red River, Texas. The EA was available for a 30-day public comment period that ended November 20, 2017. The EA was prepared as required under the National Environmental Policy Act (NEPA) of 1969.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 571–767–0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EDT) or by email: ira.silverberg@dlamil.dla.mil.

SUPPLEMENTARY INFORMATION: DLA completed an EA to address the potential environmental consequences associated with the Proposed Action at DLA Disposition Services Red River, which is on Red River Army Depot (RRAD). This FONSI incorporates the EA by reference, summarizes the results of the analyses in the EA, and documents DLA’s decision to construct and operate the Disposition Services Complex at the installation. DLA has determined that the Proposed Action is not a major federal action that significantly affects the quality of the human environment within the context of NEPA, and that no significant impacts on the human environment are associated with this decision.

No public comments were received during the EA public comment period. Red River Army Depot (RRAD), the host installation, consulted with the Texas
State Historic Preservation Officer (SHPO) at the Texas Historical Commission; Texas Parks and Wildlife Department (TPWD); and the Tribal Historic Preservation Officers of the Caddo Nation, Comanche Nation, Kiowa Tribe of Oklahoma, and the Wichita and Affiliated Tribes. The Texas SHPO provided concurrence that no historic resources would be affected by the Proposed Action. TPWD provided comments and recommendations regarding protection of migratory birds, state-listed species, and other wildlife species. DLA addressed TPWD’s comments and recommendations in the EA and responded to TPWD with an acknowledgment letter stating that construction activities should avoid or minimize potential impacts on the state-listed timber rattlesnake and other wildlife species. The Comanche Nation responded that a review of their site files indicated “No Properties” have been identified at the project area.

RRAD did not receive responses to the consultation requests with the Caddo Nation, Kiowa Tribe of Oklahoma, or the Wichita and Affiliated Tribes. An appendix was added to the EA that includes the SHPO, TPWD, and tribal consultation documents. The revised EA is available electronically at the Federal eRulemaking Portal at http://www.regulations.gov within Docket ID: DOD–2017–OS–0057.

Purpose and Need for Action: The purpose of the Proposed Action is to provide DLA Disposition Services Red River with a reutilization, transfer, donation, disposal complex suitable for collecting, processing, and liquidating materiel from military installations and their units across northern Texas, Oklahoma, and Arkansas. The Proposed Action is needed to address the inefficientness of the facilities and resultant handling of materiel at the existing disposal operations sites.

Proposed Action and Alternatives: Under the Proposed Action, DLA would not construct and operate a new DLA Disposition Services Complex at RRAD. No changes to existing facilities or their operations would result. The continued movement of materiel for disposal across the installation is unnecessary and inefficient and would continue to create traffic conflicts with installation production and safety risks. The No Action Alternative would not meet the purpose of and need for the Proposed Action.

Potential Environmental Impacts: No significant effects on environmental resources would be expected from the Proposed Action. Insignificant, adverse effects on land use and recreation, noise, air quality, geological resources, water resources, biological resources, infrastructure and transportation, and hazardous materials and wastes would be expected. Additionally, insignificant, beneficial effects on noise and infrastructure and transportation would be expected. Details of the environmental consequences are discussed in the EA, which is hereby incorporated by reference.

Determination: DLA has determined that the implementation of the Proposed Action will not have a significant effect on the human environment. Human environment was interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment. Specifically, no highly uncertain or controversial impacts, unique or unknown risks, or cumulatively significant effects were identified. Implementation of the Proposed Action will not violate any federal, state, or local laws. Based on the results of the analyses performed during preparation of the EA and consideration of comments received during the public comment period, Mr. Patrick Wright, Acting Director, DLA Installation Management, concludes that implementation of the Proposed Action at DLA Disposition Services Red River does not constitute a major federal action significantly affecting the quality of the human environment within the context of NEPA. Therefore, an environmental impact statement for the Proposed Action is not required.

Shelly E. Finke,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEPARTMENT OF DEFENSE
Office of the Secretary

[Docket ID: DOD–2018–OS–0033]

Notice of Availability of an Environmental Assessment Addressing Construction and Operation of a Fiscal Year 2019 General Purpose Warehouse at Defense Logistics Agency Distribution Red River, Texas

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of availability (NOA).

SUMMARY: DLA announces the availability of an Environmental Assessment (EA) documenting the potential environmental effects associated with the Proposed Action to construct and operate a Fiscal Year 2019 General Purpose Warehouse at DLA Distribution Red River, Texas, which is on Red River Army Depot.

DATES: The public comment period will end on July 9, 2018.

ADDRESSES: You may submit comments, identified by DOD–2018–OS–0033, to one of the following:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
DEPARTMENT OF DEFENSE
Office of the Secretary
[Docket ID DOD–2018–OS–0016]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by July 9, 2018.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at oira_submission@omb.eop.gov. Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493, or whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title: Associated Form; and OMB Number: DLA Culture/Climate Survey; OMB Control Number 0704–XXXX.

Type of Request: New.

Number of Respondents: 860.

Responses Per Respondent: 1.

Annual Responses: 860.

Average Burden per Response: 45 minutes.

Annual Burden Hours: 645 hours.

Needs and Uses: The purpose of the DLA Culture/Climate Survey is to provide a confidential mechanism for employees to share their feedback on the DLA organization culture and climate. DLA culture is assessed using the Denison Model of Organizational Culture and the associated survey instrument. The climate is assessed using a DLA-developed assessment on current strategic initiatives. As a result, the DLA Culture/Climate Survey provides an opportunity to engage DLA employees and leaders in thoughtful, data-driven discussions that lead to informed action and improve our collective organizational performance.

Affected Public: Individuals or households.

Frequency: Biennially.

Respondent’s Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at http://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Requests for copies of the information collection proposal should be sent to Mr. Licari at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: June 5, 2018.

Shelly E. Finke,
Alternate OSD Federal Register, Liaison Officer, Department of Defense.

DEPARTMENT OF DEFENSE
Office of the Secretary
[Docket ID DOD–2018–OS–0034]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of the Undersecretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency’s estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by August 7, 2018.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at http://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Under Secretary of Defense (Personnel and
Parents of Dependent Students

| If the age of the older parent is | 25 or less | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 |
|----------------------------------|-----------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Then the education savings and asset protection allowance is | 0 | 0 | 1,300 | 2,000 | 2,600 | 3,300 | 4,000 | 4,600 | 5,300 | 5,900 | 6,600 | 7,300 | 7,900 | 8,600 | 9,200 | 9,900 | 10,100 | 10,400 | 10,600 | 10,900 | 11,100 | 11,400 | 11,600 | 11,900 | 12,200 | 12,500 | 12,900 | 13,200 | 13,500 | 13,900 | 14,300 | 14,700 | 15,100 | 15,500 | 15,900 | 16,400 | 8,300 |

Dated: June 5, 2018.

Shelly E. Finke,
Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–12383 Filed 6–7–18; 8:45 am]

BILLING CODE 5001–06–P
## PARENTS OF DEPENDENT STUDENTS—Continued

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<th>Married</th>
<th>Single</th>
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<td>65 or older</td>
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2. On page 22969, table “Independent Students With Dependents Other Than a Spouse” is corrected as set forth below:

## INDEPENDENT STUDENTS WITH DEPENDENTS OTHER THAN A SPOUSE

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<tr>
<td>65 or older</td>
<td>18,900</td>
<td>9,500</td>
</tr>
</tbody>
</table>
ENVIRONMENTAL PROTECTION AGENCY

Proposed Information Collection Request; Comment Request; Air Stationary Source Compliance and Enforcement Information Reporting (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “Air Stationary Source Compliance and Enforcement Information Reporting” (EPA ICR No. 0107.12, OMB Control No. 2060– 0096) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through January 31, 2019. 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.

We are also soliciting comment on several options for improving the reporting of Clean Air Act stationary source facility compliance information in order to improve the display, usability, and accuracy of these data for presentation to the public through EPA’s Enforcement Compliance History Online (ECHO) capability.

DATES: Comments must be submitted on or before August 7, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA– HQ– OECA– 2018– 0248 online using www.regulations.gov (our preferred method), by email to dockets oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA’s policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: David A. Meredith, Enforcement Targeting and Data Division, Office of Compliance, (2222A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202– 564– 4152; email address: meredith.david@epa.gov.

SUPPLEMENTARY INFORMATION:

Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202– 566– 1744. For additional information about EPA’s public docket, visit http://www.epa.gov/dockets.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. Burden is defined at 5 CFR 1320.03(b). EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another Federal Register notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Air Stationary Source Compliance and Enforcement Information Reporting is an activity whereby State, Local, Native American, Territorial, and Commonwealth governments (hereafter referred to as either “states/locals” or “state and local agencies”) make air stationary source compliance information available to the U.S. Environmental Protection Agency (EPA or the Agency) on a cyclic basis via input to the Air component of the Integrated Compliance Information System (ICIS-Air). ICIS-Air replaced the Air Facility System (AFS) in October 2014 when the Agency, with support from state and local agencies, completed the modernization of AFS into ICIS-Air. ICIS-Air supports EPA and state and local agency efforts to ensure compliance with the nation’s environmental laws pertaining to air, via the collection and management of important Clean Air Act (CAA or the “Act”) compliance and enforcement information. ICIS-Air is a sub-component of ICIS, which provides compliance and enforcement information on thousands of facilities regulated under numerous federal statutes. The information provided to EPA via ICIS-Air includes source characterization, compliance monitoring, and enforcement activities. EPA will use this information to assess progress toward meeting emission requirements developed under the authority of the CAA, and to protect and maintain air quality, public health, and the environment. Agencies receive delegation of the CAA through regulated grant authorities, and report compliance/enforcement activities undertaken at stationary sources pursuant to the Minimum Data Requirements (MDRs) as outlined in this ICR. The provisions of Section 114(a)(1) of the Clean Air Act, 42 U.S.C. Section 7414(a)(1) provide the broad authority for the reporting of compliance monitoring and enforcement information, along with Subpart Q—Reports in 40 CFR 51: Sections 51.324(a) and (b), and 51.327. This renewal requires the continuation of reporting of previously established MDRs via either direct, on-line entry or electronic data transfer (EDT) to ICIS-Air.

U.S. EPA and states are cooperating to improve the display, usability, and accuracy of EPA’s Enforcement and Compliance History Online (ECHO). ECHO is a critical tool for accessing and analyzing information about facilities regulated under the Clean Air Act and other environmental statutes. As a first step, a team of state and EPA representatives has identified some changes to ECHO that will enhance the user experience and improve ECHO’s display of facility compliance-related data. As such, EPA is soliciting state and local input on three options presented for the reporting of Federally Reportable Violation (FRV) dates. These options are presented in the 2/27/18 Joint EPA-State paper written to identify improvements to the display, usability, and accuracy of EPA’s ECHO. That
as a whole, would experience a reduction in reporting burden due to the ease of reporting to ICIS-Air, a modern and more robust information system. For this ICR renewal, EPA will use experience from the last three years to provide burden estimates that adequately reflect the actual burden. EPA will consider any comment received and will conduct consultation with delegated agencies that are direct users of ICIS-Air, as well as those using EDT to report MDRs. Since ICIS-Air is a relatively new platform, the estimates provided are likely to change.


Randolph L. Hill,
Director, Enforcement Targeting & Data Division, Office of Compliance.

[FR Doc. 2018-12375 Filed 6-7-18; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FR–9978–85—Region 10]

Extension of Comment Period for Proposed Issuance of NPDES General Permit for Hydroelectric Facilities Within the State of Idaho (IDG360000)

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed issuance of NPDES General Permit; extension of comment period.

SUMMARY: The Environmental Protection Agency (EPA) Region 10 is extending the comment period for the proposed issuance of a National Pollutant Discharge Elimination System (NPDES) General Permit for Hydroelectric Facilities discharging to waters within the State of Idaho (Permit No. IDG360000). The agency is extending the comment period for 30 days in response to requests from Idaho Power Co. and Utility Water Act Group.

DATES: The comment period for the proposed General Permit published in the Federal Register on April 27, 2018 (83 FR 18555) is being extended. Comments must be received on or before July 11, 2018.

FOR FURTHER INFORMATION CONTACT: Dru Keenan, 206–553–1219, Keenan.Dru@epa.gov.

SUPPLEMENTARY INFORMATION: On April 27, 2018 (83 FR 18555), the EPA Region 10 published the proposed general NPDES permit for hydroelectric facilities located in Idaho in the Federal Register. The original deadline to submit comments was June 11, 2018. This action extends the comment period for 30 days. Written comments must now be received on or before July 11, 2018.

Permit documents may be found on the EPA Region 10 website at: https://www.epa.gov/npdes-permits/draft-npdes-general-permit-hydroelectric-generating-facilities-idaho. Copies of the draft General Permit and Fact Sheet are also available upon request. Requests may be made to Audrey Washington at (206) 553–0523 or to Dru Keenan at (206) 553–1219. Requests may also be electronically mailed to: Washington.audrey@epa.gov, or keenan.dru@epa.gov.


Daniel D. Opalski,
Director, Office of Water and Watersheds, Region 10.

[FR Doc. 2018–12389 Filed 6–7–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9039–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7156 or https://www2.epa.gov/nepa/.

Weekly receipt of Environmental Impact Statements Filed 05/28/2018 Through 06/01/2018 Pursuant to 40 CFR 1506.9.

Notice
Section 309(a) of the Clean Air Act requires that EPA, make public its comments on EISs issued by other, Federal agencies. EPA’s comment letters on EISs are available at: https://cdxnodengn.epa.gov/cdx-enea-public/action/eis/search.


EIS No. 20180120, Final Supplement, NRC, NY, Generic Environmental
Impact Statement for License Renewal of Nuclear Plants Supplement 38 Regarding Indian Point Nuclear Generating Unit Nos. 2 and 3, Review Period Ends: 07/09/2018, Contact: William Burton 301–415–6332 EIS No. 20180121, Draft Supplement, USACE, NM, Middle Rio Grande Flood Protection Bernalillo to Belen New Mexico Integrated General Reevaluation Report and Supplemental Environmental Impact Statement, Comment Period Ends: 07/23/2018, Contact: Michael D. Porter 505–342–3264 EIS No. 20180122, Draft, NRC, LA, Generic Environmental Impact Statement for License Renewal of Nuclear Plants, Supplement 58, Regarding River Bend Station, Unit 1, Comment Period Ends: 07/23/2018, Contact: David Drucker 301–415–6223 EIS No. 20180123, Draft, FERC, CA, Yuba River Development Project, Comment Period Ends: 07/30/2018, Contact: Alan Mitichnick 928–502–6074 EIS No. 20180124, Draft, USFS, MT, Draft Environmental Impact Statement for the Draft Revised Forest Plan Helena—Lewis and Clark National Forest, Comment Period Ends: 09/06/2018, Contact: Deborah Entwistle 406–495–3774 EIS No. 20180125, Draft Supplement, USACE, WA, Mill Creek Flood Control Project Operations and Maintenance, Comment Period Ends: 07/23/2018, Contact: Benjamin Tice 509–527–7267 EIS No. 20180126, Draft, USACE, FL, Central Everglades Planning Project District Section 203 Everglades Agricultural Area Southern Reservoir and Stormwater Treatment Area, Comment Period Ends: 07/24/2018, Contact: Stacie Auvenshine 904–314–7614 EIS No. 20180127, Draft, USFS, WA, Sunrise Vegetation and Fuels Management, Comment Period Ends: 08/08/2018, Contact: Johnny Collin 509–943–4643 EIS No. 20180128, Final, USFS, CO, Steamboat Ski Area Improvements, Review Period Ends: 07/17/2018, Contact: Erica Dickerman 970–870–2185 Amended Notice Revision to the Federal Register Notice published 06/01/2018, extend comment period from 07/02/2018 to 07/31/2018, EIS No. 20180111, Draft, NMFS, NAT, Draft Environmental Impact Statement for Issuing Annual Catch Limits to the Alaska Eskimo Whaling Commission for a Subsistence Hunt on Bowhead Whales for the Years 2019 and Beyond, Contact: John Henderschedt, 301–427–8385 Dated: June 5, 2018. Rob Tomiak, Director, Office of Federal Activities. [FR Doc. 2018–12334 Filed 6–7–18; 8:45 am] BILLING CODE 6560–50–P ENVIROMENTAL PROTECTION AGENCY [EPA–HQ–OAR–2018–0295; FRL–9979–20–OAR] RIN 2060–AT40, 2060–AT39, 2060–AT38, 2060–AT37, 2060–AT36 Response to Clean Air Act Section 126(b) Petitions From Delaware and Maryland AGENCY: Environmental Protection Agency (EPA). ACTION: Notice of proposed action on petitions. SUMMARY: The Environmental Protection Agency (EPA) is proposing to deny four petitions submitted by the state of Delaware and one petition submitted by the state of Maryland under Clean Air Act (CAA or Act) section 126(b). The petitions were submitted between July and November 2016. Each of Delaware’s four petitions requested that the EPA make a finding that emissions from individual sources in Pennsylvania or West Virginia are significantly contributing to Delaware’s nonattainment of the 2008 or 2015 ozone national ambient air quality standards (NAAQS). Maryland’s petition requested that the EPA make a finding that emissions from 36 electric generating units in Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia are significantly contributing to ozone levels that exceed the 2008 8-hour ozone NAAQS in Maryland, and, therefore, are interfering with maintenance of the 2008 ozone NAAQS. The EPA proposes to deny all five petitions because Delaware and Maryland have not met their burden to demonstrate that the sources emit or would emit in violation of the CAA’s “good neighbor” provision (i.e., the petitions have not demonstrated that the sources will significantly contribute to nonattainment or interfere with maintenance of the 2008 or 2015 ozone NAAQS in the petitioning states). The EPA is further proposing to deny the petitions based on the agency’s independent analysis that the identified sources do not currently emit and are not expected to emit pollution in violation of the good neighbor provision for either the 2008 or 2015 ozone NAAQS. DATES: Comments. Comments must be received on or before July 23, 2018. Public Hearing. The EPA will hold a public hearing on the proposed action. Details will be announced in a separate Federal Register document. ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0295, at http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (e.g., on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets. FOR FURTHER INFORMATION CONTACT: Questions concerning this proposed notice should be directed to Mr. Lev Gabrilovich, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail Code C539–01, Research Triangle Park, NC 27711, telephone (919) 541–1496; email at gabrilovich.lev@epa.gov. SUPPLEMENTARY INFORMATION: The information in this document is organized as follows: I. General Information II. Executive Summary of the EPA’s Decision on CAA Section 126(b) Petitions From Delaware and Maryland III. Background and Legal Authority A. Ozone and Public Health B. Clean Air Act Sections 110 and 126 C. The EPA’s Historical Approach to Addressing Interstate Transport of Ozone Under the Good Neighbor Provision D. The CAA Section 126(b) Petitions From Delaware E. The CAA Section 126(b) Petition From Maryland IV. The EPA’s Proposed Decision on
Delaware’s and Maryland’s CAA Section 126(b) Petitions

A. The EPA’s Approach for Granting or Denying CAA Section 126(b) Petitions

Regarding the 2008 and 2015 8-Hour Ozone NAAQS

B. The EPA’s Evaluation of Whether the Petitions Are Sufficient To Support a Section 126(b) Finding

C. The EPA’s Independent Analysis of the CAA Section 126(b) Petitions

D. The EPA’s Independent Analysis of Sources Without Selective Catalytic Reduction Post Combustion Controls

V. Conclusion

VI. Determinations Under Section 307(b)(1)

VII. Statutory Authority

I. General Information

Throughout this document, wherever “we,” “us,” or “our” is used, we mean the United States (U.S.) EPA.

Where can I get a copy of this document and other related information?


II. Executive Summary of the EPA’s Decision on CAA Section 126(b) Petitions From Delaware and Maryland

In 2016, the states of Delaware and Maryland submitted a total of five petitions requesting that the EPA make findings pursuant to CAA section 126(b) that emissions from numerous upwind sources significantly contribute to nonattainment and/or interfere with maintenance of the ozone NAAQS in violation of CAA section 110(a)(2)(D)(i)(I), otherwise known as the good neighbor provision. Delaware submitted four petitions, each alleging good neighbor violations related to the 2008 and 2015 ozone NAAQS by individual sources located in Pennsylvania or West Virginia. Maryland submitted a single petition alleging good neighbor violations related to the 2008 ozone NAAQS by 36 electric generating units (EGUs) in five states.

The EPA is evaluating the petitions consistent with the same four-step regional analytic framework that the EPA has used in previous regulatory actions addressing regional interstate ozone transport problems. The EPA is therefore using this framework to evaluate whether the petitions meet the standard to demonstrate under CAA section 126(b) that the sources emit or would emit in violation of the good neighbor provision based on both current and anticipated future emissions levels. The EPA identifies two bases for denying the petitions. First, the agency’s historical approach to evaluating CAA section 126(b) petitions looks to see whether a petition, standing alone, identifies or establishes an analytic basis for the requested CAA section 126(b) finding, and the agency identified several elements of the states’ analysis that are considered insufficient to support the states’ conclusions. Second, the EPA also can rely on its own independent analyses to evaluate the potential basis for the requested CAA section 126(b) finding. The EPA is, therefore, proposing a finding based on its own analysis, that there are no additional highly cost-effective emissions reductions available at the sources, and, thus, that none of the named sources currently emit or would emit in violation of the good neighbor provision with respect to the relevant ozone NAAQS.

Section III of this notice provides background information regarding the EPA’s approach to addressing the interstate transport of ozone under CAA sections 110(a)(2)(D)(i) and 126(b), and provides a summary of the relevant issues raised in Delaware’s and Maryland’s CAA section 126(b) petitions. Section IV of this notice details the EPA’s proposed action to deny these petitions, including explaining the EPA’s approach for granting or denying CAA section 126(b) petitions regarding the 2008 and 2015 8-hour ozone NAAQS, identifying technical insufficiencies in the petitions, and explaining the EPA’s own analysis evaluating whether the sources named in the petitions emit or would emit in violation of the good neighbor provision for the pertinent NAAQS.

III. Background and Legal Authority

A. Ozone and Public Health

Ground-level ozone is not emitted directly into the air, but is a secondary air pollutant created by chemical reactions between nitrogen oxides (NOx) and volatile organic compounds (VOCs) in the presence of sunlight. These precursor emissions can be transported downwind directly or, after transformation in the atmosphere, as ozone. As a result, ozone formation, atmospheric residence, and transport can occur on a regional scale (i.e., hundreds of miles). For further discussion of ozone-formation chemistry, interstate transport issues, and health effects, see the Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS (CSAPR Update), 81 FR 74504, 74513–14 (October 26, 2016). On March 12, 2008, the EPA promulgated a revision to the ozone NAAQS, lowering both the primary and secondary standards to 75 parts per billion (ppb).1 On October 1, 2015, the EPA revised the ground-level ozone NAAQS to 70 ppb.2

B. Clean Air Act Sections 110 and 126

The statutory authority for this action is provided by CAA sections 126 and 110(a)(2)(D)(i). Section 126(b) of the CAA provides, among other things, that any state or political subdivision may petition the Administrator of the EPA to find that any major source or group of stationary sources in an upwind state emits or would emit any air pollutant in violation of the prohibition of CAA section 110(a)(2)(D)(i).3 Petitions submitted pursuant to this section are commonly referred to as CAA section 126(b) petitions. Similarly, findings by the Administrator, pursuant to this section, that a source or group of sources emits air pollutants in violation of the CAA section 110(a)(2)(D)(i) prohibition are commonly referred to as CAA section 126(b) findings.

CAA section 126(c) explains the effect of a CAA section 126(b) finding and establishes the conditions under which continued operation of a source subject to such a finding may be permitted. Specifically, CAA section 126(c) provides that it is a violation of section 126 of the Act and of the applicable state implementation plan (SIP): (1) For any major proposed new or modified source subject to a CAA section 126(b) finding to be constructed or operate in violation of the prohibition of CAA section 110(a)(2)(D)(i); or (2) for any major existing source for which such a finding has been made to stay in operation more than 3 months after the date of the finding. The statute, however, also gives the Administrator discretion to permit the continued operation of a source beyond 3 months if the source complies with emissions limitations and compliance schedules provided by the EPA to bring about compliance with the requirements contained in CAA sections 110(a)(2)(D)(i) and 126 as expeditiously as practicable, but in any event no later

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1 See National Ambient Air Quality Standards for Ozone, Final Rule, 73 FR 16436 (March 27, 2008).
2 See National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015).
3 The text of CAA section 126 as codified in the U.S. Code cross-references section 110(a)(2)(D)(i) instead of section 110(a)(2)(D)(ii). The courts have confirmed that this is a scrivener’s error and the correct cross-reference is to CAA section 110(a)(2)(D)(i). See Appalachian Power Co. v. EPA, 249 F.3d 1032, 1040–44 (D.C. Cir. 2001).
than 3 years from the date of the finding.  

Section 110(a)(2)(D)(i) of the CAA, referred to as the good neighbor provision of the Act, requires states to prohibit certain emissions from in-state sources if such emissions impact the air quality in downwind states. Specifically, CAA sections 110(a)(1) and 110(a)(2)(D)(i)(I) require all states, within 3 years of promulgation of a new or revised NAAQS, to submit SIPs that contain adequate provisions prohibiting any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to that NAAQS. As described further in Section III.C, the EPA has developed a number of regional rulemakings to address CAA section 110(a)(2)(D)(i)(I) for the various ozone NAAQS. The EPA’s most recent rulemaking, the CSAPR Update, was promulgated to address interstate transport under section 110(a)(2)(D)(i)(I) for the 2008 ozone NAAQS. 81 FR 74504 (October 26, 2016). The EPA notes that the petitions from both states were submitted before the implementation of the emissions budgets promulgated in the CSAPR Update.

C. The EPA’s Historical Approach To Addressing Interstate Transport of Ozone Under the Good Neighbor Provision

Given that formation, atmospheric residence, and transport of ozone occur on a regional scale (i.e., hundreds of miles) over much of the eastern U.S., the EPA has historically addressed interstate transport of ozone pursuant to the good neighbor provision through a series of regional rulemakings focused on the reduction of NOx emissions. In developing these rulemakings, the EPA has typically found that downwind states’ problems attaining and maintaining the ozone NAAQS result, in part, from the contribution of pollution from multiple upwind sources located in different upwind states.

The EPA has promulgated four regional interstate transport rulemakings that have addressed the good neighbor provision with respect to various ozone NAAQS considering the regional nature of ozone transport. Each of these rulemakings essentially followed the same four-step framework to quantify and implement emissions reductions necessary to address the interstate transport requirements of the good neighbor provision. These steps are: (1) identifying downwind air quality problems relative to the ozone NAAQS. The EPA has identified downwind areas with air quality problems (referred to as “receptors”) considering monitored ozone data where appropriate and air quality modeling projections to a future compliance year. Pursuant to the opinion in North Carolina v. EPA, 531 F.3d 896, 908–911 (D.C. Cir. 2008), the agency identified areas expected to be in nonattainment with the ozone NAAQS and those areas that may struggle to maintain the NAAQS; (2) determining which upwind states are linked to these identified downwind air quality problems and warrant further analysis to determine whether their emissions violate the good neighbor provision. In the EPA’s most recent rulemakings, the EPA identified such upwind states to be those modeled to contribute at or above a threshold equivalent to one percent of the applicable NAAQS; (3) for states linked to downwind air quality problems, identifying upwind emissions on a statewide basis that will significantly contribute to nonattainment or interfere with maintenance of a standard. In all four of the EPA’s prior rulemakings, the EPA apportioned emissions reduction responsibility among multiple upwind states linked to downwind air quality problems using cost- and air quality-based criteria to quantify the amount of a linked upwind state’s emissions that must be prohibited pursuant to the good neighbor provision; and (4) for states that are found to have emissions that significantly contribute to nonattainment or interfere with maintenance of the NAAQS downwind, implementing the necessary emissions reductions within the state. The EPA has done this for its federal implementation plans (FIPs) addressing the good neighbor provision for the ozone NAAQS by requiring affected sources in upwind states to participate in allowance trading programs to achieve the necessary emissions reductions.4

The EPA’s first such rulemaking, the NOx SIP Call, addressed interstate transport with respect to the 1979 ozone NAAQS. 63 FR 57356 (October 27, 1998). The EPA concluded in the NOx SIP Call that “[t]he fact that virtually every nonattainment problem is caused by numerous sources over a wide geographic area is a factor suggesting that the solution to the problem is the implementation over a wide area of controls on many sources, each of which may have a small or unmeasurable ambient impact by itself.” 63 FR 57356, 57377 (October 27, 1998). The NOx SIP Call promulgated statewide emissions budgets and required upwind states to adopt SIPs that would decrease NOx emissions by amounts that would meet these budgets, thereby eliminating the emissions that significantly contribute to nonattainment or interfere with maintenance of the ozone NAAQS in downwind states. The EPA also promulgated a model rule for a regional allowance trading program called the NOx Budget Trading Program that states could adopt in their SIPs as a mechanism to achieve some or all of the required emissions reductions. All of the jurisdictions covered by the NOx SIP Call ultimately chose to adopt the NOx Budget Trading Program into their SIPs. The NOx SIP Call was upheld by the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in all pertinent respects. See Michigan v. EPA, 213 F.3d 663 (2000).

In coordination with the NOx SIP Call rulemaking under CAA section 110(a)(2)(D)(i)(I), the EPA also addressed several pending CAA section 126(b) petitions submitted by eight northeastern states regarding the same air quality issues addressed by the NOx SIP Call (i.e., interstate transport for the 1979 ozone NAAQS). These CAA section 126(b) petitions asked the EPA to find that ozone emissions from numerous sources located in 22 states and the District of Columbia had adverse air quality impacts on the petitioning downwind states. Based on technical determinations made in the NOx SIP Call regarding upwind state impacts on downwind air quality, the EPA in May 1999 made technical determinations regarding the claims in the petitions, but did not at that time make the CAA section 126(b) findings requested by the petitions. 64 FR 28250 (May 25, 1999). In making these technical determinations, the EPA concluded that the NOx SIP Call would fully address and remediate the claims raised in these petitions, and that the EPA would therefore not need to take separate action to remedy any potential violations of the CAA section 110(a)(2)(D)(i) prohibition. 64 FR 28252. However, subsequent litigation over the NOx SIP Call led the EPA to “de-link” the CAA section 126(b) petition response from the NOx SIP Call; the EPA made final CAA section 126(b)
findings for 12 states and the District of Columbia. The EPA found that sources in these states emitted in violation of the prohibition in the good neighbor provision with respect to the 1979 ozone NAAQS based on the affirmative technical determinations made in the May 1999 rulemaking. In order to remedy the violation under CAA section 126(c), the EPA required affected sources in the upwind states to participate in a regional allowance trading program whose requirements were designed to be interchangeable with the requirements of the optional NOx Budget Trading Program model rule provided under the NOx SIP Call. 65 FR 2674 (January 18, 2000). The EPA’s action on these section 126(b) petitions was upheld by the D.C. Circuit. See Appalachian Power Co. v. EPA, 249 F.3d 1032 (D.C. Cir. 2001).

The EPA next promulgated the Clean Air Interstate Rule (CAIR) to address interstate transport under the good neighbor provision with respect to the 1997 ozone NAAQS, as well as the 1997 fine particulate matter (PM2.5) NAAQS. The EPA adopted the same framework for quantifying the level of states’ significant contribution to downwind nonattainment in CAIR as it used in the NOx SIP Call, based on the determination in the NOx SIP Call that downwind ozone nonattainment is due to the impact of emissions from numerous upwind sources and states. 70 FR 25162, 25172 (May 12, 2005). The EPA explained that “the collectively, two or more States contribute transported pollution to a single downwind area, so that the ‘collective contribution’ is much larger than the contribution of any single State.” 70 FR 25186. CAIR included two distinct regulatory processes: (1) A regulation to define significant contribution (i.e., the emissions reduction obligation) under the good neighbor provision and provide for submission of SIPs eliminating that contribution, 70 FR 25162 (May 12, 2005); and (2) a regulation to promulgate, where necessary, FIPs imposing emissions limitations (1 FR 25326 (April 28, 2006)). The FIPs required EGUs in affected states to participate in regional allowance trading programs, which replaced the previous NOx Budget Trading Program.

In conjunction with the second CAIR regulation promulgating FIPs, the EPA acted on a CAA section 126(b) petition received from the state of North Carolina on March 19, 2004, seeking a finding that large EGUs located in 13 states were significantly contributing to nonattainment and/or interfering with maintenance of the 1997 ozone NAAQS and the 1997 PM2.5 NAAQS in North Carolina. Citing the analyses conducted to support the promulgation of CAIR, the EPA denied North Carolina’s CAA section 126(b) petition in full based on a determination that either the named states were not adversely impacting downwind air quality in violation of the good neighbor provision or such impacts were fully remedied by implementation of the emissions reductions required by the CAIR FIPs. 71 FR 25328, 25330 (April 28, 2006). The D.C. Circuit found that EPA’s approach to section 110(a)(2)(D)(i)(I) in CAIR was “fundamentally flawed” in several respects, and the rule was remanded in July 2008 with the instruction that the EPA replace the rule “from the ground up.” North Carolina v. EPA, 531 F.3d at 929. The decision did not find fault with the EPA’s general multi-step framework for addressing interstate ozone transport, but rather concluded the EPA’s analysis did not address all elements required by the statute. The EPA’s separate action denying North Carolina’s CAA section 126(b) petition was not challenged.

On August 8, 2011, the EPA promulgated the Cross-State Air Pollution Rule (CSAPR) to replace CAIR. 76 FR 48208 (August 8, 2011). CSAPR addressed the same ozone and PM2.5 NAAQS as CAIR and, in addition, addressed interstate transport for the 2006 PM2.5 NAAQS by requiring 28 states to reduce sulfur dioxide (SO2) emissions, annual NOx emissions, and/or ozone season NOx emissions that would significantly contribute to other states’ nonattainment or interfere with other states’ abilities to maintain these air quality standards. Consistent with prior determinations made in the NOx SIP Call and CAIR, the EPA again found that multiple upwind states contributed to downwind ozone nonattainment. Specifically, the EPA found “that the total ‘collective contribution’ from upwind sources represents a large portion of PM2.5 and ozone at downwind locations and that the total amount of transport is comprised of the individual contribution from numerous upwind states.” 76 FR 48237. Accordingly, the EPA conducted a regional analysis, calculated emissions budgets for affected states, and required EGUs in these states to participate in new regional allowance trading programs to reduce statewide emissions levels. CSAPR was subject to nearly 4 years of litigation. Ultimately, the Supreme Court upheld the EPA’s approach to calculating emissions reductions to eliminate and apportioning upwind state responsibility under the good neighbor provision, but also held that the EPA was precluded from requiring more emissions reductions than necessary to address downwind air quality problems, or “over-controlling.” See EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584, 1607–09 (2014).

Most recently, the EPA promulgated the CSAPR Update to address the good neighbor provision requirements for the 2008 ozone NAAQS. 81 FR 74504 (October 26, 2016). The final CSAPR Update built upon previous efforts to address the collective contributions of ozone pollution from 22 states in the eastern U.S. to widespread downwind air quality problems, including the NOx SIP Call, CAIR, and the original CSAPR. As was also the case for the previous rulemakings, the EPA identified emissions from large EGUs as significantly contributing and/or interfering with maintenance based on cost and air quality factors. The CSAPR Update finalized EGU NOx ozone season emissions budgets for affected states that were developed using uniform control stringency available at a marginal cost of $1.400 per ton of NOx reduced. This level of control stringency represented ozone season NOx reductions that could be achieved in the 2017 analytic year, which was relevant to the upcoming 2018 attainment date for moderate ozone nonattainment areas, and included the potential for operating and optimizing existing selective catalytic reduction (SCR) post-combustion controls; installing state-of-the-art NOx combustion controls; and shifting generation to existing units with lower NOx emissions rates within the same state.

The CSAPR Update finalized enforceable measures necessary to achieve the emission reductions in each state by requiring power plants in covered states to participate in the CSAPR NOx Ozone Season Group 2 allowance trading program. The CSAPR trading programs and the EPA’s prior emissions trading programs (e.g., the NOx Budget Trading Program associated with the NOx SIP Call) have provided a proven, cost-effective implementation framework for achieving emissions reductions. In addition to providing environmental certainty (i.e., a cap on regional and statewide emissions), these programs have also provided regulated sources with flexibility when choosing...
compliance strategies. This implementation approach was shaped by previous rulemakings and reflects the evolution of these programs in response to court decisions and practical experience gained by states, industry, and the EPA.

In finalizing the CSAPR Update, the EPA determined the rule may only be a partial resolution of the good neighbor obligation for all but one of the states subject to that action, including those addressed in Delaware’s and Maryland’s petitions (Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia), and that the emissions reductions required by the rule “may not be all that is needed” to address transported emissions.\(^6\) 81 FR 74521–22 (October 26, 2016). The EPA noted that the information available at that time indicated that downwind air quality problems would remain in 2017 after implementation of the CSAPR Update, and that upwind states continued to be linked to those downwind problems at or above the one-percent threshold. However, the EPA could not determine whether, at step three of the four-step framework, the EPA had quantified all emissions reductions that may be considered highly cost effective because the rule did not evaluate non-EGU ozone season NO\(_x\) reductions and further EGU control strategies (i.e., the implementation of new post-combustion controls) that are achievable on timeframes extending beyond 2017 analytic year.

Of particular relevance to this action, the EPA determined in the CSAPR Update that emissions from the states identified in Maryland’s petition were linked to maintenance concerns for the 2008 ozone NAAQS in Maryland based on air quality modeling projections to 2017. 81 FR 74538–39. With respect to Delaware, the EPA in the CSAPR Update did not identify any downwind air quality problems in Delaware with respect to the 2008 ozone NAAQS, and, therefore, did not determine that emissions from any of the states identified in the four petitions would be linked to Delaware. The CSAPR Update modeling indicated no monitors in Delaware with a projected average or maximum design value above the level of the 2008 ozone NAAQS in 2017.\(^7\)

For states linked to downwind air quality problems, the EPA in the CSAPR Update found there were cost-effective emissions reductions that could be achieved within upwind states at a marginal cost of $1,400 per ton, quantified an emissions budget for each state based on that level of control potential, and required EGUs located within the state, including the sources identified in Maryland and Delaware’s petitions, to comply with the EPA’s allowance trading program under the CSAPR Update beginning with the 2017 ozone season. The EPA found that these emissions budgets were necessary to achieve the required emissions reductions and mitigate impacts on downwind states’ air quality in time for the July 2018 moderate area attainment date for the 2008 ozone NAAQS.

D. The CAA Section 126(b) Petitions From Delaware

In 2016, the state of Delaware, through the Delaware Department of Natural Resources and Environmental Control (Delaware), submitted four petitions clarifying the four individual sources in Pennsylvania and West Virginia significantly contribute to Delaware’s nonattainment of the 2008 and 2015 8-hour ozone NAAQS. In particular, Delaware’s petitions allege that emissions from the Harrison Power Station (Harrison), the Homer City Generating Station (Homer City), and the Brunner Island Steam Generating Station (Brunner Island) in Pennsylvania, and the Conemaugh Generating Station (Conemaugh) in West Virginia, significantly contribute to exceedances of the 2008 8-hour ozone NAAQS in the state of Delaware. The petitions identify a total of 59 exceedance days in the six ozone seasons between 2010 and 2015. Furthermore, Delaware contends that if the 2015 8-hour ozone NAAQS had been in effect during this period, Delaware would have experienced a total of 113 exceedance days in those ozone seasons. Notably, Harrison is equipped with low NO\(_x\) burners (LNBs), overfire air (OFA), and SCR for control of NO\(_x\) emissions at all three units. Homer City is equipped with LNBs, OFA, and SCR for control of NO\(_x\) emissions at all three units. Conemaugh is equipped with LNBs, close-coupled and separated overfire air (CC/SOFA), and SCR for control of NO\(_x\) emissions at both units. Brunner Island is equipped with LNBs and combustion air controls.

1. Common Arguments in Delaware Petitions

Each of the Delaware petitions alleges that an individual source significantly contributes to nonattainment of the 2008 and 2015 8-hour ozone NAAQS in Delaware based on two common arguments. First, all four petitions allege that the EPA’s modeling conducted in support of the CSAPR Update shows that the states in which these sources are located contribute one percent or more of the 2008 8-hour ozone NAAQS to ozone concentrations in Delaware.

Second, all four petitions point to additional modeling for support. The Brunner Island and Harrison petitions cite an August 6, 2015, technical memorandum from Sonoma Technology, Inc. (STI), which describes contribution modeling conducted with respect to Brunner Island. The Conemaugh and Homer City petitions cite October 24, 2016, CAMx modeling documentation. Delaware did not provide the EPA with this documentation. Based on this modeling, the petitions claim that all four sources had modeled contributions above one percent of the 2008 8-hour ozone NAAQS to locations in Delaware on select days during the 2011 ozone season.

All four petitions also contend that the absence of short-term NO\(_x\) emissions limits causes the named sources to significantly contribute to Delaware’s nonattainment of the 2008 and 2015 ozone NAAQS. The petitions, therefore, ask the EPA to implement short-term NO\(_x\) emissions limits as a remedy under CAA section 126(c). The petitions identify existing regulatory programs aimed at limiting NO\(_x\) emissions at the sources, but argue that these programs are not effective at preventing emissions from significantly contributing to downwind air quality problems in Delaware. In the case of Brunner Island, Homer City, and Conemaugh, Delaware argues that the Pennsylvania NO\(_x\) reasonable available control technology (RACT) regulation includes a 30-day averaging period for determining emissions rates, which will allow the facilities to emit above the rate limit on specific days while still meeting the 30-day average limit. Furthermore, the state argues that although all four facilities named in Delaware’s petitions have been subject to several NO\(_x\) emissions cap-and-trade programs that effectively put a seasonal NO\(_x\) emissions mass cap on the fleet of subject units, the subject units are not required to limit their NO\(_x\) emissions over any particular portion of the ozone season as long as they are able to obtain sufficient NO\(_x\) allowances to cover each unit’s actual ozone season NO\(_x\) mass emissions. The state alleges that the sources have been able to attain compliance without having to make any

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\(^6\) The EPA determined that the emission reductions required by the CSAPR Update satisfied the full scope of the good neighbor obligation for Tennessee with respect to the 2008 ozone NAAQS. 81 FR 74551–52.

\(^7\) See modeling conducted for purposes of the proposed CSAPR Update in 2015. 80 FR 75760, 75725–728 (December 3, 2015).
significant reductions in their ozone season average NO\textsubscript{X} emissions rates. Delaware also acknowledges that Brunner Island can use natural gas as fuel at all three units, lowering the units’ NO\textsubscript{X} emissions, but argues that Brunner Island’s ability to also use coal indicates that, without a short-term NO\textsubscript{X} emissions limit, the units will continue to significantly contribute to nonattainment or interfere with maintenance of the ozone NAAQS in Delaware. In the case of Conemaugh, Harrison, and Homer City, Delaware similarly contends that current NO\textsubscript{X} emissions regulations applicable to sources in Pennsylvania and West Virginia do not prevent significant contribution to Delaware’s nonattainment of the ozone NAAQS. As indicated in this notice, unlike Brunner Island, these sources all have SCR to control NO\textsubscript{X} emissions. Delaware argues that a review of emissions rates since the SCRs were installed indicates that the SCRs are being turned off or operated at reduced levels of effectiveness in the ozone season. Thus, in Delaware’s view, these sources also need a short-term NO\textsubscript{X} emissions limit to incentivize effective and consistent NO\textsubscript{X} control operation. The following sections describe additional information Delaware provided in each specific petition.

2. Delaware’s Petition Regarding the Harrison Power Station

Delaware’s August 8, 2016 CAA section 126(b) petition addresses the Harrison Power Station, identified as a 2,052-megawatt facility located near Haywood, Harrison County, West Virginia, with three coal-fired steam EGUs. To support its petition, Delaware states that, based on the STI modeling, the Harrison Power Station had a modeled impact above one percent of the NAAQS on August 10, 2011. Delaware further states that a review of emissions data indicates that the facility emitted 61,588 tons of NO\textsubscript{X} on that day. Delaware concludes that emissions data indicate that daily ozone season NO\textsubscript{X} emissions from the Harrison Power Station frequently exceed the 61,588 tons/day value that the petition estimated had a significant impact on Delaware’s monitors.

Delaware indicates that the Harrison Power Station is subject to operating permit NO\textsubscript{X} emissions rate limits and has been subject to various NO\textsubscript{X} emissions allowance trading programs, which Delaware asserts put a seasonal NO\textsubscript{X} emissions mass cap on the fleet of subject units. Delaware asserts, however, that these programs do not require the subject units to limit their NO\textsubscript{X} emissions over any particular portion of the ozone season as long as each EGU is at a 54.516 and 67.173 tons. Furthermore, Delaware indicated that Delaware monitors were exceeding the 2008 ozone NAAQS on eight of the days in 2011 with alleged significant impacts. Delaware analyzed air parcel trajectories modeled with the Hybrid Single Particle Lagrangian Integrated Trajectory (HYSPLIT) on selected days on which the state alleged it experienced significant impacts from the source. According to Delaware, these trajectories indicating contribution from Conemaugh’s NO\textsubscript{X} emissions, which coincided with the STI model’s estimated ozone impact events, showed that emissions from Conemaugh are significantly contributing to ozone concentrations in Delaware.

3. Delaware’s Petition Regarding the Homer City Generating Station

Delaware’s November 10, 2016, CAA section 126(b) petition cites the Homer City Generating Station, identified as a 2,012-megawatt facility located in Indiana County, Pennsylvania, with two coal-fired steam electric generating units. To support their petition, Delaware states that, based on the STI modeling, the Homer City Generating Station had a modeled impact above one percent on ten separate days in 2011, which coincided with daily NO\textsubscript{X} mass emissions from Conemaugh ranging between 54.516 and 67.173 tons. Furthermore, Delaware indicated that Delaware monitors were exceeding the 2008 ozone NAAQS on eight of the days in 2011 with alleged significant impacts. Delaware analyzed air parcel trajectories modeled with the Hybrid Single Particle Lagrangian Integrated Trajectory (HYSPLIT) on selected days on which the state alleged it experienced significant impacts from the source. According to Delaware, these trajectories indicating contribution from Conemaugh’s NO\textsubscript{X} emissions, which coincided with the STI model’s estimated ozone impact events, showed that emissions from Conemaugh are significantly contributing to ozone concentrations in Delaware.

4. Delaware’s Petition Regarding the Conemaugh Generating Station

Delaware’s November 28, 2016, CAA section 126(b) petition cites the Conemaugh Generating Station, identified as a 1,872-megawatt facility located in Indiana County, Pennsylvania, with two coal-fired steam electric generating units. To support its petition, Delaware states that, based on the STI modeling, the Conemaugh Generating Station had a modeled impact above one percent on ten separate days in 2011, which coincided with daily NO\textsubscript{X} mass emissions from Conemaugh ranging between 54.516 and 67.173 tons. Furthermore, Delaware indicated that Delaware monitors were exceeding the 2008 ozone NAAQS on eight of the days in 2011 with alleged significant impacts. Delaware analyzed air parcel trajectories modeled with the Hybrid Single Particle Lagrangian Integrated Trajectory (HYSPLIT) on selected days on which the state alleged it experienced significant impacts from the source. According to Delaware, these trajectories indicating contribution from Conemaugh’s NO\textsubscript{X} emissions, which coincided with the STI model’s estimated ozone impact events, showed that emissions from Conemaugh are significantly contributing to ozone concentrations in Delaware.
York County, Pennsylvania with three tangentially-fired steam boiler EGUs, each equipped with low NOx burner technology with closed-coupled/ separated over fire air (LNC3) combustion controls.13

According to Delaware, a modeling analysis conducted by STI estimated that during the 2011 ozone season the Brunner Island facility’s NOx emissions had a significant impact on Delaware’s ambient ozone on 43 separate days relative to the 2015 8-hour ozone NAAQS of 70 ppb and on 41 separate days relative to the 2008 8-hour ozone NAAQS of 75 ppb. The highest estimated impact was predicted on June 8, 2011, with a modeled impact value of 4.83 ppb. Delaware states that the data also indicate that Brunner Island facility NOx emissions contributed at significant levels to ozone NAAQS exceedances in Delaware on 9 of the 15 days in 2011. However, Delaware does not identify which of the identified days were exceedance days or the specific ozone NAAQS exceeded. Delaware also notes that the STI modeling information and Air Markets Program Data (AMPD) emissions data indicate that on September 13, 2011, Brunner Island had a modeled impact on Delaware ozone approximately twice the value identified as the threshold for significant impact (1.41 ppb estimated impact compared to 0.70 ppb for significant impact). According to the petition, this impact was caused by emissions amounting to about half of the facility’s recorded peak daily NOx, and is an indication that even lower amounts of Brunner Island facility NOx mass emissions (compared to the 27.4 tons/day value documented in the EPA’s AMPD) may still have significant impact on Delaware’s measured ozone levels under certain atmospheric conditions. However, the petition does not identify whether September 13, 2011, was a day that exceeded the 2008 ozone NAAQS.

6. Subsequent Actions and Correspondence Regarding the Delaware Petitions

Subsequent to receiving the petitions, the EPA published final rules extending the statutory deadline for the agency to take final action on all four of Delaware’s section 126(b) petitions. Section 126(b) of the Act requires the EPA to either make a finding or deny a petition within 60 days of receipt of the petition and after holding a public hearing. However, any action taken by the EPA under CAA section 126(b) is subject to the procedural requirements of CAA section 307(d). See CAA section 307(d)(1)(N). This section of the CAA requires the EPA to conduct notice-and-comment rulemaking, including issuance of a notice of proposed action, a period for public comment, and a public hearing before making a final determination whether to make the requested finding. In lieu of the time required for notice-and-comment rulemaking, CAA section 307(d)(10) provides for a time extension, under certain circumstances, for rulemakings subject to the section 307(d) procedural requirements. In accordance with CAA section 307(d)(10), the EPA determined that the 60-day period for action on Delaware’s petitions would be insufficient for the EPA to complete the necessary technical review, develop an adequate proposal, and allow time for notice and comment, including an opportunity for public hearing. Therefore, on August 23, 2016, the EPA published a notice extending the deadline to act on Delaware’s Brunner Island petition to March 5, 2017.14 On September 27, 2016, the EPA published a notice extending the deadline to act on Delaware’s Harrison Power Station petition to April 7, 2017.15 On December 29, 2016, the EPA published a notice extending the deadline to act on Delaware’s Homer City petition to July 9, 2017.16 On January 23, 2017, the EPA published a notice extending the deadline to act on Delaware’s Conemaugh petition to August 3, 2017.17 The notices extending these deadlines can be found in the docket for this rulemaking.

On March 5, 2017, the Chesapeake Bay Foundation (CBF) submitted a letter in support of Delaware’s petition regarding Brunner Island. The CBF supports Delaware’s argument that emissions from the named coal-fired EGUs significantly contribute to nonattainment and interfere with maintenance of the ozone NAAQS in Delaware. On April 11, 2017, the CBF sent a second letter in support of Delaware’s petition regarding Harrison. The CBF supports Delaware’s argument that emissions data since 2011 demonstrate that Harrison’s operators have either ceased to operate the SCR systems regularly or have chosen to operate them in a sub-optimal manner. In both letters, the CBF argued that the EPA should implement an emissions rate limit at both facilities based on short averaging periods and indicated that Delaware’s proposed remedy would help reduce nitrogen deposition to the Chesapeake Bay watershed, with beneficial effects upon the health of the Bay.

On June 20, 2017, the Midwest Ozone Group (MOG) submitted a letter urging the EPA to deny the Conemaugh petition and asserted that Delaware does not have ozone nonattainment or maintenance problems upon which to base a CAA section 126(b) petition. The MOG contends that Delaware air quality currently meets the 2008 8-hour ozone NAAQS, was projected to attain the standard in 201718, and will continue to improve with the implementation of existing regulatory programs. The MOG also suggests that the EPA cannot grant a CAA section 126(b) petition for the 2015 ozone NAAQS until after the EPA has issued designations for that standard.

The EPA acknowledges receipt of these letters and has made them available in the docket for this action. However, the EPA is not in this action responding directly to these letters. Rather, the EPA encourages interested parties to review this proposal and then submit relevant comments during the public comment period.

E. The CAA Section 126(b) Petition From Maryland

On November 16, 2016, the state of Maryland, through the Maryland Department of the Environment, submitted a CAA section 126(b) petition alleging that emissions from 36 EGUs significantly contribute to ozone levels that exceed the 2008 ozone NAAQS in Maryland and therefore interfere with both attainment and maintenance of the NAAQS.19 These sources are coal-fired EGUs located in Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia, which Maryland notes are states that EPA has already determined are significantly contributing to nonattainment in Maryland under the 2008 ozone NAAQS. Maryland indicates that all of these sources have SCR or...
Selective Non-Catalytic Reduction (SNCR) to control NO\textsubscript{X} emissions. In addition, Maryland’s technical support document discusses modeling conducted by the University of Maryland, which claims to show that ozone concentrations would reduce if these EGUs were to optimize running their SCR and SNCR controls, and provides control optimization modeling scenarios which project the ozone impacts of optimizing emissions controls in 2016. Maryland suggests, by way of using its own state regulation as an example, that optimizing controls means operating controls consistent with technological limitations, manufacturers’ specifications, good engineering and maintenance practices, and good air pollution control practices for minimizing emissions.

The petition further alleges that Maryland’s proposed remedy—discussed further below—will influence how areas in Maryland and other Mid-Atlantic states are designated under the new 2015 ozone NAAQS. According to Maryland, if implemented in 2017, it would most likely allow the Baltimore area and the Washington, DC, multi-state area, which includes portions of Maryland, to both be designated attainment for the 2015 ozone NAAQS. The EPA notes that the cover letter of Maryland’s petition specifically requests that EPA make a finding that “the 36 electric generating units (EGUs) . . . are emitting pollutants in violation of the provisions of Section 110(a)(2)(D)(i)(I) of the CAA with respect to the 2008 ozone National Ambient Air Quality Standards.” and the petition throughout refers only to the 2008 ozone NAAQS when identifying alleged air quality problems in Maryland and the impacts from upwind sources. Accordingly, while Maryland suggests that its requested remedy for 2008 ozone will assist in achieving attainment of the 2015 ozone NAAQS, the state has not specifically requested that EPA make a finding with respect to the 2015 ozone NAAQS, and, therefore, the EPA is not evaluating the petition for this standard.

Maryland argues that these 36 EGUs have existing post-combustion control mechanisms that should prevent significant contribution, the facilities have either ceased to operate the controls regularly during the ozone season or have chosen to operate them in a sub-optimal manner. Maryland presents an analysis based on 2005–2015 ozone season data to support this contention. Maryland argues that whether controls are optimally run can be determined by comparing current ozone season average emissions rates to the lowest ozone season average emissions rate after 2005 or after the unit installed SCR or SNCR. Maryland alleges that NO\textsubscript{X} emissions rates at the 36 facilities have increased significantly since the SCR and SNCR installation and initial testing, indicating that these EGUs are not operating their post-combustion controls efficiently on each day of the ozone season.

Maryland also submitted a number of technical memoranda to support its argument. Maryland submitted analyses of control technology optimization for coal-fired EGUs in eastern states, which they contend demonstrate that NO\textsubscript{X} emissions rates at specific EGUs are well above what is considered representative of an EGU running post-combustion controls efficiently; that 2015 and 2016 EPA data show that many EGUs have not been running their post-combustion controls as efficiently as they have in the past during the ozone season; and that the EPA should therefore ensure these controls are operating during the 2017 ozone season by including requirements or permit conditions requiring each named EGU to minimize emissions by optimizing existing control technologies, enforced through use of a 30-day rolling average rate.

Maryland also submitted the following documents: A review of its own NO\textsubscript{X} regulations for coal fired EGUs; a detailed study conducted by Maryland and the University of Maryland regarding regional ozone transport research and analysis efforts in Maryland; an August 6, 2015, STI report alleging that source apportionment modeling indicates that emissions from Brunner Island (a source not specifically addressed in Maryland’s petition) contribute significantly to ozone formation in Pennsylvania and neighboring states during the modeled ozone season; a list of recommended language for the EPA to include in federal orders related to the named EGUs to remedy significant contribution; and an evaluation of cost savings Maryland alleges the units have incurred in 2014 by not fully running their controls compared with the cost of running their controls at full efficiency. As discussed previously, Maryland also submitted a memorandum detailing modeling analyses conducted by the University of Maryland, which presents projected reductions in ozone concentrations in Maryland that would occur as a result of optimized SCR and SNCR operations at the 36 sources named in Maryland’s petition. Maryland argues that these projected reductions in ozone concentrations at Maryland monitors demonstrate that optimizing the post-combustion controls at the 36 units with SCR or SNCR would allow Maryland to attain, or come very close to attaining, the 2008 8-hour ozone NAAQS.

Additionally, Maryland supplemented its petition with several further appendices submitted in 2017. Maryland submitted an additional optimization analysis comparing NO\textsubscript{X} emissions rates in 2006, 2015, and 2016 for EGUs listed in its petition; a comparison of 2016 ozone season average emissions rates to the lowest demonstrated ozone season average emissions rates between 2005 and 2015 at 369 coal-fired EGUs in 29 states identified as the Eastern Modeling Domain; a comparison of average emissions data at 21 units in Pennsylvania in the first quarter of 2017 to the lowest demonstrated ozone season average emissions rate between 2005–2016; and additional photochemical modeling conducted by the University of Maryland of the impact of the 36 EGUs in the five states on ozone concentrations in Maryland, which concludes that emissions from these units significantly contribute to ozone concentrations in Maryland and therefore contribute to nonattainment and interfere with the maintenance of the 8-hour ozone NAAQS.

Maryland’s petition also requests a remedy that will compel the named units to optimize their SCR and SNCR. Maryland indicates that its petition is focused on ensuring controls are run at the units every day of the ozone season. According to Maryland, the CSAPR Update, earlier federal allowance trading programs, and many state regulations allow for longer term averaging, which means that controls do not necessarily need to be run effectively every day to comply with these requirements. Maryland claims that this has resulted in situations where sources in the five upwind states have not run their controls efficiently on many days with high ozone, and, therefore, these sources are impacting

\[21\] See id.
\[22\] Id. Appendix B.
\[23\] Id. Appendix C.
\[24\] Id. Appendix D.
\[25\] Id. Appendix E.
\[26\] Id. Appendix F.
Maryland contends that emissions at the 36 EGUs can be reduced at the ozone season starting in May of 2017. Each day of the ozone season starting in May of 2017, the 36 EGUs must be abated on approximately 39,000 tons of NO\textsubscript{X} reductions could have been achieved in the ozone season if the 36 targeted EGUs had simply run their controls efficiently. Therefore, Maryland states that, based on the EPA’s past approaches in establishing significant contributions based on highly cost-effective controls, the NO\textsubscript{X} emissions from these 36 EGUs must be abated on each day of the ozone season starting in May of 2017.

Maryland contends that emissions at the 36 EGUs can be reduced at reasonable cost, or with potentially no new actual costs to the EGUs at all, because this requested remedy rests on the use of existing control equipment. Maryland suggests two methods to ensure optimized use of controls at these sources. First, Maryland requests that the EPA include language in federal and state regulations or operating permits requiring the owners or operators of the relevant EGUs to use all installed pollution control technology consistent with technological limitations, manufacturers’ specifications, good engineering and maintenance practices, and good air pollution control practices. Second, Maryland requests that the EPA enforce this requirement by comparing each unit’s maximum 30-day rolling average emissions rate to the unit’s lowest reported ozone emissions rate. Maryland also requests that this remedy be implemented by 2017 to help areas in Maryland achieve attainment in time to inform the 2015 ozone NAAQS area designations.

1. Subsequent Actions and Correspondence Regarding the Maryland Petition

Consistent with CAA section 307(d), as discussed in Section III.D of this notice, the EPA determined that the 60-day period for responding to Maryland’s petition is insufficient for the EPA to complete the necessary technical review, develop an adequate proposal, and allow time for notice and comment, including an opportunity for public hearing, on a proposed finding regarding whether the 36 EGUs identified in the petition significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in Maryland. On January 3, 2017, the EPA published a final rule extending the deadline for acting on Maryland’s section 126(b) petition to July 15, 2017.\footnote{33 82 FR 22 (January 3, 2017).}

On May 17, 2017, the MOG submitted a letter asking the EPA to deny Maryland’s section 126(b) petition. The MOG argues that all monitors in Maryland are either attaining the 2008 8-hour ozone NAAQS or are very close to attaining the standard, and that modeling indicates that all Maryland monitors will attain the 2008 8-hour ozone NAAQS in 2025. Furthermore, the MOG argues that the CSAPR Update moots Maryland’s petition. Finally, the MOG argues that the EPA must assess the impact of international emissions when reviewing a section 126(b) petition. On May 18, 2017, the Indiana Energy Association submitted a letter making similar assertions, and urged the EPA to deny Maryland’s section 126(b) petition.

The EPA acknowledges receipt of these letters, and has made them available in the docket for this action. However, the EPA is not responding directly to these letters in this action. Rather, the EPA encourages interested parties to review this proposal and then submit relevant comments during the public comment period.

IV. The EPA’s Proposed Decision on Delaware’s and Maryland’s CAA Section 126(b) Petitions

A. The EPA’s Approach for Granting or Denying CAA Section 126(b) Petitions Regarding the 2008 and 2015 8-Hour Ozone NAAQS

As discussed in Section III.B of this notice, section 126(b) of the CAA provides a mechanism for states and other political subdivisions to seek abatement of pollution in other states that may affect their air quality. However, it does not identify specific criteria or a specific methodology for the Administrator to apply when deciding whether to make a CAA section 126(b) finding or deny a petition. Therefore, the EPA has discretion to identify relevant criteria and develop a reasonable methodology for determining whether a CAA section 126(b) finding should be made. See, e.g., Appalachian Power, 249 F. 3d at 1050 (finding that given section 126(b)’s silence on what it means for a source to violate section 110(a)(2)(D)(I), the EPA’s approach, if reasonable, is entitled to deference under Chevron); Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837, 842–43 (1984); Smiley v. Citibank, 517 U.S. 735, 744–45 (1996).

As an initial matter, the EPA’s historical approach to evaluating CAA section 126(b) petitions looks first to see whether a petition establishes a sufficient basis for the requested CAA section 126(b) finding. The EPA first evaluates the technical analysis in the petition to see if that analysis, standing alone, is sufficient to support a CAA section 126(b) finding. The EPA focuses on the analysis in the petition because the statute does not require the EPA to conduct an independent technical analysis to evaluate claims made in CAA section 126(b) petitions. The petitioner, thus, bears the burden of establishing, as an initial matter, a technical basis for the specific finding requested. The EPA has no obligation to prepare an analysis to supplement a petition that fails, on its face, to include an initial technical demonstration. Such a petition, or a petition that fails to identify the specific finding requested, can be denied as insufficient.

Nonetheless, the EPA has the discretion to conduct independent analyses when helpful in evaluating the basis for a potential CAA section 126(b) finding or developing a remedy if a finding is made. See e.g., 76 FR 19662, 19666 (April 7, 2011) (proposed response to petition from New Jersey regarding SO\textsubscript{2} emissions from the Portland Generating Station); 83 FR 16064, 16070 (April 13, 2018) (final response to petition from Connecticut regarding ozone emissions from the Brunner Island Steam Electric Station). As explained in the following sections, in this instance, given the EPA’s concerns with the adequacy of the information submitted as part of the CAA section 126(b) petitions, and the fact that the EPA has previously issued a rulemaking defining and at least partially addressing the same environmental concern that the petitions seek to address, the EPA determined that it was appropriate to conduct an independent analysis to...
determine whether it should grant or deny the petitions. Such an analysis, however, is not required by the statute and may not be necessary or appropriate in other circumstances.

With respect to the statutory requirements of both section 110(a)(2)(D)(i) and section 126 of the CAA, the EPA has consistently acknowledged that Congress created these provisions as two independent statutory tools to address the problem of interstate pollution transport. See, e.g., 76 FR 69052, 69054 (November 7, 2011). Congress provided two separate statutory processes to address interstate transport without indicating any preference for one over the other, suggesting it viewed either approach as a legitimate means to produce the desired result. While either provision may be applied to address interstate transport, they are also closely linked in that a violation of the prohibition in CAA section 110(a)(2)(D)(i) is a condition precedent for action under CAA section 126(b) and, critically, that significant contribution and interference with maintenance are construed identically for purposes of both provisions (since the identical terms are naturally interpreted as meaning the same thing in the two linked provisions). See Appalachian Power, 249 F. 3d at 1049–50.

Thus, in addressing a CAA section 126(b) petition that addresses ozone transport, the EPA believes it is appropriate to interpret these ambiguous terms consistent with the EPA’s historical approach to evaluating interstate ozone pollution transport under the good neighbor provision, and its interpretation and application of that related provision of the statute. As described in Sections III.A and III.C of this notice, ozone is a regional pollutant and previous EPA analyses and regulatory actions have evaluated the regional interstate ozone transport problem using a four-step regional analytic framework. The EPA most recently applied this four-step framework in the promulgation of the CSAPR Update to address interstate transport with respect to the 2008 ozone NAAQS under CAA section 110(a)(2)(D)(i)(I). Given the specific cross-reference in CAA section 126(b) to the substantive prohibition in CAA section 110(a)(2)(D)(i), the EPA believes any prior findings made under the good neighbor provision are informative—if not determinative—for a CAA section 126(b) action, and thus the EPA’s four-step approach under CAA section 110(a)(2)(D)(i)(I) is also appropriate for evaluating under CAA section 126(b) whether an upwind source or group of sources will significantly contribute to nonattainment or interfere with maintenance of the 2008 8-hour ozone NAAQS in a petitioning downwind state. Because the EPA interprets the statutory phrases “significantly contribute to nonattainment” and “interfere with maintenance,” which appear in both statutory provisions, to mean the same thing in both those contexts, the EPA’s decision whether to grant or deny a CAA section 126(b) petition regarding both the 2008 8-hour ozone and 2015 ozone NAAQS depends on: (1) Whether there is a downwind air quality problem in the petitioning state (i.e., step one of the four-step framework); (2) whether the upwind state where the source subject to the petition is located is linked to the downwind air quality problem (i.e., step two); and, (3) if such a linkage exists, whether there are additional highly cost-effective controls achievable at the source(s) named in the CAA section 126(b) petition (i.e., step three). The application of the four-step framework to EPA’s analysis of a CAA section 126(b) petition regarding the 2008 ozone NAAQS is appropriate given the EPA has previously interpreted significant contribution and interference with maintenance under CAA section 110(a)(2)(D)(i) under this framework via the CSAPR Update.

Unlike the 2008 ozone NAAQS, the EPA has not historically engaged in a rulemaking action to adopt the good neighbor provision for the 2015 ozone NAAQS. However, the EPA has recently released technical information intended to inform states’ development of SIPs to address this standard. As part of the memo releasing the technical information, the EPA acknowledged that states have flexibility to pursue approaches that may differ from the EPA’s historical approach to evaluating interstate transport in developing their SIPs, which are due in October 2018. Nonetheless, the EPA’s technical analysis and the potential flexibilities identified in the memo generally followed the basic elements of the EPA’s historical four-step framework. Thus, in light of the EPA’s discretion to identify relevant criteria and develop a reasonable methodology for determining whether a CAA section 126(b) finding should be made, the EPA continues to evaluate the claims regarding the 2015 ozone NAAQS in Delaware’s section 126(b) petitions consistent with the EPA’s four-step framework.

The EPA notes that Congress did not specify how the EPA should determine that a major source or group of stationary sources “emits or would emit” any air pollutant in violation of the prohibition of CAA section 110(a)(2)(D)(i)(I) under the terms of section 126(b). Thus, the EPA also believes it is reasonable and appropriate at each step to consider whether the facility “emits or would emit” in light of the facility’s current operating conditions. Therefore, the EPA interprets the phrase “emits or would emit” in the context of acting on Delaware’s and Maryland’s petitions regarding the 2008 and 2015 ozone NAAQS to mean that a source may “emit” in violation of the good neighbor provision if, based on current emissions levels, the upwind state contributes to downwind air quality problems (i.e., steps one and two), and the source may be further controlled through implementation of highly cost-effective controls (i.e., step 3). Similarly, a source “would emit” in violation of the good neighbor provision if, based on reasonably anticipated future emissions levels (accounting for existing conditions), the upwind state contributes to downwind air quality problems (i.e., steps one and two) and the source could be further controlled through implementation of highly cost-effective controls (i.e., step 3). Consistent with this interpretation, the EPA has therefore evaluated, in the following sections, whether the sources cited in the petitions emit or would emit in violation of the good neighbor provision based on both current and future anticipated emissions levels.

In interpreting the phrase “emits or would emit” in violation of the prohibition of section [110(a)(2)(D)(i)],” if the EPA or a state has already adopted provisions that eliminate the significant contribution to nonattainment or interference with maintenance of the...
NA AQs in downwind states, then there simply is no violation of the CAA section 110(a)(2)(D)(i)(I) prohibition, and hence no grounds to grant a section 126(b) petition. Put another way, requiring additional reductions would result in eliminating emissions that do not contribute significantly to nonattainment or interfere with maintenance of the NAAQS, an action beyond the scope of the prohibition in CAA section 110(a)(2)(D)(i)(I) and therefore beyond the scope of the EPA’s authority to make the requested finding under CAA section 126(b). See EPA v. EME Homer City Generation, L.P., 134 S. Ct. at 1604 n.18, 1608–09 (holding the EPA may not over-control by requiring sources in upwind states to reduce emissions by more than necessary to eliminate significant contribution to nonattainment or interference with maintenance of the NAAQS in downwind states under the good neighbor provision).

Thus, for example, if the EPA has already approved a state’s SIP as adequate to meet the requirements of CAA section 110(a)(2)(D)(i)(I), the EPA will not find that a source in that state was emitting in violation of the prohibition of CAA section 110(a)(2)(D)(i)(I) absent new information demonstrating that the SIP is now insufficient to address the prohibition. Similarly, if the EPA has promulgated a FIP that fully addressed the deficiency, the FIP would eliminate emissions that significantly contribute to nonattainment or interfere with maintenance in a downwind state, and, hence, absent new information to the contrary, EPA will not find that sources in the upwind state are emitting or would emit in violation of the CAA section 110(a)(2)(D)(i)(I) prohibition.

The EPA notes that the approval of a SIP or promulgation of a FIP implementing section 110(a)(2)(D)(i)(I) means that a state’s emissions are adequately prohibited for the particular set of facts analyzed under approval of a SIP or promulgation of a FIP. If a petitioner produces new data or information showing a different level of contribution or other facts not considered when the SIP or FIP was promulgated, compliance with a SIP or FIP may not be determinative regarding whether the upwind sources would emit in violation of the prohibition of CAA section 110(a)(2)(D)(i)(I). See 64 FR 28250, 28274 n.15 (May 25, 1999); 71 FR 25328, 25336 n.6 (April 28, 2006); Appalachian Power, 249 F.3d at 1067 (later developments can provide the basis for another CAA section 126(b) petition). Thus, in circumstances where a SIP or FIP addressing CAA section 110(a)(2)(D)(i)(I) is being implemented, the EPA will evaluate the CAA section 126(b) petition to determine if it raises new information that merits further consideration.

B. The EPA’s Evaluation of Whether the Petitions Are Sufficient To Support a Section 126(b) Finding

As an initial matter in reviewing a CAA section 126(b) petition, the EPA evaluates the technical analysis in the petition to see if that analysis, standing alone, is sufficient to support the requested CAA section 126(b) findings. In this regard, the EPA has determined that material elements of the analysis provided in Delaware’s and Maryland’s petitions are technically deficient and, thereby, proposes to deny the petitions, in part, on the basis that the conclusions that the petitions draw are not supported by the petitions’ technical assessments.

1. Petitions From Delaware

As discussed in Section IV.A, the EPA interprets the good neighbor provision for purposes of the pending CAA section 126(b) petitions consistent with the EPA’s historical four-step framework. With respect to step one of the four-step framework, the EPA began by evaluating Delaware’s four petitions to determine if the state identified a downwind air quality problem (nonattainment or maintenance) that may be impacted by ozone transport from other states. EPA conducted this evaluation with regard to both the 2008 and 2015 ozone NAAQS.

First, with respect to the 2008 ozone NAAQS, Delaware does not provide sufficient information to indicate that there is a current or expected future downwind air quality problem in the state. While the Delaware petitions identify individual exceedances of the ozone standard in the state between the 2000 and 2016 ozone seasons, this does not necessarily demonstrate that there is a resulting nonattainment or maintenance problem. Ozone NAAQS violations are determined based on the fourth-highest daily maximum ozone concentration, averaged across 3 consecutive years. Thus, individual exceedances at monitors do not by themselves indicate that a state is not attaining or maintaining the NAAQS.

Second, with respect to the 2015 ozone NAAQS, Delaware argues that if that NAAQS had been in effect from 2011 through 2016, Delaware monitors would have recorded more exceedances than they did under the 2008 ozone NAAQS. However, again, the identification of individual exceedances does not speak to whether there are current violations of the standard. Additionally, the EPA evaluates downwind ozone air quality problems for purposes of step one of the four-step framework using modeled future air quality concentrations for a year that considers the relevant attainment deadlines for the NAAQS. This approach is based on the EPA’s interpretation of the language in the good neighbor provision indicating that states should prohibit emissions that “will” significantly contribute to nonattainment or interfere with maintenance of the NAAQS. See North Carolina, 531 F.3d at 913–914 (affirming as reasonable the EPA’s interpretation of “will” to refer to future, projected ozone concentrations). However, the petitions do not provide any analysis indicating that Delaware may be violating or have difficulty maintaining the 2008 or 2015 ozone NAAQS in a future year associated with the relevant attainment dates.

Next, with respect to step two of the four-step framework, material elements of Delaware’s analysis regarding the contributions from the Brummer Island, Herrington, Homer City, and Conemaugh EGUs to air quality in Delaware are deficient and, therefore, the conclusions that the petitions draw are not supported by the technical assessment. As noted earlier, all four petitions rely upon air quality modeling that uses 2011 emissions to quantify the contribution from each of the four named sources to locations in Delaware on individual days in 2011. However, 2011 emissions are generally higher than, and therefore not representative of, current or future projected emissions levels at these EGUs and in the rest of the region, which the EPA believes is most relevant to determining whether a source “emits or would emit” in violation of the good neighbor provision. Thus, the 2011 modeling does not provide representative data regarding current or future contributions.

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37 See 80 FR 65296 (October 26, 2015) for a detailed explanation of the calculation of the 3-year 8-hour average and the methodology set forth in 40 CFR part 50, appendix U.

38 81 FR 74517.

39 As an example of how emissions have changed between 2011 and a recent historical year, the EPA notes that Pennsylvania’s 2017 EGU NOX ozone season emissions were 79 percent below 2011 levels. Brummer Island is located in Pennsylvania, and reduced its individual ozone season NOX emissions by 88 percent in 2017 relative to 2011 levels. (https://www.epa.gov/ampd). Additional emissions data from 2011 and a recent historical year is included in the docket, which also shows that 2011 emissions are generally higher than emissions in recent years. See 2011 to 2017 NOX Comparisons, Ozone Season, available in the docket for this action.
from these EGU. When evaluating a CAA section 126(b) petition, EPA believes it is important to rely on current and relevant data known at the time the agency takes action. Were the EPA to act based on non-representative information solely because it was provided in a petition, that result could be an arbitrary and unreasonable decision by the EPA, and could, for example, impose controls or emissions limitations that are not appropriately tailored to the nature of the problem at the time of the EPA’s final action or at the time the control or limitation would actually be implemented. This could result in unnecessary over-control (or under-control) of emissions, beyond (or short of) what is required to address the good neighbor provision, in violation of the Supreme Court’s holding in EPA v. EME Homer City Generation, L.P., 134 S. Ct. at 1608–09.

Further, the analyses provided by Delaware regarding the alleged impacts of the four sources on downwind air quality includes some information on the frequency and magnitude of ozone impacts, but the information is unclear as to the modeled and/or measured ozone levels on those days. Delaware’s Homer City petition identifies modeled contributions from emissions at that upwind source to three downwind monitoring sites in Delaware on July 18, 2011. However, the petition fails to identify whether there were measured and/or modeled exceedances of the ozone NAAQS on this day at those sites. Delaware’s Conemaugh and Brunner Island petitions identify the days, but not the monitoring sites where Delaware claims emissions from these sources contributed above the threshold. Moreover, these two petitions do not provide information on whether the contributions were to ozone values that exceed the ozone NAAQS. Delaware’s Conemaugh petition identifies 2011 contributions on days in Delaware that exceeded the 2008 NAAQS, but the petition does not provide information to show that the contributions above the threshold were predicted at monitoring sites that were exceeding the 2008 or 2015 ozone NAAQS. Accordingly, for the reasons described in this section, Delaware’s analysis in its four petitions does not allow the EPA to conclude that there is a current or future nonattainment or maintenance problem in Delaware, and therefore, the EPA cannot determine that emissions from the four sources cited in the petitions are significantly contributing to nonattainment or interfering with maintenance in Delaware with respect to either the 2008 or 2015 ozone NAAQS.

2. Petition From Maryland

The EPA has also evaluated and determined that material elements of the analysis provided in Maryland’s petition are technically deficient, and, thereby, proposes to deny the petition, in part based on the fact the conclusions that the petition draws are not supported by the technical assessment. As discussed in Section III.E of this notice, Maryland alleges that 36 named sources are operating their post-combustion controls sub-optimally based on a comparison of their lowest observed NO\textsubscript{X} emissions rates between 2005 and 2008, which Maryland describes as the “best” observed emissions rates, to emissions rates from the 2015 and 2016 ozone seasons. Maryland contends that these sources, therefore, emitting in violation of the prohibition CAA section 110(a)(2)(D)(i)(I) in the absence of a short-term limit that requires the controls be optimized.

The EPA believes that the petition’s assumption about achievable operating rates presents a technical weakness because the lowest historical rate at any particular unit may not be a rate that can be consistently achieved on a continual operating basis for technical reasons. In the CSAPR Update, the EPA analyzed EGU NO\textsubscript{X} reduction potential and corresponding NO\textsubscript{X} ozone season emissions budgets based on NO\textsubscript{X} emissions rates that can be consistently achieved for EGUs with SCRs that were not currently being optimized or which were currently idled at the time of the EPA’s analysis.\textsuperscript{41} To determine the rate that could be consistently achieved, the EPA evaluated coal-fired EGU NO\textsubscript{X} ozone season emission data from 2009 through 2015 and calculated an average NO\textsubscript{X} ozone season emissions rate across the fleet of coal-fired EGUs with SCR for each of these 7 years. The EPA calculated selected and rejected the lowest or second lowest ozone season NO\textsubscript{X} rates, because the EPA determined that these rates may reflect new SCR systems and SCR systems all of whose components are new (e.g., due to simultaneous replacement of multiple layers of catalyst rather than routine replacement of a single layer). Data from these new systems are not representative of ongoing achievable NO\textsubscript{X} rates considering that some SCR systems may have some broken-in components and routine maintenance schedules entailing replacement of individual components. Thus, in the CSAPR Update, the EPA determined that the third lowest fleet-wide average coal-fired EGU NO\textsubscript{X} rate for EGUs with operating SCRs is most representative of ongoing, achievable emission rates. The EPA observed in that rule that the third lowest fleet-wide average coal-fired EGU NO\textsubscript{X} rate for EGUs with SCR is 0.10 lbs/mmBtu. 81 FR 74543. Reliance on the lowest historical emissions rate to evaluate the feasibility and cost effectiveness of controls would likely overestimate the emissions reductions and, consequently, underestimate the costs to restart idled or unoptimized controls.\textsuperscript{42} Therefore, EPA does not agree with Maryland’s conclusion that it is appropriate to identify whether controls are optimized at the EGUs addressed in the petition, and, thus, whether a short-term limit would be necessary, based on the units’ lowest observed emissions rates. Thus, the EPA cannot conclude based on Maryland’s petition that these sources emit or would emit in violation of CAA section 110(a)(2)(D)(i)(I) for the 2008 ozone NAAQS.

C. The EPA’s Independent Analysis of the CAA Section 126(b) Petitions

As discussed in Section IV.A of this notice, the EPA may decide to conduct independent analyses when helpful in evaluating the basis for a potential CAA section 126(b) finding or developing a remedy if a finding is made. In this

\textsuperscript{40}Existing EPA analyses of interstate ozone pollution transport focus on contributions to high ozone days at the downwind receptor in order to evaluate the impact on nonattainment and maintenance at the receptor. For example, in the CSAPR Update modeling, ozone contributions were calculated using data for the days with the highest future year modeled ozone concentrations. For the 2008 ozone NAAQS, only the highest measured ozone days from each year are considered for the calculation of ozone design values (the values that determine whether there is a measured NAAQS violation). Therefore, measured ozone values that are far below the level of the NAAQS do not cause an exceedance or violation of the NAAQS. For this reason, only ozone contributions to days that are among the highest modeled ozone days at the receptor are relevant to determining if a state or source is linked to downwind nonattainment or maintenance issues.

\textsuperscript{41}81 FR 74543.

\textsuperscript{42}Similarly, the method used by Maryland to estimate the input NO\textsubscript{X} emissions rate—i.e., setting the estimated uncontrolled NO\textsubscript{X} rate as a factor of 1 divided by 0.08—is not well supported. In its modeling with IPM, the EPA has used a value of 90 percent reduction in NO\textsubscript{X} emissions to estimate the effect of adding an SCR up to a floor rate limit of 0.07 lb/mmBtu or 0.05 lb/mmBtu depending on coal type (see Table 5–5 in IPM 5.13 documentation available at https://www.epa.gov/sites/production/files/2015-12/documents/chapter_5_emission_control_technologies_0.pdf). The reductions result from a combination of simultaneously upgrading combustion controls as well as adding post-combustion controls. Furthermore, Maryland does not provide any supporting argument for its assertion regarding the factor of 0.7 (i.e., 30 percent reduction) to account for low NO\textsubscript{X} burners and other emissions control reductions.
instance, in conducting the independent analyses that it has decided to undertake to evaluate the petitions at issue, the EPA determined that, consistent with the EPA’s four-step framework for implementing CAA section 110(a)(2)(D)(i)(I) for the ozone NAAQS, the EPA’s decision whether to grant or deny a CAA section 126(b) petition based on the 2008 and 2015 ozone NAAQS depends on whether there is a downwind air quality problem in the petitioning state (i.e., step one of the four-step framework); whether the upwind state where the source subject to the petition is located is linked to the downwind air quality problem (i.e., step two); and, if such a linkage exists, whether, among other factors, there are additional high cost-effective emissions reductions achievable at the source(s) named in the CAA section 126(b) petition (i.e., step three).

1. The EPA’s Step One and Two Analyses for Delaware and Maryland

With regard to the Delaware petitions, while the EPA as discussed in Section IV.B believes that they do not adequately establish the presence of a current or future nonattainment or maintenance problem in Delaware., the EPA also independently examined whether there is an air quality problem under the 2008 and 2015 ozone NAAQS (step one), and whether the states containing the named sources are linked to such a problem in Delaware (step two).

The EPA first looked to air quality modeling projecting ozone concentrations at air quality monitoring sites to 2017, which was conducted for purposes of evaluating the first and second steps of the four-step framework to interstate transport for the 2008 ozone NAAQS as part of the CSAPR Update. The EPA used these projections for air quality monitoring sites and current ozone monitoring data at these sites to identify receptors that were anticipated to have problems attaining or maintaining the 2008 ozone NAAQS in 2017. As noted in Section III.D, all four petitions allege that the EPA’s modeling conducted in support of the CSAPR Update shows that the states in which these sources are located contribute one percent or more of the 2008 8-hour ozone NAAQS to ozone concentrations in Delaware and, therefore, that those states’ sources are significantly impacting air quality within the state.

However, this modeling indicated that Delaware was not projected to have any nonattainment or maintenance receptors in 2017 with respect to the 2008 ozone NAAQS. Therefore, the modeling in support of the CSAPR Update did not establish that the named states are linked to a downwind air quality problem regarding the 2008 ozone NAAQS. Furthermore, the EPA examined Delaware’s 2014–2016 design values, and found that no monitors were violating the 2008 ozone NAAQS. Accordingly, contrary to Delaware’s characterization of the EPA’s modeling, the EPA did not determine that any states, including those (Pennsylvania and West Virginia) where the sources named in Delaware’s petitions are located, will significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in Delaware. Thus, the EPA has no basis to conclude that any of the sources named by Delaware in its petitions are linked to a downwind air quality problem in Delaware with regard to the 2008 ozone NAAQS.

Additionally, the EPA independently examined whether there is a downwind air quality problem in Delaware with regard to the 2015 ozone NAAQS. The modeling conducted in support of the CSAPR Update shows one monitor—monitor ID 100051003 in Sussex County—having a maximum 2017 projected design value above the 2015 ozone NAAQS, and the EPA further notes information indicating that two monitors may exceed the 2015 ozone NAAQS based on 2014–2016 design values. However, as described in Section IV.B of this notice, the EPA evaluates downwind air quality problems for the purposes of step one of the four-step framework using modeled future air quality concentrations for a year that considers the relevant attainment deadlines for the NAAQS. Recent analyses projecting emissions levels to a future year indicate that no air quality monitors in Delaware are projected to have nonattainment or maintenance problems with respect to the 2015 ozone NAAQS by 2023, which is the last year of ozone season data that will be considered in order to determine whether downwind nonattainment areas classified as moderate have attained the threshold of one percent of the NAAQS. As noted in Section III.D, all four of Delaware’s petitions are not in violation of the good neighbor provision discussed in Section IV.B.I., available future year information does not suggest Delaware will have air quality problems by the relevant attainment date for the 2015 ozone NAAQS. The EPA is proposing to determine that the named sources in all four of Delaware’s petitions are not in violation of the good neighbor provision with respect to Delaware for the 2008 and 2015 NAAQS; hence, in part, on the EPA’s independent analyses of steps one, two, and three of the four-step framework.

With respect to the Maryland petition, as the state noted in its petition, the EPA already conducted an analysis in the CSAPR Update regarding the impact of the five upwind states named in the state’s petition on downwind air quality in Maryland with respect to the 2008 ozone NAAQS. In addition to using modeling to identify downwind air quality problems, the EPA also used air quality modeling to assess contributions from upwind states to these downwind receptors and evaluated these contributions relative to a screening threshold of one percent of the NAAQS. States with contributions that equal or exceed one percent of the NAAQS were identified as warranting further analysis to determine whether they significantly contribute to nonattainment or interfere with maintenance at the downwind receptors. States with contributions below one percent of the NAAQS were considered to not significantly contribute to nonattainment or interfere with maintenance of the NAAQS in downwind states. The EPA determined in the final CSAPR Update that, based on its 2017 modeling projections, statewide emissions from sources in Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia were linked to monitor ID 240231001 in Harford County, Maryland; that monitor was expected to have nonattainment and maintenance problems for the 2008 NAAQS. However, as discussed in Section III.C of this notice, the conclusion that a state’s emissions met or exceeded this threshold only indicate that further analysis is appropriate to determine whether any of the upwind state’s emissions meet the statutory criteria of significantly contributing to nonattainment or interfering with


44 See 2016 Design Value Reports, available at https://www.epa.gov/air-trends/air-quality-design-value#report. The official designations for these areas and information relied upon for those designations are contained in the EPA’s designation actions for the 2015 ozone NAAQS. See 82 FR 54232 (November 16, 2017) and the docket for Additional Air Quality Designations for the 2015 Ozone National Ambient Air Quality Standards, EPA-HQ-OAR–2017–0546, and accompanying technical support documents.

45 See Supplemental Information on the Interstate Transport State Implementation Plan Submissions for the 2008 Ozone National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I) (October 2017), available in the docket for this proposed action.
maintenance. The EPA’s independent step three analysis of the sources named in Maryland’s petition will be discussed in the following sections.

2. The EPA’s Step Three Analysis With Respect to EGUs Equipped With SCRs Named in Delaware and Maryland’s Petitions

The EPA next evaluated whether there are further highly cost-effective NO\textsubscript{X} emissions reductions available at the specific sources named in the petitions, consistent with step three of the framework. As discussed in more detail in Section III.C of this notice, further analysis in step three considers cost, technical feasibility, and air quality factors in a multifactor test to determine whether any emissions deemed to contribute to the downwind air quality factor must be controlled pursuant to the good neighbor provision. The EPA notes that we have already proposed to determine that Delaware’s petitions should be denied based on the EPA’s conclusions at steps one and two of the four-step framework. Nonetheless, the EPA is also evaluating the EGUs named in the Delaware petitions in this step three analysis because we believe it provides another independent basis for the proposed denial. The EPA is first analyzing this step with respect to those units identified in the Delaware and Maryland petitions equipped with SCR. The EPA will separately address units that are not equipped with SCR later in this section.

Three of Delaware’s petitions identify EGUs (Conemaugh, Harrison, and Homer City) that are already equipped with SCRs. Similarly, 32 of the 36 EGUs identified in Maryland’s petition are also equipped with SCRs.46 All of the states in which these EGUs are located are subject to FIPs promulgated as part of the CSAPR Update that require EGUs in each state, including the EGUs named in the petitions, to participate in the CSAPR NO\textsubscript{X} Ozone Season Group 2 allowance trading program, subject to statewide emissions budgets. In establishing the CSAPR Update EGU NO\textsubscript{X} ozone season emissions budgets, the agency quantified the emissions reductions achievable from all NO\textsubscript{X} control strategies that were feasible to implement within one year and cost-effective at a marginal cost of $1,400 per ton of NO\textsubscript{X} removed. These EGU NO\textsubscript{X} control strategies were: Optimizing NO\textsubscript{X} removal by existing, operational SCR controls; turning on and optimizing existing idled SCR controls; installing state-of-the-art NO\textsubscript{X} combustion controls; and shifting generation to existing units with lower NO\textsubscript{X} emissions rates within the same state. 81 FR 74541. Thus, the CSAPR Update emissions budgets already reflect emissions reductions associated with the turning on and optimizing of existing SCR controls at the EGUs that are the subject of the petitions, which is the same control strategy identified in the petitions as being both feasible and cost effective. At step three of the four-step framework, therefore, the EPA is proposing to determine that all identified highly cost-effective emissions reductions have already been implemented with respect to these sources, and that they therefore neither emit nor would emit in violation of the good neighbor provision. The EPA proposes to determine that this conclusion is appropriate with regard to both the 2008 ozone NAAQS (addressed in both states’ petitions) and the 2015 ozone NAAQS (addressed in the Delaware petitions) because the EPA’s determination that the cost-effective control strategy is already being implemented in the context of the allowance trading program applies regardless of which NAAQS is being addressed. In other words, because the strategy of optimizing existing controls has already been implemented for these sources via the CSAPR Update, there are no additional control strategies identified to further REDUCE NO\textsubscript{X} emissions at these sources to address the more stringent standard.

Both Delaware and Maryland contend that, based on data available at the time the petitions were filed, the sources are operating their SCR NO\textsubscript{X} emissions controls at low efficiency levels, or are not operating them at all at certain times. Delaware and Maryland therefore ask the EPA to impose unit-specific 30-day emissions rate limits or other requirements to ensure the controls will be continually operated. The EPA notes that the petitions from both states were submitted before the implementation of the emissions budgets promulgated in the CSAPR Update, and the information in the petitions therefore does not represent the most recent data regarding these EGUs’ operations. The EPA

46 These facilities are located in Indiana (Alcoa Alloys Management Inc., Clifty Creek Gilsen), IPL—Petersburg Generating Station, Kentucky (East Bend Station, Elmer Smith Station, Tennessee Valley Authority Paradise Fossil Plant), Ohio (Killen Station, Kyger Creek, W. H. Zimmer Generating Station), Pennsylvania (Bruce Mansfield, Cheswick, Homer City, Keystone, Montour), and West Virginia (Harrison Power Station, Pleasants Power Station).

47 The CSAPR Update was signed on September 7, 2016—approximately 8 months before the beginning of the 2017 ozone season on May 1.

48 As described in the CSAPR Update, optimized operation of combustion controls and SCR typically results in NO\textsubscript{X} emission rates in NO\textsubscript{X} emission rates of 0.0 lb/mmBtu or below. Combustion controls alone typically result in rates down to 0.2 lb/mmBtu but can at times achieve results in the range of 0.14 lb/mmBtu. Therefore, units equipped with SCR that have emission rates above 0.2 lb/mmBtu are likely not significantly utilizing their SCR.

49 See Discussion of Short-term Emission Limits, available in the docket for this action.

50 Id.
trading program is an insufficient means of implementing the emissions reductions associated with the optimized operation of the SCRs at these units, seasonal NO\textsubscript{X} requirements have demonstrated success at reducing peak ozone concentrations. For example, over the past decade, there has been significant improvement in ozone across the eastern U.S., in part due to season-long allowance trading programs.\textsuperscript{51} As a result, areas are now attaining the 1997 ozone NAAQS. Further, the EPA notes that the standard is a 3-year average value of three individual seasonal values. Thus, a seasonal program is harmonious with the form of the standard.

3. The EPA’s Step Three Analysis With Respect to the Named EGUs Equipped With SNCR

Maryland also alleges that two facilities operating SNCR post-combustion controls (SNCR)—Cambria Cogen in Pennsylvania and Grant Town Power Plant in West Virginia—emit or would emit in violation of the good neighbor provision and asks that the agency impose emissions limits or other requirements to ensure that the facilities operate their SNCR during the ozone season.

As discussed earlier in Section IV.C.2 of this notice, the EPA evaluated control strategies in the CSAPR Update that were considered feasible to implement by the 2017 ozone season and determined that EGU control strategies available at a marginal cost of $1.400 per ton of NO\textsubscript{X} reduced cost effective. In evaluating and selecting this cost threshold, the EPA also examined other control strategies available at different cost thresholds, including turning on existing idled SNCR, which is the remedy proposed by Maryland in its petition. The EPA identified a marginal cost of $3,400 per ton as the level of uniform control stringency that represents turning on and fully operating idled SNCR controls.\textsuperscript{52} However, the CSAPR Update finalized emissions budgets using $1,400 per ton control stringency, finding within step 3 of the transport framework that this level of stringency represented the control level at which incremental EGU NO\textsubscript{X} reductions and corresponding downwind ozone air quality improvements were maximized with respect to marginal cost. In finding that use of the $1,400 control cost level was appropriate for the 2008 ozone NAAQS, the EPA established that the more stringent emissions budget level reflecting $3,400 per ton (representing turning on idled SNCR controls) yielded fewer additional emissions reductions and fewer air quality improvements per additional dollar of control costs. In other words, based on the information, assumptions, and analysis in the CSAPR Update, establishing emissions budgets at $3,400 per ton, and therefore developing budgets based on operation of idled SNCR controls, was not determined to be cost effective for addressing good neighbor provision obligations for the 2008 ozone NAAQS.

81 FR 74550. Maryland has not provided any contradictory information demonstrating that fully operating SNCR is a cost-effective control for these units considering the marginal cost of implementation, the anticipated emissions reduction, the air quality benefits, and the increasing likelihood that other sectors might have more reductions as the cost threshold increases.\textsuperscript{53} The EPA is proposing to deny Maryland’s petition with respect to these sources based on its conclusion that fully operating with SNCR is not a cost-effective NO\textsubscript{X} emissions reduction strategy with respect to addressing transport obligations for the 2008 ozone NAAQS for these sources, and, therefore, that these sources do not emit and would not emit in violation of the good neighbor provision with respect to the 2008 ozone NAAQS.

While the EPA did not determine that fully operating SNCR across the region was cost effective with respect to addressing transport obligations for the 2008 ozone NAAQS, individual sources may nonetheless choose how to comply with the CSAPR ozone season NO\textsubscript{X} allowance trading program. The operation of existing SNCR controls is one method to achieve emissions reductions needed to comply with the requirements of the trading program. 81 FR 74561. For instance, during the 2017 ozone season, in part as the result of economic incentives under the CSAPR Update, the two Cambria units with SNCR appear to have operated their controls, resulting in average NO\textsubscript{X} emissions rates of 0.15 and 0.16 lbs/mmBtu. respectively (a drop from the 2016 rates of 0.23 and 0.24 lbs/mmBtu, respectively).\textsuperscript{54}

4. The EPA’s Step Three Analysis With Respect to Brunner Island

The remaining facility addressed in one of Delaware’s petitions is the Brunner Island facility, which currently has neither SCR nor SNCR installed. As noted earlier, the EPA has already proposed to determine that Delaware’s petitions should be denied based on the EPA’s conclusions at steps one and two of the four-step framework. Nonetheless, the EPA has evaluated Brunner Island in this step three analysis because we believe it provides another independent basis for the proposed denial.

With respect to the question of whether there are feasible and highly cost-effective NO\textsubscript{X} emissions reductions available at Brunner Island, the facility primarily burned natural gas with a low NO\textsubscript{X} emissions rate in the 2017 ozone season, and the EPA expects the facility to continue operating primarily by burning natural gas in future ozone seasons. As such, and as described in more detail in the following paragraphs, the EPA at this time finds that no additional feasible and highly cost-effective NO\textsubscript{X} emissions reductions available at Brunner Island have been identified. The EPA, therefore, has no basis to determine, consistent with the standard of review outlined in Section IV.A, that Brunner Island emits or would emit in violation of the good neighbor provision with respect to the 2008 or 2015 ozone NAAQS.

Delaware’s CAA section 126(b) petition first proposed that the operation of natural gas is an available highly cost-effective emissions reduction measure that could be implemented at Brunner Island. Brunner Island completed construction of a natural gas pipeline connection prior to the beginning of the 2017 ozone season (i.e., by May 1, 2017) and operated primarily using natural gas as fuel for the 2017 ozone season. As a result, Brunner Island’s actual ozone season NO\textsubscript{X} emissions declined from 3,765 tons in 2016 to 877 tons in 2017, and the facility’s ozone season NO\textsubscript{X} emissions rate declined from 0.370 lbs/mmBtu in 2016 to 0.090 lbs/mmBtu in 2017. Thus, Brunner Island has already implemented the emissions reductions consistent with what Delaware asserted would qualify as a cost-effective strategy for reducing NO\textsubscript{X} emissions. Accordingly, the EPA has determined that Delaware’s CAA section 126(b)

\textsuperscript{52} Since the EPA does not agree, and Maryland has not demonstrated in the first instance, that the operation of SNCR at these units is cost effective, the EPA need not address Maryland’s claim that short-term emission limits may be appropriate. In any event, the EPA notes that the same concerns with relying on the lowest historical emission rate for purposes of determining what is achievable for SCRs, discussed in Section IV.B.2, would also apply to Maryland’s contentions with respect to SNCRs.

\textsuperscript{54} See 2015, 2016, and 2017 Ozone-Season NO\textsubscript{X} rates (lbs/mmBtu) for 41 units named in the petitions, available in the docket for this action.
petition does not demonstrate that, at this current level of emissions, Brunner Island emits in violation of the good neighbor provision.

Similarly, the EPA concludes that Delaware’s petition does not demonstrate that Brunner Island would emit in violation of the good neighbor provision. The EPA believes that Brunner Island will continue to primarily use natural gas as fuel during future ozone seasons for several economic reasons. First, compliance with the CSAPR Update provides an economic incentive to cost-effectively reduce NOX emissions. Specifically, Brunner Island’s participation in the CSAPR NOX Ozone Season Group 2 allowance trading program provides an economic incentive to produce electricity in ways that lower ozone-season NOX, such as by burning natural gas relative to burning coal at this particular power plant. Under the CSAPR Update, each ton of NOX emitted by a covered EGU has an economic value—either a direct cost in the case that a power plant must purchase an allowance to cover that ton of emissions for CSAPR Update compliance or an opportunity cost in the case that a power plant must use an allowance in its account for compliance and, thereby, foregoes the opportunity to sell that allowance on the market. The EPA notes that Brunner Island’s 2017 emissions would have been approximately 2,714 tons more than its actual 2017 emissions if it had operated as a coal-fired generator, as it did in 2016. This reduction in NOX emissions that is attributable to primarily burning natural gas has an economic value in the CSAPR allowance trading market.

Second, the continued fuel-based economic incentives suggesting that Brunner Island will continue to primarily burn natural gas during the ozone season. Brunner Island elected to add the capability to primarily utilize natural gas by way of a large capital investment in a new natural gas pipeline capacity connection. Brunner Island’s operators would have planned for and constructed this project during the recent period of relatively low natural gas prices. In the years preceding the completion of this natural gas pipeline connection project, the average annual Henry Hub natural gas spot prices ranged from $2.52/mmBtu to $4.37/mmBtu (i.e., between 2009 and 2016). The capital expenditure to construct a natural gas pipeline connection suggests that natural gas prices within this range make it economic (i.e., cheaper) for Brunner Island to burn natural gas to generate electricity relative to burning coal. As such, future natural gas prices in this range suggest that Brunner Island will continue to primarily burn natural gas during future ozone seasons. The EPA and other independent analysts expect future natural gas prices to remain low and within this price range exhibited from 2009 to 2016 due both to supply and distribution pipeline build-out. For example, the Energy Information Administration’s (EIA) 2018 Annual Energy Outlook (AEO) natural gas price projections for the Henry Hub spot price range from $3.06/mmBtu in 2018 to $3.83/mmBtu in 2023. Moreover, the AEO short-term energy outlook and New York Mercantile Exchange futures further support the estimated of a continued low-cost natural gas supply. These independent analyses of fuel price data and projections lead to the EPA’s expectation that fuel-market economics will continue to support Brunner Island’s primarily burning natural gas during future ozone seasons through at least 2023.

Henry Hub is a significant distribution hub located on the natural gas pipeline system located in Louisiana. Due to the significant volume of trades at this location, it is seen as the primary benchmark for the North American natural gas market. These data are publicly available at https://www.eia.gov/dnav/ng/hist/ngwhhdA.htm.

In the 2018 reference case Annual Energy Outlook (AEO) released February 6, 2018, created by the U.S. Energy Information Administration (EIA), natural gas prices for the power sector for 2018 through 2023. Available at https://www.eia.gov/outlooks/aeo/data/browser/#/?id=13-AEO2018#cases=ref2018&source key=0. Projected delivered natural gas prices for the electric power sector in the Middle Atlantic region, where Brunner Island is located, ranged between $3.56 in 2018 and $4.06/mmBtu in 2023. The projected delivered coal prices for the electric power sector in the Middle Atlantic region remain relatively constant, ranging from $2.51 to $2.56/mmBtu. These data are publicly available at https://www.eia.gov/outlooks/aeo/data/browser/#/?id=3-AEO2018&regions=1-2&cases= ref2018&start=2016&end=2023&fs=Averagechart= ref2018-d121317a-3-AEO2018-1-2&maps=ref2018- d121317a-4-AEO2018-1-2&sourcekey=0.

Moreover, the AEO short-term energy outlook available at https://www.eia.gov/outlooks/steo/report/ natgas.php.

The EPA also notes that a proposed settlement agreement between Sierra Club and Talen Energy may further ensure that Brunner Island will operate by burning gas in the ozone season in 2023 and future years. Under the settlement, Brunner Island agrees to operate only on natural gas during the ozone season (May 1-September 30) starting on January 1, 2023, (subjected to limited exceptions) and cease coal operations after December 31, 2023.

The context in which Brunner Island installed natural gas-firing capability and burned natural gas is consistent with observed recent trends in natural gas utilization within the power sector, suggesting that Brunner Island’s economic situation in which it primarily burns gas as fuel during the ozone season is not unique or limited. Comparing total heat input from 2014 with 2017 for all units that utilize natural gas and report to the EPA’s Clean Air Markets Division, historical data showed an increased use of natural gas of about 14 percent. This overall increase results from both an increase in capacity from the construction of additional units and an increased gas-fired utilization capacity factor. The available capacity increased six percent while average capacity factor increased from 23 percent to 25 percent, which reflects an eight percent increase in utilization. Comparing the projected continued broader downward trends in NOX emissions resulting in improved air quality in Delaware, the EPA anticipates that Brunner Island will continue to primarily burn natural gas during the ozone season as air quality in Delaware continues to improve. Accordingly, the EPA has no basis to conclude that the facility would emit in violation of the good neighbor provision with respect to either the 2008 or 2015 ozone NAAQS.

V. Conclusion

Based on the information discussed in this notice, the EPA is proposing to deny all four of Delaware’s CAA section 126(b) petitions, as well as Maryland’s CAA section 126(b) petition, on two bases. First, the EPA has described a number of technical deficiencies with these petitions and, therefore, proposes to deny them on the basis that Delaware and Maryland have not met their burden to demonstrate that the named sources emit or would emit in violation of the good neighbor provision with respect to the 2008 ozone NAAQS (in the case of both Delaware and Maryland) or the 2015 ozone NAAQS (with respect to Delaware).


The EPA notes that a proposed settlement agreement between Sierra Club and Talen Energy may further ensure that Brunner Island will operate by burning gas in the ozone season in 2023 and future years. Under the settlement, Brunner Island agrees to operate only on natural gas during the ozone season (May 1-September 30) starting on January 1, 2023, (subjected to limited exceptions) and cease coal operations after December 31, 2023.

From 8.4 billion mmBtu to 9.6 billion mmBtu. See EPA’s Clean Air Markets Division data available at https://ampd.epa.gov/ampd/.

In this action, note however the EPA is not proposing to determine whether the upwind states identified in any of the CAA section 126(b) petitions have fully addressed their obligation to prohibit emissions activity that contributes significantly to nonattainment in or interference with maintenance by any other state with respect to the 2008 and 2015 ozone NAAQS.
Delaware’s petitions). Second, the EPA proposes to determine, based on its own analysis, that all of the petitions fail at one or more steps of the four-step framework. For Delaware under step one, the EPA has determined there are no air quality problems in Delaware in the relevant years for both the 2008 and 2015 ozone NAAQS. The EPA has further evaluated the named sources under step three, finding: (1) That the EPA has already implemented the control strategy identified in the petitions as cost-effective for three facilities (Conemaugh, Harrison, and Homer City) in the CSAPR Update, and (2) that Brunner Island is already operating and is expected to continue operating with natural gas such that the facility has no additional cost-effective and feasible controls available. The EPA is also proposing to deny the Maryland petition because: (1) For those facilities with SCR, the EPA has already implemented the control strategy identified in the petitions as cost-effective, and (2) for the facilities with SNCR, the EPA has already determined that operation of SNCR is not cost-effective with respect to addressing transport obligations for the 2008 ozone NAAQS and therefore is not required by the good neighbor provision with respect to this NAAQS. The EPA requests comment on its proposed denial of Maryland’s and Delaware’s CAA section 126(b) petitions, including the bases for the decision described herein.

VI. Determinations Under Section 307(b)(1)

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit if (i) the agency action consists of “nationwide applicable regulations promulgated, or final action taken, by the Administrator,” or (ii) such action is locally or regionally applicable, if “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.”

The EPA proposes to find that any final action regarding these pending section 126(b) petitions is “nationwide applicable” or, in the alternative, is based on a determination of “nationwide scope and effect” within the meaning of section 307(b)(1). Through this rulemaking action, the EPA is proposing to determine that any final action related to this proposal is nationally applicable or, in the alternative, is based on a determination of nationwide scope and effect for purposes of section 307(b)(1).

Thus, the EPA proposes that pursuant to section 307(b)(1) any petitions for review of any final actions regarding the rulemaking would be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date any final action is published in the Federal Register.

VII. Statutory Authority

42 U.S.C. 7410, 7426, 7601.


E. Scott Pruitt,
Administrator.

[FR Doc. 2018–12374 Filed 6–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY


RIN 2060–AT40, 2060–AT39, 2060–AT38, 2060–AT37, 2060–AT36

Response to Clean Air Act Section 126(b) Petitions From Delaware and Maryland

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearing.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that a public hearing will be held on the EPA’s proposed response to petitions from Delaware and Maryland pursuant to section 126 of the Clean Air Act (CAA or Act). The EPA is proposing to deny four CAA section 126(b) petitions submitted by the state of Delaware and one CAA section 126(b) petition submitted by the state of Maryland between July and November 2016. The hearing will be held on June 22, 2018, in Washington, DC.

DATES: The public hearing will be held on June 22, 2018, in Washington, DC. Please refer to SUPPLEMENTARY INFORMATION for additional information on the public hearing.

ADDRESSES:

Public Hearing. The June 22, 2018, public hearing will be held at the EPA, William Jefferson Clinton East Building, Room 1153, 1201 Constitution Avenue NW, Washington, DC 20004. Identification is required. If your driver’s license is issued by America Samoa, you must present an additional form of identification to enter (see SUPPLEMENTARY INFORMATION for additional information on this location).

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in http://www.regulations.gov or in hard copy at EPA Docket Center Reading Room, William Jefferson Clinton West Building, 1301 Constitution Avenue NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The phone
number for the Public Reading Room is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: If you would like to speak at the public hearing, please contact Ms. Pamela Long, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS), Air Quality Planning Division (C504–01), Research Triangle Park, NC 27711, telephone (919) 541–0641, fax number (919) 541–5509, email address long.pam@epa.gov, no later than June 20, 2018. If you have any questions relating to the public hearing, please contact Ms. Long.

If you have questions concerning the petitions from Maryland and Delaware, please contact Mr. Lev Gabrilovich, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS), Air Quality Planning Division (C539–01), Research Triangle Park, NC 27711, telephone (919) 541–1496, email address gabrilovich.lev@epa.gov.

SUPPLEMENTARY INFORMATION: The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the EPA’s proposed response to the petitions from Maryland and Delaware. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information that are submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. Written comments must be postmarked by the last day of the comment period.

The public hearing will convene at 9:00 a.m. and end at 6:00 p.m. Eastern Time (ET) or at least two hours after the last registered speaker has spoken. The EPA will make every effort to accommodate all individuals interested in providing oral testimony. A lunch break is scheduled from 12:00 p.m. until 1:00 p.m. Please note that this hearing will be held at a U.S. government facility. Individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. The REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. These requirements took effect on July 21, 2014. If your driver’s license is issued by American Samoa, you must present an additional form of identification to enter the federal building where the public hearing will be held. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver’s licenses and military identification cards. For additional information for the status of your state regarding REAL ID, go to http://www.dhs.gov/real-id-enforcement-brief.

If you would like to present oral testimony at the hearing, please notify Ms. Pamela Long, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards (OAQPS), Air Quality Planning Division (C504–01), Research Triangle Park, NC 27711, telephone (919) 541–0641, fax number (919) 541–5509, email address long.pam@epa.gov, no later than 4:00 p.m. ET on June 20, 2018. Ms. Long will arrange a general time slot for you to speak. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing.

Oral testimony will be limited to 5 minutes for each commenter. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) or in hard copy form. Commenters should notify Ms. Long if they need specific translation services for non-English speaking commenters.

The hearing schedule, including the list of speakers, will be posted on the EPA’s website at https://www.epa.gov/ozone-pollution/ozone-national-ambient-air-quality-standards-naaqs-section-126-petitions prior to the hearing. Verbatim transcripts of the hearing and written statements will be included in the docket for the action.

How can I get copies of this document and other related information?


Dated: June 5, 2018.
Panagiotis Tsirigotis, Director, Office of Air Quality Planning and Standards.

ENVIRONMENTAL PROTECTION AGENCY
[9978–67–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Rhode Island

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA’s approval of the State of Rhode Island’s request to revise/modify certain of its EPA-approved programs to allow electronic reporting.

DATES: EPA approves the authorized program revisions/modifications as of June 8, 2018.

FOR FURTHER INFORMATION CONTACT: Devon Martin, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2603, martin.devon@epa.gov.

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the Federal Register (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-approved programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On May 2, 2018, the Rhode Island Department of Environmental Management (RI DEM) submitted an application titled “NPDES e-Reporting Tool” for revisions/modifications to its EPA-approved programs under title 40 CFR to allow new electronic reporting. EPA reviewed RI DEM’s request to revise/modify its EPA-authorized
programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions/modifications set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA’s decision to approve Rhode Island’s request to revise/modify its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 122, 125, and 403–471, is being published in the

Federal Register:

Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System; and

Part 403—General Pretreatment Regulations for Existing and New Sources of Pollution.

RI DEM was notified of EPA’s determination to approve its application with respect to the authorized programs listed above.

Matthew Leopard,
Director, Office of Information Management.

[FR Doc. 2018–12348 Filed 6–7–18; 8:45 am]  
BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2018–1130]  

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. This form will enable EXIM to identify the specific details of the proposed co-financing transaction between a U.S. exporter, EXIM, and a foreign export credit agency; the information collected includes vital facts such as the amount of U.S.-made content in the export, the amount of financing requested from EXIM, and the proposed financing amount from the foreign export credit agency. These details are necessary for approving this unique transaction structure and coordinating our support with that of the foreign export credit agency to ultimately complete the transaction and support U.S. exports—and U.S. jobs.

DATES: Comments should be received on or before July 9, 2018 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on WWW.REGULATIONS.GOV (EIB 11–04) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038, Attn: OMB 3048–0037. The form can be viewed at: https://www.exim.gov/sites/default/files/pub/pending/eib11–04.pdf.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB11–04 Co-Financing with Foreign Export Credit Agency.

OMB Number: 3048–0037.

Type of Review: Regular.

Need and Use: The information collected will provide information needed to determine compliance and creditworthiness for transaction requests submitted to the Export Import Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 60.

Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 15 hours.

Frequency of Reporting or Use: As needed.

Government Expenses: Reviewing Time per Year: 15 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $637.50 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $765.

Bassam Doughman,  
IT Specialist.

[FR Doc. 2018–12392 Filed 6–7–18; 8:45 am]  
BILLING CODE 6690–01–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Regular Meeting; Farm Credit System Insurance Corporation Board

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Notice, regular meeting.

SUMMARY: Notice is hereby given of the regular meeting of the Farm Credit System Insurance Corporation Board (Board).

DATES: The meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on June 14, 2018, from 2:00 p.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit System Insurance Corporation Board, (703) 883–4009, TTY (703) 883–4056,aultmand@fca.gov.

ADDRESSES: Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102. Submit attendance requests via email to VisitorRequest@FCA.gov. See SUPPLEMENTARY INFORMATION for further information about attendance requests.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. Please send an email to VisitorRequest@FCA.gov at least 24 hours before the meeting. In your email include: Name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale L. Aultman, Secretary to the Farm Credit System Insurance Corporation Board, at (703) 883–4009. The matters to be considered at the meeting are:

Closed Session

• FCSIC Report on System Performance and Liquidity

Open Session

A. Approval of Minutes

• March 8, 2018 (Open and Closed)

B. Business Reports

• FCSIC Financial Reports

• Report on Insured Obligations

• Quarterly Report on Annual Performance Plan

C. New Business

• Policy Statement Concerning Assistance

• Mid-Year Review of Insurance Premium Rates

Dated: June 5, 2018

Dale L. Aultman,  
Secretary, Farm Credit System Insurance Corporation Board.

[FR Doc. 2018–12360 Filed 6–7–18; 8:45 am]  
BILLING CODE 6710–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction


ACTION: Notice, correction.

SUMMARY: The Agency for Healthcare Research and Quality published a correction document in the Federal Register of May 29, 2018 regarding AHRQ Seeking Input on Library of Patient-Centered Outcomes Research Resources. This document contained an error in the email address where comments should be submitted.

FOR FURTHER INFORMATION CONTACT: Carla Ladner at 301–427–1205 or AHRQ_Fed_Register@ahrq.hhs.gov.

Correction

In the correction to the Federal Register of May 29, 2018, in FR Doc. 2018–11472, on page 1, line 29, correct the caption under ADDRESSES to read: Electronic responses are preferred and should be sent to: PCORResources@ahrq.hhs.gov.

Dated: June 4, 2018.

Carla M. Ladner,
Correspondence Analyst/Federal Register Liaison—AHRQ.

[FR Doc. 2018–12312 Filed 6–7–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; National Advisory Council for Healthcare Research and Quality: Request for Nominations for Public Members

AGENCY: Agency for Healthcare Research and Quality (AHRQ). HHS.

ACTION: Notice of request for nominations for public members.

SUMMARY: The Council is to advise the Secretary of HHS (Secretary) and the Director of the Agency for Healthcare Research and Quality (AHRQ) on matters related to activities of the Agency to carry out its mission. AHRQ’s mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

DATES: Nominations should be received on or before 60 days after date of publication.

ADDRESSES: Nominations should be sent to Jaime Zimmerman AHRQ, 5600 Fishers Lane, 06E37A, Rockville, Maryland 20857. Nominations may also be emailed to NationalAdvisoryCouncil@ahrq.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, AHRQ, at (301) 427–1456.

SUPPLEMENTARY INFORMATION: 42 U.S.C. 299c establishes a National Advisory Council for Healthcare Research and Quality (the Council). Seven current members’ terms will expire in November 2018. To fill these positions, we are seeking individuals who are distinguished in: (1) The conduct of research, demonstration projects, and evaluations with respect to health care; (2) the fields of health care quality research or health care improvement; (3) the practice of medicine; (4) other health professions; (5) representing the private health care sector (including health plans, providers, and purchasers) or administrators of health care delivery systems; (6) the fields of health care economics, information systems, law, ethics, business, or public policy; and, (7) representing the interests of patients and consumers of health care. 42 U.S.C. 299c(c)(2).

Individuals are particularly sought with experience and success in activities specified in the summary above. 42 U.S.C. 299c provides that the Secretary shall appoint to the National Advisory Council for Healthcare Research and Quality twenty one appropriately qualified individuals. At least seventeen members shall be representatives of the public and at least one member shall be a specialist in the rural aspects of one or more of the professions or fields listed in the above summary. In addition, the Secretary designates, as ex officio members, representatives from other Federal agencies, principally agencies that conduct or support health care research, as well as Federal officials the Secretary may consider appropriate. 42 U.S.C. 299c(c)(3). Consistent with revised guidance regarding the ban on lobbyists serving as members of advisory boards and commissions, AHRQ will accept nominations for Federally-registered lobbyists to serve on the Council in a representative capacity.

The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ’s Director on the direction of and programs undertaken by AHRQ.

Seven individuals will be selected by the Secretary to serve on the Council beginning with the meeting in the spring of 2019. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Self-nominations are accepted. Nominations shall include: (1) A copy of the nominee’s resume or curriculum vitae; and (2) a statement that the nominee is willing to serve as a member of the Council. Selected candidates will be asked to provide detailed information concerning their financial interests, consultant positions and research grants and contracts, to permit evaluation of possible sources of conflict of interest. Please note that once a candidate is nominated, AHRQ may consider that nomination for future positions on the Council.

The Department seeks a broad geographic representation. In addition, AHRQ conducts and supports research concerning priority populations, which include: Low-income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. See 42 U.S.C. 299c. Nominations of persons with expertise in health care for these priority populations are encouraged.

Francis D. Chesley, Jr.,
Acting Deputy Director.

[FR Doc. 2018–12361 Filed 6–7–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2018–0055, NIOSH 156–D]

Request for the Technical Review of 3 Draft Immediately Dangerous to Life or Health (IDLH) Value Profiles

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC),
Each IDLH Value Profile provides a detailed summary of the health hazards of acute exposures to high airborne concentrations and the rationale for the proposed IDLH value with the chemical(s) of interest.

Background: In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66—Derivation of Immediately Dangerous to Life or Health (IDLH) Values [NIOSH 2013]. Since the establishment of the IDLH values in the 1970s, NIOSH has continued to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical-specific IDLH values. The information presented in this CIB represents the most recent update of the scientific rationale and the methodology (hereby referred to as the IDLH methodology) used to derive IDLH values. The primary objectives of this document are to:

1. Provide a brief history of the development of IDLH values.

2. Update the scientific bases and risk assessment methodology used to derive IDLH values from quality data.

3. Provide transparency behind the rationale and derivation process for IDLH values.

4. Demonstrate how scientifically credible IDLH values can be derived from available data resources.

The IDLH methodology is based on a weight-of-evidence approach that applies scientific judgment for critical evaluation of the quality and consistency of scientific data and in extrapolation from the available data to the IDLH value. The weight-of-evidence approach refers to critical examination of all available data from diverse lines of evidence and the derivation of a scientific interpretation on the basis of the collective body of data, including its relevance, quality, and reported results. Conceptually, the derivation process for IDLH values is similar to that used in other risk-assessment applications, including these steps:

1. Hazard characterization.

2. Identification of critical adverse effects.

3. Identification of a POD.

4. Application of appropriate UF’s, based on the study and POD.

5. Determination of the final risk value.

Reference

Dated: June 5, 2018.

John J. Howard,
Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–12364 Filed 6–7–18; 8:45 am]
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–0969; Docket No. CDC–2018–0044]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is proposing to collect data from providers who care for women with reproductive age in the United States, to obtain information on changes in attitudes and practices among family planning providers and clinics in the United States related to recommendations from national contraception guidelines.

DATES: CDC must receive written comments on or before August 7, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0044 by any of the following methods:

• Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

• Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics. This project seeks to obtain information on changes in attitudes and practices among family planning providers and clinics in the United States related to recommendations from national contraception guidelines.

The Division of Reproductive Health (DRH) at the Centers for Disease Control and Prevention (CDC) and the HHS Office of Population Affairs (OPA) develop and disseminate guidance to improve use of contraceptive methods and to enhance the quality of family planning services. The U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC), the first national guidance on family planning containing evidence-based recommendations for the safe use of contraceptive methods for women and men with specific characteristics and medical conditions, was first published by the CDC in June 2010. The US Selected Practice Recommendations for Contraceptive Use (US SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate, was first published by the CDC in June 2013. The US MEC and US SPR were updated after review of the scientific evidence and consultation with national experts in family planning: the revised US MEC and US SPR were published in August 2016. Providing Quality Family Planning Services (QFP), which provides evidence-informed recommendations to improve client care and service delivery infrastructure to support the provision of quality family planning services to women and men of reproductive age in the United States, was published by CDC and OPA in April 2014. The US MEC, US SPR, and QFP have been widely disseminated to health care providers and other constituents via professional organizations, federal program grantees, scientific and programmatic meetings, scientific manuscripts, online resources, and other avenues.

To monitor changes in attitudes and practices regarding provision of contraception among family planning providers and clinics, we initiated a multi-phase assessment. In 2009–2010, CDC carried out the first phase of the assessment, collecting information before the release of the US MEC (OMB No. 0920–0008). In 2013–2014, CDC, in collaboration with OPA, carried out the second phase of the assessment, collecting information before the release of the US SPR and QFP (OMB No. 0920–0969). These information collections provided useful knowledge about attitudes and practices of family planning providers. CDC and OPA used the findings to develop educational materials and opportunities for health care providers.

In 2018, in collaboration with OPA, CDC plans to request a reinstatement of OMB No. 0920–0969, ‘Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics’ to carry out the third phase of the assessment. As in the previous phases, the information collection will allow CDC and OPA to improve family planning related practice by: (1) Understanding the current use of contraception guidance in practice,
including awareness and use of the US MEC, US SPR and QFP; (2) describing current attitudes and practices among family planning providers and clinics related to recommendations included in the US MEC, US SPR, and QFP and assessing changes from previous data collections; and (3) identifying training needs in use of guidance and family planning service delivery (e.g., provider tools, continuing education modules).

As in previous phases of data collection, CDC plans to administer surveys to private and public sector family planning providers and clinic administrators in the United States. The design, methodology, and analytic approach that CDC plans to implement are based on methods previously approved for the 2013–2014 survey, with different instruments being administered to providers and clinic administrators. Minor changes to survey content will be made to eliminate unnecessary questions, add new questions of interest, and improve formatting, usability, and data quality. OMB approval is requested for one year. The estimated burden per response for providers is 15 minutes and has not changed since the previous OMB approval. The estimated burden per response for administrators will be reduced from 40 minutes to 35 minutes. The total burden for participants is estimated at 1,916 hours. Participation is voluntary and there are no costs to respondents other than their time.

### ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title X clinic providers (public sector)</td>
<td>2018–2019 Survey of Health Care Providers about Family Planning Attitudes and Practices.</td>
<td>1,000</td>
<td>1</td>
<td>15/60</td>
<td>250</td>
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<tr>
<td>Non-Title X publicly funded clinic providers (public sector).</td>
<td>2018–2019 Survey of Health Care Providers about Family Planning Attitudes and Practices.</td>
<td>1,000</td>
<td>1</td>
<td>15/60</td>
<td>250</td>
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<tr>
<td>Title X clinic administrators (public sector).</td>
<td>2018–2019 Survey of Administrators of Health Centers that Provide Family Planning.</td>
<td>1,000</td>
<td>1</td>
<td>35/60</td>
<td>583</td>
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<td>Non-Title X publicly funded clinic administrators (public sector).</td>
<td>2018–2019 Survey of Administrators of Health Centers that Provide Family Planning.</td>
<td>1,000</td>
<td>1</td>
<td>35/60</td>
<td>583</td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,916</td>
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</table>

Jeffrey M. Zirger,

[FR Doc. 2018–12373 Filed 6–7–18; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–18–18ACN; Docket No. CDC–2018–0042]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Undetermined cause of Serratia marcescens infections—Multiple States, 2018. The goal of this investigation is to identify potential risk factors leading to an outbreak of Serratia marcescens infections among U.S. healthcare patients. Data will be used to identify a cause of the infections and prevent additional events from occurring.

DATES: CDC must receive written comments on or before August 7, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0042 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.
extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Undetermined cause of Serratia marcescens infections—Multiple States, 2018—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Serratia marcescens is a Gram-negative bacillus that can be found in the environment and thrives in moist environments. In healthcare settings, it can be found on the hands of healthcare workers and as a contaminant of medical products and devices, particularly aqueous products. It is a known cause of healthcare-associated infections, particularly urinary tract infection, wound infections, and bloodstream infections, and it is an important opportunistic pathogen in neonatal and pediatric intensive care units. Serratia marcescens has been implicated previously in multistate outbreaks of bloodstream infections caused by intrinsic contamination of prefilled syringes of heparin and isotonic sodium chloride solution.

On March 27, 2018, the Colorado Department of Public Health and Environment (CDPHE) notified CDC of 4 cases of Serratia marcescens bacteremia among pediatric patients with central lines in an acute care hospital between January 20 and March 23, 2018. This cluster of cases was above the normal baseline of 1–3 cases per year at that facility. The facility examined exposures including common staff and medications and identified commonalities related to the maintenance and care of central lines as well as several medical products including prefilled normal saline syringes and prefilled heparin flushes.

On March 28, CDPHE issued a call for cases to other state and local health departments through the Epidemic Information Exchange (Epi-X) system. On March 29, the Tennessee Department of Health (TDH) notified CDC of 3 cases of Serratia marcescens bacteremia in pediatric patients with central lines in a pediatric hospital between March 6 and March 21, 2018; initial examination of medications and common products identified central venous catheter line products as a possible source of infections, including prefilled heparin and normal saline syringes.

CDC is currently conducting a multistate investigation to support state health departments. Currently, eight state health departments have reported a total of 26 cases to CDC. However, since more than nine states are ultimately expected to participate, CDC is pursuing emergency OMB clearance to collect patient-level information from ten or more state/local health departments.

Most identified patient infections are bloodstream infections, but other body sites (e.g., respiratory) have also been described. Because these events could be linked to a healthcare product (e.g., medical device or pharmaceutical product) with widespread distribution, broad case-finding efforts are needed. Early investigations identified prefilled normal saline syringes and prefilled heparin flushes as common exposures, however healthcare facility records often provide an inadequate basis for identifying the specific product or lot number that was administered to a particular patient, and only facility-level information is available. The products identified in common at this stage of the investigation are widespread in healthcare facilities across the United States and incorrect identification as the source of infections could reasonably be anticipated to create panic in regards to use of these products and limitations in the safe care delivered to thousands of patients.

Communications with the Food and Drug Administration (FDA) and product manufacturers indicate a nation-wide shortage of saline following disruption of manufacturing in Puerto Rico during Hurricane Maria in September 2017. FDA has stated that saline shortages in the U.S. mean that alternatives to prefilled saline are limited. In addition, the products are manufactured and subject to Current Good Manufacturing Practice regulations including terminal sterilization of many products using steam sterilization, which reduce opportunities for contamination.

This information is essential to the CDC’s ability to identify a cause of these events and prevent additional events from occurring.

Nationwide case-finding has been implemented through the Epi-X system. The target audience of the case finding will include, but not be limited to, state and local health departments. They will be asked to report any potential cases to CDC. Information on each case will be collected using a data collection form that can be completed online or filled out and returned to CDC. Depending on the nature of each case, CDC may reach out to relevant healthcare facilities or healthcare staff for additional information and recommendation of any prevention measures.

### Estimated Annualized Burden Hours

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hrs)</th>
<th>Total burden (in hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare staff</td>
<td>Case finding for data collection</td>
<td>25</td>
<td>2</td>
<td>25/50</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
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</tbody>
</table>
Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on February 13, 2018 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
(c) Enhance the quality, utility, and clarity of the information to be collected;
(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Assessment of Occupational Injury among Fire Fighters Using a Follow-back Survey—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Studies have reported that fire fighters have high rates of non-fatal injuries and illnesses as compared to the general worker population. As fire fighters undertake many critical public safety activities and are tasked with protecting the safety and health of the public, it follows that understanding and preventing injuries and exposures among fire fighters will have a benefit reaching beyond the workers to the general public.

As mandated in the Occupational Safety and Health Act of 1970 (Pub. L. 91–596), the mission of NIOSH is to conduct research and investigations on occupational safety and health. Related to this mission, the purpose of this project is to conduct research that will provide a detailed description of non-fatal occupational injuries and exposures incurred by fire fighters. This information will offer detailed insight into events that lead to the largest number of nonfatal injuries and exposures among fire fighters. The project will use two related data sources. The first source is data abstracted from medical records of fire fighters treated in a nationally stratified sample of emergency departments. These data are routinely collected through the occupational supplement to the National Electronic Injury Surveillance System (NEISS-Work). The second data source, for which NIOSH is seeking OMB approval for three years, is responses to telephone interview surveys of the injured and exposed fire fighters identified within NEISS-Work.

The proposed telephone interview surveys will supplement NEISS-Work data with an extensive description of fire fighter injuries and exposures, including worker characteristics, injury types, injury circumstances, injury outcomes, and use of personal protective equipment. Previous reports describing occupational injuries and exposures to fire fighters provide limited details on specific regions or sub-segments of the population. As compared to these earlier studies, the scope of the telephone interview data will be broader as it includes sampled cases nationwide and has no limitations in regards to type of employment (i.e., volunteer versus career). Results from the telephone interviews will be weighted and reported as national estimates.

The sample size for the telephone interview survey is estimated to be approximately 240 fire fighters annually for the proposed three year duration of the study. This is based on the number of fire fighters identified in previous years of NEISS-Work data and a 30 to 40% response rate that is comparable to the rate of previously conducted National Electronic Injury Surveillance System telephone interview studies. Each telephone interview will take approximately 30 minutes to complete, resulting in an annualized burden estimate of 120 hours. Using the routine NEISS-Work data, an analysis of all identified EMS workers will be performed to determine if there are differences between the telephone interview responder and non-responder groups.

The Division of Safety Research (DSR) within NIOSH is conducting this project. DSR has a strong interest in improving surveillance of fire fighter injuries and exposures to provide the information necessary for effectively targeting and implementing prevention efforts and, consequently, reducing occupational injuries and exposures to fire fighters. The Consumer Product Safety Commission (CPSC) will also contribute to this project, as they are responsible for coordinating the collection of all NEISS-Work data and for overseeing the collection of all telephone interview data. The estimated annual Burden Hours are 120. There is no cost to respondents other than their time.
### ESTIMATED ANNUALIZED BURDEN HOURS

<table>
<thead>
<tr>
<th>Type of respondents</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
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<tbody>
<tr>
<td>Fire fighters</td>
<td>Follow-back survey</td>
<td>240</td>
<td>1</td>
<td>30/60</td>
</tr>
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</table>

Jeffrey M. Zirger,  
**Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.**

[FR Doc. 2016–12371 Filed 6–7–18; 8:45 am]

BILLING CODE 4163–18–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Centers for Medicare & Medicaid Services**


### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services.  
**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 July 9, 2018.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 Off 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:

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:** Reports Clearance Office at (410) 786–1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. **Type of Information Collection Request:** Revision of a currently approved collection. **Title of Information Collection:** Medicare Part D Reporting Requirements and Supporting Regulations; **Use:** Data collected via Medicare Part D Reporting Requirements is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Each section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP) level, e.g., Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

For CY2019 Reporting Requirements, the following 6 reporting sections will be reported and collected at the Contract-level or Plan-level: (1) Enrollment and disenrollment—to evaluate sponsors’ processing of enrollment, disenrollment, and reinstatement requests in accordance with CMS requirements. (2) Medication Therapy Management (MTM) Programs—to evaluate Part D MTM programs, and sponsors’ adherence to CMS requirements. (3) Grievances—to assess sponsors’ compliance with timely and appropriate resolution of grievances filed by their enrollees. (4) Improving Drug Utilization Review Controls—to determine the impact of formulary-level edits at point of sale in sponsors’ processing of opioid prescriptions. (5) Coverage Determinations and Redeterminations—to assess sponsors’ compliance with appropriate resolution of coverage determinations and redeterminations requested by their enrollees. (6) Employer/Union Sponsored Sponsors—to ensure PDPs and the employer groups that contract with the PDPs properly utilize appropriate waivers and modifications.

**Form Number:** CMS–10185 (OMB Control number: 0938–0992); **Frequency:** Annually and semi-annually; **Affected Public:** Private sector (Business or other for-profits); **Number of Respondents:**
2. Type of Information Collection Request: Extension of a currently approved information collection; Title of Information Collection: Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Use: The American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111–5) was enacted on February 17, 2009. The Recovery Act includes many measures to modernize our nation’s infrastructure, and improve affordable health care. Expanded use of health information technology (HIT) and certified electronic health record (EHR) technology will improve the quality and value of America’s health care. Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the “Health Information Technology for Economic and Clinical Health Act” or the “HITECH Act.” The HITECH Act creates incentive programs for eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for payment adjustments in the Medicare FFS and MA programs starting in FY 2015 for EPs and eligible hospitals participating in Medicare that are not meaningfully using certified EHR technology. These payment adjustments do not pertain to Medicaid providers.

The first final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the Federal Register on July 28, 2010 (CMS–20033–F), specified the initial criteria EPs, eligible hospitals and CAHs, and MA organizations must meet in order to qualify for incentive payments; calculation of incentive payment amounts; payment adjustments under Medicare professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. On the same date, the Office of the National Coordinator of Health Information Technology (ONC) issued a closely related final rule (45 CFR part 170, RIN 0991–AB58) that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT) (45 CFR part 170, RIN 0991–AB59). The functionality of certified EHR technology should facilitate the implementation of meaningful use. Subsequently, final rules have been issued by CMS (77 FR 53968) and ONC (77 FR 72985) to create a Stage 2 of meaningful use criteria and other changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

The information collection requirements contained in this information collection request are needed to implement the HIT/TECH Act. In order to avoid duplicate payments, all EPs are enumerated through their National Provider Identifier (NPI), while all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider’s tax identification number and NPI or CCN combination in order to make payment, validate payment NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs. Form Number: CMS–10336 (OMB Control Number: 0938–1158); Frequency: Occasionally; Affected Public: Private sector; Number of Respondents: 201,694; Total Annual Responses: 201,694; Total Annual Hours: 2,131,142. (For policy questions regarding this collection contact Elizabeth Holland at (410) 786–1309.)

3. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; Use: This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. Form Number: CMS–10341 (OMB control number: 0938–1162); Frequency: Yearly and quarterly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 37; Total Annual Responses: 300; Total Annual Hours: 24,092. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.)

4. Type of Information Collection Request: Extension without change of a currently approved collection; Title of Information Collection: Medicare Fee-for-Service Early Review of Medical Records; Use: The Medical Review program is designed to prevent improper payments in the Medicare FFS program. Whenever possible, MACs are encouraged to automate this process; however it may require the evaluation of medical records and related documents to determine whether Medicare claims were billed in compliance with coverage, coding, payment, and billing policies.

The information required under this collection is requested by Medicare contractors to determine proper payment, or if there is a suspicion of fraud. Medicare contractors request the information from providers/suppliers submitting claims for payment when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. Extensive instructions to CMS contractors on medical review procedures and guidelines are contained in CMS’ Program Integrity Manual, 100–08 which can be found at can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/ CMS019033.html. Form Number: CMS–10417 (OMB control number: 0938–0969); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profits; Not-for-profit institutions; Number of Respondents: 2,410,278; Total Annual Responses: 2,410,278; Total Annual Hours: 1,187,189. (For policy questions regarding this collection contact Daniel Schwartz at 410–786–4197.)

5. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Hospice Information for Medicare Part D Plans; Use: The form would be completed by the prescriber or the beneficiary’s hospice, or if the prescriber or hospice provides the information verbally to the Part D sponsor, the form would be completed by the sponsor. Information provided on the form would be used by the Part D sponsor to establish coverage
of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is “unrelated” to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary’s change in hospice status and care plan option to pay within the initial grace period established by the plan. Section 1876(c)(3)(B) establishes that individuals may be dis-enrolled from Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary dis-enrollment procedures at 42 CFR 422.74 and 423.44. In addition, section 1876(c)(3)(B) establishes that individuals may be disenrolled from coverage as specified in regulations. Thus, current regulations at 42 CFR 417.460 specify that specifically a Health Maintenance Organization (HMO) or competitive medical plan (CMP), may dis-enroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. Within these regulatory provisions, individuals dis-enrolled for nonpayment of premiums are afforded a grace period in which to request reinstatement. As part of the reinstatement request process, they must demonstrate good cause for failure to pay within the initial grace period that led to their involuntary dis-enrollment and pay all overdue premiums within three calendar months after the dis-enrollment date. Form Number: CMS–10544 (OMB control number: 0938–1271); Frequency: Reporting—Monthly; Affected Public: Private Sector (business or other for-profit institutions); Number of Respondents: 10,008; Total Annual Responses: 10,008; Total Annual Hours: 6,665. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

Dated: June 5, 2018.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10418]

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 August 7, 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:

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–10418 Annual MLR and Rebate Calculation Report and MLR Rebate Notices

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before
submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection
1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Annual MLR and Rebate Calculation Report and MLR Rebate Notices; Use: Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk corridors, and risk adjustment programs established under section 1342 of the Patient Protection and Affordable Care Act. Form Number: CMS–10418 (OMB control number: 0938–1164); Frequency: Annually; Affected Public: Private Sector, Business or other for-profit and not-for-profit institutions; Number of Respondents: 522; Number of Responses: 2,138; Total Annual Hours: 170,589. (For policy questions regarding this collection contact Christina Whitefield at 301–492–4172.)

Dated: June 5, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–12394 Filed 6–7–18; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration

[Docket No. FDA–2017–N–6730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 9, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAS Staff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting: Electronic Submission Requirements

OMB Control Number 0910–0437—Extension

The information collection associated with 21 CFR part 803 is approved under OMB control number 0910–0437. We request revision of the information collection approval as described in this document.

In the Federal Register of December 26, 2017 (82 FR 60922), FDA published a notification and request for comments entitled “Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers” (the notification) which, among other things, proposed a program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form—the Voluntary Malfunction Summary Reporting Program. The proposed program would permit manufacturers of devices in certain product codes to report malfunctions for those devices on a quarterly basis and in a summary format (instead of reporting them as individual, 30-day reports), subject to certain conditions. Therefore, we have added a line item to the reporting burden table in OMB control number 0910–0437, “Medical Device Reporting: Electronic Submission Requirements,” for the proposed Voluntary Malfunction Summary Reporting Program.

FDA believes that submission of voluntary summary reports in the format described in this document would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively. The proposed Voluntary Malfunction Summary Reporting Program is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. The proposed program would neither apply to importers or device user facilities, nor affect...
requirements under part 803 for
importers or device user facilities. The
proposed program would not apply to
reportable death or serious injury
events, as described in section III.A of
the notification (82 FR 60922 at 60924).
In addition, the reporting requirements
at § 803.53, which require a 5-day report
to be filed at the written request of FDA
or if a manufacturer becomes aware of
an MDR reportable event that
necessitates remedial action to prevent
an unreasonable risk of substantial harm
to the public health, would continue to
apply to manufacturers participating in
the proposed program. The conditions
of the proposed Voluntary Summary
Malfunction Reporting Program would
also require manufacturers to submit
individual malfunction reports in
certain circumstances (see section III.A
of the notification). These factors were
considered in determining the revised
burden estimates described in table 1.
In the Federal Register of December
26, 2017 (82 FR 60922), FDA published
a 60-day notice requesting public
comment on the proposed collection of
information. FDA received one
comment related to the information
collection, that stated that the average
burden on manufacturers per response
of 6 minutes appears to be a very low
estimate.
FDA disagrees with this comment.
The estimation of time is the amount of
time needed to submit a summary
malfunction report. It is essentially the
same amount of time needed to submit
an individual report because the event
narrative should be the same, with the
exception of one additional line that is
entered that indicates the number of
adverse events represented by the
report. It does not include the time
needed to investigate the issue.
Manufacturers have 120 calendar days
from the date they become aware of a
reportable malfunction to submit a
summary malfunction report that is
allowed as part of this voluntary
reporting program.

For the convenience of the reader, we
have noted below the information
collection line-items (ICs) that we
anticipate would be affected by the
Voluntary Malfunction Summary
Reporting Program. While the other ICs
from OMB control number 0910–0437
are not affected by the Voluntary
Malfunction Summary Reporting
Program, for consistency and accuracy,
we have adjusted the respondent
estimates for the ICs using more recent
data.

FDA estimates the burden of this
collection of information as follows:

### Table 1—Estimated Annual Reporting Burden 1

<table>
<thead>
<tr>
<th>Activity/CFR section</th>
<th>FDA Form No.</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemptions—803.19 2</td>
<td>...............</td>
<td>85</td>
<td>4</td>
<td>340</td>
<td>1</td>
<td>340</td>
</tr>
<tr>
<td>User Facility Reporting—803.30 and 803.32 2</td>
<td>...............</td>
<td>520</td>
<td>10.06</td>
<td>5,232</td>
<td>0.35</td>
<td>1,831</td>
</tr>
<tr>
<td>User Facility Annual Reporting—803.33 2</td>
<td>3419</td>
<td>159</td>
<td>1</td>
<td>159</td>
<td>1</td>
<td>159</td>
</tr>
<tr>
<td>Importer Reporting, Death and Serious Injury—803.40 and 803.42 2</td>
<td>...............</td>
<td>578</td>
<td>1</td>
<td>578</td>
<td>1</td>
<td>578</td>
</tr>
<tr>
<td>Manufacturer Reporting—803.50 through 803.53 3</td>
<td>...............</td>
<td>1,240</td>
<td>272.50</td>
<td>337,900</td>
<td>0.10</td>
<td>33,790</td>
</tr>
<tr>
<td>Voluntary Malfunction Summary Reporting Program 3</td>
<td>...............</td>
<td>1,240</td>
<td>54.47</td>
<td>67,546</td>
<td>0.10</td>
<td>6,755</td>
</tr>
<tr>
<td>Supplemental Reports—803.56 3</td>
<td>...............</td>
<td>1,050</td>
<td>128.71</td>
<td>135,148</td>
<td>0.10</td>
<td>13,515</td>
</tr>
<tr>
<td>Total</td>
<td>...............</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
</tr>
</tbody>
</table>

1 There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
2 This IC has been adjusted based on calendar year (CY) 2016 data; however, there is no program change to this IC.
3 This IC revises OMB control number 0910–0437 to reflect the Voluntary Malfunction Summary Reporting Program.

### Table 2—Estimated Annual Recordkeeping Burden 1

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR Procedures—803.17 2</td>
<td>1,240</td>
<td>1</td>
<td>1,240</td>
<td>3.3</td>
<td>4,092</td>
</tr>
<tr>
<td>MDR Files—803.18 2</td>
<td>1,240</td>
<td>1</td>
<td>1,240</td>
<td>1.5</td>
<td>1,860</td>
</tr>
<tr>
<td>Total</td>
<td>...............</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
</tr>
</tbody>
</table>

1 There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
2 This IC has been adjusted based on CY 2016 data; however, there is no program change to this IC.

### Table 3—Estimated Annual Third-Party Disclosure Burden 1

<table>
<thead>
<tr>
<th>Activity/21 CFR section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importer Reporting, Death and Serious Injury—803.40 and 803.42 2</td>
<td>578</td>
<td>25</td>
<td>14,450</td>
<td>0.35</td>
<td>5,058</td>
</tr>
</tbody>
</table>

1 There is no change to the capital costs or operating and maintenance costs associated with the revision of the collection of information.
2 This IC has been adjusted based on CY 2016 data; however, there is no program change to this IC.
3 Number has been rounded.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2018–N–1881]
Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis; Public Workshop; Request for Comments
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of public workshop; request for comments.
SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis.” The purpose of the public workshop is to discuss the clinical trial design challenges and future considerations for inhaled antibacterial products to treat cystic fibrosis (CF) and non-CF bronchiectasis.
DATES: The public workshop will be held on June 27, 2018, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by July 16, 2018. 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., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. 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.
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 July 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time on July 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.
Electronic Submissions
Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–N–1881 for “Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis.” 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

For consistency and accuracy, we have adjusted the respondent estimates for all the ICs from OMB control number 0910–0437, including those that are not affected by the Voluntary Malfunction Summary Reporting Program, to reflect more recent data from calendar year (CY) 2016 (the currently approved estimates are based on CY 2006–2009 data). This adjustment, along with the revisions for the Voluntary Malfunction Summary Reporting Program increases the estimated total burden of OMB control number 0910–0437 by 21,532 hours (currently approved for 46,446 hours; requesting 67,978 hours).

We have added the new burden estimate for the Voluntary Malfunction Summary Reporting Program. This increases the reporting burden estimate by 6,755 hours.

We have revised the burden estimates for “Manufacturer Reporting” and “Supplemental Reports” to update the respondent estimates using more recent data, as described above, and to reflect the revisions resulting from the availability of the Voluntary Malfunction Summary Reporting Program. We believe the availability of the summary reporting option for manufacturers of certain devices would cause a decrease in the number of individual manufacturer reports for malfunctions submitted under §§ 803.50 and 803.52. However, because we also adjusted the respondent estimates for the ICs using more recent data from CY 2016, the estimated burden for these ICs is an increase of 12,139 hours from the currently approved burden estimates (the previous estimate based on CY 2006–2008 data was 35,166 hours for these ICs only). We attribute the increase to the increase in the number of submissions we received in recent years, rather than the revisions related to the Voluntary Malfunction Summary Reporting Program.

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.
FR Doc. 2018–12336 Filed 6–7–18; 8:45 am
BILLING CODE 4164–01–P
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.

I. Background
FDA is announcing a public workshop regarding the development of inhaled antibacterial drugs for CF and non-CF bronchiectasis. As such, discussions will focus on challenges and potential paths forward for inhaled antibacterial drugs pertaining to CF and non-CF bronchiectasis.

II. Topics for Discussion at the Public Workshop
FDA is particularly interested in discussing challenges and considerations regarding CF and non-CF bronchiectasis. Discussions are planned around the following topics for each of the disease areas:

- **Trial design challenges**
- **Trial endpoints**
- **Trial populations, duration of therapy, duration of microbiologic testing and followup**
- **Device considerations**

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

**Registration:** Registration is free and based on space availability, with priority given to early registrants.

Persons interested in attending this public workshop must register online by June 11, 2018, midnight Eastern Time. To register, please email complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to InhaledAntibacterialsWorkshop2018@fda.hhs.gov.

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 7:30 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 Jessica Barnes or Lori Benner (see FOR FURTHER INFORMATION CONTACT) no later than June 19, 2018.

**Requests for Oral Presentations:** During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by June 19, 2018. All requests to make oral presentations must be received by the close of registration on June 15, 2018. If selected for presentation, any presentation materials must be emailed to InhaledAntibacterialsWorkshop2018@fda.hhs.gov no later than June 21, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Streaming Webcast of the public workshop:** This public workshop will also be webcast at the following site: https://collaboration.fda.gov/inhaledantibacterials/.

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 website addresses in this document, as of the date this document publishes in the Federal Register, but websites 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 (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm602331.htm.

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–12341 Filed 6–7–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0529]

Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability (NOA) that appeared in the Federal Register of March 16, 2018. In the NOA, FDA requested public comment on the draft concept paper regarding the potential for illicit trade markets to develop in response to a tobacco product standard. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the NOA published March 16, 2018 (83 FR 11754). Submit either electronic or written comments by July 16, 2018.
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 July 16, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of July 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–N–0529 for “Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.fdsys.gov/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: Christopher Griffiths or Nate Mease, Office for Tobacco Products, Food and Drug Administration, 10983 New Hampshire Ave., Silver Spring, MD 20903, 1–877–287–1373, AskCTP@ fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

Food and Drug Administration


Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRAMain.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at https://www.reginfo.gov/public/do/PRAMain. An Agency may not conduct or sponsor, and a person is not required
to respond to, a collection of information unless it displays a currently valid OMB control number.

**TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB**

<table>
<thead>
<tr>
<th>Title of collection</th>
<th>OMB control No.</th>
<th>Date approval expires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Products—General Records and Postmarket Adverse Experience Reporting</td>
<td>0910–0308</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Export Certificates for FDA Regulated Products under U.S.C. Section 801(e) and 802</td>
<td>0910–0498</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Content and Format of Labeling for Human Pregnancy, Neonatal, and Lactation Medications</td>
<td>0910–0624</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics</td>
<td>0910–0629</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Evaluation of the Food and Drug Administration's Point-of-Sale Campaign</td>
<td>0910–0765</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Biological Products—Labeling for Human Pregnancy, Neonatal, and Lactation Medications</td>
<td>0910–0851</td>
<td>4/30/2021</td>
</tr>
</tbody>
</table>

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–12338 Filed 6–7–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2009–N–0232]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer’s Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Interstate Shellfish Dealer's Certificate.

DATES: Submit either electronic or written comments on the collection of information by August 7, 2018. Address: Dockets Management Staff, Food and Drug Administration, HFA–305, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Federal Register
Vol. 83, No. 111/Friday, June 8, 2018/Notices 26699

at the end of August 7, 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, Food and Drug Administration, HFA–305, 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–2009–N–0232 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer’s Certificate.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.
- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For
more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealer’s Certificate
OMB Control Number 0910–0021—Extension

Under Section 243 of the Public Health Service Act (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and are authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority’s criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, “Interstate Shellfish Dealer’s Certificate.” FDA uses this information to publish the “Interstate Certified Shellfish Shippers List,” a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>FDA Form No.</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission of Interstate Shellfish Dealer’s Certificate.</td>
<td>3038</td>
<td>40</td>
<td>57</td>
<td>2,280</td>
<td>0.10 (6 minutes)</td>
<td>228</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer’s Certificates annually, for a total burden of 228 hours (2,280 submissions \times 0.10 hours = 228 hours). This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–12340 Filed 6–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; CNBFT Study Section Special Emphasis Panel.

Date: June 7, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwards@cscr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Review: Intervening with Caregivers and Integrated Cancer-Related Behavioral Research.

Date: June 29, 2018.

Time: 2:00 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

(Virtual Meeting).

Contact Person: John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, newmanjh@cscr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Risk, Prevention and Health Behavior.

Date: July 9–10, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Martha M. Faraday, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 435–3575, faradaym@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Secondary Analyses of Existing Datasets in Heart, Lung, and Blood Diseases and Sleep Disorders.

Date: July 9–10, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–0684, olufokunbisam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neural Basis of Neurodegenerative Disorders and SCI.

Date: July 9, 2018.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

(Virtual Meeting).

Contact Person: Paula Elyse Schauwecker, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5211, Bethesda, MD 20892, 301–760–8207, schauweckerpe@csr.nih.gov.


Dated: June 4, 2018.

Sylvia L. Neal, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12401 Filed 6–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Alcohol Research Center Grants; Reviews (RFA AA18–001).

Date: July 26, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 3565 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, srinivar@mail.nih.gov.


Dated: June 4, 2018.

Sylvia L. Neal, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12401 Filed 6–7–18; 8:45 am]

BILLING CODE 4140–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NSD Member Conflict SEP.

Date: July 2, 2018.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Birgit Neuhaber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5562, neuhaber@ninds.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Training and Career Development Special Emphasis Panel.

Date: July 9, 2018.

Time: 12:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Elizabeth A. Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–1917, webber@ninds.nih.gov.

[Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS]

Date: June 4, 2018.

Sylvia L. Neal.

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–12399 Filed 6–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant and/or contract applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant and/or contract applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Informatics Tools for Cancer Surveillance.

Date: June 22, 2018.

Time: 9:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant application.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W116, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W116, Bethesda, MD 20892–9750, 240–276–5413, klaus.piontek@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project Review VI (P01).

Date: June 25, 2018.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W116, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W116, Bethesda, MD 20892–9750, 240–276–5413, klaus.piontek@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; R13 Conference Grant Review.

Date: June 27, 2018.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20850 (Telephone Conference Call).

[FR Doc. 2018–12396 Filed 6–7–18; 8:45 am]

BILLING CODE 4140–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Contract Review Meeting 2.

Date: August 7, 2018.
Time: 10:00 a.m. to 5:00 p.m.
Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W102, Bethesda, MD 20892–9750, 240–276–6349, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Contract Review Meeting 3.

Date: August 8, 2018.
Time: 10:00 a.m. to 5:00 p.m.
Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W260, Rockville, MD 20850 (Telephone Conference Call).

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Contract Review Meeting 4.

Date: July 11, 2018.
Time: 2:00 p.m. to 5:00 p.m.
Place: National Institute on Alcohol Abuse and Alcoholism, Rockledge II, 6700 B Rockledge Drive, Room 2116, Bethesda, MD 20817, (Telephone Conference Call).

Name of Committee: National Institutes of Health, HHS)
Dated: June 5, 2018.
Melanie J. Pantoja, Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HOMELAND SECURITY
Coast Guard
[Certificate of Alternative Compliance for the Ferry RODANTHE]

AGENCY: Coast Guard, DHS.
ACTION: Notification of issuance of a certificate of alternative compliance.
SUMMARY: The Coast Guard announces that the Fifth District, Chief of Prevention Division has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for the North Carolina’s Department of Transportation ferry RODANTHE, Official Number (O.N.) 1285078, Bollinger Hull Number: 693. We are issuing this notice because its publication is required by statute. Due to the construction and placement of the pilothouse offset to the starboard side of the vessel, the ferry RODANTHE cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel’s design and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard’s marine safety mission.
DATES: The Certificate of Alternative Compliance was issued on June 1, 2018.
FURTHER INFORMATION CONTACT: For information or questions about this notice call or email LCDR Ronaydee M. Marquez, District Five, Chief, Inspections and Investigations, U.S. Coast Guard; telephone: 757–398–6682, email: Ronaydee.M.Marquez@uscg.mil.
SUPPLEMENTARY INFORMATION: The United States is signatory to the International Maritime Organization’s International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them...
unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot comply fully with those requirements without interfering with the special function of the vessel.\(^1\)

The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is being built or operated for a determination that compliance with alternative requirements is justified,\(^2\) and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot comply fully with 72 COLREGS light, shape, and sound signal provisions without interference with the vessel’s special function.\(^3\) If the Coast Guard issues a COAC, it must publish notice of this action in the Federal Register.\(^4\)

The Fifth District, Chief of Prevention Division, U.S. Coast Guard, certifies that the RODANTHE, O.N. 1285078 is a vessel of special construction or purpose, and that, with respect to the position of the masthead light and sidelights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS, without interfering with the normal operation, construction, or design of the vessel. The design and configuration of the pilothouse offset to the starboard side of the vessel allows an open deck to carry large vehicles. There are no structures on the fore and aft centerline or left of the centerline on which a masthead light or sidelights could be affixed. Instead, the masthead light is located on the top center of the pilothouse and the port sidelight is located on the port side of the pilothouse, which is offset to the starboard side of the vessel. The Fifth District, Chief of Prevention Division further finds and certifies that the masthead light and sidelights are in the closest possible compliance with the applicable provisions of the 72 COLREGS.\(^5\)

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18. Dated: June 1, 2018.

J.R. Barnes, Capt., U.S. Coast Guard, Chief, Prevention Division, Fifth Coast Guard District.

[FR Doc. 2018–12337 Filed 6–7–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–27]


AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: Comments Due Date: July 9, 2018.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: OIRA Submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna.P.Guido@hud.gov or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The Federal Register notice that solicited public comment on the information collection for a period of 60 days was published on March 15, 2018 at 83 FR 11556.

A. Overview of Information Collection


OMB Approval Number: 2506–0117.

Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The Department collection of this information is in compliance with statutory provisions of the Cranston–Gonzalez National Affordable Housing Act of 1990 that requires participating jurisdictions to submit a Comprehensive Housing Affordability Strategy (Section 105(b)); the 1974 Housing and Community Development Act, as amended, that requires states and localities to submit a Community Development Plan (Section 104(b)(4) and Section 104(m)); and statutory provisions of these Acts that requires states and localities to submit applications and reports for these formula grant programs. The information is needed to provide HUD with preliminary assessment as to the statutory and regulatory eligibility of proposed grantee projects for informing citizens of intended uses of program funds.

<table>
<thead>
<tr>
<th>Information collection</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Responses per annum</th>
<th>Burden hour per response</th>
<th>Annual burden hours</th>
<th>Hourly cost per response</th>
<th>Annual cost</th>
</tr>
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<tbody>
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<td>2506–0117—localities</td>
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<td>1.00</td>
<td>1,216.00</td>
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<td>14,198,076.80</td>
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<td>741.00</td>
<td>37,050.00</td>
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<td>Total</td>
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<td>393,338.00</td>
<td></td>
<td><strong>39.85</strong></td>
<td><strong>15,674,519.30</strong></td>
</tr>
</tbody>
</table>

\(^1\) 33 U.S.C. 1605.

\(^2\) 33 CFR 81.9.

\(^3\) 33 U.S.C. 1605(c) and 33 CFR 81.18.

\(^4\) 33 U.S.C. 1605(a); 33 CFR 81.9.
**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. The accuracy of the agency’s estimate of the burden of the proposed collection of information;
3. Ways to enhance the quality, utility, and clarity of the information to be collected; and
4. Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**


Anna P. Guido, Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–12403 Filed 6–7–18; 8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FW 5–R6–ES–2018–N032; F 5851113060000–189–FF06E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of permit applications; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

**DATES:** We must receive your written comments by July 9, 2018.

**ADDRESSES:** Document availability and comment submission: Submit requests for copies of the applications and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (e.g., T Ex XXXX):

- Email: permitsR6ES@fws.gov.

**FOR FURTHER INFORMATION CONTACT:** Kathy Konishi, Recovery Permits Coordinator, Ecological Services, 303–236–4224 (phone); permitsR6ES@fws.gov (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

**SUPPLEMENTARY INFORMATION:**

**Background**

The ESA prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

**Permit Applications Available for Review and Comment**

We invite local, State, and Federal agencies, Tribes, and the public to comment on the following applications.

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Applicant, city, state</th>
<th>Species</th>
<th>Location</th>
<th>Activity</th>
<th>Type of take</th>
<th>Permit action</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE054237–3</td>
<td>USDA Forest Service</td>
<td>Southwestern willow flycatcher (Empidonax trailli extimus)</td>
<td>Colorado</td>
<td>Survey and monitor to determine baseline population numbers.</td>
<td>Disturbance</td>
<td>Amend.</td>
</tr>
<tr>
<td>TE73239C–0</td>
<td>U.S. Army Corps of Engineers, Kansas City, MO.</td>
<td>Pallid sturgeon (Scaphirhynchus albus).</td>
<td>Kansas, Missouri</td>
<td>Survey and monitor to determine baseline population numbers.</td>
<td>Capture, handle, and radio tag; transfer limited numbers to U.S. Fish and Wildlife Service hatcheries for propagation efforts.</td>
<td>New.</td>
</tr>
</tbody>
</table>
Public Availability of Comments

Written comments we receive become part of the administrative record associated with this Federal Register notice. 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 disclosure, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the Federal Register.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

Michael Thabault,
Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2018–12343 Filed 6–7–18; 8:45 am]
BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[189A2100DD/AACKC001030/A0A501010.999900253G]

Indian Gaming; Approval of a Tribal-State Class III Gaming Compact in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Shawnee Tribe and the State of Oklahoma entered into a compact governing class III gaming; this notice announces the approval of the Tribal Gaming Compact between the Shawnee Tribe and the State of Oklahoma.

DATES: This compact takes effect on June 8, 2018.


SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 et seq., the Secretary of the Interior shall publish in the Federal Register notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts are subject to review and approval by the Secretary. The Compact authorizes the Tribe to engage in certain class III gaming activities, provides for certain geographical exclusivity, limits the number of gaming machines at existing racetracks, and prohibits non-tribal operation of certain machines and covered games.

Dated: May 7, 2018.

John Tahsuda,
Principal Deputy Assistant Secretary—Indian Affairs, Exercising the Authority of the Assistant Secretary—Indian Affairs.
[FR Doc. 2018–12343 Filed 6–7–18; 8:45 am]
BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWYR05000.L1610000.XP0000; WYW168593]

Public Land Order No. 7868; Withdrawal of Public Lands To Protect the Johnny Behind the Rocks Recreation Zone; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws 4,564.75 acres of public lands from location and entry under the United States Mining Laws, subject to valid existing rights, but not from leasing under the mineral or geothermal leasing laws, for a period of 20 years, for the protection of cultural and recreational resources associated with the Johnny Behind the Rocks Recreation Zone.
The area described aggregates 4,564.75 acres in Fremont County.

2. The withdrawal made by this Order does not alter the applicability of the public land laws other than the mining laws.

3. This withdrawal will expire 20 years from the effective date of this Order, unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be extended.

Dated: June 4, 2018.

Ryan K. Zinke,
Secretary of the Interior.

DEPARTMENT OF THE INTERIOR
Bureau of Ocean Energy Management

Request for Feedback on BOEM’s Proposed Path Forward for Future Offshore Renewable Energy Leasing on the Atlantic Outer Continental Shelf


ACTION: Request for feedback, reopening of comment period.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) issued a Request for Feedback (RFF) in the Federal Register on April 6, 2018, seeking public input on its proposed path forward and factors affecting future renewable leasing offshore the United States Atlantic Coast. That notice had a comment period deadline of May 21, 2018. Several stakeholders have contacted BOEM and requested additional time to submit a comment. BOEM is reopening the comment period.

DATES: All comments submitted in response to this RFF and extension must be received by BOEM no later than 11:59 p.m. Eastern Time on July 5, 2018. BOEM will consider submissions sent by mail as long as they are postmarked by the last day of the comment period.

ADDRESSES: Comments should be submitted in one of the two following ways:


2. Written Comments: In written form, delivered by hand or by mail, enclosed in an envelope labeled, “Comments on Request for Feedback” to: Office of Renewable Energy Programs, Bureau of Ocean Energy Management, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166.

FOR FURTHER INFORMATION CONTACT: Jeffrey Browning, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166, (703) 787–1577 or Jeffrey.Browning@boem.gov.

SUPPLEMENTARY INFORMATION:


Background and Purpose: The RFF seeks input from stakeholders regarding areas where offshore wind development offshore the United States Atlantic Coast may or may not be appropriate, and what factors BOEM should consider in the early stages of its future planning processes in that area. The RFF, described in detail in the Federal Register (83 FR 14881 (April 6, 2018)), had an initial comment deadline of May 21, 2018, but several stakeholders have requested additional time to comment. BOEM agrees that it would be helpful in this instance to reopen the comment period through July 5, 2018.

Protection of Privileged or Confidential Information: BOEM will protect privileged or confidential information that you submit, as provided in the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and confidential commercial or financial information. If you wish to protect the confidentiality of such information, clearly mark it and request that BOEM treat it as confidential. BOEM will not disclose such information, except as provided in FOIA. Please label privileged or confidential commercial information “Contains Confidential Information” and consider submitting such information as a separate attachment.

BOEM will not treat as confidential any aggregate summaries or portions of comments not containing such information. Additionally, BOEM may not treat as confidential the legal title of the commenting entity (e.g., the name of your company). Information that is not labeled as privileged or confidential may be regarded by BOEM as suitable for public release.

Dated: June 4, 2018.

Walter D. Cruickshank,
Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2018–12316 Filed 6–7–18; 8:45 am]
SUPPLEMENTARY INFORMATION:

The U.S. Nuclear Regulatory Commission (NRC) is considering renewal of Source Material License SUA–1350 issued to Kennecott Uranium Corporation (KUC) for continued operations at the Sweetwater Uranium Project (SUP) in Sweetwater County, Wyoming. As required by part 51 of title 10 of the Code of Federal Regulations (10 CFR), “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” the NRC performed an EA. Based on the results of the EA, the NRC has determined not to prepare an environmental impact statement (EIS) for the amendment and is issuing a FONSI.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would authorize KUC to operate a conventional uranium mill at the SUP for an additional ten years. The licensee’s application dated July 24, 2014, is available at ADAMS Package Accession No. ML14251A113.

Need for the Proposed Action

The proposed action would allow KUC to recover uranium at the SUP. The licensee would process the recovered uranium into yellowcake on site at the SUP. Yellowcake is a type of uranium concentrate powder obtained from leach solutions in an intermediate step in the processing of uranium ores that is used to produce various products, including fuel for commercially-operated nuclear power reactors.

Environmental Impacts of the Proposed Action

The NRC staff has assessed the potential environmental impacts from operations and decommissioning at the SUP. The NRC staff assessed the impacts of the proposed action on land use; historical and cultural resources; visual and scenic resources; climatology, meteorology and air quality; geology, minerals, and soils; water resources; ecological resources; socioeconomics; noise; traffic and transportation; public and occupational health and safety; and waste management. The NRC staff concluded that the renewal of Source Material License SUA–1350 authorizing KUC to continue operations for ten years at the SUP has no significant environmental impacts.
SUP would not significantly affect the quality of the human environment. Approval of the proposed action would not result in increased radiological risk to public health or the environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (i.e., the “no-action” alternative). The no-action alternative would mean that the NRC would not approve license SUA–1350, and KUC would commence decommissioning activities.

Agencies and Persons Consulted

In accordance with its stated policy, on March 26, 2018, the NRC staff consulted with the U.S. Fish and Wildlife Service (FWS), the Wyoming State Historic Preservation Officer (SHPO), and the Wyoming Department of Environmental Quality (WDEQ) regarding the proposed action. The FWS stated that no federally listed or proposed endangered or threatened species occur within the area affected by the proposed action. The SHPO notified NRC that it had no comments related to the historic and cultural resources on the proposed license renewal. The WDEQ stated that it had no comments on the draft EA.

Additional Information

The NRC staff conducted an environmental review in accordance with 10 CFR part 51, which implements the requirements of the National Environmental Policy Act of 1969, as amended (NEPA). The results of the NRC’s environmental review can be found in the final EA (ADAMS Accession No. ML18135A206). Based on the results of this environmental assessment, the NRC has determined not to prepare an EIS for license renewal of the SUP and is instead issuing a FONSI.

After weighing the impacts of the license renewal and comparing to the no-action alternative, the NRC staff, in accordance with 10 CFR 51.31, sets forth its NEPA recommendation regarding the proposed action (granting the request for renewal of license SUA–1350). Unless safety issues mandate otherwise, the NRC staff’s recommendation related to the environmental aspects of the proposed action is that an NRC license renewal be issued.

III. Finding of No Significant Impact

Based on its review of the proposed action, and in accordance with the requirements in 10 CFR part 51, the NRC staff has determined that license renewal of SUP would not significantly affect the quality of the human environment. Based on the EA, the NRC staff determined that approval of the proposed action would not result in a significantly increased radiological risk to public health or the environment.

The NRC staff has determined that pursuant to 10 CFR 51.31, preparation of an EIS is not required for the proposed action and, pursuant to 10 CFR 51.32, a FONSI is appropriate.

Dated at Rockville, Maryland, on June 5, 2018.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,
Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–12350 Filed 6–7–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–390 and 50–391; NRC–2018–0107]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to request a hearing and to petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received, and is considering approval of, an application from Tennessee Valley Authority (TVA or the licensee) for amendments to Facility Operating License Nos. NPF–90 and NPF–96, which authorizes the operation of Watts Bar Nuclear Plant (WBN), Unit Nos. 1 and 2, respectively. The amendments would allow the loading of tritium producing burnable absorber rods (TPBARs) in WBN, Unit 2 and would make associated technical specification changes for WBN, Unit Nos. 1 and 2. Because this amendment request contains sensitive unclassified non-safeguards information (SUNSI), an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: A request for a hearing or petition for leave to intervene must be filed by August 7, 2018. Any potential party as defined in § 2.4 of title 10 of the Code of Federal Regulations (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by June 18, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0107 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• Federal Rulemaking website: Go to http://www.regulations.gov and search for Docket ID NRC–2018–0107. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

• NRC’s Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• 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.


SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of amendments to Facility Operating License Nos. NPF–90 and NPF–96, issued to TVA, for operation of the WBN, Unit Nos. 1 and 2, located in Rhea County, Tennessee.

The proposed amendments would revise the WBN, Unit 2 Technical Specification (TS) 4.2.1, “Fuel Assemblies,” to add a limit for the number of TPBARs that can be loaded in the WBN, Unit 2, core; the proposed limit would be 1,792 TPBARs. The proposed amendments would also revise TS 3.7.15, “Spent Fuel Assembly Storage”; TS 3.9.9, “Spent Fuel Boron Concentration”; and TS 4.3.3, “Fuel Storage,” and add TS 3.7.18, “Fuel Storage Pool Boron Concentration”; and
TS 5.7.2.21, “Spent Fuel Storage Rack Neutron Absorber Monitoring Program,” for WBN, Unit Nos. 1 and 2.

The proposed change to TS 3.7.15 is to revise the fuel storage limitations on fuel assemblies by eliminating the burnup-related criteria. The proposed change to TS 3.9.9 is to modify the minimum fuel storage pool boron concentration during refueling operations when fuel is stored in the pool. The proposed change to TS 4.3 is to replace the storage limitations on fuel assembly burnup and storage with a single requirement to maintain a specified boron concentration in the spent fuel pool. The proposed change would add TS 3.7.18 to revise the minimum storage pool boron concentration when fuel is stored in the pool. The proposed change would add a new program as TS 5.7.2.21 to monitor the condition of the neutron absorber material used in the spent fuel pool storage racks to ensure it will continue to perform its assumed design functions. These changes will support a planned increase in the TPBAR inventory in the WBN, Unit 2 reactor core to support national security needs.

Before any issuance of the proposed license amendments, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC’s regulations.

The amendments will not be issued prior to a hearing unless the staff makes a determination that the amendments involve no significant hazards considerations. If a request for a hearing is received, the NRC’s staff may issue the amendments after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC’s regulations are accessible electronically from the NRC Library on the NRC’s website at http://www.nrc.gov/radio/car-doc-collections/cfr/. Alternatively, a copy of the regulations is available at the NRC’s Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d), the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner’s right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner’s interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Controversies must be limited to matters within the scope of the proceeding. The contentions must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC’s regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(b)(1). The petition should state the nature and extent of the petitioner’s interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(b)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the
provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC’s E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some instances in paper format. Such filings may seek assistance by contacting the NRC’s E-Filing system.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852; Attention: Rulemaking and Adjudications Staff; or by email to MSHD. Resource@nrc.gov, or by a toll-free call at 1–866–672–7640.

Information about applying for a digital ID certificate is available on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals/getting-started.html. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC’s website at http://www.nrc.gov/site-help/electronic-sub-ref-mat.html. A filing is considered complete at the time the document is submitted through the NRC’s E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system times-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC’s Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system. A person filing electronically using the NRC’s adjudicatory E-Filing system may seek assistance by contacting the NRC’s Electronic Filing Help Desk through the “Contact Us” link located on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals.html, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852; Attention: Rulemaking and Adjudications Staff; or by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1–866–672–7640.

For further details with respect to this action, see the application for license amendment dated December 20, 2017 (ADAMS Accession No. ML173542B22), as supplemented on February 15 and April 9, 2018 (ADAMS Accession Nos. ML18047A181 and ML18100A953, respectively). This amendment request contains SUNSI.
Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A “potential party” is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are OGCmailcenter@nrc.gov and OGCmailcenter@nrc.gov, respectively. The request must include the following information:

1. A description of the licensing action with a citation to this Federal Register notice;

2. The name and address of the potential party and a description of the potential party’s particularized interest that could be harmed by the action identified in C.(1); and

3. The identity of the individual or entity requesting access to SUNSI and the requester’s basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

1. There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

2. The requester has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requester satisfies both D.(1) and D.(2) above, the NRC staff will notify the requester in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requester may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requester no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner’s receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.


1. If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requester in writing, briefly stating the reason or reasons for the denial.

2. The requester may challenge the NRC staff’s adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

3. Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party’s interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2.

The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 4th of June, 2018.

1 While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC’s “E-Filing Rule,” the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

2 Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

3 Requesters should note that the filing requirements of the NRC’s E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.
For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

Attachment 1—General Target
Schedule for Processing and Resolving
Requests for Access to Sensitive
Unclassified Non-Safeguards
Information in This Proceeding

<table>
<thead>
<tr>
<th>Day</th>
<th>Event/activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Publication of Federal Register notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.</td>
</tr>
<tr>
<td>10</td>
<td>Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.</td>
</tr>
<tr>
<td>60</td>
<td>Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).</td>
</tr>
<tr>
<td>20</td>
<td>U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff’s determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).</td>
</tr>
<tr>
<td>25</td>
<td>If NRC staff finds no “need” or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff’s denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds “need” for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff’s grant of access.</td>
</tr>
<tr>
<td>30</td>
<td>Deadline for NRC staff reply to motions to reverse NRC staff determination(s).</td>
</tr>
<tr>
<td>40</td>
<td>(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.</td>
</tr>
<tr>
<td>A</td>
<td>If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.</td>
</tr>
<tr>
<td>A + 3</td>
<td>Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.</td>
</tr>
<tr>
<td>A + 28</td>
<td>Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner’s receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI contentions by that later deadline.</td>
</tr>
<tr>
<td>A + 53</td>
<td>(Contestion receipt +25) Answers to contentions whose development depends upon access to SUNSI.</td>
</tr>
<tr>
<td>A + 60</td>
<td>(Answer receipt +7) Petitioner/Intervenor reply to answers.</td>
</tr>
<tr>
<td>&gt;A + 60</td>
<td>Decision on contention admission.</td>
</tr>
</tbody>
</table>

POSTAL REGULATORY COMMISSION


New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing 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: June 12, 2018.

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
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service has 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 website (http://www.prc.gov). Non-public portions of the Postal Service’s request(s), if any, can be accessed through compliance
II. Docketed Proceeding(s)

1. Docket No(s): CP2015–80; Filing Title: USPS Notice of Amendment to Priority Mail Contract 123. Filed Under Seal; Filing Acceptance Date: June 1, 2018; Filing Authority: 39 CFR 3015.5; Public Representative: Lawrence Fenster; Comments Due: June 12, 2018.

2. Docket No(s): CP2017–259; Filing Title: Notice of the United States Postal Service of Filing Modification Two to a Global Plus 3 Negotiated Service Agreement; Filing Acceptance Date: June 1, 2018; Filing Authority: 39 CFR 3015.5; Public Representative: Lawrence Fenster; Comments Due: June 12, 2018.


This notice will be published in the Federal Register.

Stacy L. Ruble,
Secretary.

[FR Doc. 2018–12384 Filed 6–7–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a public meeting on Wednesday, June 13, 2018 at 2:00 p.m. (ET).

PLACE: The public meeting will be held in the Knowles Conference Center at Georgia State University College of Law, 85 Park Place Northeast, Atlanta, GA 30303.

STATUS: This meeting will begin at 2:00 p.m. (ET) and will be open to the public. Doors will open at 1:30 p.m. Visitors will be subject to security checks. The public meeting will be webcast from 2:00 p.m. to 3:00 p.m. on the Commission’s website at www.sec.gov. The public is encouraged to RSVP for the meeting at https://www.sec.gov/investing-america.

MATTERS TO BE CONSIDERED: This Sunshine Act notice is being issued because a quorum of the Commission may attend the meeting. The purpose of the meeting is to provide retail investors with an opportunity to engage with SEC officials, including the Commissioners.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: June 6, 2018.

Brent J. Fields,
Secretary.

[FR Doc. 2018–12541 Filed 6–6–18; 4:15 pm]

BILLING CODE 8011–01–P
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations: Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend and Reorganize Specific Chapters in the Schedule of Fees

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),1 and Rule 19b–4 thereunder,2 the Commission is hereby giving notice that it has determined that it is impracticable to delay the operation of the proposed rule change pursuant to Section 19(b)(2) of the Act and paragraph (f) of Rule 19b–4 in effecting the proposed rule change.

The Exchange proposes to amend and reorganize Chapters II, IV, V, and VI of the MRX Schedule of Fees.

The Exchange currently lists all INET Port Fees within Chapter II, Part C. The Exchange proposes to delete this rule text and relocate it to proposed new Chapter IV and entitle that chapter as "Ports and Other Services." The Exchange believes that this title more accurately describes the types of fees contained in this chapter. The Exchange proposes to restructure the port fees. First, the Exchange proposes to add language at the beginning of this new chapter to state, "The below charges are assessed by MRX for connectivity to MRX." The Exchange believes that this sentence makes clear that the fees apply to MRX. The Exchange proposes to define a port as "a logical connection or session that enables a market participant to send inbound messages and/or receive outbound messages from the Exchange using various communication protocols." The Exchange believes this definition will assist members in distinguishing ports from other offerings.

The Exchange proposes to restructure the port fees into 4 categories. The Exchange proposes to list order and quote protocols first, order and execution offerings next, followed by data ports and other ports as the last section. The Exchange proposes to list data offerings that are offered at no cost. The Exchange believes that aligning its offerings, where relevant, with other affiliated markets would provide more transparency as to the offerings for market participants.

The Exchange proposes to add a new section (i) and include the following introductory sentence, "The following order and quote protocols are available on MRX." The Exchange proposes to list the order entry protocol port fees for FIX, SQF, SQF Purge Port and OTTO in this section. The fees are not being amended, the existing fees are being relocated into new section (i).

The Exchange proposes to add a new section (ii) and include the following introductory sentence, "The following order and execution information is available to Members." The Exchange intends to list other port or interface information into this section that are available to MRX Members. The Exchange is relocating the CTI and FIX DROP port fees. No changes are being made to those fees. The Exchange also proposes to list TradeInfo MRX Interface into this section. The Exchange has recently filed to establish this Interface within the MRX rules.5 The Exchange proposes to note this interface is available on MRX at no cost.

The Exchange proposes to add a new section (iii) and include the following language, "The following data port fees apply in connection with data subscriptions pursuant to MRX Rules at Chapter V. These ports are available to non-MRX Members." Today, MRX does not assess a fee for these ports outlined in new section (iii). Similar to other Nasdaq Affiliated Markets the Exchange proposes to list all of the ports that Members and Non-Members obtain today at no cost. The Exchange believes that listing these ports in addition to the data subscriptions will bring more transparency to the Schedule of Fees.

The Exchange proposes to add a new section (iv) entitled "Other ports" and relocate the Disaster Recovery Ports into this section. The Exchange also proposes to make clear that a Disaster Recovery Port is available for any port listed in proposed sections (i)–(iii).

Market Data

The Exchange proposes to adopt a new Chapter V and entitle this section Market Data. Today, MRX does not assess fees for Market Data. The

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3 MRX rules are located at: http://nasdaqmrx.cchwallstreet.com/.
4 Nasdaq offers various services across its 6 affiliated options markets, MRX, Nasdaq PHLX LLC, Nasdaq BX, Inc., The Nasdaq Options Market LLC, Nasdaq GEMX, LLC, and Nasdaq ISF, LLC ("Nasdaq Affiliated Markets").
Exchange proposes to list its Market Data within Chapter V and note that there is no cost. The Exchange’s Market Data fees are listed in Rule 718. The Exchange has listed these fees within Chapter V to bring more transparency to the Schedule of Fees. Finally, the Exchange proposes to renumber Chapter IV, Connectivity Fees as new Chapter VI to account for the two new chapters proposed for the Rulebook.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”), in general, and furthers the objectives of Section 6(b)(5) of the Act, in particular, that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest, by providing greater transparency as to the ports offered on MRX.

The Exchange’s proposal to remove the Table of Contents, relocate the INET Fees, retitle and restructure those fees and adopt a new Market Data section at Chapter V are administrative. These changes are consistent with the protection of investor and the public interest because the amendments are intended to bring greater clarity to the Rulebook. The Exchange’s proposal to reorganize the port fees into sections and include pricing for ports that are offered at no cost is also consistent with the protection of investor and the public interest because it will bring greater transparency to the Exchange’s current offerings. The Exchange’s proposal to display the various market data within newly proposed Chapter V will also bring greater transparency to the Exchange’s current offerings.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal does not impose an undue burden on competition, rather the Exchange is seeking to provide greater transparency within its rules with respect to the various ports and market data offered on MRX.

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 and subparagraph (f)(6) of Rule 19b–4 thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) 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 proposed rule change may become effective and operative immediately upon filing. The Exchange states that it believes the waiver will further the protection of investors and the public interest because it will provide greater transparency as to various ports available to market participants. The Exchange further states that the proposed rule change will bring greater clarity to the Schedule of Fees. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.

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);
- Send an email to rule-comments@sec.gov. Please include File Number SR–MRX–2018–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number SR–MRX–2018–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements and communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit.
personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2018–17 and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.14

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2016–12320 Filed 6–7–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations: Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Memorialize Order and Execution Information Into MRX Rule 718

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),1 and Rule 19b–4 thereunder,2 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 memorialize its order and execution information into MRX Rule 718, entitled “Data Feeds.” The Exchange proposes to rename this rule “Data Feeds and Trade Information.” The Exchange also proposes to amend Rule 100 to add definitions.

MRX Rule 718(a)

The Exchange proposes to amend the Nasdaq MRX Top Quote Feed. The Exchange stated in that description that this feed calculates and disseminates MRX’s best bid and offer position, with aggregated size (including total size in aggregate, for Public Customer3 size in the aggregate and Priority Customer4 size in the aggregate), based on displayable order and quote interest in the System. The Exchange proposes to amend this rule text to instead provide, “this feed calculates and disseminates MRX’s best bid and offer position, with aggregated size (including total size in aggregate, for Professional Order5 size in the aggregate and Priority Customer Order size in the aggregate), based on displayable order and quote interest in the System.” The Exchange intended to specify that Professional Orders and Priority Customer Orders are segregated and aggregated. The Public Customer definition is too broad because it includes a portion of Priority Customer, which was already specified within the description. The Exchange proposes to remove Public Customer and replace it with Professional Order to be more specific and amend Priority Customer to Priority Customer Order to reference the types of orders that are aggregated to conform the rule text.

MRX Rule 718(b)

The Exchange proposes to adopt a new MRX Rule 718(b) and memorialize the following order and execution information which was discussed in other rule filings by the Exchange: (i) Clearing Trade Information or “CTI”; and (ii) FIX DROP.6 The Exchange is also adding a description for TradeInfo. The TradeInfo user interface is being offered today on MRX at no cost.

The Exchange notes that while CTI and FIX Drop information are accessible through a port, TradeInfo is an interface. The Exchange notes this distinction to make clear the manner of delivery for each of these information types.

CTI

The Exchange stated in its Prior Filing that “CTI is a real-time clearing trade message that is sent to a Member after an execution has occurred and contains trade details. The message containing the trade details is also simultaneously sent to The Options Clearing Corporation. The information includes, among other things, the following: (i) The Clearing Member Trade Agreement or “CMTA” or The Options Clearing Corporation or “OCC” number; (ii) Exchange badge or house number; (iii) the Exchange internal firm identifier; and (iv) an indicator which will distinguish electronic and non-electronically delivered orders; (v) liquidity indicators and transaction type for billing purposes; (vi) capacity.”

The Exchange is proposing to amend the CTI description and memorialize it within MRX Rule 718(b)(1). The Exchange proposes to eliminate the sentence which states, “The message containing the trade details is also simultaneously sent to The Options Clearing Corporation.” The Exchange’s System sends clearing information to OCC for each transaction. This sentence does not add information that is useful or relevant and therefore the Exchange proposes to remove it. The Exchange also proposes to delete the words “an indicator which will distinguish electronic and non-electronically delivered orders.” The only method on MRX to deliver an order is electronically.

The Exchange proposes to adopt new definitions for “account number,”7

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3 The term “Public Customer” means a person or entity that is not a broker or dealer in securities. See Rule 100(a)(44).
4 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 account(s). See 100(a)(41A). The term “Priority Customer Order” means an order for the account of a Priority Customer. See Rule 100(a)(43A).
5 The term “Professional Order” means an order that is for the account of a person or entity that is not a Priority Customer. See Rule 100(a)(43C).
7 See note 3 above.
8 An “account number” shall mean a number assigned to a Member. Members may have more
“badge,” 9 and “mnemonic” 10 to be utilized within the CTI definition and uniformly throughout the Rulebook. The Exchange proposes to renumber Rule 100 to accommodate the new definitions. The Exchange proposes to replace the phrase in Rule 718(b)(1) subsection (ii) from previously filed Exchange badge or house number to proposed definitions for badge or mnemonic. The Exchange proposes to replace the phrase in Rule 718(b)(1) subsection (iii) from Exchange internal firm identifier to proposed definition for account number. The Exchange proposes to expand on Rule 718(b)(1) subsection (iv) by replacing the phrase “an indicator which will distinguish electronic and non-electronically delivered orders” with “information which identifies the transaction type (e.g. auction type) for billing purposes.” Finally, the Exchange is adding an “and” before Rule 718(b)(1) subsection (v) “capacity” and changing the wording to “market participant capacity.” The Exchange has renumbered the CTI sections to account for the language that was removed from the description. Finally, the Exchange is making a grammatical change and adding parenthesis around defined terms. The Exchange is expressing more specifically the type of data contained in CTI.

FIX DROP

The Exchange stated in its Prior Filing that “FIX DROP provides real-time order and execution update is a message that is sent to a Member after an order has been received/modified or an execution has occurred and contains trade details. The information includes, among other things, the following: (1) Executions; (2) cancellations; (3) modifications to an existing order; and (4) busts or post-trade corrections.” 11

The Exchange proposes to memorialize FIX DROP within MRX Rule 718(b)(3). The Exchange notes that at the end of the first sentence of the description it is adding “specific to that Member” to make clear that FIX DROP only provides a Member its specific trade information. Also, an “and” is included before new (iv) as the numbers have been changed to roman numerals.

TradeInfo

The Exchange proposes to establish its TradeInfo offering at MRX Rule 718(b)(2). TradeInfo, a user interface, permits a Member to: (i) Search all orders submitted in a particular security or all orders of a particular type, regardless of their status (open, canceled, executed, etc.); (ii) view orders and executions; and (iii) download orders and executions for recordkeeping purposes. TradeInfo users may also cancel open orders at the order, port or firm mnemonic level through TradeInfo. TradeInfo is offered today to Members on MRX at no cost.

The Exchange considers it appropriate to establish and memorialize the order and execution information available on MRX within a rule so that Members may understand the trade information which is available on the Exchange as it pertains to a firm’s trading information. This data is available to all Members and is specific to a Member’s transactions on MRX.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”), 12 in general, and furthers the objectives of Section 6(b)(5) of the Act. 13 In particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest, by providing greater transparency as to the order and execution information offered on MRX. Each proposal is described in more detail below.

MRX Rule 718(a)

The Exchange’s proposal to amend the Nasdaq MRX Top Quote Feed to specify that Professional Orders and Priority Customer Orders are segregated and aggregated is consistent with the protection of investors and the public interest because the Exchange is correcting the categories of orders, which are segregated and aggregated. The Public Customer definition is too broad because it includes a portion of Priority Customer, which was already specified within the description. The Exchange proposes to remove Public Customer and replace it with Professional Order to be more specific and amend Priority Customer to Priority Customer Order to reference the types of orders that are aggregated to conform the rule text. The Exchange believes that this amendment will bring more transparency to the information within the feed.

MRX Rule 718(b)

The Exchange believes that memorializing CTI and FIX DROP within a rule will provide Members with transparency as to the order and information offerings available on MRX specific to their trading on MRX. The Exchange’s proposal to establish TradeInfo is consistent with the Act because the Exchange is detailing the contents of this offering as well as providing transparency as to the availability of TradeInfo. The Exchange believes that offering Members TradeInfo, which allows Members to view executions as well as other capabilities with respect to order management, enhances the ability of a Member to manage its orders. The Exchange believes that providing Members with tools to manage orders is consistent with the Act and serves to protect investors and the public interest. Further, the Exchange believes that this proposal is consistent with the Act because TradeInfo provides information regarding information available to market participants, specifically with respect to trades they execute on MRX. The information is available to all Members.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, 14 the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal does not impose an undue burden on competition, rather the Exchange is seeking to provide greater transparency within its rules with respect to the Nasdaq MRX Top Quote Feed as well as order and execution information offered on MRX. The information is available to all Members. Specifically, TradeInfo is available to any Member that requests this service. The TradeInfo product will provide a Member information regarding that Member’s executions.

9 A “badge” shall mean an account number with a letter suffix assigned to Market Makers. A Market Maker account may be associated with multiple badges. See proposed Rule 100(a)(5).

10 A “mnemonic” shall mean an acronym comprised of letters and/or numbers assigned to Electronic Access Members. An Electronic Access Member account may be associated with multiple mnemonics. See proposed Rule 100(a)(34).

11 Id.


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 and subparagraph (f)(6) of Rule 19b–4 thereunder.16

A proposed rule change filed under Rule 19b–4(f)(6)17 normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)18 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 proposed rule change may become effective and operative immediately upon filing. The Exchange states that waiver of the operative delay will allow the Exchange to correct the Nasdaq MRX Top Quote Feed and update its rules immediately regarding order and execution information offered on MRX. The Exchange further states that it believes the waiver will further the protection of investors and the public interest because it will provide greater transparency as to the Nasdaq MRX Top Quote Feed as well as trade detail available to market participants. Further, the Exchange states that memorializing Tradefno will provide Members with greater information concerning a Member’s executions on MRX and make its availability transparent. The Commission believes that the 30-day operative delay is consistent with the protection of investors and the public interest.

Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.19

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments
- Use the Commission’s internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–MRX–2018–16 on the subject line.

Paper Comments
- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number SR–MRX–2018–16 on the subject line.

I. 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.

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing of Proposed Rule Change To Adopt Rules Governing the Trading of Complex Qualified Contingent Cross and Complex Customer Cross Orders

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on May 22, 2018, BOX Options Exchange LLC (the “Exchange”) filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to adopt rules governing the trading of Complex Qualified Contingent Cross and Complex Customer Cross Orders. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission’s Public Reference Room and also on the

17 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.
19 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).

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing rules that will make existing functionality available to additional order types on BOX. Specifically, the Exchange is proposing rules to codify Complex Customer Cross Orders and Complex Qualified Contingent Cross (“QCC”) Orders on the Exchange. The Exchange notes that the proposed changes are similar to the rules of another exchange. In addition, the Exchange is proposing to expand certain Complex Order protections to the newly codified QCC Order and Complex Customer Cross Orders.

Complex Customer Cross Orders

First, the Exchange is proposing to add text related to Complex Customer Cross Orders. Proposed Rule 7240(b)(4)(iii) defines a Complex Customer Cross Order as a type of Complex Order which is comprised of one Public Customer Complex Order to buy and one Public Customer Complex Order to sell (the same strategy) at the same price and for the same quantity.

The Exchange uses the same crossing mechanism for the processing and execution of Complex Customer Cross Orders that is used for Customer Cross Orders in the regular market. Accordingly, proposed Rule 7110(c)(7) shall govern the trading of Complex Customer Cross Orders, as defined in Rule 7240(b)(4)(iii), on BOX. Proposed Rule 7110(c)(7) describes the execution price requirements that are specific to Complex Customer Cross Orders. Specifically, Complex Customer Cross Orders are automatically executed upon entry provided that the execution (i) is at least $0.01 better than (inside) the cBBO and any Public Customer Complex Order on the Complex Order Book; (ii) is at or better than any non-Public Customer Complex Order on the Complex Order Book; and (iii) is at or between the cNBBO. The purpose of the requirement that the execution must be at least $0.01 better than the cBBO is to ensure that there is no interference between the regular and complex markets. The purpose of the requirement that the execution must be at least $0.01 better than any Public Customer Complex Order on the Complex Order Book is to ensure that the Complex Customer Cross Order does not trade in front of any resting Public Customer Complex Orders. The purpose of the requirement that the Complex Customer Cross Order be executed at or between the cNBBO is to ensure that net execution price is within the best net price available in the market and is in line with the requirement that simple Customer Cross Orders must execute at or within the NBBO.

The system will reject a Complex Customer Cross Order if, at the time of receipt of the Complex Customer Cross Order, the strategy is subject to an ongoing auction (including COPIP, Facilitation, and Solicitation auctions) or there is an exposed order on the strategy pursuant to Rule 7240(b)(3)(B). The purpose of this provision is to maintain an orderly market by avoiding the execution of Complex Customer Cross Orders with components that are involved in other system functions that could affect the execution price of the Complex Customer Cross Order, and by avoiding concurrent processing on the Exchange involving the same strategy. Proposed Rule 7110(c)(7)(ii) states that Complex Customer Cross Orders will be automatically cancelled if they cannot be executed. Proposed Rule 7110(c)(7)(iii) provides that Complex Customer Cross Orders may only be entered in the minimum trading increments applicable to Complex Orders under Rule 7240(b)(1).

As a regulatory matter, proposed Rule 7110(c)(7)(iii) states that IM–7140–1 applies to the entry and execution of Complex Customer Cross Orders.

The following example illustrates the execution of a Complex Customer Cross Order:

Example 1—Execution of a Complex Customer Cross Order

BOX Leg A Book: 6.00–6.50
BOX Leg B Book: 3.00–3.30

Strategy: Buy A Call, Sell B Call

The cNBBO is 2.70–3.20
The cBBO is 3.00–3.30

The Complex Order Book contains a Public Customer order to sell the strategy at 3.20. The Exchange receives a Complex Customer Cross Order to buy an option on the Complex Order Book. Additionally, the order price is at or between the cNBBO. Therefore, the Complex Customer Cross Order is automatically executed upon entry.

The Exchange notes that the proposed rules for Complex Customer Cross Orders are based on the rules of another exchange with certain minor differences. First, the MIAX Rule requires the execution price to be better than the best net price of a complex order. The proposal requires the execution price to be better than any Public Customer Complex Orders on the Complex Order Book and no worse than the price of any non-Public Customer Complex Orders. The Exchange believes this difference is minor because the execution price must respect the orders on the Complex Order Book and not trade ahead of Public Customer Orders on the Complex Order Book, which is in line with regular Customer Cross

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2. See MIAX Rules 518(b)(5), 515(h)(3), 515(h)(4) and 518(b)(6).
4. Proposed Rule 7240(b)(4)(iii) is based on MIAX Rule 518(b)(5).
5. Proposed Rule 7110(c)(7) is based on MIAX Rule 515(h)(3).
6. The term “cBBO” means the best net bid and offer price for a Complex Order Strategy based on the BBO on the BOX Book for the individual options components of such Strategy. See Rule 7240(a)(1).
8. The term “cNBBO” means the best net bid and offer price for a Complex Order Strategy based on the NBBO for the individual options components of such Strategy. See Rule 7240(a)(1).
9. Proposed Rule 7110(c)(7) provides that Complex Customer Cross Orders may only be entered in the minimum trading increments applicable to Complex Orders under Rule 7240(b)(1).
10. As a regulatory matter, proposed Rule 7110(c)(7)(iii) states that IM–7140–1 applies to the entry and execution of Complex Customer Cross Orders.
11. The following example illustrates the execution of a Complex Customer Cross Order:

Example 1—Execution of a Complex Customer Cross Order

BOX Leg A Book: 6.00–6.50
BOX Leg B Book: 3.00–3.30

Strategy: Buy A Call, Sell B Call

The cNBBO is 2.70–3.20
The cBBO is 3.00–3.30

The Complex Order Book contains a Public Customer order to sell the strategy at 3.20. The Exchange receives a Complex Customer Cross Order to buy an option on the Complex Order Book. Additionally, the order price is at or between the cNBBO. Therefore, the Complex Customer Cross Order is automatically executed upon entry.

The Exchange notes that the proposed rules for Complex Customer Cross Orders are based on the rules of another exchange with certain minor differences. First, the MIAX Rule requires the execution price to be better than the best net price of a complex order. The proposal requires the execution price to be better than any Public Customer Complex Orders on the Complex Order Book and no worse than the price of any non-Public Customer Complex Orders. The Exchange believes this difference is minor because the execution price must respect the orders on the Complex Order Book and not trade ahead of Public Customer Orders on the Complex Order Book, which is in line with regular Customer Cross

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11. Rule 7140(b) prevents an Options Participant executing agency orders to increase its economic gain from trading against the order without first giving other trading interest on BOX an opportunity to trade with the agency order pursuant to Rule 7150 (Price Improvement Period). Rule 7245 (Complex Order Price Improvement Period) or Rule 7270 (Block Trades). However, the Exchange recognizes that it may be possible for an Options Participant to establish a relationship with a Customer or other person (including affiliates) to deny agency orders the opportunity to interact on BOX and to realize similar economic benefits as it would achieve by executing agency orders as principal. It will be a violation of this Rule for an Options Participant to circumvent this Rule by providing an opportunity for a Customer or other person (including affiliates) to execute against agency orders handled by the Options Participant immediately upon their entry into the Trading Host. See IM–7140–1.
12. See MIAX Rules 515(h)(3) and 518(b)(5).
Orders. Pursuant to Rule 7110(c)(5) a Customer Cross Order must execute at a price that is at or between the best bid and offer on BOX and is not at the same price as a Public Customer Order on the BOX Book. Additionally, the Exchange is proposing to have the execution price be within the cNBBO, which MIAX does not provide. The Exchange believes this difference is minor because the Exchange is simply ensuring that the execution price respect the best net prices available in the market. Additionally, similarly to the above, regular Complex Cross Orders may not trade through the NBBO.

Next, although both the proposed Rule and MIAX’s Rule require the execution to be at least $0.01 better than best price based on orders on the regular books, MIAX includes non-displayed trading interest when determining the best price based on the regular books, which the Exchange is not proposing because the Exchange does not have non-displayed interest.

Lastly, MIAX rejects a Complex Customer Cross Order if, at the time of receipt, any component of the strategy is subject to a PRIME Auction, a Route Timer, or liquidity refresh pause. The Exchange is not proposing the same Timer, or liquidity refresh pause. The subject to a PRIME Auction, a Route receipt, any component of the strategy is Customer Cross Order if, at the time of receipt of the presents at or between the best price based on the regular books, which the Exchange does not have non-displayed interest.

Next, MIAX rejects a Complex Customer Cross Order if, at the time of receipt, any component of the strategy is subject to a PRIME Auction, a Route Timer, or liquidity refresh pause. The Exchange is not proposing the same Timer, or liquidity refresh pause. The subject to a PRIME Auction, a Route receipt, any component of the strategy is Customer Cross Order if, at the time of receipt of the presents at or between the best price based on the regular books, which the Exchange does not have non-displayed interest.

Complex QCC Orders

Next, the Exchange is proposing to add text related to Complex QCC Orders. Pursuant to proposed Rule 7240(b)(4)(iv), a Complex QCC Order is comprised of an originating Complex Order to buy or sell where each component is at least 1,000 contracts that is identified as being part of a qualified contingent trade, coupled with a contra-side Complex Order or orders totaling an equal number of contracts.

The Exchange uses the same crossing mechanism for the processing and execution of Complex QCC Orders that is used for QCC Orders in the regular market. Accordingly, proposed Rule 7110(c)(8) shall govern trading of Complex QCC Orders, as defined in Rule 7240(b)(4)(iv), on BOX. Proposed Rule 7110(c)(8) describes the execution price requirements that are specific for Complex QCC Orders. Specifically, Complex QCC Orders are automatically executed upon entry provided that the execution (i) is not at the same price as a Public Customer Complex Order; (ii) is at least $0.01 better than (inside) the cBBO; (iii) is at or better than any non-Public Customer Complex on the Complex Order Book; and (iv) each option leg executes at or between the NBBO. The purpose of the requirement that the execution must be at least $0.01 better than the cBBO is to ensure that there is no interference between the regular and complex markets. The purpose of the requirement that the execution must not be at the same price as any Public Customer Complex Order on the Complex Order Book is to ensure that the Complex Customer Cross Order does not trade in front of any resting Public Customer Complex Orders. The purpose of the requirement that the individual options legs of the Complex QCC Order be executed at or between the NBBO is to ensure that the execution price of each option leg is within the best price available in the market and is in line with the requirement that simple QCC Orders must execute at or within the NBBO.

The system does not consider the NBBO price for the stock component because the Exchange does not execute the stock component; the Exchange executes the option components at a net price and ensures that, among other things, the execution price of (i) the strategy is at least $0.01 better than the cBBO; and (ii) each option leg is at or between the NBBO.

The Exchange believes the proposed Complex QCC pricing methodology aligns with the Qualified Contingent Trade ("QCT") Exemption, as defined below. The parties to a contingent trade are focused on the spread or ratio between the transaction prices for each of the component instruments (i.e., the net price of the entire contingent trade), rather than on the absolute price of any single component. Pursuant to the requirements of the NMS QCT Exemption, the spread or ratio stands regardless of the market prices of the individual orders at their time of execution. As the Commission noted in the Original QCT Exemption, “the difficulty of maintaining a hedge, and the risk of falling out of hedge, could dissuade participants from engaging in contingent trades, or at least raise the cost of such trades.” Thus, the Commission found that, if each stock leg of a qualified contingent trade were required to meet the trade-through provisions of Rule 611 of Regulation NMS, such trades could become too risky and costly to be employed successfully and noted that the elimination or reduction of this trading strategy potentially could remove liquidity from the market. This is also true for QCC Orders in options, and thus the Exchange believes that its proposal is consistent with the Original QCT Exemption.

The system will reject a Complex QCC Order if, at the time of receipt of the Complex QCC Order, the strategy is subject to an ongoing auction (including COPIP, Facilitation, and Solicitation)

\[\text{\textsuperscript{15}}\text{A “qualified contingent trade” is a transaction consisting of two or more component orders, executed as agent or principal, where: (1) At least one component is an NMS Stock, as defined in Rule 600 of Regulation NMS under the Exchange Act; (2) all components are executed with a product or price contingency that either has been agreed to by all the respective counterparties or arranged for by a broker-dealer as principal or agent; (3) the execution of each component is contingent upon the execution of all other components at or near the same time; (4) the specific relationship between the component orders (e.g., the spread between the prices of the component orders) is determined by the time the complex order is placed; (5) the component orders bear a derivative relationship to one another, represent different classes of shares of the same issuer, or involve the securities of participants in mergers or with intentions to merge that have been announced or cancelled; and (6) the transaction is fully hedged (without regard to any prior existing position) as a result of other components of the contingent trade. See IM–7110–2.}\]

\[\text{\textsuperscript{16}}\text{Proposed Rule 7240(b)(4)(iv) is based on MIAX Rule 518(h).}\]

\[\text{\textsuperscript{17}}\text{See Securities Exchange Act Release No. 80661 (May 11, 2017), 82 FR 22682 (May 17, 2017) (SR–BOX–2017–14). The Exchange notes that regular QCC Orders on BOX are allowed to execute automatically upon entry without exposure provided the execution is at or between the same price as a Public Customer Order on the BOX Book: and (2) is at or between the NBBO.}\]

\[\text{\textsuperscript{18}}\text{Proposed Rule 7110(c)(8) is based on MIAX Rule 518(h)(4).}\]


\[\text{\textsuperscript{20}}\text{The Exchange represents that QCTs will be subject to existing trading surveillance administered by the Financial Industry Regulatory Authority (“FINRA”) on behalf of the Exchange, which are designated to detect violations of Exchange rules and applicable federal securities laws. The Exchange believes the existing surveillance of QCTs is sufficient to ensure compliance with the proposed rule.}\]
auctions) or there is an exposed order on the strategy pursuant to Rule 7240(b)(3)(B). The purpose of this provision is to maintain an orderly market by avoiding the execution of Complex QCC Order with components that are involved in other system functions that could affect the execution price of the Complex QCC Order, and by avoiding concurrent processing on the Exchange involving the same strategy. Proposed Rule 7110(c)(8)(ii) states that Complex QCC Orders will be automatically cancelled if they cannot be executed. Proposed Rule 7110(c)(8)(ii) provides that Complex QCC Orders may only be entered in the minimum trading increments applicable to Complex Orders under Rule 7240(b)(1).

The following example illustrates the execution of a Complex QCC Order:

Example 2—Execution of a Complex QCC Order

BOX Leg A Book: 6.00–6.60
BOX Leg B Book: 3.00–3.30
Leg A NBBO: 6.00–6.60
Leg B NBBO: 3.00–3.30

Strategy: Buy A Call, Sell B Call

The cBBO is 2.70–3.30.

The Complex Order Book contains a broker-dealer order to sell the strategy at 3.29.

The Exchange receives a Complex QCC Order for the simultaneous purchase and sale of the strategy at a net price of 3.29, 1,000 times. Since the order can be executed at or between the NBBO for each leg of the strategy, is not at a worse price than the non-Public Customer Order on the Complex Order Book, is at least $0.01 better than the cBBO and the order size is met, the Complex QCC Order is automatically executed upon entry.

The proposed rules governing Complex QCC Orders are based on the rules of another exchange with certain differences. First, MIAX requires the individual legs be executed at the same price as a Priority Customer Order on the book. The Exchange does not propose to include this provision of MIAX’s rule as the BOX system handles Complex Orders differently. Specifically, Complex Orders on BOX are executed at a net debit or credit, and therefore it is understandable that the execution parameters would be controlled by the net price of the strategy rather than the individual legs. A Complex Order may execute as a net credit or debit with one other Participant; provided, the price of at least one leg of the Complex Order must trade at a price that is better than the corresponding bid or offer in the marketplace by at least one minimum trading increment (i.e., one cent) as set forth in Rule 7240(b)(1). As such, and to stay in line with how Complex Orders are handled on BOX, the Exchange is proposing that the net execution price of the Complex QCC Order be better than the cBBO. As discussed above, this is in line with the approach to Complex Orders in general on the Exchange. Further, the Exchange believes it is important to respect all interest in the regular Book and not only Public Customer interest, as is the case with MIAX, which is why the Exchange requires the Complex QCC Order to be better than the cBBO.

To illustrate this, assume a Complex QCC Order at $2.01 is received by the system for strategy A+B. There is a Public Customer Order to buy leg A on the Book for $1.00 and a Public Customer Order to buy leg B on the Book for $1.00. Under the proposal, the Complex QCC Order would be accepted by the system because the execution price is at least $0.01 better than the cBBO. The Exchange does not believe that this result harms the resting Public Customer Orders. Specifically, given the execution price of $2.01, the sell side of the Complex QCC Order could not interact with the resting Public Customer Orders because there is no interest on the individual legs that, when combined, equal the execution price of $2.01. If, however, in addition to the Public Customer order to buy leg B at $1.00, there is a non-Public Customer order to buy leg B at $1.01, the Complex QCC Order at $2.01 would be rejected. This is because the execution price is no longer better than the cBBO.

As such, the Public Customer Order on leg A is protected because there is interest on the individual legs that, when combined, equal the proposed execution price of the Complex QCC Order. Further, since the agreed upon price between market participants was $2.01, it would be detrimental to require the order to be executed at a worse price than is necessary. While the BOX proposal does not have the same price protection for Public Customers as MIAX Complex QCC rule, the Exchange believes the proposal, which provides a level of price protection to all Participants, remains consistent with the Act.

The Exchange is proposing the additional requirements that the execution price is not at the same price as a Public Customer Complex Order and at or better than any non-Public Customer Complex Order on the Complex Order Book as compared to MIAX. The Exchange believes that these additional requirements are reasonable because the Exchange is respecting resting Complex Orders.

Lastly, MIAX rejects a Complex QCC Order if, at the time of receipt, any component of the strategy is subject to a PRIME Auction, a Route Timer, or liquidity refresh pause. The Exchange is not proposing the same conditions. With respect to not rejecting when a component is subject to an auction, the Exchange notes that this approach is in line with the treatment of a COPIP when there is an ongoing PIP on a component of the Complex Order. Specifically, the Exchange will accept Complex Orders designated for the COPIP where there is a PIP on an individual component. Further, the Exchange notes that orders on the regular book are protected by the fact that the execution price must be at least $0.01 better than the cBBO. Additionally, in order to ensure orderly markets involving multiple Complex Orders with common components, the Exchange is proposing additional circumstances in which a Complex QCC Order will be rejected, specifically, when there is an exposed order on the strategy, or there is an ongoing Facilitation or Solicitation auction on the strategy.

Lastly, the Exchange proposes to expand certain Complex Order protections to Complex QCC Orders and Complex Customer Cross Orders. Specifically, the Exchange proposes to amend Rule IM–7240–1(a)(5) and IM–7240(b)(5) to apply these price protection checks to Complex QCC Orders and Complex Customer Cross

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22 See Rule 7240(b)(2)(1)(i). In addition, Complex Qualified Open Outcry Orders may be executed at a price without giving priority to equivalent bids or offers in the individual series legs on the initiating side, provided at least one options leg betters the corresponding bid or offer on the BOX Book by at least one minimum trading increment (i.e., one cent) as set forth in Rule 7240(b)(1). See 7600(c).

23 Assume for the example that the cBBO is 2.00–5.00. The 2.00 bid is comprised of the Public Customer Orders on the individual leg books and 5.00 is a resting Complex Order.

24 As outlined in the proposal, this is consistent with how the system currently handles the interaction between Complex Orders and the individual leg Books. The Exchange notes that the same behavior occurs regardless of the account of the order on the individual leg Books. For example, if the orders on the leg Books were for the account of a broker-dealer, the execution price of the Complex QCC would still need to be $0.01 better than the cBBO.

25 The cBBO would now be 2.01–5.00.
Orders. The Exchange notes that another options exchange has similar price checks.28

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),29 in general, and Section 6(b)(5) of the Act,30 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The proposal to amend Rules 7110 and 7240 to codify rules covering Complex Customer Cross and Complex QCC Orders is consistent with Section 6(b)(5) of the Act because this proposal promotes just and equitable principles of trade and protects investors and the public interest by providing increased opportunities for the execution of Complex Orders. The Exchange believes that the proposed Complex Customer Cross and Complex QCC Rules will benefit Participants and the marketplace as a whole by adopting rules that allow for the trading of these types of orders on the Exchange. The Exchange believes the proposed rules for Complex Customer Cross and Complex QCC Orders remove impediments to and perfects the mechanism of a free and open market and a national market system and will result in more efficient trading and enhance the likelihood of the Complex Orders executing at the best prices by providing additional order types resulting in potentially greater liquidity available for trading on the Exchange.

The proposed rule change will provide rules that make existing functionality available to additional order types. Providing rules that make Customer Cross and QCC available for Complex Orders removes impediments to and perfects the mechanisms of a free and open market and a national market system because Participants will be given additional ways in which they can execute Complex Orders.

The proposed rule change will protect investors and the public interest by assuring the existing priority and allocation rules applicable to the processing and execution of Customer Cross Orders, QCC Orders, and Complex Orders remains consistent with the processing and execution of these order types, unless otherwise specifically set forth in the rules.

The Exchange further believes that the proposed methodology for the execution of Complex QCC Orders without consideration of the NBBO of the stock component is consistent with the QCT Exemption. As stated above, the QCT Exemption provides an exception for the stock leg of qualified contingent trades from trade-through requirements. Therefore, the system considers the NBBO of the options legs of the Complex QCC Order, and not the NBBO for the stock component, in calculating the pricing requirement for Complex QCC Orders.

The system does not consider the NBBO price for the stock component because the Exchange does not execute the stock component of the Exchange executes the option components at a net price and ensures that the net execution price for the strategy (i) is at or better than the Nbbo; (ii) is at or better than the same price as a Public Customer Complex Order; (iii) is at or better than any non-Public Customer Complex Order on the Complex Order Book; and (iv) each leg is at or between the NBBO.

The Exchange believes that the proposal to reject a Complex Customer Cross or Complex QCC Order at the time of receipt of the order when the strategy is subject to an ongoing auction (including COPIP, Facilitation and Solicitation auctions), or there is an exposed order on the strategy, removes impediments to and perfects the mechanism of a free and open market by ensuring orderly markets involving multiple complex orders with common components.

The proposed rule change to implement a debit/credit check for Complex QCC and Complex Customer Cross Orders is consistent with the Act. With the use of debit/credit checks, the Exchange can further assist with the maintenance of a fair and orderly market by mitigating the potential risks associated with Complex Orders trading at prices that are inconsistent with their strategies (which may result in executions at prices that are extreme and potentially erroneous), which ultimately protects investors.

This proposed implementation of the debit/credit check promotes just and equitable principles of trade, as it is based on the same general option and volatility pricing principles which the Exchange understands are used by market participants in their option pricing models.

Additionally, the Exchange also believes that calculating a maximum price for true butterfly spreads, vertical spreads, and box spreads will assist with the maintenance of fair and orderly markets by helping to mitigate the potential risks associated with Complex QCC and Complex Customer Cross Orders trading at extreme and potentially erroneous prices that are inconsistent with particular Complex Order strategies. Further, the Exchange believes that the maximum price is designed to mitigate the potential risks of executions at prices that are not within an acceptable price range, as a means to help mitigate the potential risks associated with Complex Orders trading at prices that are inconsistent with their strategies, in addition to the debit/credit check. As such, the proposed rule change is designed to protect investors and the public interest.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change to provide rules governing the trading of Complex Customer Cross and Complex QCC Orders will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule is being proposed as a competitive response to the rules of another exchange.31 Additionally, the proposed rule change is intended to promote competition by adding rules for new order types that enable Participants to execute Complex Orders on the Exchange. The Exchange believes that this enhances inter-market competition by enabling the Exchange to compete for this type of order flow with other exchanges that have similar rules and functionalities in place.

Further, the Exchange does not believe that the proposed Complex Order protections will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In this regard and as indicated above, the Exchange notes that the rule change is being proposed as a competitive response to the rules of another exchange.32 Additionally, the Exchange believes the proposed rule change is beneficial to Participants as it will provide increased protections that will prevent the execution of certain Complex Orders that were entered in
error. The Exchange believes the proposal is pro-competitive and should serve to attract additional Complex Orders to the Exchange. Further, the Exchange does not believe the proposed change will not impose a burden on intramarket competition because it is available to all Participants.

For the reasons stated, the Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and the Exchange believes the proposed change will, in fact, enhance competition.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the Federal Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or
(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission’s internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File Number SR–BOX–2018–14 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–BOX–2018–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street, NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2018–14, and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.33

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–12319 Filed 6–7–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend and Reorganize Chapter V of the ISE Schedule of Fees

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on May 22, 2018, 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 and reorganize Chapter V of the ISE Schedule of Fees.

The text of the proposed rule change is available on the Exchange’s website at http://ise.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Chapter V of the ISE Schedule of Fees to: (i) Eliminate the Table of Contents; (ii) retitle Section V, currently titled “Trading Application;” (iii) retitle Parts A, B and C of Chapter V which are currently titled “Installation,” “Software License & Maintenance” and “Reserved” respectively; and (iv) eliminate the Part D title, “INET Port Fees” and amend and reorganize the current port fees. Each change will be described in more detail below. The Exchange believes that the proposed amendments to the Schedule of Fees will provide more clarity as to the current fees. The Exchange notes that no fee changes are being introduced with this rule change. The Exchange is simply reorganizing its rules to conform to other Nasdaq affiliate markets by aligning the location and description of its rules on each market.
The Exchange proposes to eliminate the Table of Contents in the ISE Schedule of Fees. The Table Contents are unnecessary. The website where the ISE rules are listed contains hyperlinks and a skeleton of the available rules within the site and enables market participants to view all rules in that section.

Section V, Trading Application

The Exchange proposes to relocate the Table of Contents and retitle the various parts of Chapter V are administrative. These changes are consistent with the protection of investor and the public interest because the amendments are intended to bring greater clarity to the Rulebook. The Exchange’s proposal to reorganize the port fees into sections and include transparency to the Exchange’s current offerings.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal does not impose an undue burden on competition, rather the Exchange is seeking to provide greater transparency within its rules with respect to the various ports offered on ISE.

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

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4 The Exchange offers various services across its 6 affiliated options markets, ISE, Nasdaq Phlx LLC, Nasdaq IX, Inc., The Nasdaq Options Market LLC, Nasdaq GEMX, LLC and Nasdaq MRX, LLC (“Nasdaq Affiliated Markets”).


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 and subparagraph (f)(6) of Rule 19b–4 thereunder.10 A proposed rule change filed under Rule 19b–4(f)(6)11 normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)12 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 proposed rule change may become effective and operative immediately upon filing. The Exchange states that it believes the waiver will further the protection of investors and the public interest because it will provide greater transparency as to various ports available to market participants. The Exchange further states that the proposed rule change will bring greater clarity to the Schedule of Fees. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.13

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 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–ISE–2018–48 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–2018–48. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2018–48 and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.14

Eduardo A. Aleman, Assistant Secretary.

[FR Doc. 2018–12322 Filed 6–7–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend and Reorganize Chapter IV of the GEMX Schedule of Fees

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on May 22, 2018, Nasdaq GEMX, LLC (“GEMX” 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 and reorganize Chapter IV of the GEMX Schedule of Fees. The text of the proposed rule change is available on the Exchange’s website at http://nasdaqgemx.chwwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Chapters IV of the GEMX Schedule of Fees to: (i) Eliminate the Table of

The Exchange proposes to add a new section (iii) and include the following language, “The following data port fees apply in connection with data subscriptions pursuant to GEMX Rules at Chapter V. These ports are available to non-GEMX Members and GEMX Members.” Today, GEMX does not assess a fee for these ports outlined in this section (iii). Similar to other Nasdaq Affiliated Markets the Exchange proposes to list all of the ports that Members and Non-Members obtain today at no cost. The Exchange believes that listing these ports in addition to the data subscriptions will bring more transparency to the Schedule of Fees. The Exchange proposes to also add a new section (iv) entitled “Other ports” and relocate the Disaster Recovery Ports into this section. The Exchange also proposes to make clear that a Disaster Recovery Port is available for any port listed in proposed sections (i)–(iii). The Exchange proposes to reserve current Chapter IV, Part E.

2. Statutory Basis
The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”), in general, and furthers the objectives of Section 6(b)(5) of the Act, in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest, by providing greater transparency as to the ports offered on GEMX.

The Exchange’s proposal to remove the Table of Contents, relocate the Port Fees, retitle and restructure those fees and reserve Chapter IV, Part E are administrative. These changes are consistent with the protection of investor and the public interest because the amendments are intended to bring greater clarity to the Rulebook. The Exchange’s proposal to reorganize the port fees into sections and include pricing for ports that are offered at no cost is also consistent with the protection of investor and the public interest because it will bring greater transparency to the Exchange’s current offerings.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal does not impose an undue burden on competition, rather the Exchange is seeking to provide greater transparency within its rules with respect to the various ports offered on GEMX.

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)(ii) of the Act and

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3 GEMX rules are located at: http://nasdagemx.com/.

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14 The Exchange offers various services across its 6 affiliated options markets, Nasdaq Phlx LLC, Nasdaq IX, Inc., The Nasdaq Options Market LLC, Nasdaq GEMX, LLC, Nasdaq MRX, LLC and Nasdaq ISE, LLC (“Nasdaq Affiliated Markets”).
15 See SR-GEMX-2016-17 (not yet published).
A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) 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 proposed rule change may become effective and operate immediately upon filing. The Exchange states that it believes the waiver will further the protection of investors and the public interest because it will provide greater transparency as to various ports available to market participants. The Exchange further states that the proposed rule change will bring greater clarity to the Schedule of Fees. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.13

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 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:

- 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–GEMX–2018–18 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–GEMX–2018–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2018–18 and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.14

Eduardo A. Alemán,
Assistant Secretary.

[FR Doc. 2018–12321 Filed 6–7–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Memorialize Order and Execution Information Into GEMX Rule 718

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on May 23, 2018, Nasdaq GEMX, LLC (“GEMX” 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. Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to memorialize its order and execution information into GEMX Rule 718, entitled “Data Feeds.”

The text of the proposed rule change is available on the Exchange’s website at http://nasdagemx.chewallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add order and execution information into GEMX

Rule 718, entitled “Data Feeds,” The Exchange proposes to rename this rule “Data Feeds and Trade Information.” The Exchange also proposes to amend Rule 100 to add definitions.

GEMX Rule 718(a)

The Exchange proposes to amend the Nasdaq GEMX Top Quote Feed. The Exchange stated in that description that this feed calculates and disseminates GEMX’s best bid and offer position, with aggregated size (including total size in aggregate, for Public Customer 3 size in the aggregate and Priority Customer 5 size in the aggregate), based on displayable order and quote interest in the System. The Exchange proposes to amend this rule text to instead provide, “this feed calculates and disseminates GEMX’s best bid and offer position, with aggregated size (including total size in aggregate, for Professional Order size in the aggregate and Priority Customer Order size in the aggregate), based on displayable order and quote interest in the System.” The Exchange intended to specify that Professional Orders and Priority Customer Orders are segregated and aggregated. The Public Customer definition is too broad because it includes a portion of Priority Customer, which was already specified within the description. The Exchange proposes to remove Public Customer and replace it with Professional Order to be more specific and amend Priority Customer to Priority Customer Order to reference the types of orders that are aggregated to conform the rule text.

GEMX Rule 718(b)

The Exchange proposes to add its order and execution information into GEMX Rule 718, entitled “Data Feeds.” The Exchange proposes to rename this rule “Data Feeds and Trade Information.” The Exchange also proposes to amend Rule 100 to add definitions.

The Exchange proposes to adopt a new GEMX Rule 718(b) and memorialize the following order and execution information which was discussed in other rule filings by the Exchange: (i) Clearing Trade Information or “CTI”; and (ii) FIX DROP. The Exchange is also adding a description for TradeInfo. The TradeInfo user interface is being offered today on GEMX at no cost.

The Exchange notes that while CTI and FIX Drop information are accessible through a port, TradeInfo is an interface. The Exchange notes this distinction to make clear the manner of delivery for each of these information types.

CTI

The Exchange stated in its Prior Filing that “CTI is a real-time clearing message that is sent to a Member after an execution has occurred and contains trade details. The message containing the trade details is also simultaneously sent to The Options Clearing Corporation. The information includes, among other things, the following: (i) The Clearing Member Trade Agreement or “CMTA” or The Options Clearing Corporation or “OCC” number; (ii) Exchange badge or house number; (iii) the Exchange internal firm identifier; and (iv) an indicator which will distinguish electronic and non-electronically delivered orders; (v) liquidity indicators and transaction type for billing purposes; (vi) capacity.”

The Exchange is proposing to amend the CTI description and memorialize it within GEMX Rule 718(b)(1). The Exchange proposes to eliminate the sentence which states, “The message containing the trade details is also simultaneously sent to The Options Clearing Corporation.” The Exchange’s System sends clearing information to OCC for each transaction. This sentence does not add information that is useful or relevant and therefore the Exchange proposes to remove it. The Exchange also proposes to delete the words “an indicator which will distinguish electronic and non-electronically delivered orders.” The only method on GEMX to deliver an order is electronically.

The Exchange is also adopting definitions for “account number,” “badge,” “and” and “mnemonic” to be utilized within the CTI definition and uniformly throughout the Rulebook. The Exchange proposes to renumber Rule 100 to accommodate the new definitions. The Exchange is reserving 2 numbers for future use of other definitions. The Exchange proposes to replace the phrase in Rule 718(b)(1) subsection (ii) from previously filed Exchange badge or house number to proposed definition for badge or mnemonic. The Exchange proposes to replace the phrase in Rule 718(b)(1) subsection (iii) from Exchange internal firm identifier to proposed definition for account number. The Exchange proposes to expand on Rule 718(b)(1) subsection (iv) by replacing the phrase “an indicator which will distinguish electronic and non-electronically delivered orders” with “information which identifies the transaction type (e.g. auction type) for billing purposes.”

Finally, the Exchange Further, the Exchange is adding an “and” before “(v) capacity” and changing the wording to “market participant capacity.” The Exchange has renumbered the CTI sections to account for the language that was removed from the description. Finally, the Exchange is adding an “and” before Rule 718(b)(1) subsection (v) “capacity” and changing the wording to “market participant capacity.” The Exchange is expressing more specifically the type of data contained in CTI.

FIX DROP

The Exchange stated in its Prior Filing that “FIX DROP provides real-time order and execution update is a message that is sent to a Member after an order has been received/modifed or an execution has occurred and contains trade details. The information includes, among other things, the following: (1) Executions; (2) cancellations; (3) modifications to an existing order; and (4) busts or post-trade corrections.”

The Exchange proposes to memorialize FIX DROP within GEMX Rule 718(b)(3). The Exchange notes that at the end of the first sentence of the description it is adding “specific to that Member” to make clear that FIX DROP only provides a Member its specific trade information. Also, an “and” is included before new (iv) as the numbers have been changed to roman numerals.

TradeInfo

The Exchange proposes to establish its TradeInfo offering at GEMX Rule 718(b)(2). TradeInfo, a user interface, permits a Member to: (i) Search all orders submitted in a particular security

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3 The term “Public Customer” means a person or entity that is not a broker or dealer in securities. See Rule 100(a)(44).

4 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 account(s). See 100(a)(41A). The term “Priority Customer Order” means an order for the account of a Priority Customer. See Rule 100(a)(43A).

5 The term “Professional Order” means an order that is for the account of a person or entity that is not a Priority Customer. See Rule 100(a)(43C).


7 Id.

8 An “account number” shall mean a number assigned to a Member. Members may have more than one account number. See proposed Rule 100(a)(4).

9 A “badge” shall mean an account number with a letter suffix assigned to Market Makers. A Market Maker account may be associated with multiple badges. See proposed Rule 100(a)(5).

10 A “mnemonic” shall mean an acronym comprised of letters and/or numbers assigned to Electronic Access Members. An Electronic Access Member account may be associated with multiple mnemonics. See proposed Rule 100(a)(34).

11 Id.
or all orders of a particular type, regardless of their status (open, canceled, executed, etc.); (ii) view orders and executions; and (iii) download orders and executions for recordkeeping purposes. TradInfo users may also cancel open orders at the order, port or firm mnemonic level through TradInfo. TradInfo is offered today to Members on GEMX at no cost.

The Exchange considers it appropriate to establish and memorialize the order and execution information available on GEMX within a rule so that Members may understand the trade information which is available on the Exchange as it pertains to a firm’s trading information. This data is available to all Members and is specific to a Member’s transactions on GEMX.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”), 12 in general, and further the objectives of Section 6(b)(5) of the Act, 13 in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest, by providing greater transparency as to the order and execution information offered on GEMX. Each proposal is described in more detail below.

GEMX Rule 718(b)

The Exchange believes that memorializing CTI and FIX DROP within a rule will provide Members with transparency as to the order and information offerings available on GEMX specific to their trading on GEMX. The Exchange’s proposal to establish TradInfo is consistent with the Act because the Exchange is detailing the contents of this offering as well as providing transparency as to the availability of TradInfo. The Exchange believes that offering Members TradInfo, which allows Members to view executions as well as other capabilities with respect to order management, enhances the ability of a Member to manage its orders. The Exchange believes that providing Members with tools to manage orders is consistent with the Act and serves to protect investors and the public interest.

Further, the Exchange believes that this proposal is consistent with the Act because TradInfo provides information regarding information available to market participants, specifically with respect to trades they execute on GEMX. The information is available to all Members.

B. Self-Regulatory Organization’s Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, 14 the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange’s proposal does not impose an undue burden on competition, rather the Exchange is seeking to provide greater transparency within its rules with respect to the Nasdaq GEMX Top Quote Feed as well as order and execution information offered on GEMX. The information is available to all Members. Specifically, TradInfo is available to any Member that requests this service. The TradInfo product will provide a Member information regarding that Member’s executions.

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

16 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.
19 For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on 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)(ii) of the Act 15 and subparagraph (f)(6) of Rule 19b–4 thereunder. 16

A proposed rule change filed under Rule 19b–4(f)(6) 17 normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) 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 proposed rule change may become effective and operative immediately upon filing. The Exchange states that waiver of the operative delay will allow the Exchange to correct the Nasdaq GEMX Top Quote Feed and update its rules immediately regarding order and execution information offered on GEMX. The Exchange further states that it believes the waiver will further the protection of investors and the public interest because it will provide greater transparency as to the Nasdaq GEMX Top Quote Feed as well as trade detail available to market participants. Further, the Exchange states that memorializing TradInfo will provide Members with greater information concerning a Member’s executions on GEMX and make its availability transparent. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing. 19

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
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–GEMX–2018–17 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–GEMX–2018–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2018–17 and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.23

Eduardo A. Aleman,
Assistant Secretary.

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Amendments to the ICE Clear Europe Delivery Procedures

June 4, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),1 and Rule 19b–4 thereunder,2 notice is hereby given that on May 29, 2018, ICE Clear Europe Limited ("ICE Clear Europe" or the "Clearing House")3 filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in Items I, II, and III. This notice initiates proceedings pursuant to Section 19(b)(2) of the Act,4 and Section 19(b)(3)(F) of the Act.5

A. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

ICE Clear Europe is amending its Delivery Procedures to make certain modifications and clarifications to the delivery terms relating to the IFEU Robusta Coffee Futures Contract. The amendments also remove outdated references, correct typographical errors, insert references to current ICE systems and align naming conventions used throughout the Delivery Procedures. The changes are intended to be consistent with changes made to the IFEU contract specifications for the Robusta Coffee Futures Contract. In particular, the amendments to the Delivery Procedures will shorten the delivery period from the delivery notice to the final settlement day from 14 calendar days to 4 calendar days to reflect suggestions from market participants that the current period was unnecessarily long. A shorter period also more closely aligns with other similar futures contracts, including the ICE Futures US Coffee Futures Contract.

As a result of this change, the amendments also remove the existing “Early Take Up” concept as this is no longer necessary given the shorter settlement period.

The changes also remove the Delivery Documentation Summary section, because this simply repeats what is set out in the Delivery Procedures above and is therefore, unnecessary.

B. Statutory Basis

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments shorten the delivery period for the Robusta Coffee Futures Contracts, and make certain related


4 Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Delivery Procedures.
improvements to the delivery process, consistent with market feedback, recent changes to relevant IFEU rules and other similar futures contracts, such as the ICE Futures US Coffee Futures Contract. The changes thus facilitate prompt and accurate clearance and settlement of the Robusta Coffee Futures Contracts.

In addition, Rule 17Ad–22(o)(10) requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to establish and maintain written standards that state its obligations with respect to the delivery of physical instruments. As discussed above, ICE Clear Europe is updating its Delivery Procedures to reflect the shortened delivery period, to remove the “Early Take Up” concept which is no longer necessary in light of that shorter period, and to make certain other clarifications and updates, consistent with the delivery terms set out in the IFEU contract specifications.

(B) Clearing Agency’s Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to update the Delivery Procedures for the IFEU Robusta Coffee Futures Contract specifications, as discussed above. ICE Clear Europe does not believe the amendments would adversely affect Clearing Members, materially affect the cost of clearing, adversely affect access to clearing in Robusta Coffee Futures Contract for Clearing Members or their customers, or otherwise adversely affect competition in clearing services. Accordingly, ICE Clear Europe does not believe that the amendments would impose any impact or burden on competition that is not appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed amendments.

III. Date of Effectiveness of the Proposed Rule Change, Security-Based Swap Submission and Advance Notice and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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)
- Send an email to rule-comments@sec.gov. Please include File Number SR–ICEEU–2018–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2018–008 and should be submitted on or before June 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 

Eduardo A. Aleman, 
Assistant Secretary.

[FR Doc. 2018–12323 Filed 6–7–18; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0025]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions, and extensions, of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency’s burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: OIRA_Submission@omb.eop.gov

17 CFR 240.17A–22(e)(10).
consider your comments, we must receive them no later than August 7, 2018. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Fee Agreement for Representation before the Social Security Administration—0960—NEW. Under the Social Security Act (Act), SSA requires individuals who represent a claimant before the agency and want to receive a fee for their services to obtain SSA’s authorization of the fee. One way to obtain the authorization is to submit the fee agreement. To facilitate this process, individuals can use Form SSA–1693. SSA uses the information from the SSA–1693 to review the request and authorize any fee to representatives who seek to charge and collect a fee from a claimant. The respondents are the representatives who help claimants through the application process.

Note: SSA originally published this Notice on November 22, 2017, at 82 FR 55707, and received several public comments. In response to those public comments, SSA revised the SSA–1693, and is republishing this Notice.

Type of Request: Request for a new information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden of response (minutes)</th>
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<td>1</td>
<td>12</td>
<td>120,000</td>
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2. State Supplementation Provisions: Agreement; Payments—20 CFR 416.2095–416.2098, and 20 CFR 416.2099—0960–0240. Section 1618 of the Act requires those states administering their own supplementary income payment program(s) to demonstrate compliance with the Act by passing Federal cost-of-living increases on to individuals who are eligible for state supplementary payments, and informing SSA of their compliance. In general, states report their supplementary payment information annually by the maintenance-of-payment levels method. However, SSA may ask them to report up to four times in a year by the total-expenditures method. Regardless of the method, the states confirm their compliance with the requirements, and provide any changes to their optional supplementary payment rates. SSA uses the information to determine each state’s compliance or noncompliance with the pass-along requirements of the Act to determine eligibility for Medicaid reimbursement. If a state fails to keep payments at the required level, it becomes ineligible for Medicaid reimbursement under Title XIX of the Act. Respondents are state agencies administering supplemental programs.

Type of Request: Extension of an OMB-approved information collection.

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<thead>
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<th>Modality of completion</th>
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3. Substitution of Party Upon Death of Claimant—20 CFR 404.957(c)(4) and 416.1457(c)(4)—0960–0288. An administrative law judge (ALJ) may dismiss a request for a hearing on a pending claim of a deceased individual for Social Security benefits or Supplemental Security Income (SSI) payments. Individuals who believe the dismissal may adversely affect their notice may complete Form HA–539, which allows them to request to become a substitute party for the deceased claimant. The ALJs and the hearing office support staff use the information from the HA–539 to: (1) Maintain a written record of request; (2) establish the relationship of the requester to the deceased claimant; (3) determine the substituted individual’s wishes regarding an oral hearing or decision on the record; and (4) admit the data into the claimant’s official record as an exhibit. The respondents are individuals requesting to be substitute parties for a deceased claimant.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
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4. Claimant Statement about Loan of Food or Shelter; Statement about Food or Shelter Provided to Another—20 CFR 416.1130–416.1148—0960–0529. SSA bases an SSI claimant or recipient’s eligibility on need, as measured by the
amount of income an individual receives. Per our calculations, income includes other people providing in-kind support and maintenance in the form of food and shelter to SSI applicants or recipients. SSA uses Forms SSA–5062 and SSA–L5063 to obtain statements about food or shelter provided to SSI claimants or recipients. SSA uses this information to determine whether food or shelters are bona fide loans or income for SSI purposes. This determination may affect claimants’ or recipients’ eligibility for SSI as well as the amounts of their SSI payments. The respondents are claimants and recipients for SSI payments, and individuals who provide loans of food or shelter to them.

**Type of Request:** Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
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<td>SSA–L5063</td>
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<td>20,420</td>
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</table>

5. **Testimony by Employees and the Production of Records and Information in Legal Proceedings—20 CFR 403.100–403.155.** Regulations at 20 CFR 403.100–403.155 of the Code of Federal Regulations establish SSA’s policies and procedures for an individual; organization; or government entity to request official agency information, records, or testimony of an agency employee in a legal proceeding when the agency is not a party. The request, which respondents submit in writing to SSA, must: (1) Fully set out the nature and relevance of the sought testimony; (2) explain why the information is not available by other means; (3) explain why it is in SSA’s interest to provide the testimony; and (4) provide the date, time, and place for the testimony. Respondents are individuals or entities who request testimony from SSA employees in connection with a legal proceeding.

**Type of Request:** Extension of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
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<tbody>
<tr>
<td>20 CFR 403.100–403.155</td>
<td>100</td>
<td>1</td>
<td>60</td>
<td>100</td>
</tr>
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</table>

6. **Function Report Adult-Third Party—20 CFR 404.1512 & 416.912–0960–0635.** Individuals receiving or applying for Social Security Disability Insurance (SSDI) or SSI provide SSA with medical evidence and other proof SSA requires to prove their disability. SSA, and Disability Determination Services (DDS) on our behalf, collect this information using Form SSA–3380–BK. We use the information to document how claimant’s disabilities affect their ability to function, and to determine eligibility for SSI and SSDI claims. The respondents are third parties familiar with the functional limitations (or lack thereof) of claimants who apply for SSI and SSDI benefits.

**Type of Request:** Revision of an OMB-approved information collection.

<table>
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<tr>
<th>Modality of completion</th>
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<td>61</td>
<td>721,528</td>
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7. **Request for Deceased Individual’s Social Security Record—20 CFR 402.130–0960–0665.** When a member of the public requests an individual’s Social Security record, SSA needs the name and address of the requestor as well as a description of the requested record to process the request. SSA uses the information the respondent provides on Form SSA–711, or via an internet request through SSA’s electronic Freedom of Information Act (eFOIA) website to: (1) Verify the wage earner is deceased; and (2) access the correct Social Security record. Respondents are members of the public requesting deceased individuals’ Social Security records.

**Type of Request:** Revision of an OMB-approved information collection.
contracts to implement, acquire, or insurance issuers with government health care providers or health Public Health Service Act requires agencies. Similarly, section 3004 of the context of working with government technology (IT), particularly in the meaningful use of health information Economic and Clinical Health (HITECH) Act promotes the adoption and 404.1614 and 416.1014—0960–0798.

Verification of Prisoner Identity Statements ........................ 1,000 200 200,000 3 10,000

9. Notification of a Social Security Number (SSN) To An Employer for Wage Reporting—20 CFR 422.103(a)—0960–0778. Individuals applying for employment must provide a Social Security Number, or indicate they have applied for one. However, when an individual applies for an initial SSN, there is a delay between the assignment of the number and the delivery of the SSN card. At an individual’s request, SSA uses Form SSA–132 to send the individual’s SSN to an employer. Mailing this information to the employer: (1) Ensures the employer has the correct SSN for the individual; (2) allows SSA to receive correct earnings information for wage reporting purposes; and (3) reduces the delay in the initial SSN assignment and delivery of the SSN information directly to the employer. It also enables SSA to verify the employer as a safeguard for the applicant’s personally identifiable information. The majority of individuals who take advantage of this option are in the United States with exchange visitor and student visas; however, we allow any applicant for an SSN to use the SSA–132. The respondents are individuals applying for an initial SSN who ask SSA to mail confirmation of their application or the SSN to their employers.

Type of Request: Revision of an OMB-approved information collection.

SSA–132 .......................................................................................................... 326,000 1 2 10,867

10. Social Security Administration Health IT Partner Program Assessment—Participating Facilities and Available Content Form—20 CFR 404.1614 and 416.1014—0960–0798. The Health Information Technology for Economic and Clinical Health (HITECH) Act promotes the adoption and meaningful use of health information technology (IT), particularly in the context of working with government agencies. Similarly, section 3004 of the Public Health Service Act requires health care providers or health insurance issuers with government contracts to implement, acquire, or upgrade their health IT systems and products to meet adopted standards and implementation specifications. To support expansion of SSA’s health IT initiative as defined under HITECH, SSA developed Form SSA–680, the Health IT Partner Program Assessment—participating Facilities and Available Content Form. The SSA–680 allows healthcare providers to provide the information SSA needs to determine their ability to exchange health information with us electronically. We evaluate potential partners (i.e., healthcare providers and organizations) on: (1) The accessibility of health information they possess; and (2) the content value of their electronic health records’ systems for our disability adjudication processes. SSA reviews the completeness of organizations’ SSA–680 responses as one part of our careful analysis of their readiness to enter into a health IT partnership with us. The respondents are healthcare providers and organizations exchanging information with the agency.

Type of Request: Extension of an OMB-approved information collection.
II. SSA submitted the information collection below to OMB for clearance. Your comments regarding this information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than July 9, 2018. Individuals can obtain copies of the OMB clearance packages by writing to OR.Reports.Clearance@ssa.gov.

Statement of Reclamation Action—31 CFR 210—0960–0734. Regulations governing the Federal Government Participation in the Automated Clearing House: (1) Allow SSA to send Social Security payments to Canada; and (2) mandate the reclamation of funds paid erroneously to a Canadian bank, or financial institution, after the death of a Social Security beneficiary. SSA uses Form SSA–1713, Notice of Reclamation Action, to determine if, how, and when the Canadian bank or financial institution is going to return erroneous payments after the death of a Social Security beneficiary who elected to have payments sent to Canada. Form SSA–1712 (or SSA–1712 CN), Notice of Reclamation—Canada Payment Made in the United States, is the cover sheet SSA prepares to request return of the payment. The respondents are Canadian banks and financial institutions who erroneously received Social Security payments.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
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<td>SSA–680</td>
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Dated: June 4, 2018.

Faye Lipsky,
Reports Clearance Director, Social Security Administration.

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0024]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions, and one extension, of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency’s burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

OMB, Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: OIRA_Submission@omb.eop.gov.

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: OR.Reports.Clearance@ssa.gov.

Or you may submit your comments online through www.regulations.gov, referencing Docket ID Number [SSA–2018–0024].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than August 7, 2018. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Employment Relationship Questionnaire—20 CFR 404.1007—0960–0040. When SSA needs information to determine a worker’s employment status for the purpose of maintaining a worker’s earning records, the agency uses Form SSA–7160–F4 to determine the existence of an employer-employee relationship. We use the information to develop the employment relationship; specifically, to determine whether a beneficiary is self-employed or an employee. The respondents are individuals seeking to establish their status as employees, and their alleged employers.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
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<td>SSA–7160–F4—State/Local Government</td>
<td>800</td>
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2. Application for Circuit Court Law—20 CFR 404.985 & 416.1458—0960–0581. Persons claiming an acquiescence ruling (AR) would change SSA’s prior determination or decision must submit a written readjudication request with specific information. SSA reviews the information in the requests to determine if the issues stated in the AR pertain to the claimant’s case, and if the claimant is entitled to readjudication. If readjudication is appropriate, SSA considers the issues the AR covers. Any new determination or decision is subject to administrative or judicial review as specified in the regulations, and the respondents are self-employed individuals potentially eligible for Social Security benefits.

Type of Request: Revision of an OMB-approved information collection.

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<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Request for Withdrawal of Application—20 CFR 404.640—0960–0015. Form SSA–521 documents the information SSA needs to process the withdrawal of an application for benefits. A paper SSA–521 is our preferred instrument for executing a withdrawal request; however, any written request for withdrawal signed by the claimant or a proper applicant on the claimant’s behalf will suffice. Individuals who wish to withdraw their applications for benefits complete Form SSA–521, or sign the completed form for each request to withdraw. SSA uses the information from the SSA–521 to process the request for withdrawal. The respondents are applicants for, and recipients of, Social Security Old Age, Survivors, and Disability Insurance (OASDI).</td>
<td></td>
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| SSA–521 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4. Request for Workers’ Compensation/Public Disability Benefit Information—20 CFR 404.408(c)—0960–0090. Claimants for Social Security disability payments who are also receiving Worker’s Compensation/Public Disability Benefits (WC/PDB) must notify SSA about their WC/PDB, so the agency can reduce claimants’ Social Security disability payments accordingly. If claimants provide necessary evidence, such as a copy of their award notice, benefit check, etc., that is sufficient verification. In cases where claimants cannot provide such evidence, SSA uses Form SSA–1709. The entity paying the WC/PDB benefits, its agent (such as an insurance carrier), or an administering public agency complete this form. The respondents are Federal, State, and local agencies, insurance carriers, and public or private self-insured companies administering WC/PDB benefits to disability claimants.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
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<tbody>
<tr>
<td>SSA–766</td>
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5. Third Party Liability Information Statement—42 CFR 433.136–433.139—0960–0323. To reduce Medicaid costs, Medicaid state agencies identify third party insurers liable for medical care or services for Medicaid beneficiaries. Regulations at 2 CFR 433.136–433.139 require Medicaid state agencies to obtain this information on Medicaid applications and redeterminations as a condition of Medicaid eligibility. States may enter into agreements with the Commissioner of Social Security to make Medicaid eligibility determinations for aged, blind, and disabled beneficiaries in those states. Applications for and redeterminations ofSSI eligibility in jurisdictions with such agreements are applications and redeterminations of Medicaid eligibility. Under these agreements, SSA obtains third party liability information using Form SSA–8019–U2, and provides that information to the Medicaid state agencies. The Medicaid state agencies use the information to bill third parties liable for medical care, support, or services for a beneficiary to guarantee that Medicaid remains the payer of last resort. The respondents are SSI claimants and recipients.

Type of Request: Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
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<tr>
<td>SSA–1709</td>
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6. Permanent Residence in the United States Under Color of Law (PRUCOL)—20 CFR 416.1615 and 416.1618—0960–0451. As per 20 CFR 416.1415 and 416.1618 of the Code of Federal Regulations, SSA requires claimants or recipients to submit evidence of their alien status when they apply for SSI payments, and periodically thereafter as part of the eligibility determination process for SSI. When SSA cannot verify evidence of alien status through the regular claimant interview process, SSA verifies the validity of the evidence of PRUCOL for grandfathered nonqualified aliens with the Department of Homeland Security (DHS), and determines if the individual qualifies for PRUCOL status based on the DHS response. SSA does not maintain any forms or applications for respondents to use, rather, the regulations listed in 20 CFR 416.1615 and 416.1618 specify the information respondents need to submit to SSA to show evidence of PRUCOL. Without this information, SSA is unable to determine whether the PRUCOL individual is eligible for SSI payments. Respondents are qualified and unqualified aliens who apply for SSI payments under PRUCOL.

Type of Request: Extension of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
</tr>
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</table>
7. Authorization for the Social Security Administration to Obtain Account Records from a Financial Institution and Request for Records (Medicare)—20 CFR 418.3420–0960–0729. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D program for voluntary prescription drug coverage of premium, deductible, and copayment costs for individuals with limited income and resources. The MMA mandates that the Government provide subsidies for those individuals who qualify for the program, and who meet eligibility criteria for help with premium, deductible, or co-payment costs. SSA uses the SSA–4640, Authorization for the Social Security Administration to Obtain Account Records from a Financial Institution and Request for Records (Medicare), to determine if subsidy applicants or recipients qualify, or continue to qualify, for the subsidy. SSA uses Form SSA–4640 to: (1) Obtain the individual’s consent to verify balances of financial institution (FI) accounts; and (2) obtain verification of such balances from the FI. Respondents are Medicare Part D program subsidy applicants or claimants, and their financial institutions.

**Type of Request:** Revision of an OMB-approved information collection.

<table>
<thead>
<tr>
<th>Modality of completion</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average burden per response (minutes)</th>
<th>Estimated total annual burden (hours)</th>
</tr>
</thead>
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<tr>
<td>SSA–4640—Medicare Part D Subsidy Applicants</td>
<td>5,000</td>
<td>1</td>
<td>1</td>
<td>83</td>
</tr>
<tr>
<td>SSA–4640—Financial Institutions</td>
<td>5,000</td>
<td>1</td>
<td>4</td>
<td>333</td>
</tr>
<tr>
<td>Total</td>
<td>10,000</td>
<td></td>
<td></td>
<td>416</td>
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</tbody>
</table>

Dated: June 4, 2018.

Faye Lipsy, Reports Clearance Director, Social Security Administration.

[FR Doc. 2018–12314 Filed 6–7–18; 8:45 am]

BILLING CODE 4191–02–P

**SOCIAL SECURITY ADMINISTRATION**

[Docket No. SSA 2017–0059]

**Privacy Act of 1974; Matching Program**

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new matching program with the Railroad Retirement Board (RRB). This matching agreement sets forth the terms, safeguards, and procedures under which RRB, as the source agency, will disclose RRB annuity payment data to SSA, the recipient agency. SSA will use the information to verify Supplemental Security Income (SSI) and Special Veterans Benefits (SVB) eligibility and benefit payment amounts. SSA will also record the railroad annuity amounts RRB paid to SSI and SVB recipients in the Supplemental Security Income Record (SSR).

**DATES:** The deadline to submit comments on the proposed matching program is 30 days from the date of publication in the Federal Register. The matching program will be applicable on September 2, 2018 and will expire on March 1, 2020, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will be in effect for a period of 18 months.

**ADDRESSES:** Interested parties may comment on this notice by either telefaxing to (410) 966–0869, writing to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, G–401 WHR Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, or email at Mary.Ann.Zimmerman@ssa.gov. All comments received will be available for public inspection by contacting Ms. Zimmerman at this street address.

**FOR FURTHER INFORMATION CONTACT:** Interested parties may submit general questions about the matching program to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, by any of the means shown above.

Mary Ann Zimmerman,
Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.

**Participating Agencies:** SSA and RRB.

**Authority for Conducting the Matching Program:** The legal authority for this agreement is executed in compliance with the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988, the regulations and guidance promulgated thereunder. Legal authority for the disclosure under this agreement for the SSI portion are 1631(i)(1)(A) and (B) and 1631(f) of the Social Security Act (Act) (42 U.S.C. 1383(e)(1)(A) and (B) and 1383(f)). The legal authority for the disclosure under this agreement for the SVB portion is 806(b) of the Act (42 U.S.C. 1006(b)).

**Purpose(s):** The purpose of this matching program is to set forth the terms, safeguards, and procedures under which RRB, as the source agency, will disclose RRB annuity payment data to SSA, the recipient agency. SSA will use the information to verify SSI and SVB eligibility and benefit payment amounts. SSA will also record the railroad annuity amounts RRB paid to SSI and SVB recipients in the SSR.

**Categories of Individuals:** The individuals whose information is involved in this matching program are applicants for and recipients of SSI payments and SVB benefits.

**Categories of Records:** SSA will match the Social Security number, name, date of birth, and RRB claim number on the RRB file and the SSR.

**System(s) of Records:** RRB will provide SSA with an electronic data file containing annuity payment data from RRB’s system of records. RRB—22 Railroad Retirement, Survivor, and Pensioner Benefits System, last published on May 15, 2015 (80 FR 28018). SSA will match RRB’s data with data maintained in the SSR, Supplemental Security Income Record and Special Veterans Benefits, SSA/OITPBS, 60–0103, published on January 11, 2006 (71 FR 1830) and December 10, 2007 (72 FR 69723). SVB data also resides on the SSR.

[FR Doc. 2018–12314 Filed 6–7–18; 8:45 am]
DEPARTMENT OF STATE

[Public Notice 10429]

60-Day Notice of Proposed Information Collection: JADE Act Questionnaire

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to August 7, 2018.

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

Web: Persons with access to the internet may comment on this notice by going to www.Regulations.gov. You can search for the document by entering “Docket Number: DOS–2018–0018” in the Search field. Then click the “Comment Now” button and complete the comment form.

Email: PRA_BurdenComments@state.gov.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

SUPPLEMENTARY INFORMATION:

Title of Information Collection: JADE Act Questionnaire.

OMB Control Number: None.

Type of Request: New Collection.

Originating Office: CA/VO/L/R.

Form Number: DS–5537.

Respondents: Burmese applicants for U.S. visas.

Estimated Number of Respondents: 20,500.

Estimated Number of Responses: 20,500.

Average Time per Response: 30 minutes.

Total Estimated Burden Time: 10,250 hours.

Frequency: Once per visa application.

Obligation to Respond: Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

Enhance the quality, utility, and clarity of the information to be collected.

Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Tom Lantos Block Burmese Jade Junta’s Anti-Democratic Efforts (JADE) Act of 2008, Public Law 110–286, renders certain individuals involved in specified Burmese organizations or activities ineligible for U.S. visas, including: leaders of the State Peace and Development Council (SPDC), the Burmese military, or the Union Solidarity Development Association (USDA); officials of the SPDC, the Burmese military, or the USDA involved in human rights violations and impeding democracy in Burma; and Burmese persons who provided substantial economic or political support to the SPDC, Burmese military, or USDA. Immediate family members of these individuals are also ineligible for United States visas. Department of State consular officers will use the information provided to evaluate and adjudicate the individual applicant’s eligibility for a visa consistent with these requirements.

Methodology

Visa applicants from Burma will fill out and submit the supplemental form and provide it to consular officers. Consular officers will use the form to screen for potential visa ineligibility under the JADE Act.

Edward J Ramotowski,
Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 682 (Sub-No. 9)]

2017 Tax Information for Use in the Revenue Shortfall Allocation Method

AGENCY: Surface Transportation Board.

ACTION: Notice.

SUMMARY: The Board is publishing, and providing the public an opportunity to comment on, the 2017 weighted average state tax rates for each Class I railroad, as calculated by the Association of American Railroads (AAR), for use in the Revenue Shortfall Allocation Method (RSAM).

DATES: Comments are due by July 9, 2018. If any comment opposing AAR’s calculation is filed, AAR’s reply will be due by July 30, 2018. If no comments are filed by the due date, AAR’s calculation of the 2017 weighted average state tax rates will be automatically adopted by the Board, effective July 10, 2018.

ADDRESSES: Comments may be submitted either via the Board’s e-filing format or in traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-FILING link on the Board’s website at http://www.stb.gov. Any person submitting a filing in the traditional paper format should send an original and 10 copies referring to Docket No. EP 682 (Sub-No. 9) to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Sarah Fancher, (202) 245–0355. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The RSAM figure is one of three benchmarks that together are used to determine the reasonableness of a challenged rate under the Board’s Simplified Standards for Rail Rate Cases, EP 646 (Sub-No. 1), slip op. at 10 (STB served Sept. 5, 2007),1 as further revised in Simplified Standards for Rail Rate Cases—Taxes in Revenue Shortfall Allocation Method, EP 646 (Sub-No. 2) (STB served Nov. 21, 2008). RSAM is intended to measure the average markup that the railroad would need to collect from all of its “potentially captive traffic” (traffic with a revenue-to-variable-cost ratio above 180%) to earn adequate revenues as measured by the Board under the Adult.

1 Aff’d sub nom. CSX Transp., Inc. v. STB, 568 F.3d 236 (D.C. Cir. 2009).
mistakenly compared pre-tax and after-tax revenues. In that decision, the Board stated that it would institute a separate proceeding in which Class I railroads would be required to submit the annual tax information necessary for the Board’s annual RSAM calculation. Id. at 5–6.

In Annual Submission of Tax Information for Use in the Revenue Shortfall Allocation Method, EP 682 (STB served Feb. 26, 2010), the Board adopted rules to require AAR—a national trade association—to annually calculate and submit to the Board the weighted average state tax rate for each Class I railroad. See 49 CFR 1135.2(a).

On May 29, 2018, AAR filed its calculation of the weighted average state tax rates for 2017, listed below for each Class I railroad:

<table>
<thead>
<tr>
<th>Railroad</th>
<th>2017 (%)</th>
<th>2016 (%)</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNSF Railway Company</td>
<td>5.289</td>
<td>5.288</td>
<td>0.001</td>
</tr>
<tr>
<td>CSX Transportation, Inc</td>
<td>5.628</td>
<td>5.160</td>
<td>0.468</td>
</tr>
<tr>
<td>Grand Trunk Corporation</td>
<td>7.961</td>
<td>7.761</td>
<td>0.200</td>
</tr>
<tr>
<td>The Kansas City Southern Railway</td>
<td>5.409</td>
<td>5.447</td>
<td>-0.038</td>
</tr>
<tr>
<td>Norfolk Southern Combined</td>
<td>6.194</td>
<td>5.410</td>
<td>0.784</td>
</tr>
<tr>
<td>Soo Line Corporation</td>
<td>8.134</td>
<td>8.071</td>
<td>0.063</td>
</tr>
<tr>
<td>Union Pacific Railroad Company</td>
<td>5.666</td>
<td>5.636</td>
<td>0.030</td>
</tr>
</tbody>
</table>

Any party wishing to comment on AAR’s calculation of the 2017 weighted average state tax rates should file a comment by July 9, 2018. See 49 CFR 1135.2(c). If any comments opposing AAR’s calculations are filed, AAR’s reply will be due by July 30, 2018. Id. If any comments are filed, the Board will review AAR’s submission, together with the comments, and serve a decision within 60 days of the close of the record that either accepts, rejects, or modifies AAR’s railroad-specific tax information. Id. If no comments are filed by July 9, 2018, AAR’s submitted weighted average state tax rates will be automatically adopted by the Board, effective July 10, 2018. Id.

Decided: June 4, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Brendetta Jones, Clearance Clerk.

[FR Doc. 2018–12349 Filed 6–7–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Sterling Highway Milepost 45 to 60 Project in Alaska

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation of claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by FHWA that are final. The actions relate to the proposed Sterling Highway Milepost 45–60 Project in the Kenai Peninsula Borough in the State of Alaska. Those actions grant approvals for the project.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l). A claim seeking judicial review of FHWA actions on the highway project will be barred unless the claim is filed on or before November 5, 2018. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period applies.

FOR FURTHER INFORMATION CONTACT: John Lohrey, Planner, Federal Highway Administration, Alaska Division, 709 West 9th Street, Room 851, Juneau, AK 99802, telephone (907) 586–7418; email: John.Lohrey@dot.gov. The FHWA Alaska Division Office’s normal business hours are 8:00 a.m. to 5:00 p.m. (Alaska Time), Monday through Friday, except Federal holidays. You may also contact Kelly Summers, P.E., Project Manager, Alaska Department of Transportation and Public Facilities, Central Region, P.O. Box 196900, Anchorage, AK 99519–6900, telephone (907) 465–0542; email: Kelly.Summers@alaska.gov. The DOT&P Central Region’s normal business hours are 8:00 a.m. to 4:30 p.m. (Alaska Time), Monday through Friday, except State and Federal holidays.

SUPPLEMENTAL INFORMATION: Notice is hereby given that FHWA has taken final agency action subject to 23 U.S.C. 139(l) by issuing approvals for the Sterling Highway Milepost 45 to 60 Project in the State of Alaska, project number F–021–2(15)/53014. The selected route is the Juneau Creek Alternative. The route passes north of the existing alignment again for approximately two miles, will diverge and will result in a newly constructed highway for approximately 10 miles (with a new bridge over Juneau Creek Canyon), and will join and reconstruct the existing alignment for approximately 2.5 miles to an intersection with Skilak Loop Rd. near MP 58.

The actions by the Federal agencies, and the law under which such actions were taken, are described in the Final Environmental Impact Statement and Final Section 4(f) Evaluation (Final EIS) for the project, approved March 7, 2018, and in the FHWA Record of Decision (ROD) issued on May 31, 2018. The Final EIS and ROD approved by FHWA are available on the project website: http://sterlinghighway.net and may be viewed at the FHWA and DOT&P addresses provided above.

This Notice applies to all Federal Agency decisions as of the issuance date of this notice and to all laws under which such actions were taken, including but not limited to:


2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].

SUMMARY: FMCSA announces a meeting of its Medical Review Board (MRB) on Monday and Tuesday, June 25–26, 2018. DATES: The meeting will be held on Monday and Tuesday, June 25–26, 2018, from 9:15 a.m. to 4:30 p.m., Eastern Daylight Time (EDT). ADDRESSES: The meeting will be held at the FMCSA National Training Center, 1310 N Courthouse Road, Arlington, VA, 6th floor. Copies of the task statement and an agenda for the entire meeting will be made available in advance of the meeting at www.fmcsa.dot.gov/mrb.

FOR FURTHER INFORMATION CONTACT: Ms. Shannon L. Watson, Senior Advisor to the Associate Administrator for Policy, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

II. Agenda

The MRB is composed of five medical experts who each serve 2-year terms. Section 4116 of SAFETEA–LU requires the Secretary of Transportation, with the advice of the MRB and the chief medical examiner, to establish, review, and revise “medical standards for operators of commercial motor vehicles that will ensure that the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely.” The MRB operates in accordance with FACA under the terms of its charter, filed November 25, 2017.

II. Agenda

The MRB will finalize its Task 17–1 recommendations to the Agency that it began at its July 2017 meeting on the revision of the Agency’s handbook for medical examiners (ME) on the National Registry of Certified Medical Examiners (National Registry), for their use in evaluating interstate commercial motor vehicle (CMV) drivers for a medical qualification determination.

III. Meeting Participation

The meeting is open to the public for its entirety. Oral comments from the public will be heard during the meeting, at the discretion of the MRB Chairman. Members of the public may submit written comments on the topics to be considered during the meeting by Wednesday, June 13, to Federal Docket Management System (FDMC) Docket Number FMCSA–2008–0362 for the MRB using any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.
- Hand Delivery: U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC, between 9 a.m. and 5 p.m., ET. Monday through Friday, except Federal holidays.

Issued on: June 4, 2018.

Larry W. Minor, Associate Administrator for Policy.

[FR Doc. 2018–12354 Filed 6–7–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2007–28043]

Hours of Service (HOS) of Drivers; American Pyrotechnics Assn. (APA); Request To Add New Members to Current APA Exemption; Request for Comments

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: The American Pyrotechnics Association (APA) has requested an exemption for three member companies—Artisan Pyrotechnics Inc., Montana Display Fireworks, Inc., and ZY Pyrotechnics, LLC dba Skyshooter Displays, Inc.—from the prohibition on driving commercial motor vehicles (CMVs) after the 14th hour after the driver comes on duty. Fifty APA members currently hold such an exemption during the Independence Day period each year, terminating on July 8, 2020. If granted, this exemption would terminate at the same time as the other 50 exempted carriers. The APA maintains that the terms and conditions of the limited exemption would ensure a level of safety equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: Comments are due no later than July 9, 2018.

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–26367]

Medical Review Board (MRB) Meeting: Public Meeting

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of advisory committee meeting.
ADDRRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2007–28043 using any of the following methods:

• Federal eRulemaking Portal: www.regulations.gov. Follow the online instructions for submitting comments.
• Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
• Hand Delivery or Courier: West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
• Fax: 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4225. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2007–28043), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2007–28043” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, “FMCSA–2007–28043” in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button and choose the document listed to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31313(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the Federal Register (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by compliance with the current regulation (49 CFR 381.305). The decision of the Agency must be published in the Federal Register (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

APA Application for Exemption

The HOS rule in 49 CFR 395.3(a)(2) prohibits the driver of a property-carrying CMV from driving after the 14th hour after coming on duty following 10 consecutive hours off duty. In 2016, the APA, a trade association representing the domestic fireworks industry was granted exemptions for 51 member companies through the annual Independence Day periods ending on July 8, 2020 [81 FR 43701, July 5, 2016]. One of the 51 APA member companies, Island Fireworks, DOT #414583, no longer requires the exemption, leaving the total at 50. APA has requested an exemption for Artisan Pyrotechnics Inc., DOT #1898096, Montana Display Fireworks, Inc., DOT #1030231, and ZY Pyrotechnics, LLC dba Skyshooter Displays, Inc., DOT #2149202, which would increase the total to 53. The exemption for these APA carriers, if granted, would expire on July 8, 2020. Although this is less than the 5-year exemption period authorized by 49 U.S.C. 31315(b)(2), as amended by section 5208(a)(3) of the Fixing America’s Surface Transportation (FAST) Act (Pub. L. 114–94, 129 Stat. 1312, 1537, Dec. 4, 3015), FMCSA believes that the interests of the APA members and the Agency would best be served by harmonizing, as far as possible, the expiration dates of all such fireworks-related exemptions. Like the other 50 member companies, the three new member companies would be subject to all of the terms and conditions of the exemption.

The initial APA application for relief from the 14-hour rule was submitted in 2004. That application fully describes the nature of the pyrotechnic operations of CMV

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drivers during a typical Independence Day period.

As stated in the 2004 request, the
CMV drivers employed by APA member
companies are trained pyro-technicians
who hold commercial driver’s licenses
(CDLs) with hazardous materials (HM)
endorsements. They transport fireworks
and related equipment by CMVs on a
very demanding schedule during a brief
Independence Day period, often to
remote locations. After they arrive, the
drivers are responsible for set-up and
staging of the fireworks shows.

The APA states that it is seeking an
additional exemption for the three new
member companies because compliance
with the current 14-hour rule in 49 CFR
395.3(a)(2) would impose a substantial
economic hardship on numerous cities,
towns and municipalities, as well as its
member companies. To meet the
demand for fireworks without the
exemptions, APA states that its member
companies would be required to hire a
second driver for most trips. The APA
advises that the result would be a
substantial increase in the cost of the
fireworks shows—beyond the means of
many of its members’ customers—and
that many Americans would be denied
this important component of the
celebration of Independence Day.

Method To Ensure an Equivalent or
Greater Level of Safety

The APA believes that the exemption
would not adversely affect the safety of
the fireworks transportation provided by
this motor carrier. According to APA, its
member companies have operated under
this exemption for 11 previous
Independence Day periods without a
reported motor carrier safety incident.
Moreover, it asserts, without the extra
time provided by the exemption, safety
would decline because APA drivers
would be unable to return to their home
base after each show. They would be
forced to park the CMVs carrying HM
1.1G, 1.3G and 1.4G products in areas
less secure than the motor carrier’s
home base. As a condition of holding
the exemption, each motor carrier is
required to notify FMCSA within 5
business days of any accident (as
defined in 49 CFR 390.5) involving the
operation of any of its CMVs while under
this exemption. To date, FMCSA has
received no accident notifications, nor
is the Agency aware of any accidents
reportable under terms of the prior APA
exemptions.

In its exemption request, APA asserts
that the operational demands of this
unique industry minimize the risks of
CMV crashes. In the last few days before
July 4, these drivers transport fireworks
over relatively short routes from
distribution points to the site of the
fireworks display, and normally do so in
the early morning when traffic is light.
At the site, they spend considerable
time installing, wiring, and safety-
checking the fireworks displays,
followed by several hours off duty in the
late afternoon and early evening prior to
the event. During this time, the drivers
are able to rest and nap, thereby
reducing or eliminating the fatigue
accumulated during the day. Before
beginning another duty day, these
drivers must take 10 consecutive hours
off duty, the same as other CMV drivers.

Terms and Conditions of the Exemption

Period of the Exemption

The requested exemption from 49
CFR 395.3(a)(2) would be effective from
June 28 through July 8, at 11:59 p.m.
local time, each year through 2020.

Terms and Conditions of the Exemption

During the 2018 Independence Day
period, the exemption from 49 CFR
395.3(a)(2) would be limited to drivers
employed by the 50 motor carriers
already covered by the exemption, plus
(if approved) the three carriers now
seeking an exemption. Section
395.3(a)(2) prohibits a driver from
driving a CMV after the 14th hour after
coming on duty and does not permit off-
duty periods to extend the 14-hour
limit. Drivers covered by this exemption
would be able to exclude off-duty and
sleeper-berth time of any length from
the calculation of the 14-hour limit.
This exemption would be contingent on
each driver driving no more than 11
hours in the 14-hour period after
coming on duty, as extended by any off-
duty or sleeper-berth time in accordance
with this exception. The exemption
would be further contingent on each
driver having a full 10 consecutive
hours off duty following 14 hours on
duty prior to beginning a new driving
period. The carriers and drivers must
comply with all other requirements of
the Federal Motor Carrier Safety
Regulations (49 CFR parts 350–399) and
Hazardous Materials Regulations (49
CFR parts 105–180).

Preemption

In accordance with 49 U.S.C.
31315(d), as implemented by 49 CFR
391.600, during the period this
exemption is in effect, no State shall
enforce any law or regulation applicable
to interstate commerce that conflicts
with or is inconsistent with this
exemption with respect to a firm or
person operating under the exemption.
States may, but are not required to,
adopt the same exemption with respect
to operations in intrastate commerce.

FMCSA Notification

Exempt motor carriers would be
required to notify FMCSA within 5
business days of any accidents (as
defined by 49 CFR 390.5) involving the
operation of any of their CMVs while
under this exemption. The notification
must be by email to MCPPS@DOT.GOV
and include the following information:
a. Name of the Exemption: “APA”,
b. Date of the accident,
c. City or town, and State, in which
the accident occurred, or which is
closest to the scene of the accident,
d. Driver’s name and driver’s license
State, number, and class,
e. Co-Driver’s name and driver’s
license State, number, and class,
f. Vehicle company number and
power unit license plate State and
number,
g. Number of individuals suffering
physical injury,
h. Number of fatalities,
i. The police-reported cause of the
accident,
j. Whether the driver was cited for
violation of any traffic laws, or motor
carrier safety regulations, and
k. The total driving time and the total
on-duty time of the CMV driver at
the time of the accident.

In addition, if there are any injuries or
fatalities, the carrier must forward the
police accident report to MCPPS@DOT.GOV
as soon as available.

Termination

The FMCSA does not believe the
motor carriers and drivers covered by
this exemption, if granted, would
experience any deterioration of their
safety record.

However, should this occur, FMCSA
would take all steps necessary to protect
the public interest, including revocation
of the exemption. The FMCSA will
immediately revoke the exemption for
failure to comply with its terms and
conditions. Exempt motor carriers
and drivers would be subject to FMCSA
monitoring while operating under this
exemption.

Issued on: June 4, 2018.
Larry W. Minor,
Associate Administrator for Policy.
[FR Doc. 2018–12355 Filed 6–7–18; 8:45 am]
DEPARTMENT OF THE TREASURY
Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Bank Appeals Follow-Up Questionnaire

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

Currently, the OCC is soliciting comment concerning the renewal of an existing collection titled “Bank Appeals Follow-Up Questionnaire.” The OCC also is giving notice that it has submitted the collection to OMB for review.

DATES: You should submit written comments by July 9, 2018.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- Email: prainfo@occ.treas.gov.
- Fax: (571) 465–4326.

Instructions: You must include “OCC” as the agency name and “1557–0332” in your comment. In general, the OCC will publish your comment on www.reginfo.gov without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0332, U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503 or by email to oira_submission@omb.eop.gov.

You may review comments and other related materials that pertain to this information collection following the close of the 30-Day comment period for this notice by any of the following methods:

- Viewing Comments Electronically: Go to www.reginfo.gov. Click on the “Information Collection Review” tab. Underneath the “Currently under Review” section heading, from the dropdown menu, select “Department of Treasury” and then click “submit.” This information collection can be located by searching using OMB control number “1557–0332” or “Bank Appeals Follow-Up Questionnaire.” Upon finding the appropriate information collection, click on the related “ICR Reference Number.” On the next screen, select “View Supporting Statement and Other Documents” and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating www.reginfo.gov, please contact the Regulatory Information Service Center at (202) 482–7340.
- Viewing Comments Personally: You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: OCC Clearance Officer, (202) 649–5490, for persons who are deaf or hearing impaired, TTY, (202) 649–5597.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the following collection.

Title: Bank Appeals Follow-Up Questionnaire.

OMB Control No.: 1557–0332.

Description: The OCC’s Office of the Ombudsman (Ombudsman) is committed to assessing its efforts to provide a fair and expeditious appeals process to institutions under OCC supervision. To perform this assessment, it is necessary to obtain feedback from individual appellant institutions on the effectiveness of the Ombudsman’s efforts to provide a fair and expeditious appeals process and suggestions to enhance the bank appeals process.

For each appeal submitted, the Ombudsman uses the information gathered to assess the appeal’s consistency with OCC Bulletin 2013–15, “Bank Appeals Process,” dated June 7, 2013, and to enhance its bank appeals program.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 15.

Estimated Annual Burden: 2.5 hours.

Frequency of Response: On occasion.

The OCC issued a notice for 60 days of comment on February 26, 2018, 83 FR 8316. No comments were received.

Comments continue to be on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information shall have practical utility;

(b) The accuracy of the OCC’s estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 4, 2018.

Karen Solomon,
Acting Senior Deputy Comptroller and Chief Counsel.

[FR Doc. 2018–12347 Filed 6–7–18; 8:45 am]
BILLING CODE 4810–33–P
DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Guidance regarding Charitable Remainder Trusts and Special Valuation Rules for Transfers of Interests and Trusts.

DATES: Written comments should be received on or before August 7, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to Roberto Mora-Figueroa, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the regulation should be directed to Sara Covington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Sara.L.Covington@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Guidance Regarding Charitable Remainder Trusts and Special Valuation Rules for Transfers of Interests and Trusts.

OMB Number: 1545–2131.

Form Number: 1127.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 75.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 4, 2018.

Laurie Brimmer,
Senior Tax Analyst.

[FR Doc. 2018–12406 Filed 6–7–18; 8:45 am]
DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0321]

Agency Information Collection Activity: Appointment of Veterans Service Organization as Claimant’s Representative and Appointment of Individual as Claimant’s Representative

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 7, 2018.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0321” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor at (202) 461–5870.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA’s functions, including whether the information will have practical utility; (2) the accuracy of VBA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on or off other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 4, 2018.

Laurie Brimmer,
Senior Tax Analyst.

[FR Doc. 2018–12331 Filed 6–7–18; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0098]

Agency Information Collection Activity Under OMB Review: Dependents’ Application for VA Education Benefits

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 9, 2018.

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. 2900–0098” 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. 2900–0098” in any correspondence.


Title: Dependents’ Application for VA Education Benefits.

OMB Control Number: 2900–0098.

Type of Review: Extension of a currently approved collection.

Abstract: VA forms 21–22 and 21–22a are used to collect the information needed to determine whom claimants have appointed to represent them in the preparation, presentation, and prosecution of claims for VA benefits. The information is also used to determine the extent of representatives’ access to claimants’ records.

Affected Public: Individuals and households.

Estimated Annual Burden: 26,583 hours.

Estimated Average Burden Per Respondent: 5 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 319,005.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,
Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–12331 Filed 6–7–18; 8:45 am]
BILLING CODE 4830–01–P
help determine whether an applying individual qualifies for DEA or Fry Scholarship benefits. The information will also be used to determine if the program of education the applicant wishes to pursue is approved for educational assistance. The form is used to obtain the necessary information from the claimant, and a determination cannot be made without this information.

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 83 FR 03908 on February 27, 2018, pages 8572 and 8573.

Affected Public: Individuals or Households.

Estimated: Annual Burden: 29,739 hours.

Estimated Average Burden per Respondent = 45 and 25 min (paper and electronic, respectively).

Frequency of Response: one-time.

Estimated Number of Respondents: 50,981.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,
Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA’s functions, including whether the information will have practical utility; (2) the accuracy of VBA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.


Title: Claim for Disability Insurance Benefits, VA Form 29–357.

OMB Control Number: 2900–0016.

Type of Review: Extension without change of a currently approved collection.

Abstract: This form is used by the policyholder to claim disability insurance benefits on S–DVI, NSLI and USGLI policies. The information requested is authorized by law, 38 U.S.C. 1912, 1915, 1922, 1942 and 1948.

Affecting Public: Individuals and households.

Estimated Annual Burden: 14,175.

Estimated Average Burden per Respondent: 1 Hour and 45 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 8,100.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,
Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0043]

Agency Information Collection Activity Under OMB Review: Application Request To Add and/or Remove Dependents

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 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 July 9, 2018.

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. 2900–0043” 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. 2900–0043” in any correspondence.


Title: Application Request to Add and/or Remove Dependents (VA Form 21–686c).

OMB Control Number: 2900–0043.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–686c is used to obtain current information about marital
status and dependent child(ren). This information is needed to determine the correct rate of payment for veterans and beneficiaries who may be entitled to an additional allowance for dependents or to remove dependents.

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 83 FR 03333 on February 20th, 2018, pages 7301 and 7302.

Affected Public: Individuals or Households.

Estimated Annual Burden: 113,000 hours.

Estimated Average Burden Per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 226,000.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,
Department Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2018–12329 Filed 6–7–18; 8:45 am]
BILLING CODE 8320–01–P
Part II

Environmental Protection Agency

40 CFR Part 50
Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides; Proposed Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50


RIN 2060–AT68

Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed action.

SUMMARY: Based on the Environmental Protection Agency’s (EPA’s) review of the air quality criteria addressing human health effects and the primary national ambient air quality standard (NAAQS) for sulfur oxides (SO₂), the EPA is proposing to retain the current standard, without revision.

DATES: Comments must be received on or before July 23, 2018.

If, by June 15, 2018, the EPA receives a request from a member of the public to speak at a public hearing concerning the proposed decision (see SUPPLEMENTARY INFORMATION below), we will hold a public hearing, with information about the hearing provided in a subsequent notice in the Federal Register.


Instructions: Follow the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, the cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

If a public hearing is to be held on this proposed action (see SUPPLEMENTARY INFORMATION below), in addition to publishing a Federal Register notice, the EPA will post information regarding it, including date and time, online at https://www.epa.gov/so2-pollution/primary-national-ambient-air-quality-standard-naaqs-sulfur-dioxide.

Docket: All documents in the dockets pertaining to this action are listed on the www.regulations.gov website. This includes documents in the docket for the proposed decision (Docket ID No. EPA–HQ–OAR–2013–0566) and a separate docket, established for the Integrated Science Assessment (ISA) for this review (Docket ID No. EPA–HQ–ORD–2013–0357) that has been incorporated by reference into the docket for this proposed decision. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and may be viewed, with prior arrangement, at the EPA Docket Center. Publicly available docket materials are available electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket Information Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket Information Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Hagan, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–06, Research Triangle Park, NC 27711; telephone: (919) 541–3153; fax: (919) 541–0237; email: hagan.nicole@epa.gov.

SUPPLEMENTARY INFORMATION:

General Information
Preparing Comments for the EPA

1. Submitting CBI
Do not submit this information to the EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

2. Tips for Preparing Your Comments
When submitting comments, remember to:
• Identify the action by docket number and other identifying information (subject heading, Federal Register date and page number).
• Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
• Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
• Describe any assumptions and provide any technical information and/or data that you used.
• Provide specific examples to illustrate your concerns, and suggest alternatives.
• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
• Make sure to submit your comments by the comment period deadline identified.

Public Hearing: If, by June 15, 2018, the EPA receives a request from a member of the public to speak at a public hearing concerning the proposed decision, we will hold a public hearing, with information about the hearing provided in a subsequent notice in the Federal Register. To request a hearing, to register to speak at a hearing or to inquire if a hearing will be held, please contact Ms. Regina Chappell at (919) 541–3650 or by email at chappell.regina@epa.gov. If a public hearing is to be held on this proposed action, the EPA will also post information regarding it, including, date and time, online at https://www.epa.gov/so2-pollution/primary-national-ambient-air-quality-standard-naaqs-sulfur-dioxide.

Availability of Information Related to This Action
A number of the documents that are relevant to this proposed decision are available through the EPA’s website at https://www.epa.gov/naaqs/sulfur-dioxide-so2-primary-ambient-air-quality-standards. These documents include the Integrated Review Plan for the Primary...
The following topics are discussed in this preamble:

Executive Summary

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This document presents the Administrator’s proposed decision in the current review of the primary (health-based) NAAQS for \( \text{SO}_x \), a group of closely related gaseous compounds that include sulfur dioxide (\( \text{SO}_2 \)). Of these compounds, \( \text{SO}_2 \) (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The current primary standard is set at a level of 75 ppb, as the 99th percentile of daily maximum 1-hour \( \text{SO}_2 \) concentrations, averaged over 3 years. This document summarizes the background and rationale for the Administrator’s proposed decision to retain the current standard, without revision, and solicits comment on this proposed decision and on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision. The EPA solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

This review of the primary \( \text{SO}_2 \) standard is required by the Clean Air Act (CAA) on a periodic basis. The schedule for completing this review is established by a consent decree, which established May 25, 2018 as the deadline for signature of a notice setting forth the proposed decision in this review and January 28, 2019 as the deadline for signature on a final decision notice.

The last review of the primary \( \text{SO}_2 \) NAAQS was completed in 2010 (75 FR 35520, June 22, 2010). In that review, the EPA significantly strengthened the primary standard, establishing a 1-hour standard and revoking the 24-hour and annual standards. The 1-hour standard was established to provide protection from respiratory effects associated with exposures as short as a few minutes based on evidence from health studies that documented respiratory effects in people with asthma exposed to \( \text{SO}_2 \) for 5 to 10 minutes while breathing at elevated rates. Revisions to the NAAQS were accompanied by revisions to the ambient air monitoring and reporting regulations, requiring the reporting of hourly maximum 5-minute \( \text{SO}_2 \) concentrations, in addition to the hourly concentrations.

Emissions of \( \text{SO}_2 \) and associated concentrations in ambient air have declined appreciably since 2010 and over the longer term. For example, emissions nationally are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016 (PA, Figure 2–2; 2014 NEI). Such declines in \( \text{SO}_2 \) emissions are likely related to the implementation of national control programs developed under the Clean Air Act Amendments of 1990, as well as changes in market conditions, e.g., reduction in energy generation by coal (PA, section 2.1, Figure 2–2; U.S. EIA, 2017). One-hour concentrations of \( \text{SO}_2 \) in ambient air the U.S. declined more than 82% from 1980 to 2016 at locations continuously monitored over this period (PA, Figure 2–4). The decline since 2000 has been 69% at a larger number of locations continuously monitored since that time (PA, Figure 2–5). Daily maximum 5-minute concentrations have also consistently declined from 2011 to 2016 (PA, Figure 2–6).

In this review, as in past reviews of the primary NAAQS for \( \text{SO}_x \), the health effects evidence evaluated in the ISA is focused on \( \text{SO}_2 \). The health effects of particulate atmospheric transformation products of \( \text{SO}_x \), such as sulfates, are addressed in the review of the NAAQS for particulate matter (PM).

Additionally, the welfare effects of sulfur oxides and the ecological effects of particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM, while the visibility, climate, and materials damage-related welfare effects of particulate sulfur compounds are being evaluated in the review of the secondary NAAQS for PM.

The proposed decision to retain the current primary NAAQS for \( \text{SO}_2 \) without revision, has been informed by careful consideration of the key aspects...
of the currently available health effects evidence and conclusions contained in the ISA, quantitative risk and exposure information presented in the REA, considerations of this evidence and information discussed in the Policy Assessment, advice from the Clean Air Scientific Advisory Committee (CASAC), and public input received as part of the ongoing review of the primary NAAQS for \( \text{SO}_x \).

The health effects evidence newly available in this review, as critically assessed in the ISA in conjunction with the full body of evidence, reaffirms the conclusions from the last review. The health effects evidence continues to support the conclusion that respiratory health effects evidence continues to support the conclusion from the last review. The clearest evidence for this conclusion comes from controlled human exposure studies, available at the time of the last review, that show that people with asthma experience respiratory effects following very short (e.g., 5–10 minute) exposures to \( \text{SO}_2 \) while breathing at elevated rates. Epidemiologic evidence, including studies not available in the last review, also supports this conclusion, primarily due to studies reporting positive associations between ambient air concentrations and emergency department visits and hospital admissions, particularly for children.

The quantitative analyses of population exposure and risk also inform the proposed decision. These analyses expand and improve upon the quantitative analyses available in the last review. Unlike the REA available in the last review, which analyzed single-year air quality scenarios for potential standard levels bracketing the now current level, the current REA assesses an air quality scenario for three years of air quality conditions that just meet the now-current standard, considering all of its elements, including its 3-year form. Other ways in which the current REA analyses are improved and expanded include improvements to models, model inputs and underlying databases, including the vastly expanded ambient air monitoring dataset for 5-minute concentrations, available as a result of changes in the last review to data reporting requirements.

Based on this evidence and quantitative information, as well as CASAC advice and public comment thus far in this review, the Administrator proposes to conclude that the current primary \( \text{SO}_x \) standard is requisite to protect public health, with an adequate margin of safety, from effects of \( \text{SO}_x \) in ambient air and should be retained, without revision. These proposed conclusions are consistent with CASAC recommendations. In its advice to the Administrator, the CASAC concurred with the preliminary conclusions in the draft PA that “the current scientific literature does not support revision of the primary NAAQS for \( \text{SO}_2 \)” (Cox and Diez Roux, 2018b, p. 1 of letter). The CASAC further stated that it “supports retaining the current standard, and specifically recommends that all four elements (indicator, averaging time, form, and level) should remain the same” (Cox and Diez Roux, 2018b, p. 1 of letter). The Administrator solicits comment on the proposed conclusion that the current standard is requisite to protect public health, with an adequate margin of safety, and on the proposed decision to retain the standard, without revision. The Administrator also solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision, as discussed in detail in section II below. The EPA solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

I. Background

This review focuses on the presence in ambient air of \( \text{SO}_x \), a group of closely related gaseous compounds that includes \( \text{SO}_2 \) and sulfur trioxide and of which \( \text{SO}_2 \) (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The health effects of particulate atmospheric transformation products of \( \text{SO}_x \), such as sulfates, are addressed in the review of the NAAQS for PM (U.S. EPA 2014a, 2016a). Additionally, the ecological welfare effects of sulfur are considered. Particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM (U.S. EPA, 2014a, 2017b), while the visibility, climate, and materials damage-related welfare effects of particulate sulfur compounds are being evaluated in the review of the secondary NAAQS for PM.\(^1\)

A. Legislative Requirements

Two sections of the Clean Air Act (CAA or the Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in his “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;” “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;” and “for which . . . [the Administrator] plans to issue air quality criteria . . . .” 42 U.S.C. 7408(b), Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one “‘the attainment and maintenance of which in the judgment of the Administrator is requisite for the protection of the public health.’” A secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”\(^2\)

\(^1\) Additional information on the review of secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM with regard to ecological welfare effects is available at: https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards. Additional information on the review of the PM NAAQS is available at: https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards.

\(^2\) The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” See S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970). See also Lead Industries Ass’n v. EPA, 647 F.2d 1130, 1152 (D.C. Cir 1980); American Lung Association v. EPA, 134 F.3d 388, 389 (D.C. Cir. 1998) (“NAAQS must protect not only average healthy individuals, but also those sensitive citizens—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.”).
The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. See Lead Industries Association v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980); American Petroleum Institute v. Costle, 665 F.2d 1176, 1186 (D.C. Cir. 1981); American Farm Bureau Federation v. EPA, 559 F.3d 512, 533 (D.C. Cir. 2009); Association of Battery Recyclers v. EPA, 604 F.3d 613, 617–18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. However, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentrations, see Lead Industries Association v. EPA, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk,4 and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator’s judgment. See Lead Industries Association v. EPA, 647 F.2d at 1161–62.

In setting primary and secondary standards that are “requisite” to protect public health and welfare, respectively, as provided in section 109(b), the EPA’s task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. See generally Whitman v. American Trucking Associations, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, “[a]tainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards.” American Petroleum Institute v. Costle, 665 F.2d at 1185.

Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate . . . .” Section 109(d)(2) requires that an independent scientific review committee “shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards . . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate . . . .” Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).5

B. Related SO2 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, states are to submit, for EPA approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the prevention of significant deterioration program that covers these pollutants. See 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. Review of the Air Quality Criteria and Standard for Sulfur Oxides

The initial air quality criteria for SO2 were issued in 1969 (34 FR 1988, February 11, 1969). Based on these criteria, the EPA, in initially promulgating NAAQS for SO2 in 1971, established the indicator as SO2. The SO2 area are a group of closely related gaseous compounds that include sulfur dioxide and sulfur trioxide and of which sulfur dioxide (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The two primary standards set in 1971 were 0.14 parts per million (ppm) averaged over a 24-hour period, not to be exceeded more than once per year, and 0.03 ppm, as an annual arithmetic mean (36 FR 8186, April 30, 1971).

The first review of the air quality criteria and primary standards for SO2 was initiated in the early 1980s and concluded in 1996 with the decision to retain the standards without revision (61 FR 25566, May 22, 1996). In reaching this decision, the Administrator considered the evidence newly available since the standards were set that documented asthma-related respiratory effects in people with asthma exposed for very short periods, such as 5 to 10 minutes. Based on his consideration of an exposure analysis using the then-limited monitoring data and early exposure modeling methods, the Administrator judged that revisions to the standards were not needed to provide requisite public health protection from SO2 in ambient air at that time (61 FR 25566, May 22, 1996). This decision was challenged and the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) found that the EPA had failed to adequately explain its determination that no revision to the primary SO2 standards was appropriate and remanded the determination back to the EPA for further explanation (American Lung Association v. EPA, 134 F.3d 388 [D.C. Cir. 1998]).

This remand was addressed in the most recent review, which was completed in 2010. In that review, the EPA promulgated a new 1-hour standard and also promulgated

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4 As used here and similarly throughout this notice, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestyle. Section II.B.2 below describes the identification of sensitive groups (called-at-risk groups or at-risk populations) in this review.

provisions for the revocation of the then-existing 24-hour and annual primary standards. The new 1-hour standard was set with a level of 75 parts per billion (ppb), a form of the 3-year average of the annual 99th percentile of daily maximum 1-hour SO\textsubscript{2} concentrations, and with SO\textsubscript{2} as the indicator. The Administrator judged that such a standard would provide the requisite protection for at-risk populations, such as people with asthma, against the array of adverse respiratory health effects related to short-term SO\textsubscript{2} exposures, including those as short as 5 minutes. With regard to long-term exposures, the new standard was expected to maintain 24-hour and annual concentrations generally well below the levels of the previous standards, and the available evidence did not indicate the need for separate standards designed to protect against long-term exposures (75 FR 35520, June 22, 2010). The EPA also revised the SO\textsubscript{2} ambient air monitoring regulations to require that monitoring agencies using continuous SO\textsubscript{2} methods report the highest 3-minute concentration for each hour of the day; 7 agencies may report all twelve 3-minute concentrations for each hour, including the maximum, although it is not required (75 FR 35568, June 22, 2010). This rule was challenged in court, and the D.C. Circuit denied or dismissed on jurisdictional grounds all the claims in the petitions for review. National Environmental Development Association’s Clean Air Project v. EPA, 686 F.3d 803, 805 (D.C. Cir. 2012).

In May 2013, the EPA initiated the current review by issuing a call for information in the \textit{Federal Register} and also announced a public workshop to inform the review (78 FR 27387, May 10, 2013). As was the case for the prior review, this review is focused on health effects associated with SO\textsubscript{2} and the public health protection afforded by the existing standard. Participants in the kickoff workshop included a wide range of external experts as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/... exposure analysis, atmospheric science, and biology). Workshop discussions focused on key policy-relevant issues around which the Agency would structure the review and the newly available scientific information related to these issues. Based in part on the workshop discussions, the EPA developed the draft integrated review plan (IRP) outlining the schedule, process, and key policy-relevant questions to guide this review of the SO\textsubscript{2} air quality criteria and standards (U.S. EPA, 2014b). The draft IRP was released for public comment and was reviewed by the CASAC at a public teleconference on April 22, 2014 (79 FR 14035, March 12, 2014; Frey and Diez Roux, 2014). The final IRP was developed with consideration of comments from the CASAC and the public (U.S. EPA, 2014a; 79 FR 16325, May 23, 2014; 79 FR 66721, November 10, 2014).

As an early step in development of the Integrated Science Assessment (ISA) for this review, the EPA’s National Center for Environmental Assessment (NCEA) hosted a public workshop at which preliminary drafts of key ISA chapters were reviewed by subject matter experts (79 FR 33750, June 12, 2014). Comments received from this review as well as comments from the public and the CASAC on the draft IRP were considered in preparation of the first draft ISA (U.S. EPA, 2015), released in November 2015 (80 FR 73183, November 24, 2015). The first draft ISA was reviewed by the CASAC at a public meeting in January 2016 and a public teleconference in April 2016 (80 FR 79330, December 21, 2015; 80 FR 79330, December 21, 2015; Diez Roux, 2016). The EPA released the second draft ISA in December 2016 (U.S. EPA, 2016b; 81 FR 89097, December 9, 2016), which was reviewed by the CASAC at a public meeting in March 2017 and a public teleconference in June 2017 (82 FR 11449, February 23, 2017; 82 FR 23563, May 23, 2017; Diez Roux, 2017a). The final ISA was released in December 2017 (U.S. EPA, 2017a; 82 FR 56600, December 13, 2017). In considering the need for quantitative exposure and risk analyses in this review, the EPA completed the Risk and Exposure Assessment (REAS) Planning Document in February 2017 (U.S. EPA, 2017c; 82 FR 11356, February 22, 2017), and held a consultation with the CASAC at a public meeting in March 2017 (82 FR 11449, February 23, 2017; Diez Roux, 2017b). In consideration of the CASAC’s comments at this consultation and public comments, the EPA developed the draft REA and draft Policy Assessment (PA), which were released on August 24, 2017 (U.S. EPA, 2017d,e; 82 FR 43756, September 19, 2017). The draft REA and draft PA were reviewed by the CASAC on September 18–19, 2017 (82 FR 37213, August 9, 2017; Cox and Diez Roux, 2018a,b). The EPA considered the advice and comments from the CASAC on the draft REA and draft PA as well as public comments, in developing the draft REA and final PA, which were released in early May 2018 (U.S. EPA, 2018a,b).

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in July 2016 by a group of plaintiffs which included a claim that the EPA had failed to complete its review of the primary SO\textsubscript{2} NAAQS within five years, as required by the CAA. The consent decree, which was entered by the court on April 28, 2017, provides that the EPA will sign, for publication, notices setting forth proposed and final decisions concerning its review of the primary NAAQS for SO\textsubscript{2} no later than May 23, 2018 and January 28, 2019, respectively.9

\subsection*{D. Air Quality Information}

This section presents information on sources and emissions of SO\textsubscript{2} and ambient concentrations, with a focus on information that is most relevant for the review of the primary SO\textsubscript{2} standard. This section is drawn from the more detailed discussion of SO\textsubscript{2} air quality in the PA and the ISA. It presents a summary of SO\textsubscript{2} sources and emissions (II.B.1) and ambient concentrations (II.B.2).

1. Sources and Emissions of Sulfur Oxides

Sulfur oxides are emitted into air from specific sources (e.g., fuel combustion processes) and are also formed in the atmosphere from other atmospheric compounds (e.g., as an oxidation product of reduced sulfur compounds, such as sulfides). Sulfur oxides are also transformed in the atmosphere to particulate sulfur compounds, such as sulfates.10 Sulfur oxides known to occur...
in the troposphere include SO$_2$ and sulfur trioxide (SO$_3$) (ISA, section 2.3). With regard to SO$_2$, it “is known to be present in the emissions of coal-fired power plants, factories, and refineries, but it reacts with water vapor in the stacks or immediately after release into the atmosphere to form H$_2$SO$_3$,” and “gas-phase H$_2$SO$_4$ . . . quickly condenses onto existing atmospheric particles or participates in new particle formation” (ISA, section 2.3). Thus, as a result of rapid atmospheric chemical reactions involving SO$_2$, the most previous oxidation reactions in the atmosphere is SO$_3$ (ISA, section 2.3).  

Fossil fuel combustion is the main anthropogenic source of SO$_2$ emissions, while volcanoes and landscape fires (wildfires as well as controlled burns) are the main natural sources (ISA, section 2.1).  

Industrial chemical production, pulp and paper production, natural biological activity (plants, fungi, and prokaryotes), and volcanoes are among many sources of reduced sulfur compounds that contribute, through various oxidation reactions in the atmosphere, to the formation of SO$_2$ in the atmosphere (ISA, section 2.1). Anthropogenic SO$_2$ emissions originate primarily from point sources, including coal-fired electricity generating units (EGUs) and other industrial facilities (ISA, section 2.2.1). The largest SO$_2$-emitting sector within the U.S. is electricity generation, and 97% of SO$_2$ from electricity generation is from coal combustion. Other anthropogenic sources of SO$_2$ emissions include industrial fuel combustion and process emissions, industrial processing, commercial marine activity, and the use of fire in landscape management and agriculture (ISA, section 2.2.1).

National average SO$_2$ emissions are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016 (PA, Figure 2–2; 2014 NEI). Such declines in SO$_2$ emissions are likely related to the implementation of national control programs developed under the Clean Air Interstate Amendments of 1990, including Phase I and II of the Acid Rain Program, the Clean Air Interstate Rule, the Cross-State Air Pollution Rule, and the Mercury Air Toxic Standards, as well as changes in market conditions, e.g., reduction in energy generation by coal (PA, section 2.1, Figure 2–2; U.S. EIA, 2017).  

Regulations on sulfur content of diesel fuel, both for onroad vehicles and nonroad engines and equipment, may also contribute to declining trends in SO$_2$ emissions. Declines in emissions from all sources between 1971, when SO$_2$ NAAQS were first established, and 1990, when the Amendments were adopted, were on the order of 5,000 tpy deriving primarily from reductions in emissions from the metals processing sector (ISA, Figure 2–5).

2. Ambient Concentrations

Ambient air concentrations of SO$_2$ in the U.S. have declined substantially from 1980 to 2016, more than 82% in terms of the form of the current standard (the 99th percentile daily maximum 1-hour concentrations averaged over three years) at locations continuously monitored over this period (PA, Figure 2–4). The decline since 2000 has been 69% at the larger number of locations continuously monitored since that time (PA, Figure 2–5).  

As a result of the reporting requirements promulgated in 2010 (as summarized in section 1.5 above) maximum hourly five-minute concentrations of SO$_2$ in ambient air are available at SO$_2$ NAAQS compliance monitoring sites (PA, Figure 2–3; FR 75 35554, June 22, 2010). These newly available data document reductions in peak 5-minute concentrations across the U.S. For example, over the period from 2011 to 2016, the 99th percentile 5-minute SO$_2$ concentrations declined approximately 53% (PA, Figure 2–6, Appendix B).

Concentrations of SO$_2$ vary across the U.S. and tend to be higher in areas with sources having relatively higher SO$_2$ emissions (e.g., locations influenced by emissions from EGU). Consistent with the locations of larger SO$_2$ sources, higher concentrations are primarily located in the eastern half of the continental U.S., especially in the Ohio River valley, upper Midwest, and along the Atlantic coast (PA, Figure 2–7). The point source nature of SO$_2$ emissions contributes to the relatively high spatial variability of SO$_2$ concentrations compared with pollutants such as ozone (ISA, section 3.2.3). Another factor in the spatial variability is the dispersion and oxidation of SO$_2$ in the atmosphere, processes that contribute to decreasing concentrations with increasing distance from the source. Point source emissions of sulfur oxides create a plume of higher concentrations, which may or may not impact large portions of surrounding populated areas depending on meteorological conditions and terrain.

Analyses in the ISA of data for 2013–2015 in six areas indicate that 1-hour daily maximum SO$_2$ concentrations vary across seasons, with the greatest variations seen in the upper percentile concentrations (versus average or lower percentiles) for each season (ISA, section 2.5.3.2). This seasonal variation as well as month-to-month variations are generally consistent with month-to-month emissions patterns and the expected atmospheric chemistry of SO$_2$ for a given season. Consistent with the nationwide diel patterns reported in the last review, 1-hour average and 5-minute hourly maximum SO$_2$ concentrations for 2013–2015 in all six areas evaluated were generally low during nighttime and approached maxima values during daytime hours (ISA, section 2.5.3.3, Figures 2–23 and 2–24). The timing and duration of daytime maxima in the six sites evaluated in the ISA were likely related to a combination of source emissions and meteorological parameters (ISA, section 2.5.3.4, Table 2–4).
II. Rationale for Proposed Decision

This section presents the rationale for the Administrator’s proposed decision to retain the current primary SO₂ standard. This rationale is based on a thorough review of the latest scientific information generally published through August 2016, as presented in the ISA, on human health effects associated with SO₂ and pertaining to the presence of SO₂ in ambient air. The Administrator’s rationale also takes into account: (1) The PA evaluation of the policy-relevant information in the ISA and quantitative analyses of air quality, human exposure and health risks in the REA; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA, REA, and PA at public meetings and in the CASAC’s letters to the Administrator; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator’s proposed decision and its foundations, section II.A provides background on the general approach for review of the primary SO₂ standard, including a summary of the approach used in the last review (section II.A.1) and the general approach for the current review (section II.A.2). Section II.B summarizes the currently available health effects evidence, focusing on consideration of key policy-relevant aspects. Section II.C summarizes the exposure and risk information for this review, drawing on the quantitative analyses for SO₂ presented in the REA. Section II.D presents the Administrator’s proposed conclusions on the current standard (section II.D.3), drawing on both evidence-based and exposure/risk-based considerations (section II.D.1) and advice from the CASAC (section II.D.2).

A. General Approach

The past and current approaches described below are both based, most fundamentally, on using the EPA’s assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator’s judgment regarding a primary standard for SO₂ that protects public health with an adequate margin of safety. The EPA’s assessments are primarily documented in the ISA, REA and PA, all of which have received CASAC review and public comment (80 FR 73183, November 24, 2015; 81 FR 89097, December 9, 2016; 82 FR 11356, February 22, 2017; 82 FR 43756, September 19, 2017). In bridging the gap between the scientific assessments of the ISA and REA and the judgments required of the Administrator in determining whether the current standard remains adequate to protect public health with an adequate margin of safety, the PA evaluates policy implications of the evaluation of the current evidence in ISA and the quantitative analyses in the REA. In evaluating the health protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

We note that in drawing conclusions with regard to the primary standard, the final decision is based on the adequacy of the current standard is largely a public health policy judgment to be made by the Administrator. The Administrator’s final decision will draw upon scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act. These provisions require the Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.

1. Approach in the Last Review

The last review of the primary NAAQS for SO₂ was completed in 2010 (75 FR 35520, June 22, 2010). The decision in that review to substantially revise the standards (establishing a 1-hour standard and revoking the 24-hour and annual standards) was based on the extensive body of evidence of respiratory effects in people with asthma that has expanded in this area over the four decades since the first SO₂ standards were set in 1971 (U.S. EPA 1982, 1986, 1994, 2008a). In so doing, the 2010 decision considered the full body of evidence, as assessed in the 2008 ISA; the 2009 REA, which included the staff assessment of the policy-relevant information contained in the ISA and analyses of air quality, exposure and risk; the advice and recommendations of the CASAC; and public comment. In addition to epidemiologic evidence linking respiratory outcomes in people with asthma to short-term SO₂ air quality metrics, a key element of the expanded evidence base in the 2010 review was a series of controlled human exposure studies which document bronchoconstriction-related effects on lung function in people with asthma exposed while breathing at elevated rates for periods as short as five minutes. Another key element was the air quality database, expanded since the previous review (completed in 1996), which documented the then-recent pattern of peak 5-minute SO₂ concentrations. The EPA used these data in the quantitative exposure and risk assessments to provide an up-to-date ambient air quality context for interpreting the health effects evidence in the 2010 review. Together these aspects of the 2010 review additionally addressed the issues raised in the court remand to the EPA of the Agency’s 1996 decision not to revise the standards at that time to specifically address 5-minute exposures (75 FR 35523, June 22, 2010). In so doing, the EPA strengthened the primary NAAQS for so-called “elevated ventilation” (or “moderate or greater exertion”) was used in the 2009 REA and Federal Register notices in the last review to refer to activity levels that in adults would be associated with ventilation rates at or above 40 liters per minute; an equivalent ventilation rate was derived in order to identify corresponding rates for the range of ages and sizes of the simulated populations (U.S. EPA 2009, section 4.1.4.4). Accordingly, these phrases are used in the current review when quantifying exposures from the last review. Otherwise, however, the documents for this review generally use the phrase “elevated breathing rates” to refer to the same situation.

In addition to the review’s opening “call for information” (78 FR 27387, May 10, 2013), “the U.S. EPA routinely conducted literature searches to identify relevant peer-reviewed studies published since the previous ISA (i.e., from January 2008 through August 2016)” (ISA, p. 1-3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: https://hero.epa.gov/hero/sulfur-oxides

20 As noted in section I.A above, such protection is specified for the sensitive group of individuals and not to a single person in the sensitive group

21 The phrase “elevated ventilation” (or “moderate or greater exertion”) was used in the 2009 REA and Federal Register notices in the last review to refer to activity levels that in adults would be associated with ventilation rates at or above 40 liters per minute; an equivalent ventilation rate was derived in order to identify corresponding rates for the range of ages and sizes of the simulated populations (U.S. EPA, 2009, section 4.1.4.4). Accordingly, these phrases are used in the current review when quantifying exposures from the last review. Otherwise, however, the documents for this review generally use the phrase “elevated breathing rates” to refer to the same situation.
SO2 to provide the requisite protection of public health with an adequate margin of safety and to specifically afford increased protection for at-risk populations, such as people with asthma, against adverse respiratory health effects related to short-term SO2 exposures (75 FR 35550, June 22, 2010).

Thus, the 2010 decision focused on the effects most pertinent to SO2 in ambient air and recognized the long-standing evidence regarding the sensitivity of some people with asthma to brief SO2 exposures experienced while breathing at elevated rates. The Administrator gave particular attention to the robust evidence base, comprised of findings from controlled human exposure, epidemiologic, and animal toxicological studies that collectively were judged “sufficient to infer a causal relationship” between short-term SO2 exposures ranging from 5 minutes to 24 hours and respiratory morbidity (75 FR 35535, June 22, 2010). The “definitive evidence” for this conclusion came from studies of 5- to 10-minute controlled exposures that reported respiratory symptoms and decreased lung function in exercising individuals with asthma (2008 ISA, section 5.3). Supporting evidence was provided by epidemiologic studies of a broader range of respiratory outcomes, with uncertainty noted about the magnitude of the study effect estimates, quantification of the exposure concentration-response relationship, potential confounding by copollutants, and other areas (75 FR 35535–36, June 22, 2010; 2008 ISA, section 5.3).

The conclusions reached in the last review were based primarily on interpretation of the short-term health effects evidence, particularly the interpretation of the evidence from controlled human exposure studies within the context of the quantitative exposure and risk analyses. The epidemiologic evidence also provided support for various aspects of the decision. In making judgments on the public health significance of health effects related to ambient air-related SO2 exposures, the Administrator considered statements from the American Thoracic Society (ATS) regarding adverse effects of air pollution,23 the CASAC’s written advice and recommendations,24 and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22, 2010; ATS, 1985, 2000). Based on these considerations, the Administrator, in reaching decisions in the last review, gave weight to the findings of respiratory effects in exercising people with asthma after 5- to 10-minute exposures as low as 200 ppb. With regard to higher exposures, at or above 400 ppb, she noted their association with respiratory symptoms as indication of their clear adversity, as well as the greater number of study subjects responding with lung function decrements. Moreover, she took note of the greater severity of the response, recognizing effects associated with exposures as low as 200 ppb to be less severe (75 FR 35547, June 22, 2010).

In reaching her conclusion on the adequacy of the then-existing primary standards, the Administrator gave particular attention to the exposure and risk estimates from the 2009 REA for air quality conditions just meeting the then-existing (24-hour and annual) standards. In so doing, the Administrator also noted epidemiologic study findings of associations with respiratory outcomes in studies of locations where maximum 24-hour average SO2 concentrations were below the level of the then existing 24-hour standard. The 2009 REA estimated that substantial percentages of children with asthma might be expected to experience at least once annually, exposures that had been associated with moderate or greater SO2 concentration decrements25 in the controlled human exposure studies (75 FR 35536, June 22, 2010). The Administrator judged that such exposures can result in adverse health effects in people with asthma and found that the estimated population frequencies for such exposures (24% of at-risk population with at least one occurrence per year at or above 400 ppb and 73% with at least one occurrence per year at or above 200 ppb) were significant from a public health perspective and that the then-existing primary standards did not adequately protect public health (75 FR 35536, June 22, 2010).

Based on consideration of the entire body of evidence and information available in the review, as well as the advice from the CASAC and public comments, the Administrator concluded that the appropriate approach to revising the standards was to replace the then-existing 24-hour standard with a new, short-term standard set to provide requisite protection with an adequate margin of safety to people with asthma and afford protection from the adverse health effects of 3-minute to 24-hour SO2 exposures (75 FR 35536, June 22, 2010). Accordingly, the available scientific evidence was then considered in reaching conclusions on the four elements of such a new standard: indicator, averaging time, form, and level. Further, upon reviewing the evidence with regard to the potential for effects from long-term exposures, the Administrator revoked the annual standard. In so doing, she recognized the lack of sufficient health evidence to support a long-term standard and that the new short-term standard would have the effect of generally maintaining the annual SO2 concentrations well below the level of the revoked annual standard (75 FR 35550, June 22, 2010).

With regard to the indicator for the new short-term standard, the EPA continued to focus on SO2 as the most appropriate indicator for SO2 because the available scientific information regarding health effects was overwhelmingly indexed by SO2. Furthermore, although the presence of SOX species other than SO2 in ambient air had been recognized, no alternative to SO2 had been advanced as a more appropriate surrogate for SOX (75 FR 35536, June 22, 2010). Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO2, and epidemiologic studies typically analyzed associations of health outcomes with concentrations of SO2. Based on the information available in the last review and consistent with the views of the CASAC that “for indicator, SO2 is clearly the preferred choice” (Smet et al., 2000, p. 14), the Administrator concluded it was appropriate to continue to use SO2 as

23The 1999 statement of the ATS (published in 2000) on “What Constitutes an Adverse Health Effect of Air Pollution?” is “intended to provide guidance to policy makers and others who interpret the scientific evidence on the health effects of air pollution for the purpose of risk management” and describes “principles to be used in weighing the evidence” when considering what may be adverse and nonadverse effects on health (ATS, 2000).

24For example, the CASAC letter on the first draft SO2 REA to the Administrator stated: “CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO2” (Henderson, 2008).

25In assessments for NAAQS reviews, the magnitude of lung function responses described as indicative of a moderate response include increases in specific airway resistances (sRaw) of at least 100% (e.g., 2008 ISA; U.S. EPA, 1994, Table 8; U.S. EPA, 1996, Table 8–3). The moderate category has also generally included reductions in forced expiratory volume in 1 second (FEV1) of 10 to 20% (e.g., U.S. EPA, 1996, Table 8). For the 2008 ISA, the midpoint of that range (15%) was used to indicate a moderate response. A focus on 15% reduction in FEV1 was also consistent with the relationship observed between sRaw and FEV1 responses in the Linn et al. studies (1987, 1990) for which “a 100% increase in sRaw roughly corresponds to a 12 to 15% decrease in FEV1” (U.S. EPA, 1994, p. 20). Thus, in the 2008 review, moderate or greater SO2-related bronchoconstriction or decrements in lung function referred to the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV1 (2008 ISA, p. 3–5).
the indicator for a standard that was intended to address effects associated with exposure to SO\textsubscript{2}, alone or in combination with other SO\textsubscript{2} (75 FR 35536, June 22, 2010). In so doing, the EPA recognized that measures leading to reductions in population exposures to SO\textsubscript{2} will also likely reduce exposures to other SO\textsubscript{2} (75 FR 35536, June 22, 2010).

With regard to the averaging time for the new standard, the Administrator judged that the requisite protection from 5- to 10-minute exposure events could be provided without having a standard with a 5-minute averaging time (75 FR 35539, June 22, 2010). She further judged that a standard with a 5-minute averaging time would result in significant and unnecessary instability in public health protection (75 FR 35539, June 22, 2010).20 Accordingly, she considered longer averaging times.

Results of air quality analyses in the REA suggested that a standard based on 24-hour average SO\textsubscript{2} concentrations would not likely be an effective or efficient approach for addressing 5-minute peak SO\textsubscript{2} concentrations, likely over-controlling in some areas while under-controlling in others (2009 REA, section 10.5.2.2). In contrast, these same analyses suggested that a 1-hour averaging time would be more efficient and would be effective at limiting 5- to 10-minute exposures to SO\textsubscript{2} (75 FR 35539, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010).

In so doing, she noted that a concentration-based form averaged over three years would likely be appreciably more stable than a no-exceedance based form, which had been the form of the then-existing 24-hour standard (75 FR 35541, June 22, 2010). The CASAC additionally stated that “[t]here is adequate information to justify the use of a concentration-based form averaged over 3 years” (Samet, 2009, p. 16).

In selecting a specific concentration-based form, the Administrator considered health evidence from the ISA as well as air quality, exposure, and risk information from the REA. In so doing, the Administrator concluded that the form of the new 1-hour standard should reflect the health effects evidence presented in the ISA that indicated that the percentage of people with asthma affected and the severity of the response increased with increasing SO\textsubscript{2} concentrations (75 FR 35541, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010).

The Administrator additionally took note of advice from the CASAC. The CASAC stated that the REA had presented a “convincing rationale” for a 1-hour standard and that “a one-hour standard is the preferred averaging time” (Samet, 2009, pp. 15, 16). The CASAC further stated that it was “in agreement with having a short-term standard” and found that “the REA supports a one-hour standard as protective of public health” (Samet, 2009, p. 1). Thus, in consideration of the available information summarized here and the CASAC’s advice, the Administrator concluded that a 1-hour standard (given the appropriate level and form) was an appropriate means of controlling short-term exposures to SO\textsubscript{2} ranging from 5 minutes to 24 hours (75 FR 35539, June 22, 2010).

With regard to the statistical form for the new 1-hour standard, the Administrator judged that the form of the standard should reflect the health effects evidence presented in the ISA that indicated that the percentage of people with asthma affected and the severity of the response increased with increasing SO\textsubscript{2} concentrations (75 FR 35541, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010).

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experiencing any days in a year with at least one 5-minute exposure at or above 400 ppb while at moderate or greater exertion, and approximately 97% of those children with asthma from experiencing any days in a year with at least one exposure at or above 200 ppb while at moderate or greater exertion (75 FR 35546–47, June 22, 2010). Results for the air quality scenario for a 1-hour standard level of 50 ppb suggested that such a standard would further limit exposures, such that more than 99% of children at moderate or greater exertion would likely be protected from experiencing any days in a year with a 5-minute exposure at or above the 200 ppb benchmark concentration (75 FR 35542, June 22, 2010). In considering the implications of these estimates, and the substantial reduction in 5-minute exposures at or above 200 ppb, the Administrator did not judge that a standard level as low as 50 ppb was warranted (75 FR 35547, June 22, 2010). Before reaching her conclusion with regard to level for the 1-hour standard, the Administrator additionally considered the epidemiologic evidence, placing relatively more weight on the U.S. epidemiologic studies (some conducted in multiple locations) reporting mostly positive and sometimes statistically significant associations between ambient SO2 concentrations and emergency department visits or hospital admissions related to asthma or other respiratory symptoms, and noting a cluster of three studies for which 99th percentile 1-hour daily maximum concentrations were estimated to be between 78–150 ppb and for which the SO2 effect estimate remained positive and statistically significant in copollutant models with PM (75 FR 35547–48, June 22, 2010). 

Given the above considerations and the comments received on the proposal, the Administrator judged, based on the entire body of evidence and information available in that review (concluded in 2010), and the related uncertainties, that a standard level of 75 ppb was appropriate. She concluded that such a standard, with a 1-hour averaging time and 99th percentile form, would provide a significant increase in public health protection compared to the then-existing standards and would be expected to provide protection, with an adequate margin of safety, against the respiratory effects elicited by SO2 exposures in controlled human exposure studies and associated with ambient air concentrations in epidemiologic studies (75 FR 35548, June 22, 2010). The Administrator found that “a 1-hour standard at a level of 75 ppb is expected to substantially limit asthmatics’ exposure to 5–10 minute SO2 concentrations ≥200 ppb, thereby substantially limiting the adverse health effects associated with such exposures” (75 FR 35546, June 22, 2010). Such a standard was also considered likely “to maintain SO2 concentrations below those in locations where key U.S. epidemiologic studies have reported that ambient SO2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits” (75 FR 35548, June 22, 2010). Lastly, the Administrator noted “that a standard level of 75 ppb is consistent with the consensus recommendation of CASAC” (75 FR 35548, June 22, 2010). The Administrator also considered the likelihood of public health benefits at lower standard levels, and judged a 1-hour standard at 75 ppb to be sufficient to protect public health with an adequate margin of safety (75 FR 35547–35548, June 22, 2010).

2. Approach for the Current Review

To evaluate whether it is appropriate to consider retaining the now current primary SO2 standard, or whether consideration of revision is appropriate, the EPA has adopted an approach in this review that builds upon the general approach used in the last review and reflects the body of evidence and information now available. Accordingly, the approach takes into consideration the approach used in the last review, addressing key policy-relevant questions in light of currently available scientific and technical information. As summarized above, the Administrator’s decisions in the prior review were based on an integration of SO2 health effects information with judgments on the adversity and public health significance of key health effects, policy judgments as to when the standard is requisite to protect against public health with an adequate margin of safety, consideration of CASAC advice, and consideration of public comments.

Similarly, in this review, we draw on the current evidence and quantitative assessments of exposure pertaining to the public health risk of SO2 in ambient air. In considering the scientific and technical information here, we consider both the information available at the time of the last review and information newly available since the last review, including that which has been critically analyzed and characterized in the current ISA. The quantitative exposure and risk analyses provide a context for interpreting the evidence of lung function decrements in people with asthma breathing at elevated rates and the potential public health significance of exposures associated with air quality conditions that just meet the current standard.

B. Health Effects Information

The information summarized here is based on our scientific assessment of the health effects evidence available in this review; this assessment is documented in the ISA and its policy implications are further discussed in the PA. More than 400 studies are newly available and considered in the ISA, including more than 200 health studies. They are consistent with the evidence that was available in the last review. As in the last review, the key evidence comes from the body of controlled human exposure studies that document effects in people with asthma. Policy implications of the currently available evidence are discussed in the PA (as summarized in section II.D.1 below). The subsections below briefly summarize the following aspects of the evidence: The nature of SO2-related health effects (section II.B.1), the populations at risk (section II.B.2), exposure concentrations associated with health effects (section II.B.3), and potential public health implications (section II.B.4).

1. Nature of Effects

In this review, as in past reviews, the health effects evidence evaluated in the ISA for SO2 is focused on SO2 (ISA, p. 5–1). As summarized in section I.D.1 above, atmospheric chemistry as well as emissions contribute to SO2 being the most prevalent sulfur oxide in the atmosphere. As concluded in the ISA, “[o]f the sulfur oxides, SO2 is the most
abundant in the atmosphere, the most important in atmospheric chemistry, and the one most clearly linked to human health effects” (ISA, p. 2–1). Accordingly, the ISA states that “only SO₂ is present at concentrations in the gas phase that are relevant for chemistry in the atmospheric boundary layer and troposphere, and for human exposures” (ISA, p. 2–18). Thus, the current health effects evidence and the Agency’s review of the evidence, including the evidence newly available in this review, continues to focus on SO₂.

Sulfur dioxide is a highly reactive and water-soluble gas that once inhaled is absorbed almost entirely in the upper respiratory tract 33 (ISA, sections 4.2 and 4.3). Short exposures to SO₂ can elicit respiratory effects, particularly in individuals with asthma (ISA, p. 1–17). Under conditions of elevated breathing rates (e.g., while exercising), SO₂ penetrates into the tracheobronchial region, 34 where, in sufficient concentration, it results in responses linked to asthma exacerbation in individuals with asthma (ISA, sections 4.2, 4.3, and 5.2). More specifically, bronchoconstriction 35, which is characteristic of an asthma attack, is the most sensitive indicator of SO₂-induced lung function effects (ISA, p. 5–8). Associated with this bronchoconstriction response is an increase in airway resistance which is an index of airway hyperresponsiveness (AHR). 36 Exercising individuals without asthma have also been found to exhibit such responses, but at much higher SO₂ exposure concentrations (ISA, section 5.2.1.7). For example, the ISA finds that “healthy adults are relatively insensitive to the respiratory effects of SO₂ below 1 ppm” (ISA, p. 5–9).

Based on assessment of the currently available evidence, as in the last review, the ISA concludes that there is a causal relationship between short-term SO₂ exposures (as short as a few minutes) and respiratory effects (ISA, section 5.2.1). The clearest evidence for this causal relationship comes from the long-standing evidence base of controlled human exposure studies (U.S. EPA, 1994; 2008 ISA). These studies demonstrate asthma exacerbation-related lung function decrements 37 and respiratory symptoms (e.g., cough, chest tightness and wheeze) in people with asthma exposed to SO₂ for 5 to 10 minutes at elevated breathing rates (ISA, section 5.2.1.1). Bronchoconstriction, evidenced by decrements in lung function, that are sometimes accompanied by respiratory symptoms (e.g., cough, wheeze, chest tightening and shortness of breath), is observed to occur in these studies at SO₂ concentrations as low as 200 ppb in some people with asthma exposed while breathing at elevated rates, such as during exercise (ISA, section 5.2.1.2). 38 In contrast, respiratory effects are not generally observed in other people with asthma (nonresponders) and healthy adults exposed, while exercising, to SO₂ concentrations below 1000 ppb (ISA, sections 5.2.1.2 and 5.2.1.7). Across studies, bronchoconstriction in response to SO₂ exposure is mainly seen during conditions of elevated breathing rates, such as exercise or with mouthpiece exposures that involve laboratory-facilitated rapid, deep breathing. 39 With these conditions, breathing shifts from nasal breathing to oral/nasal breathing, which increases the concentrations of SO₂ reaching the tracheobronchial region of lower airways, where, depending on dose and the exposed individual’s susceptibility, it may cause bronchoconstriction (ISA, sections 4.1.2.2, 4.2.2, and 5.2.1.2).

The evidence base of controlled human exposure studies for people with asthma is the same in this review as in the last report. 40 Such studies reporting asthma exacerbation-related effects for individuals with asthma are summarized in Tables 5–1 and 5–2, as well as section 5.2.1.2 of the ISA. The main responses observed include increases in specific airway resistance (sRaw) and reductions in forced expiratory volume in one second (FEV₁) after 5- to 10-minute exposures. As recognized in the last review, the results of these studies indicate that among individuals with asthma, some individuals have a greater response to SO₂ than others or a measurable response at lower exposure concentrations (ISA, p. 5–14). The SO₂-induced bronchoconstriction in these studies occurs rapidly, in as little as two minutes from exposure start, and is transient, with recovery occurring upon cessation of exposure (ISA, p. 5–14; Table 5–2).

The epidemiologic evidence, some of which is newly available since the time of the last review, includes studies reporting positive associations for asthma-related hospital admissions of children or emergency department visits by children with short-term SO₂ exposures (ISA, section 5.2.1). These findings provide evidence supportive of the EPA’s conclusion of a causal relationship between short-term SO₂ exposures and respiratory effects, for which the controlled human exposure studies are the primary basis (ISA, section 5.2.1.9). With regard to newly available epidemiologic studies, there are a limited number of such studies that have investigated SO₂ effects related to asthma exacerbation, with the most supportive evidence coming from studies on asthma-related emergency department visits by children and hospital admissions of children (ISA, section 5.2.1.2). As in the last review, areas of uncertainty in the epidemiologic evidence relate to the characterization of exposure through the use of fixed site monitor concentrations as surrogates for population exposure (often over a substantially sized area and for durations greater than an hour) and the potential for confounding by PM 41 or other copollutants (ISA, section 5.2.1). In general, the pattern of associations across the newly available studies is consistent with the studies available in the last review (ISA, p. 5–75).

The evidence base for long-term 42 SO₂ exposure and respiratory effects is somewhat augmented since the last review such that the ISA in the current review concludes it to be suggestive of,

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33 The term “upper respiratory tract” refers to the portion of the respiratory tract, including the nose, mouth and larynx, that precedes the tracheobronchial region (ISA, sections 4.2 and 4.3).
34 The term “tracheobronchial region” refers to the region of the respiratory tract subsequent to the larynx and preceding the deep lung (or alveoli). This region includes the trachea and bronchi.
35 The term bronchoconstriction refers to constriction or narrowing of the airways in the respiratory tract.
36 Airway hyperresponsiveness, which is an increased propensity of the airways to narrow in response to bronchoconstrictive stimuli, is a characteristic feature of people with asthma (ISA, section 5.2.1.2).
37 The specific responses reported in the evidence base that are described in the ISA as lung function decrements are increased specific airway resistance (sRaw) and reduced forced expiratory volume in one second (FEV₁) (ISA, section 5.2.1.2).
38 The data from controlled human exposure studies and respiratory effects, for durations greater than an hour and for durations greater than an hour and the potential for confounding by PM 41 or other copollutants (ISA, section 5.2.1).
39 Laboratory-facilitated rapid deep breathing involves rapid, deep breathing through a mouthpiece that provides a mixture of oxygen with enough carbon dioxide to prevent an imbalance of gases in the blood usually resulting from hyperventilation. Breathing in the laboratory with this technique is referred to as eupneic hyperpnea.
40 The subjects in these studies have primarily been adults. The exception has been a few studies conducted in adolescents aged 12 to 18 years of age (ISA, pp. 5–22 to 5–23; PA, sections 3.2.1.3 and 3.2.1.4).
41 The potential for confounding by PM is of particular interest given that SO₂ is a precursor to PM (ISA, p. 1–7).
42 In evaluating the health effects studies in the ISA, the EPA has generally categorized exposures of durations longer than a month as “long-term” (ISA, p. 1–2).
but not sufficient to infer, a causal relationship (ISA, section 5.2.2.2). The support for this conclusion comes mainly from the limited epidemiologic study findings of associations between long-term SO\textsubscript{2} concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO\textsubscript{2} exposure to contribute to the development of asthma, especially allergic asthma, in children (ISA, section 1.6.1.2). The evidence showing increases in asthma incidence is coherent with results of animal toxicologic studies that provide a pathophysiologic basis for the development of asthma. The overall body of evidence, however, lacks consistency (ISA, section 1.6.1.2).

Further, there are uncertainties that apply to the epidemiologic evidence, including newly available evidence, across the respiratory effects examined for long-term exposure (ISA, section 5.2.2.7).

For effects other than respiratory effects, the current evidence is generally similar to the evidence available in the last review, and leads to similar conclusions. With regard to a relationship between short-term SO\textsubscript{2} exposure and total mortality, the ISA reaches the same conclusion as the previous review that the evidence is suggestive of, but not sufficient to infer, a causal relationship (ISA, section 5.5.1). This conclusion is based on the evidence of previously and newly available multicity epidemiologic studies that provide consistent evidence of positive associations coupled with uncertainty regarding the potential for SO\textsubscript{2} to have an independent effect on mortality. While recent studies have analyzed some key uncertainties and data gaps from the previous review, uncertainties still exist, given the limited number of studies that examined copollutant confounding, the evidence for a decrease in the size of SO\textsubscript{2}-mortality associations in copollutant models with nitrogen dioxide and particulate matter with mass median aerodynamic diameter below 10 microns, and the lack of a potential biological mechanism for mortality following short-term SO\textsubscript{2} exposures (ISA, section 1.6.2.4).

For other categories of health effects, the currently available evidence is inadequate to infer the presence or absence of a causal relationship, mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, copollutant confounding, and potential modes of action (ISA, sections 5.3.1, 5.3.2, 5.4, 5.5.2, 5.6). These conclusions are consistent with those made in the previous review (ISA, p. xlviii).

Thus, the current health effects evidence supports the primary conclusion that short-term exposure to SO\textsubscript{2} in ambient air causes respiratory effects, in particular, asthma exacerbation in individuals with asthma; this evidence and these conclusions are also consistent with that available in the last review. The focus in this review, as in prior reviews, is on such effects.

2. At-Risk Populations

In this document, we use the term “at-risk populations”\textsuperscript{44} to recognize populations that have a greater likelihood of experiencing SO\textsubscript{2}-related health effects, i.e., groups with characteristics that contribute to an increased risk of SO\textsubscript{2}-related health effects. In identifying factors that increase risk of SO\textsubscript{2}-related health effects, we have considered evidence regarding factors contributing to increased susceptibility, which generally include intrinsic factors, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic factors, such as sociodemographic or behavioral factors (ISA, p. 6–1).

The information newly available in this review has not substantially altered our previous understanding of at-risk populations for SO\textsubscript{2} in ambient air. As in the last review, people with asthma are at increased risk for SO\textsubscript{2}-related health effects, specifically for respiratory effects, and specifically asthma exacerbation elicited by short-term exposures while breathing at elevated rates (ISA, sections 5.2.1.2 and 6.3.1). This conclusion of the at-risk status of people with asthma is based on the well-established and well-characterized evidence from controlled human exposure studies, supported by the evidence on mode of action for SO\textsubscript{2} with additional support from epidemiologic studies (ISA, sections 5.2.1.2 and 6.3.1). Somewhat similar to the conclusion in the last review that children and older adults are potentially susceptible populations, the ISA (relying on a framework for evaluating the evidence for risk factors that has been developed since the last review)\textsuperscript{45} indicates the evidence to be suggestive of increased risk for these groups, with some limitations and inconsistencies (ISA, sections 6.5.1.1 and 6.5.1.2).\textsuperscript{46} Children with asthma, however, may be particularly at risk compared to adults with asthma (ISA, section 6.3.1). This conclusion reflects several characteristics of children as compared to adults, which include their greater responsiveness to methacholine,\textsuperscript{47} a chemical that can elicit bronchoconstriction in people with asthma, as well as their greater use of oral breathing, particularly by boys (ISA, sections 5.2.1.2 and 4.1.2). Oral breathing (vs. nasal breathing) and increased breathing rate are factors that allow for greater SO\textsubscript{2} penetration into the tracheobronchial region of the lower airways, and reflect conditions of individuals with asthma in which bronchoconstriction-related responses have been observed in the controlled exposure studies (ISA, sections 4.2.2, 5.2.1.2, and 6.3.1). Although the epidemiologic evidence includes a number of studies focused on health outcomes in children that are supportive of the qualitative conclusions of causality (ISA, section 5.2.1.2), there are few controlled human exposure studies to inform our

\textsuperscript{44} As noted in section I above, we use the term “at-risk populations” to refer to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestyle for which there is an increased risk of SO\textsubscript{2}-related health effects.

\textsuperscript{45} Since the 2010 review of the primary SO\textsubscript{2} NAAQS, the EPA has developed a formal framework to transparently characterize the strength of the evidence that can inform the identification of populations and lifestages at increased risk of a health effect related to exposure to a pollutant. This framework is part of the systematic approach taken in the ISA for this review (ISA, section 6.2).

\textsuperscript{46} The current evidence for risk to older adults relative to other lifestages comes from epidemiologic studies, for which findings are somewhat inconsistent, and studies with which there are uncertainties in association with the health outcome (ISA, section 6.5.1.2).

\textsuperscript{47} The ISA concluded that potential differences in airway responsiveness of children to SO\textsubscript{2} relative to adolescents and adults may be inferred by differences in responses to methacholine (ISA, section 5.2.1.2). Methacholine is a chemical that can elicit bronchoconstriction through its action on airway smooth muscle receptors. It is commonly used to identify people with asthma and accordingly has been used to screen subjects for studies of SO\textsubscript{2} effects. However, results of studies of the extent to which airway response to methacholine is predictive of SO\textsubscript{2} responsiveness have varied somewhat. For example, an analysis of the extent to which airway responsiveness to methacholine, a history of respiratory symptoms, and atopy were significant predictors of airway responsiveness to SO\textsubscript{2} found that about 20 to 25% of subjects ranging in age from 20 to 44 years that were hyperresponsive to methacholine were also hyperresponsive to SO\textsubscript{2} (ISA, section 5.2.1.2; Nowak et al., 1997). Another study focused on individuals with airway responsiveness to methacholine found only a weak correlation between airway responsiveness to SO\textsubscript{2} and methacholine (ISA, section 5.2.1.2; Horstman et al., 1986).
understanding of exposure concentrations associated with effects in this population group. Those studies have not included subjects younger than 12 years (ISA, p. 5–22). Some characteristics particular to school-age children younger than 12 years, such as increased propensity for mouth breathing (ISA, p. 4–5), however, suggest that this age group of children with asthma might be expected to experience larger lung function decrements than adults with asthma (ISA, p. 5–25).

Additionally, some individuals with asthma have a greater response to SO$_2$ than others with similar disease status (ISA, section 5.2.1.2; Horstman et al., 1986; Johns et al., 2010). This occurrence is quantitatively analyzed in a study newly available in this review. This study examined differences in lung function response using individual subject data available from five studies of individuals with asthma exposed to multiple concentrations of SO$_2$ for 5 to 10 minutes while breathing at elevated rates (Johns et al., 2010). As noted in the ISA, “these data demonstrate a bimodal distribution of airway responsiveness to SO$_2$ in individuals with asthma, with one subpopulation that is insensitive to the bronchoconstrictive effects of SO$_2$ even at concentrations as high as 1.0 ppm, and another subpopulation that has an increased risk for bronchoconstriction at low concentrations of SO$_2$.” (ISA, p. 5–20).

While such information provides documentation that some individuals have a greater response to SO$_2$ than others with the same disease status, the factors contributing to this greater susceptibility are not yet known (ISA, pp. 5–14 to 5–21).

The current evidence for factors evaluated in the ISA other than asthma status and lifestyle is inadequate to determine whether (e.g., sex and SES) might have an influence on risk of SO$_2$-related effects (ISA, section 6.6).

3. Exposure Concentrations Associated With Health Effects

Our understanding of exposure duration and concentrations associated with SO$_2$-related health effects is largely based, as it was in the previous review, on the longstanding evidence base of controlled human exposure studies. These studies demonstrate a dose-response relationship between 5- and 10-minute SO$_2$ exposure concentrations and decrements in lung function (e.g., increased sRaw and reduced FEV$_1$) and occurrence of respiratory symptoms in individuals with asthma exposed while breathing at elevated rates (ISA, section 1.6.1.1). Clear and consistent increases in these effects occur with increasing SO$_2$ exposure (ISA, Table 5–2 and pp. 5–35, 5–39). Further, the SO$_2$-induced bronchoconstriction occurs rapidly; exposures as short as 5 minutes have been found to elicit a similar bronchoconstrictive response as somewhat longer exposures. For example, during exposure to SO$_2$ over a 30-minute period with continuous exercise, the response to SO$_2$ has been found to develop rapidly and is maintained throughout the 30-minute exposure (ISA, p. 5–14). In a study involving short exercise periods within a 6-hour exposure, the effects observed following exercise were documented to return to baseline levels within one hour after the cessation of exercise, even with continued exposure (ISA, p. 5–14; Linn et al., 1984). Thus, the controlled human exposure evidence base demonstrates the occurrence of SO$_2$-related effects as a result of peak exposures on the order of minutes.

The controlled human exposure study findings demonstrate that SO$_2$ concentrations as low as 200 to 300 ppb for 5 to 10 minutes elicited moderate or greater lung function decrements, measured as a decrease in FEV$_1$ of at least 15% or an increase in sRaw of at least 100%, in the study subjects (ISA, sections 1.6.1.1 and 5.2.1). The percent of individuals affected, the severity of response, and the accompanying occurrence of respiratory symptoms increased with increasing SO$_2$ exposure concentrations (ISA, section 5.2.1). At concentrations ranging from 200 to 300 ppb, the lowest levels for which the ISA describes SO$_2$-related lung function decrements (in terms of 15% reductions in FEV$_1$ or doubling or tripling of sRaw), as many as 33% of exercising study subjects with asthma experienced moderate or greater decrements in lung function (ISA, section 5.2.1. Table 5–2). Analyses focused on subjects with asthma in multiple studies that are responsive to SO$_2$ at exposure concentrations below 1000 ppb found there to be statistically significant increases in lung function decrements occurring at 300 ppb (ISA, p. 153; Johns et al., 2010). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising individuals with asthma and a larger percentage of individuals with asthma experienced more severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a 20% or more decrease in FEV$_1$), compared to exposures at 200 to 300 ppb (ISA, section 5.2.1.2, p. 5–9 and Table 5–2). Additionally, at concentrations at or above 400 ppb, moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5–2 and section 5.2.1).

The lowest exposure concentration for which individual study subject data are available in terms of the sRaw and FEV$_1$ from studies that have assessed the SO$_2$ effect versus the effect of exercise in clean air is 200 ppb (ISA, Table 5–2 and Figure 5–1). In nearly all of these studies (and all of the studies for concentrations below 500 ppb), study subjects breathed freely (e.g., without using a mouthpiece). In studies that tested 200 ppb, a portion of the exercising study subjects with asthma (approximately 8 to 9%) responded with at least a doubling in sRaw or an increase in FEV$_1$ of at least 15% (ISA, Table 5–2 and Figure 5–2; PA, Table 3–1; Linn et al., 1983a; Linn et al., 1987). With regard to exposure concentrations below 200 ppb, the very limited available evidence is for
exposure as low as 100 ppb. Some differences in methodology and the reporting of results complicate comparisons of the studies of 100 ppb exposure with studies of higher concentrations. In the studies testing this concentration, subjects were exposed by mouthpiece rather than freely breathing in an exposure chamber (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989; Koenig et al., 1990; Trenga et al., 2001; ISA, section 5.2.1.2; PA, section 3.2.1.3).

Additionally, only a few of these studies included an exposure to clean air while exercising that would have allowed for determining the effect of SO\textsubscript{2} versus the effect of exercise in causing bronchoconstriction (Sheppard et al., 1981, 1984; Koenig et al., 1989). In those cases, a limited number of adult and adolescent study subjects were reported to experience small changes in sRaw, with the magnitudes of change appearing to be smaller than responses reported from studies at exposure concentrations of 200 ppb or more.\textsuperscript{52,53} Thus, the set of studies for the 100 ppb exposure concentration, while limited and complicated by differences from studies of higher concentrations with regard to reporting of results and exposure method, does not indicate this exposure concentration to result in as much as a doubling in sRaw, based on the extremely few adults and adolescents tested (Sheppard et al., 1981, 1984; Koenig et al., 1989).

Specific exposure concentrations that may be eliciting respiratory responses are not available from the epidemiological studies that find associations with outcomes such as asthma-related emergency department visits and hospitalizations. For example, in noting limitations of epidemiologic studies with regard to uncertainties in SO\textsubscript{2} exposure estimates, the ISA recognized that “[i]t is unclear whether SO\textsubscript{2} concentrations at the available fixed site monitors adequately represent variation in personal exposures especially if peak exposures are as important as indicated by the controlled human exposure studies” (ISA, p. 5–37). This extends the observation of the 2008 ISA that “it is possible that these epidemiological associations are determined in large part by peak exposures within a 24-h[our] period” (2008 ISA, p. 5–5).

Given the important role of SO\textsubscript{2} as a precursor to PM in ambient air, however, a key uncertainty in the epidemiologic evidence available in this review, as in the last review, is potential confounding by copollutants, particularly PM (ISA, p. 5–5). Among the U.S. epidemiologic studies reporting mostly positive and sometimes statistically significant associations between ambient SO\textsubscript{2} concentrations and emergency department visits or hospital admissions (some conducted in multiple locations), few studies have attempted to address this uncertainty, e.g., through the use of copollutant models. For example, as in the last review, there are three U.S. studies for which the SO\textsubscript{2} effect estimate remained positive and statistically significant in copollutant models with PM.\textsuperscript{54} No additional such studies have been newly identified in this review that might inform this issue. Thus, such uncertainties in copollutant confounding, as well as exposure measurement error, remain in the currently available epidemiologic evidence base (ISA, p. 5–6).

4. Potential Impacts on Public Health

In general, the magnitude and implications of potential impacts on public health are dependent upon the type and severity of the effect, as well as the size and other features of the population affected (ISA, section 1.7.4; PA, 3.2.1.5). With regard to SO\textsubscript{2} concentrations in ambient air, the public health implications and potential public health impacts relate to the effects causally related to SO\textsubscript{2} exposures of interest in this review. These are respiratory effects of short-term exposures, and particularly those effects associated with asthma exacerbation in people with asthma. As summarized above in section II.B.1, the most strongly demonstrated effects are bronchoconstriction-related effects resulting in decrements in lung function elicited by short term exposures during periods of elevated breathing rate; asthma-related health outcomes such as emergency department visits and hospital admissions have also been statistically associated with ambient air SO\textsubscript{2} concentration metrics in epidemiologic studies (ISA, section 5.2.1.9).

As summarized in section II.B.2 above, people with asthma are the population at risk for SO\textsubscript{2}-related effects and children with asthma are considered to be at relatively greater risk than other age groups within this at-risk population (ISA, section 6.3.1). The evidence supporting this conclusion comes primarily from studies of individuals with mild to moderate asthma,\textsuperscript{55} with very little evidence available for individuals with severe asthma. The evidence base of controlled human exposure studies of exercising people with asthma provides very limited information indicating that there are similar responses (in terms of relative decrements in lung function in response to SO\textsubscript{2} exposures) of individuals with differences in severity of their asthma.\textsuperscript{56} However, the two available studies “suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5–22; Linn et al., 1987; Trenga et al., 1999). Consideration

\textsuperscript{52}For example, the increase in sRaw reported for two young adult subjects exposed to 100 ppb in the study by Sheppard et al. (1981) was slightly less than half the response of these subjects at 250 ppb, and the results for the study by Sheppard et al. (1984) indicate that none of the eight study subjects experienced as much as a doubling in sRaw response to the mouthpiece exposure to 125 ppb while exercising. In the study of adolescents (aged 12 to 18 years), among the three individual study subjects for which respiratory resistance appears to have increased with SO\textsubscript{2} exposure, the magnitude of any increase after consideration of the response to exercise appears to be less than 100% in each subject (Koenig et al., 1990).

\textsuperscript{53}In a mouthpiece exposure system, the inhaled breath completely bypasses the nasal passages where SO\textsubscript{2} is efficiently removed, thus allowing more of the inhaled SO\textsubscript{2} to penetrate into the tracheobronchial airways (2008 ISA, p. 3–4; ISA, section 4.1.2.2). This allowance of greater penetration of SO\textsubscript{2} into the tracheobronchial airways, particularly in individuals at elevated rates, would experience greater lung function responses than if exposed to the same test concentration while freely breathing in an exposure chamber (ISA, p. 5–23; Linn et al., 1983b).

\textsuperscript{54}Based on data available for specific time periods at some monitors in the areas of these studies, the 99th percentile 1-hour daily maximum concentrations were estimated in the last review to be between 78–150 ppb (Thompson and Stewart, 2009; PA, Appendix D).

\textsuperscript{55}These studies categorized asthma severity based mainly on the individual’s use of medication to control asthma, such that individuals not regularly using medication were classified as minimal/mild, and those regularly using medication as moderate/severe (Linn et al., 1987). The ISA indicates that the moderate/severe grouping would likely be classified as moderate by today’s asthma classification standards due to the level to which their asthma was controlled and their ability to engage in moderate to heavy levels of exercise (ISA, p. 5–22; Johns et al., 2010; Reddel, 2009).

\textsuperscript{56}The ISA identifies two studies that have investigated the influence of asthma severity on responsiveness to SO\textsubscript{2}, with one finding that a larger change in lung function observed in the moderate/severe asthma group was attributable to the exercise component of the study protocol while the other did not assess the role of exercise in differences across individuals with asthma of differing severity (Linn et al., 1987; Trenga et al., 1999). The ISA states, “[h]owever, both studies suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5–22). Based on the criteria used in the study by Linn et al (1987) for placing individuals in the “moderate/severe” group, the ISA concluded that the asthma of these individuals “would likely be classified as moderate by today’s classification standards” (ISA, p. 5–22; Johns et al., 2010; Reddel, 2009).
of such baseline differences among members of at-risk populations and of the relative transience or persistence of these responses (e.g., as noted in section II.B.3 above), as well as other factors, is important to characterizing implications for public health, as recognized by the ATS in their recent statement on evaluating adverse health effects of air pollution (Thurston et al., 2017).

The Administrator’s judgment is informed by statements by the ATS on what constitutes an adverse health effect of air pollution. Building on the earlier statement by the ATS that was considered in the last review (ATS, 2000), the recent policy statement by the ATS on what constitutes an adverse health effect of air pollution provides a general framework for interpreting evidence that proposes a “set of considerations that can be applied in forming judgments” for this context (Thurston et al., 2017). The earlier ATS statement, in addition to emphasizing clinically relevant effects (e.g., the adversity of small transient changes in lung function metrics in combination with respiratory symptoms), also emphasized both the need to consider changes in “the risk profile of the exposed population” and effects on the portion of the population that may have a diminished reserve that could put its members at potentially increased risk of effects from another agent (ATS, 2000). The consideration of effects on individuals with preexisting diminished lung function continues to be recognized as important in the more recent ATS statement (Thurston et al., 2017). For example, in adding emphasis in this area, this statement conveys the view that “small lung function changes” in individuals with compromised function, such as that resulting from asthma, should be considered adverse, even without accompanying respiratory symptoms (Thurston et al., 2017). All of these concepts, including the consideration of the magnitude of effects occurring in just a subset of study subjects, are recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to consideration of the evidence base for SO2.

Such concepts are routinely considered by the Agency in weighing public health implications for decisions on primary NAAQS, as summarized in section I.A above. For example, in deliberations on a standard that provides the requisite public health protection under the Act, the EPA traditionally recognizes the nature and severity of the health effects involved, recognizing the greater public health significance of more severe health effects, including, for example, effects that have been documented to be accompanied by symptoms, and of the risk of repeated occurrences of effects (76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Another area of consideration is characterization of the population at risk, including its size and, as pertinent, the exposure/risk estimates in this regard. Such factors related to public health significance, and the kind and degree of associated uncertainties, are considered by the EPA in addressing the CAA requirement that the primary NAAQS are requisite to protect public health, including a margin of safety, as summarized in section I.A above.

Ambient air concentrations of SO2 vary considerably in areas near sources, but concentrations in the vast majority of the U.S. are well below the current standard (PA, Figure 2–7). Thus, while the population counts discussed below may convey information and context regarding the size of populations living near sizeable sources in some areas, the concentrations in most areas of the U.S. are well below the conditions assessed in the REA.

With regard to the size of the U.S. population at risk of SO2-related effects, the National Center for Health Statistics data from the 2015 National Health Interview Survey (NHIS) indicate that approximately 8% of the U.S. population has asthma (PA, Table 3–2; CDC, 2017). Among all U.S. adults, the prevalence is estimated to be 7.6%, with women having a higher estimate (9.7%) than men (5.4%). The estimated prevalence is greater in children (8.4% for children less than 18 years of age) than adults (7.6%) (PA, Table 3–2; CDC, 2017). Asthma was the leading chronic illness affecting children in 2012, the most recent year for which such an evaluation is available (Bloom et al., 2013). As noted in the PA, there are more than 24 million people with asthma currently in the U.S., including more than 6 million children (PA, sections 3.2.2.4 and 3.2.4).

Relatively greater population-level SO2 impacts (i.e., greater numbers of individuals affected) might be expected in population groups with relatively greater asthma prevalence (i.e., groups with relatively higher percentages of individuals that have asthma). Among all U.S. children, the asthma prevalence estimate is greater for boys than girls (CDC, 2017). Asthma prevalence estimates from the 2015 NHIS vary for children of different races or ethnicities and household incomes, among other factors (CDC, 2017). Among populations of different races or ethnicities, black non-Hispanic and Puerto Rican Hispanic children are estimated to have the highest prevalences, at 13.4% and 13.9%, respectively. Asthma prevalence is also increased among populations in poverty, with the prevalence estimated to be 11.1% among people living in households below the poverty level compared to 7.2% of those living above it.

The information on which to base estimates of asthma prevalence in other subgroups of children is much more limited (e.g., as discussed in the REA, section 4.1.2). For example, the more limited information from the NHIS for 2011–2015 indicates there to be a greater prevalence of asthma in children that are obese compared to those that are not (REA, section 4.1.2, Figure 4–2).58

With regard to the potential for exposure of the populations at risk from SO2 in ambient air, the PA recognizes that while SO2 concentrations have generally declined across the U.S. since 2010 when the current standard was set (PA, Figures 2–5 and 2–6), there are numerous areas where SO2 concentrations still contribute to air quality that is near or above the standard. For example, the

57 The NHIS is conducted annually by the U.S. Centers for Disease Control and Prevention. The NHIS collects health information from a nationally representative sample of the noninstitutionalized U.S. civilian population through personal interviews. Participants (or parents of participants if the survey participant is a child) who have ever been told by a doctor or other health professional that the participant had asthma and reported that they still have asthma are considered to have current asthma. Data are weighted to produce nationally representative estimates using sample weights; estimates with a relative standard error greater than or equal to 30% are generally not reported (Mazurek and Syamlal, 2018). The NHIS estimates described here are drawn from the 2015 NHIS, Table 4–1 (https://www.cdc.gov/asthma/nhis/2015/table4-1.htm).

58 Although the CDC does not report NHIS estimates for the percent of obese adults or children that have asthma, they do report that that more adults with asthma are obese than adults without asthma. As discussed in the REA, the NHIS sample size for children with asthma identified as obese is very limited (REA, section 4.1.2).

59 In consideration of the limited information regarding factors related to breathing habit (whether one is breathing through their nose or mouth) and recognizing the lack of evidence from controlled human exposure studies of SO2-induced lung function decrements in children, approximately 5 to 11 years of age, with asthma, the ISA suggests that this age group of children and “particularly boys and perhaps obese children, might be expected to experience greater responsiveness (i.e., larger decrements in lung function) following exposure to SO2 than normal-weight adolescents and adults” (ISA, pp. 4–7 and 5–36). However, the ISA does not find the evidence to be adequate to conclude differential risk status for subgroups of children with asthma (ISA, Chapter 6).
most recently available design values for the primary SO₂ standard (those based on monitoring data for the 2014–2016 period) indicate there to be 15 core-based statistical areas ⁶⁰ with design values above the existing standard level of 75 ppb, of which a number have sizeable populations. ⁶¹ In addition to this evidence of elevated ambient air SO₂ concentrations, there are limitations in the monitoring network with regard to the extent that it might be expected to capture all areas with the potential to exceed the standard (e.g., 75 FR 35551; June 22, 2010). ⁶² In recognition of these limitations, the PA also examined the proximity of populations to sizeable SO₂ point sources using the most recently available emissions inventory information (2014), which is also characterized in the ISA (ISA, section 2.2.2). ⁶³ This information indicates that there are more than 300,000 and 60,000 children living within 1 km of facilities emitting at least 1,000 and 2,000 tpy of SO₂, respectively. Within 5 km of such sources, the numbers are approximately 1.4 million and 700,000, respectively (PA, Table 3–5). While information on SO₂ concentrations in locations of maximum impact of such sources is not available for all these areas, and SO₂ concentrations vary appreciably near sources, simply considering the 2015 national estimate of asthma prevalence of approximately 8% (noted above), this information would suggest there may be as many as 24,000 to more than 100,000 children with asthma that live in areas near substantially sized sources of SO₂ emissions to ambient air (PA, section 3.2.1.5; Table 3–5).

The information discussed in this section indicates the potential for exposures to SO₂ in ambient air to be of public health importance. Such considerations contributed to the basis for the 2010 decision to appreciably strengthen the primary SO₂ NAAQS and to establish a 1-hour standard to provide public health protection for at-risk populations from short-term exposures of concern.

C. Summary of Risk and Exposure Information

Our consideration of the scientific evidence available in the current review (summarized in section II.B above), as at the time of the last review, is informed by results from a quantitative analysis of estimated population exposure and associated risk of bronchoconstriction-related effects that the evidence indicates to be elicited in some portion of exercising people with asthma by short exposures to elevated SO₂ concentrations, e.g., such exposures lasting 5 or 10 minutes. This analysis, for the air quality scenario of just meeting the current standard, estimates two types of risk metrics in terms of percentages of the simulated at-risk populations of adults with asthma and children with asthma (REA, section 4.6). The first of the two risk metrics is based on comparison of the estimated 5-minute exposure concentrations for individuals breathing at elevated rates to 5-minute exposure concentrations of potential concern (benchmark concentrations), and the second utilizes exposure-response (E–R) information from studies in which subjects experienced moderate or greater lung function decrements (specifically a doubling or more in sRaw) to estimate the portion of the simulated at-risk population likely to experience one or more days with an SO₂-related increase in sRaw of at least 100% (REA, sections 4.6.1 and 4.6.2). Both of these metrics are used in the REA to characterize health risk associated with 5-minute peak SO₂ exposures among simulated at-risk populations during periods of elevated breathing rates. These risk metrics were also derived in the REA for the last review and the associated estimates informed the Administrator’s 2010 decision to establish the current standard (75 FR 35546–35547, June 22, 2010).

The following subsections summarize key aspects of the design and methods of the quantitative assessment (section II.C.1) and the important uncertainties associated with these analyses (section II.C.2). The results of the analyses are summarized in section II.C.3.

1. Key Design Aspects

In this section, we provide an overview of key aspects of the quantitative exposure and risk assessment conducted for this review, including the study areas, air quality adjustment approach, modeling tools, at-risk populations simulated, and benchmark concentrations assessed. The assessment is described in detail in the REA and summarized in section 3.2.2 of the PA.

Given the primary overarching consideration in this review of whether the currently available information calls into question the adequacy of protection provided by the current standard, the air quality scenario analyzed in the REA focuses on air quality conditions that just meet the current standard. With this focus, the analyses estimate exposure and risk for at-risk populations in three urban study areas in: (1) Fall River, MA; (2) Indianapolis, IN; and (3) Tulsa, OK. The three study areas present a variety of circumstances related to population exposure to short-term peak concentrations of SO₂ in ambient air. These study areas range in total population size from approximately 160,000 to 540,000 and reflect different mixtures of SO₂ emissions sources, including electric utilities using fossil fuels, as well as sources such as petroleum refineries and secondary lead smelting (REA, section 3.1). The three study areas—in Massachusetts, Indiana and Oklahoma—are in three different climate regions of the U.S.: The Northeast, Ohio River Valley (Central), and South (Karl and Koss, 1984). The latter two regions comprising the part of the U.S. with generally the greatest prevalence of elevated SO₂ concentrations and large emissions sources (PA, Figure 2–7 and Appendix F). ⁶⁴ Additionally, the three study areas illustrate three different patterns of exposure to SO₂ concentrations in a populated area in the U.S. (REA, section 5.1). While the same air quality scenario

⁶⁴ Additionally, continuous 5-minute ambient air monitoring data (i.e., 3–5 minute values for each hour) are available in all three study areas (REA, section 3.2).
is simulated in all three study areas (conditions that just meet the current standard), study-area-specific source and population characteristics contribute to variation in the estimated magnitude of exposure and associated risk across study areas.

As indicated by this case study approach to assessing exposure and risk, the analyses in the REA are intended to provide assessments of an air quality scenario just meeting the current standard for a small, diverse set of study areas and associated exposed-at-risk populations that will be informative to the EPA’s consideration of potential exposures and risks that may be associated with the air quality conditions occurring under the current SO\textsubscript{2} standard. The REA analyses are not designed to provide a comprehensive national assessment of such conditions (REA, section 2.2). The objective of the REA is not to present an exhaustive analysis of exposure and risk in areas of the U.S. that currently just meet the standard and/or of exposure and risk associated with air quality adjusted to just meet the standard in areas that currently do not meet the standard.\textsuperscript{65} Rather, the purpose is to assess, based on current tools and information, the potential for exposures and risks beyond those indicated by the information available at the time the current standard was established. Accordingly, capturing an appropriate diversity in study areas and air quality conditions (that reflect the current standard scenario) is important to the role of the REA in informing the EPA’s conclusions on the public health protection afforded by the current standard (PA, section 3.2.2.2).

A broad variety of spatial and temporal patterns of SO\textsubscript{2} concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types of emissions sources in a study area and several characteristics of those sources, such as magnitude of emissions and facility age, use of various control technologies, patterns of operation, and local factors, as well as local meteorology. Estimates derived by the particular analytical approaches and methodologies used to describe the study area-specific air quality provide an indication of this variability in the spatial and temporal patterns of SO\textsubscript{2} concentrations associated with air quality conditions just meeting the current standard, while recognizing the associated uncertainty in these concentration estimates.

In this regard, the REA presents results from two different approaches to adjusting air quality. The first approach uses the highest design value across all modeled air quality receptors to adjust the air quality concentrations in each area to just meet the standard (REA, section 3.4). This is done by estimating the amount of SO\textsubscript{2} concentration reduction needed for concentrations at this highest receptor to be adjusted to just meet the current standard. Based on this amount, all other receptors impacted by the highest source(s) are adjusted proportionately. The second approach is included in the REA as a sensitivity analysis in recognition of the potential uncertainty associated with the estimated concentrations across the modeling domain, particularly the very highest concentrations. Accordingly, the second approach uses the air quality receptor having the 99th percentile of the distribution of design values (instead of the receptor having the maximum design value) to estimate the SO\textsubscript{2} concentration reductions needed to adjust the air quality to just meet the standard (REA, section 6.2.2.2).

Consistent with the health effects evidence summarized in section II.B above, the focus of the REA is on short-term (5-minute) exposures of individuals in the population with asthma during times when they are breathing at an elevated rate. Five-minute concentrations in ambient air were estimated for the current standard scenario using a combination of 1-hour concentrations from the EPA’s preferred near-field dispersion model, the American Meteorological Society/EPA regulatory model (AERMOD), with adjustment such that they just meet the current standard, and relationships between 1-hour and 5-minute concentrations occurring in the local ambient air monitoring data. Air quality modeling with AERMOD is used to capture the spatial variation in ambient SO\textsubscript{2} concentrations across an urban area, which can be relatively high in areas affected by large point sources, and which the limited number of monitoring locations in each area is unlikely to capture. This provides 1-hour concentrations at model receptor sites across the modeling domain across the 3-year modeling period (consistent with the 3-year form of the standard). These concentrations were adjusted such that the air quality modeling receptor location with the highest concentrations just met the current standard.\textsuperscript{66} Relationships between 1-hour and 5-minute concentrations at local monitors were then used to estimate 5-minute concentrations associated with the adjusted 1-hour concentrations across the 3-year period at all model receptor locations in each of the three study areas (REA, section 3.5). In this way, available continuous 5-minute ambient air monitoring data (datasets with all twelve 5-minute concentrations in each hour) were used to reflect the fine-scale temporal variation in SO\textsubscript{2} concentrations documented by these data and for which air quality modeling is limited, e.g., by limitations in the time steps of currently available model input data such as for emissions estimates.

The estimated 5-minute concentrations in ambient air across each study area were then used together with the Air Pollutants Exposure (APEX) model, a probabilistic human exposure model that simulates the activity of individuals in the population, including their exertion levels and movement through time and space, to estimate concentrations of 5-minute exposure events of the individuals in indoor, outdoor, and in-vehicle microenvironments. The use of APEX for estimating exposures allows for consideration of factors that affect exposures that are not addressed by consideration of ambient air concentrations alone. These factors include: (1) Attenuation in SO\textsubscript{2} concentrations expected to occur in some indoor microenvironments; (2) the influence of human activity patterns on the time series of exposure concentrations; and (3) accounting for human physiology and the occurrence of elevated breathing rates concurrent with SO\textsubscript{2} exposures. These factors are all key to appropriately characterizing health risk for SO\textsubscript{2}.

The APEX model has a history of application, evaluation, and progressive model development in estimating human exposure and dose for review of

\textsuperscript{65} Nor is the objective of the REA to provide a comprehensive assessment of current air quality across the U.S.

\textsuperscript{66} The air quality adjustments were implemented with a focus on reducing emissions from the source(s) contributing most to the standard exceedances until the areas just met the standard. This approach focuses on the concentrations associated with the primary contributing source(s), identifying the amount by which they need to be adjusted in order for the highest design value across all air quality receptors to just meet the current standard (REA, section 3.4). Based on this amount, all other receptors impacted by the highest source(s) are adjusted accordingly. In recognition of the potential uncertainty associated with this approach, particularly for the highest estimated concentrations, a second approach was also evaluated that bases the adjustments on the air quality receptor having the 99th percentile of the distribution of design values instead of the receptor having the maximum design value (REA, section 6.2.2.1).
NAAQS for gaseous pollutants (see, e.g., U.S. EPA, 2008b; 2010; 2014d). This general exposure modeling approach was also used in the 2009 REA for the last review of the primary standard for SO₂, although a number of updates have been made to the model and various datasets used with it (2009 REA; REA Planning Document, section 3.4). For example, exposure modeling in the current REA includes reliance on updates to several key inputs of the model, including: (1) A significantly expanded Consolidated Human Activity Database (CHAD), that now has over 55,000 diaries, with over 25,000 school-aged children; (2) updated National Health and Nutrition Examination Survey (NHANES) data (2009–2014), which are the basis for the age- and sex-specific body weight distributions that APEX samples to specify the individuals in the modeled populations; (3) the algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual’s activity-specific ventilation (or breathing) rate; and (4) the ventilation rate algorithm itself. Further, the current model uses updated population demographic data based on the most recent Census. As used in the current assessment, the APEX model probabilistically generates a sample of hypothetical individuals based on sampling from an actual population database, and simulates each individual’s movements through time and space (e.g., indoors at home, inside vehicles) to estimate his or her exposure to a pollutant. Population characteristics are taken into account to represent the demographic profile of the population in each study area. Age and gender demographics for the simulated at-risk population (adults and children with asthma) were drawn from the prevalence estimates provided by the 2011–2015 NHIS. The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, status and physical attributes (e.g., residence with air conditioning, height, weight, body surface area) and ventilation rate. Based on minute-by-minute activity levels and physiological characteristics of the simulated person, APEX estimates an equivalent ventilation rate (EVR) based on normalizing the simulated individuals’ activity-specific ventilation rate to their body surface area; the EVR is used to identify exposure periods during which an individual is at or above a specified ventilation level (REA, section 4.1). The level specified is based on the ventilation rates of subjects in the controlled human exposure studies of exercising people with asthma (ISA, Table 5–2). The APEX simulations performed for this review have focused on exposures to SO₂ emitted into ambient air that occurs in microenvironments without additional contribution from indoor SO₂ emissions sources.

The at-risk populations for which exposure and risk are estimated (people with asthma) comprise 8.0 to 8.7% of the populations in the exposure modeling domains for the three study areas (REA, section 5.1). The percent of children with asthma in the simulated populations ranges from 9.7 to 11.2% across the three study areas (REA, section 5.1). Within each study area the percent varies with age, sex and whether family income is above or below the poverty level (REA, section 4.1.2, Appendix E). This variation is greatest in the Fall River study area, with census block level, age-specific asthma prevalence estimates ranging from 7.9 to 18.6% for girls and from 10.7 to 21.5% for boys (REA, Table 4–1). As in the last review, the REA for this review uses the APEX model estimates of 5-minute exposure concentrations for simulated individuals with asthma while breathing at elevated rates to characterize health risk in two ways (REA, section 4.5). The first is the percentage of the simulated at-risk populations expected to experience days with 5-minute exposures, while breathing at elevated rates, that are at or above a range of benchmark levels. The second is the percentage of the populations expected to experience days with an occurrence of a doubling or tripling of sRaw. The benchmark concentrations were identified based on consideration of the evidence discussed in section II.B above.

For the benchmark metric, the REA uses benchmark concentrations of 400 ppb, 300 ppb, 200 ppb based on concentrations included in the well-documented controlled human exposure studies summarized in section II.B above, and also 100 ppb in consideration of uncertainties with regard to lower concentrations and population groups with more limited data, as discussed in section II.B above (REA, section 4.5.1). At the upper end of this range, 400 ppb represents the lowest concentration in free-breathing controlled human exposure studies of exercising people with asthma where moderate or greater lung function decrements occurred that were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms, with some increases in these symptoms also being statistically significant at the group level (ISA, Section 5.2.1.2 and Table 5–2). At 300 ppb, statistically significant increases in lung function decrements (specifically reduced FEV₁) have been documented in analyses of the subset of controlled human study exposure subjects with asthma that are responsive to SO₂ at concentrations below 600 or 1000 ppb (ISA, pp. 5–85 and 5–153 and Table 5–2; Johns et al., 2010). The 200 ppb benchmark concentration represents the lowest level for which individual study subject data are available in terms of the sRaw and FEV₁ from studies that have assessed the SO₂ effect versus the effect of exercise in clean air; moderate or greater lung function decrements were documented in some studies of asthmatic subjects (ISA, Table 5–2 and Figure 5–1; PA, Table 3–1; REA, section 4.6.1). For exposure concentrations below 200 ppb, limited data are available for exposures at 100 ppb that, while not directly comparable to the data at higher concentrations because of differences in methodology and metrics reported, do not indicate that study subjects experienced responses of a magnitude as high as a doubling in sRaw. However, in consideration of some study subjects with asthma experiencing moderate or greater decrements in lung function at the 200 ppb exposure concentration (approximately 8 to 9% of the study group) and of the paucity or lack of any specific study data for some groups of individuals with asthma, such as primary-school-age children and those

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67 Data for these years were obtained from the NHIS, available at https://www.cdc.gov/nchs/nhis/ data-questionnaires-documentation.htm
68 Five microenvironments (MEs) are modeled in the REA as representative of a larger number of MEs. The 2009 REA results indicate that the majority of peak SO₂ exposures occurred while individuals were within outdoor MEs (2009 REA, Figure 8–21). Based on that finding and the objective (i.e., understanding how often and where short-term peak SO₂ exposures occur), some MEs that were used in the 2009 REA were aggregated to address exposures of ambient origin that occur within a core group of indoor, outdoor, and vehicle MEs (REA, section 4.2).
69 Indoor sources of SO₂ are generally minor in comparison to SO₂ from ambient air (ISA, p. 3–6; REA, section 2.1.1 and 2.1.2).
70 As described in section 4.1.2 and Appendix E of the REA, asthma prevalence in the exposure modeling domain is estimated based on national prevalence information and study area demographic information related to age, sex and poverty status.
71 As explained in section II.B.3 above, these studies involved exposures via mouthpiece, and only a few of these studies included an exposure to clean air while exercising that would have allowed for determining the effect of SO₂ versus that of exercise in causing bronchoconstriction (ISA, section 5.2.1.2; PA, section 3.2.1.3).
with more severe asthma, a benchmark concentration of 100 ppb (one half the lowest exposure concentration tested in free breathing exposure studies that assessed the SO2 effect versus the effect of exercise in clean air) is also included.

The E–R function for estimating risk of lung function decrements was developed from the individual subject results for sRaw from the controlled exposure studies of exercising freely breathing people with asthma exposed to SO2 concentrations from 1000 ppb down to as low as 200 ppb (REA, Table 4–11). Beyond the assessment of these studies and their results in past reviews, there has been extensive evaluation of the individual subject results, including a data quality review in the last primary SO2 NAAQS review (Johns and Simmons, 2009), and detailed analysis in two subsequent publications (Johns et al., 2010; Johns and Linn, 2011). The sRaw responses reported in the controlled exposure studies have been summarized in the ISA in terms of percent of individuals experiencing responses of a magnitude equal to a doubling or tripling or more (e.g., ISA, Table 5–2; Long and Brown, 2018). Across the exposure range from 200 to 1000 ppb, the percentage of exercising study subjects with asthma having at least a doubling of sRaw increases from about 8–9% (at exposures of 200 ppb) up to approximately 50–60% (at exposures of 1000 ppb) (REA, Table 4–11). The E–R function was derived from

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2 The approach used has been applied in REAs for past NAAQS review for nitrogen oxides, carbon monoxide, ozone (U.S. EPA, 2008b; 2010; 2014d), and SO2 (U.S. EPA, 2009).

4 Across the exposure range from 200 to 1000 ppb, the percentage of exercising study subjects with asthma having at least a doubling of sRaw increases from about 8–9% (at exposures of 200 ppb) up to approximately 50–60% (at exposures of 1000 ppb) (REA, Table 4–11). The E–R function was derived from

2 Key Limitations and Uncertainties

While the general approach and methodology for the exposure-based assessment in this review is similar to that used in the last review, there are a number of ways in which the current analyses differ and incorporate improvements. For example, in addition to an expansion in the number and type of study areas assessed, input data and modeling approaches have improved in a number of ways, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas. The REA for the current review extends the time period of simulation to a 3-year simulation period, consistent with the form established for the now-current standard.

Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision.

In characterizing uncertainty associated with the risk and exposure estimates in this review, the REA used an approach intended to identify and compare the relative impact that important sources of uncertainty may have (REA, section 6.2). This approach is a qualitative uncertainty characterization approach adapted from the World Health Organization (WHO) approach for characterizing uncertainty in exposure assessment (WHO, 2008) accompanied by quantitative sensitivity analyses of key aspects of the assessment approach (REA, chapter 6). The REA considers the limitations and uncertainties underlying the analysis inputs and approaches and the extent of their influence on the resultant exposure/risk estimates. Consistent with the WHO (2008) guidance, the overall impact of the uncertainty is scaled by considering the extent or magnitude of the impact of the uncertainty as implied by the relationship between the source of the uncertainty and the exposure/risk output. The REA also evaluated the direction of influence, indicating how the source of uncertainty was judged to affect the exposure and risk estimates (e.g., likely to produce over- or under-estimates).

Several areas of uncertainty are identified as particularly important, with some similarities to those in the last review. Generally, these areas of uncertainty include estimation of the spatial distribution of SO2 concentrations across each study area under air quality conditions just meeting the current standard, including the fine-scale temporal pattern of 5-minute concentrations. Among other areas, there is also uncertainty with regard to population groups and exposure concentrations for which the health effects evidence base is limited or lacking (PA, section 3.2.2.3).

With regard to the spatial distribution of SO2 concentrations, there is some uncertainty associated with the ambient air concentration estimates in the air quality scenarios assessed. A more detailed characterization of contributors to this uncertainty is presented in the REA (REA, section 6.2), with a general summary provided in this report. One approach-related aspect contributing to this uncertainty include the model estimates of 1-hour concentrations and the approach employed to adjust the air quality surface to concentrations just meeting the current standard, as well as the estimation of 1-hour ambient air concentrations resulting from emissions sources not explicitly modeled, all of which influence the temporal and spatial pattern of concentrations and associated exposure circumstances represented in the study areas (REA, sections 6.2.1 and 6.2.2). There is also uncertainty in the estimates of 5-minute concentrations in ambient air across the modeling receptors in each study area. The ambient air monitoring dataset available to inform the 5-minute estimates, much expanded in this review over the dataset available in the last review, is used to draw on relationships occurring at one location and over one range of concentrations to estimate the fine-scale temporal pattern in concentrations at the other locations. While this is an important area of uncertainty in the REA results because the ambient air 5-minute concentrations

70 As summarized in section II.B.3 above, recognizing that even the study subjects described as “moderate/severe” group (had well-controlled asthma, were generally able to withhold medication, dependent on corticosteroids, and were able to engage in moderate to heavy levels of exercise) would likely be classified as moderate by today’s classification standards (ISA, p. 5–22; Johns et al., 2009), we have considered the evidence with regard to the response of individuals with severe asthma that are not generally represented in the full set of controlled human exposure studies. There is no evidence to indicate such individuals would experience moderate or greater SO2-related lung function decrements at lower SO2 exposure concentrations than individuals with moderate asthma. With regard to the severity of response, the limited data that are available indicate a similar magnitude of relative lung function decrements in response to SO2 as that for individuals with less severe asthma, although the individuals with more severe asthma are indicated to have a larger absolute response and a greater response to exercise prior to SO2 exposure, indicating uncertainty in the role of exercise versus SO2; and that those individuals “may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5–22).

71 In study areas in which estimated SO2 concentrations at a very small number of receptors are substantially higher than those at all other air quality receptors, the two different approach-related aspects investigated in the REA (described in section II.C.1 above) can result in very different concentrations across the area. In areas with this characteristic, the first approach (which involves determining adjustments based on concentrations at the very highest receptor locations) generally results in appreciably lower concentrations than those associated with the second approach at receptor locations beyond the small group with the very highest concentrations in the area. This is discussed in greater detail in the REA, section 6.2.2.2.
are integral to the 5-minute estimates of exposure, the approach used to represent fine-scale temporal variability in the three study areas is strongly based in the available information and has been evaluated in the REA (REA, Table 6–3; sections 3.5.2 and 3.5.3).

Another important area of uncertainty, particular to interpretation of the lung function risk estimates, concerns estimates derived for exposure concentrations below those represented in the evidence base (REA, Table 6–3). The E–R function on which the risk estimates are based generates non-zero predictions of the percentage of the at-risk population expected to experience a day with at least a doubling of sRaw for all exposures experienced while breathing at an elevated rate. The uncertainty in the response estimates increases substantially with decreasing exposure concentrations below those well represented in the data from the controlled human exposure studies (i.e., below 200 ppb).

Additionally, the assessment focuses on the daily maximum 5-minute exposure during a period of elevated breathing rate, summarizing results in terms of the days on which the magnitude of such exposure exceeds a benchmark or contributes to a doubling or tripling of sRaw. Although there is some uncertainty associated with the potential for additional, uncounted events in the same day, the health effects evidence indicates a lack of a cumulative effect of multiple exposures over several hours or a day (ISA, section 5.2.1.2) and a reduced response to repeated exercising exposure events over an hour (Kehrl et al., 1987). Further, information is somewhat limited with regard to the length of time after recovery from one exposure by which a repeat exposure would elicit a similar effect as that of the initial exposure event (REA, Table 6–3).

Another area of uncertainty concerns the potential influence of co-occurring pollutants on the relationship between short-term SO2 exposures and respiratory effects. For example, there is some limited evidence regarding the potential for an increased response to SO2 exposures occurring in the presence of other common pollutants such as PM (potentially including particulate sulfur compounds), nitrogen dioxide and ozone, although the studies are limited (e.g., with regard to their relevance to ambient exposures) and/or provide inconsistent results (ISA, pp. 5–23 to 5–26, pp. 5–143 to 5–144; 2008 ISA, section 3.1.4.7).76

Another area of uncertainty, which remains from the last review and is important to our consideration of the REA results, concerns the extent to which the quantitative results represent the populations at greatest risk of effects associated with exposures to SO2 in ambient air. As recognized in section II.B, the controlled human exposure study evidence base does not include studies of children younger than 12 years old and is limited with regard to studies of people with more severe asthma.77 The limited evidence that informs our understanding of potential risk to these groups indicates the potential for them to experience greater impacts than other population groups with asthma under similar exposure circumstances or, in the case of people with severe asthma, to have a more limited reserve for addressing this risk (ISA, section 5.2.1.2). Further, we note the lack of information on the factors contributing to increased susceptibility to SO2-induced bronchoconstriction among some people with asthma compared to others (ISA, pp. 5–19 to 5–21). These data limitations contribute uncertainty to the exposure/risk estimates with regard to the extent to which they represent the populations at greatest risk of SO2-related respiratory effects.

In summary, among the multiple uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard, several are particularly important. These include uncertainties related to estimation of 5-minute concentrations in ambient air; the lack of information from controlled human exposure studies for the lower, more prevalent, concentrations of SO2 and limited information regarding multiple exposure episodes within a day; the prevalence of different exposure circumstances represented by the three study areas; and characterization of particular subgroups of people with asthma that may be at greater risk.

3. Summary of Exposure and Risk Estimates

The REA provides estimates for two simulated at-risk populations: Adults with asthma and school-aged children78 with asthma (REA, section 2.2). Focusing on the at-risk population of children with asthma, summarized here are two sets of exposure and risk estimates for the 3-year simulation in each study area: (1) The number (and percent) of simulated persons experiencing exposures at or above the particular benchmark concentrations of interest while breathing at elevated rates; and (2) the number and percent of people estimated to experience at least one SO2-related lung function decrement in a year and the number and percent of people experiencing multiple lung function decrements associated with SO2 exposures (detailed results are presented in the REA). Both types of estimates for adults with asthma are lower, generally due to the lesser amount and frequency of time spent outdoors (REA, section 5.2). As described in section II.C.1 above, the REA provides results for two different approaches to adjusting air quality. The estimates summarized here are drawn from the results for both approaches.

Table 1 presents the results for the benchmark-based risk metric in terms of the percent of the simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above the different benchmark concentrations while breathing at elevated rates under air quality conditions just meeting the current standard (REA, Tables 6–8 and 6–9). These estimates for the Tulsa study area are much lower than those for the other two areas (Table 1). No individuals of the simulated at-risk population in that study area were estimated to experience exposures at or above 200 ppb and less than 0.5% are estimated to experience an exposure at or above the 100 ppb benchmark. In the other two study areas (Indianapolis and Fall River), approximately 20% to just over 25% of a study area’s simulated children with

76 For example, “studies of mixtures of particles and sulfur oxides indicate some enhanced effects on lung function parameters, airway responsiveness, and host defense.” However, “so some of these studies lack appropriate controls and others involve [sulfur-containing species] that may not be representative of ambient exposures” (ISA, p. 5–144). These toxicological studies in laboratory animals, which were newly available in the last review, were discussed in greater detail in the 2008 ISA. That ISA stated that “[r]espiratory responses observed in these experiments were in some cases attributed to the formation of particular sulfur-containing species” yet “the relevance of these animal toxicological studies has been called into question because of both PM (1 mg/m3 and higher) and SO2 (1 ppm and higher) utilized in these studies are much higher than ambient levels” (2008 ISA, p. 3–13).

77 We also recognize that limitations in the activity pattern information for children younger than five years old precluded their inclusion in the populations of children simulated in the REA (REA, section 4.1.2).
asymptomatic children with asthma were estimated to experience at least one day with a 5-minute exposure concentration of 200 ppb or more. The corresponding percentage estimates for experiencing two or more such days ranged as high as 0.7%, on average across the 3-year period for Indianapolis and Fall River study areas, and as high as 2.2% (for the second air quality adjustment approach in REA, Table 6–10). Additionally, as many as 1.3% and 1.1%, respectively, of children with asthma, on average across the 3-year period, were estimated to experience at least one day per year with a SO2-related doubling in sRaw (Table 2). The corresponding percentage estimates for experiencing two or more such days ranged as high as 0.7%, on average across the 3-year simulation period (REA, Table 6–11). Additionally, as much as 0.2% and 0.3%, in Fall River and Indianapolis, respectively, of the simulated populations of children with asthma, on average across the 3-year period, was estimated to experience a single day with a SO2-related tripling in sRaw (Table 2).

### Table 2—Air Quality Conditions Adjusted to Just Meet the Current Standard: Percent of Simulated Populations of Children With Asthma Estimated to Experience at Least One Daily Maximum 5-Minute Exposure Per Year at or Above Indicated Concentrations While Breathing at an Elevated Rate

<table>
<thead>
<tr>
<th>Lung function decrement (increase in sRaw)</th>
<th>5-Minute exposure concentration (ppb)</th>
<th>Fall River, MA</th>
<th>Indianapolis, IN</th>
<th>Tulsa, OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥100%</td>
<td>19.4–26.7</td>
<td>22.4–23.0</td>
<td>0.1–0.4</td>
<td></td>
</tr>
<tr>
<td>≥200%</td>
<td>&lt;0.1&lt;sup&gt;B&lt;/sup&gt;–0.7&lt;sup&gt;C&lt;/sup&gt;</td>
<td>0.6–0.7</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>≥300%</td>
<td>0.2–0.3&lt;sup&gt;D&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>≥400%</td>
<td>&lt;0.1–0.1&lt;sup&gt;D&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>A</sup> The values presented in each cell are the averages of the results for the three years simulated for the two approaches to air quality adjustment (drawn from Table 6–8 of the REA).

<sup>B</sup> <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected exposure in any year.

<sup>C</sup> The highest single year result for 200 ppb was for Fall River where the estimate ranged up to 2.2% (for the second air quality adjustment approach in REA, Table 6–8).

<sup>D</sup> The highest single year results for 300 and 400 ppb were for Indianapolis where the estimates ranged up to 0.8% and 0.3%, respectively (REA, Table 6–8).

As with the comparison-to-benchmark results, the estimates for risk of lung function decrements in terms of a doubling or more in sRaw are also lower in the Tulsa study area than the other two areas (Table 2; REA, Tables 6–10 and 6–11). Under conditions just meeting the current standard in the Indianapolis and Fall River study areas, as many as 1.3% and 1.1%, respectively, of children with asthma, on average across the 3-year period, were estimated to experience at least one day per year with a SO2-related doubling in sRaw (Table 2). The corresponding percentage estimates for experiencing two or more such days ranged as high as 0.7%, on average across the 3-year simulation period (REA, Table 6–11). Additionally, as much as 0.2% and 0.3%, in Fall River and Indianapolis, respectively, of the simulated populations of children with asthma, on average across the 3-year period, was estimated to experience a single day with a SO2-related tripling in sRaw (Table 2).

### Table 2—Air Quality Conditions Adjusted to Just Meet the Current Standard: Percent of Simulated Population of Children With Asthma Estimated to Experience at Least One Day Per Year With a SO2-Related Increase in sRaw of 100% or More

<table>
<thead>
<tr>
<th>Percent (%) of population of children (5–18 years) with asthma average per year&lt;sup&gt;A&lt;/sup&gt;</th>
<th>Lung function decrement (increase in sRaw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fall River, MA</td>
<td>Indianapolis, IN</td>
</tr>
<tr>
<td>≥100%</td>
<td>0.9–1.1&lt;sup&gt;C&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥200%</td>
<td>0.1–0.2&lt;sup&gt;D&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>A</sup> The values presented in each cell are the averages of the results for the three years simulated for the two approaches to air quality adjustment (drawn from Table 6–10 of the REA);

<sup>B</sup> <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected decrement in any year.

<sup>C</sup> The highest single year result for at least 100% increase in sRaw was for Fall River where the estimate ranged up to 1.9% (for the second air quality adjustment approach in REA, Table 6–10).

<sup>D</sup> The highest single year results for at least 200% increase in sRaw were for Indianapolis and Fall River where the estimates ranged up to 0.4% (REA, Table 6–10).

### D. Proposed Conclusions on the Current Standard

In reaching proposed conclusions on the current SO2 primary standard, the Administrator has taken into account policy-relevant evidence-based and quantitative exposure- and risk-based considerations, as well as advice from the CASAC, and public comment received thus far in the review. Evidence-based considerations draw upon the EPA’s assessment of integrated synthesis of the scientific evidence in the ISA of health effects related to SO2 exposure, with a focus on policy-relevant considerations. Exposure- and risk-based considerations draw upon the EPA's assessment of population exposure and associated risk in the REA, with a focus on effects related to asthma exacerbation in the at-risk population of people with asthma, exposed while breathing at elevated levels.
rates, expected to occur under air quality conditions just meeting the current standard.

Building on the discussions of the scientific and technical assessments presented in the ISA and the REA, and summarized in sections ILB and ILC above, section II.D.1 below summarizes evidence- and exposure/risk-based considerations discussed in the PA and associated conclusions reached in the PA. Section II.D.2 describes advice received from the CASAC. The Administrator’s proposed conclusions on the current standard are presented in section II.D.3.

1. Evidence- and Exposure/Risk-Based Considerations in the Policy Assessment

As in previous NAAQS reviews, the role of the PA in this review is to help “bridge the gap” between the Agency’s scientific and quantitative assessments presented in the ISA and REA, and the judgments required of the Administrator in deciding whether it is appropriate to retain or revise the NAAQS. Evaluations in the PA focus on the policy-relevant aspects of the assessment and integrative synthesis of the currently available health effects evidence in the ISA, the exposure and risk assessments in the REA, and comments and advice of the CASAC, with consideration of public comment on drafts of the ISA, REA, and PA. The PA describes evidence- and exposure/ risk-based considerations and presents conclusions for consideration by the Administrator in reaching his proposed decision on the current standard. The main focus of the PA conclusions is consideration of the question: Does the currently available scientific evidence and exposure/risk information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current standard?

In considering this question, the PA recognizes as an initial matter that, as is the case in NAAQS reviews in general, the Administrator’s conclusions regarding whether the current primary SO2 standard provides the requisite public health protection under the Act will depend on a variety of factors, including science policy judgments and public health policy judgments. Accordingly, these factors include public health policy judgments concerning the appropriate benchmark concentrations on which to place weight, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health effects evidence. Such judgments, in turn, rely on the interpretation of, and decisions as to the weight to place on, different aspects of the results of the REA for the three types of urban exposure circumstances assessed and associated uncertainties. Accordingly, the Administrator’s conclusions regarding the current standard will depend in part on judgments regarding aspects of the evidence and exposure/risk estimates, as well as judgments about the public health protection, including an adequate margin of safety, that is requisite under the Clean Air Act.

The PA response to the overarching question above takes into consideration the discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. The PA also considers the quantitative exposure and risk estimates drawn from the REA, including associated limitations and uncertainties, and the extent to which they may indicate different conclusions from those in the last review regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The PA additionally considers the key aspects of the evidence and exposure/ risk estimates that were emphasized in establishing the now-current standard, as well as the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that pertain to consideration of whether the currently available information supports or calls into question the adequacy of the current primary SO2 standard.

With regard to the support in the current evidence for SO2 as the indicator for SOX, the ISA concludes that of the SOX, “only SO2 is present at concentrations in the gas phase that are relevant for chemistry in the atmospheric boundary layer and troposphere, and for human exposures” (ISA, p. 2–18), and that the available health evidence for SOX is focused on SO2 (ISA, p. 5–1). Thus, the PA concludes that the current evidence, including that newly available in this review, continues to support a focus on SO2 in considering the adequacy of public health protection provided by the primary NAAQS for SO2.

As described in the PA and summarized in section II.A.1 above, selection of the averaging time for the current standard was based on the need for control of SO2 concentrations that have the potential to contribute to exposures that pose health risks to people with asthma (for which the current evidence is described in section ILB above and considered below). When the standard was set in 2010, the Administrator considered a 5-minute averaging time, concluding that such a standard would result in significant and unnecessary instability in public health protection, and that the requisite protection from 5- to 10-minute exposure events could be provided with a longer, 1-hour averaging time. A 1-hour averaging time was supported by analyses at that time and by CASAC advice. In considering pertinent information newly available in this review, the PA additionally describes analyses of newly available 5-minute and 1-hour concentrations. The PA finds these newly available quantitative analyses to demonstrate the current 1-hour standard to exert control on 5-minute exposures of potential concern that is similar to expectations for such control when the standard was set (PA, section 3.2.4).

With regard to form and level of the standard, as described in the PA and summarized in section II.A.1 above, the 99th percentile daily maximum 1-hour concentration and the level of 75 ppb were chosen for the new standard in 2010 as providing the appropriate degree of public health protection from adverse effects associated with short-term SO2 exposures. These selections were also consistent with CASAC advice at the time. Newly available in this review are analyses in the REA focused on assessment of exposure and risk for air quality conditions just meeting the current standard in all its elements. In particular, simulation of these conditions includes use of a 3-year period consistent with the form established for the current standard (PA, section 3.2.2; REA, section 1.3.1). The resultant exposure and risk estimates are presented in the REA and considered in the PA, as summarized above. Based on such considerations, the PA concluded that it is appropriate to consider retaining the current standard, without revision in any of its elements. The CASAC concurred, specifically stating “that all four elements (indicator, averaging time, form, and level) should remain the same” (Cox and Diez Roux, 2018b, p. 3 of letter). As summarized below, the PA considers the information pertaining to the four elements of the standard (indicator, averaging time, level, and form) collectively in evaluating the health protection afforded by the current standard, consistent with the general approach summarized in section II.A above.
In considering the currently available health effects evidence base, augmented in some aspects since the last review, that provides the foundation of our understanding of the health effects of SO2 in ambient air, the PA gives particular attention to the evidence from controlled human exposure studies that (1) demonstrates that very short exposures (as short as a few minutes) to SO2, while breathing at an elevated rate, induces bronchoconstriction and associated decrements in lung function, which can be accompanied by symptoms, among individuals with asthma; and, (2) supports the identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA, sections 1.6, 1.7, 1.8, 5.2, 5.6; 2008 ISA; U.S. EPA, 1994). While the evidence base has been augmented since the time of the last review, the newly available evidence does not lead to different conclusions regarding the primary health effects of SO2 in ambient air or regarding exposure concentrations associated with those effects; nor does it identify different populations at risk of SO2-related effects (PA, section 3.2.1). In this way, the health effects evidence available in this review is consistent with evidence available in the last review when the current standard was established (ISA; 2008 ISA; U.S. EPA, 1994).

This strong evidence base continues to demonstrate a causal relationship between short-term SO2 exposures and respiratory effects, particularly in people with asthma (PA, p. xlix and section 5.2.1.2). This conclusion is primarily based on evidence from controlled human exposure studies, also available at the time of the last review, that reported lung function decrements and respiratory symptoms in people with asthma exposed to SO2 for 5 to 10 minutes while breathing at an elevated rate. Support is also provided by the epidemiologic evidence that is coherent with the controlled human exposure studies. As in the last review, the currently available epidemiologic evidence, including that newly available in this review, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits (of individuals of all ages, including adults and children) with short-term SO2 exposures (ISA, section 5.2.1.2).79

The health effects evidence newly available in this review also does not extend our understanding of the range of 5-minute exposure concentrations that elicit effects in people with asthma exposed while breathing at an elevated rate beyond what was understood in the last review (PA, section 3.2.1.3). As in the last review, 200 ppb remains the lowest concentration tested in exposure studies where study subjects are freely breathing in exposure chambers (ISA, section 5.2.1.2). At that exposure concentration, approximately 8 to 9% of study subjects with asthma, breathing at an elevated rate, experienced moderate or greater lung function decrements following 5- to 10-minute controlled exposures (ISA, Table 5-2). The limited information available for exposure concentrations below 200 ppb is from mouthpiece exposure studies in which subjects were exposed to a concentration of 100 ppb, with only a few of these studies including an exposure to clean air while exercising that would have allowed for determining the effect of SO2 versus the effect of exercise alone (ISA, section 5.2.1.2; PA, section 3.2.1.3). While, for these reasons, these data are not amenable to direct quantitative comparisons with the data for higher exposure concentrations, they generally indicate a somewhat lesser response. In considering what may be indicated by the epidemiologic evidence with regard to exposure concentrations eliciting effects, we recognize complications associated with interpretation of epidemiologic studies of SO2 in ambient air that relate to whether measurements at the study monitors adequately represent the spatiotemporal variability in ambient SO2 concentrations in the study areas and associated population exposures (ISA, section 5.2.1.9).

In this review, as in the last review, there is uncertainty with regard to exposure levels eliciting effects in some population groups for which data are limited or not available from the controlled human exposure studies, such as individuals with severe asthma and children younger than 12 years old, as well as uncertainty in the extent of effects at exposure levels below those studied (PA, section 3.2.1; ISA, p. 5–22). Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for SO2, as for other pollutants, the available evidence base in this NAAQS review generally reflects a continuum, consisting of ambient levels at which scientific consensus indicates that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

As at the time of the last review, the exposure and risk estimates developed from modeling exposures to SO2 emitted into ambient air are critically important to consideration of the potential for exposures and risks of concern under air quality conditions of interest, and consequently they are critically important to judgments on the adequacy of public health protection provided by the current standard. In considering the REA analyses available in this review, the PA notes the various ways in which these analyses differ and improve upon those available in the last review. In addition to an expansion in the number and type of study areas assessed, there are a number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas (PA, section 3.2.2; REA, section 1.3.1). The current REA extends the time period of simulation by including a 3-year simulation period consistent with the form established for the now-current standard (PA, section 3.2.2; REA, section 1.3.1). Further, the years simulated reflect more recent patterns of emissions and associated exposure circumstances subsequent to the 2010 decision (PA, section 3.2.2; REA, section 1.3.1).

As at the time of the last review, people with asthma are the population at risk of respiratory effects related to SO2 in ambient air. Children with asthma may be particularly at risk (PA section 3.2.1.2; ISA, section 6.5.1.1). While in the U.S. there are more adults with asthma than children with asthma, the REA results, in terms of percent of the simulated at-risk populations, indicate higher exposures and risks for children with asthma as compared to adults. This finding relates to children’s greater frequency and duration of outdoor activity (REA, sections 2.1.2, 4.3.3, 4.4, 5.2, and 5.3). In light of these conclusions and findings, we have focused our consideration of the REA results here on the results for children with asthma.

As can be seen by the variation in exposure estimates, the three study areas in the REA represent an array of emissions sources and associated exposure circumstances, including those contributing to relatively higher and relatively lower exposures and associated risk (PA, section 3.2.2; REA, section 5.4).80 As recognized in the

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79 While uncertainties remain related to the potential for confounding by PM or other copollutants and the representation of fine-scale temporal variation in personal exposures, the findings of the epidemiologic studies continue to provide supporting evidence for the conclusion on the causal relationship (ISA, section 5.2.1.2).

80 More specifically, the three areas fall into three different geographic regions of the U.S. They range from approximately 100,000 to approximately one...
REA, the analyses there are not intended to provide a comprehensive national assessment. Rather, the analyses for this array of study areas are intended to indicate the magnitude of exposures and risks that may be expected in areas of the U.S. that just meet the current standard but may differ in ways affecting population exposures of interest. In that way, the REA is intended to be informative to the EPA’s consideration of potential exposures and risks associated with the current standard and the Administrator’s judgments regarding the protection provided by the current standard. For example, the PA considered locations within areas that just meet the current standard where the areas’ locations of relatively higher ambient air concentrations coincide with locations of higher population density. In so doing, the PA recognized that consideration of such exposures is particularly important to consideration of the public health protection afforded by the current standard, and particularly to the overarching question concerning the availability of information that calls into question the adequacy of the current standard (PA, sections 3.2.2.2 and 3.2.2.4).

With regard to the REA representation of air quality conditions associated with just meeting the current standard, the PA notes reduced uncertainty (compared to the 2009 REA) in a few aspects of the approach for developing this air quality scenario, while additionally recognizing the uncertainty associated with the application of air quality adjustments to estimate conditions just meeting the current standard (PA, sections 3.2.2.2 and 3.2.2.3; REA, section 6.2.2). Given the importance of this aspect of the REA to consideration of the level of protection provided by the current standard, the PA considers the results for each study area in terms of a range that reflects variation associated with the two different methodologies for the first air quality adjustment approach (REA, section 6.2.2.2).

In this context, the PA notes that across all three study areas, which provide an array of SO2 emissions and exposure situations, the percent of children with asthma estimated to experience at least one day with as much as a doubling in sRAW (attributable to SO2), on average across the 3-year period, ranges from <0.1% to 1.3%; the highest study area estimate is just under 2% for the highest single year (PA, section 3.2.4; PA, Table 3–4; REA, Table 6–10). Accordingly, results for the three case study areas indicate at least 98.7% or more of the at-risk population of children with asthma to be protected from experiencing a SO2-related doubling in sRAW, as an average across the 3-year period, and approximately 98% or more protected from as much as a single occurrence in the single highest year. Greater protection (e.g., 99% or more) is indicated for multiple days with a doubling in sRAW and also for single occurrences of as much as a tripling in sRAW (PA, section 3.2.4; REA, Table 6–11).

With regard to exposures compared to benchmark concentrations, the PA notes that less than 1% of children with asthma are estimated to experience, while breathing at an elevated rate, a daily maximum 5-minute exposure per year at or above 200 ppb, on average across the 3-year period, with a maximum for the study area with the highest estimates just over 2% in the highest single year (PA, section 3.2.4; PA, Table 3–3; REA, Table 6–8). Further, the percentage for at least one day with such an exposure at or above 400 ppb is 0.1% or less, as an average across the 3-year period, and 0.3% or less in each of the three years simulated across the three study areas (PA, section 3.2.4; PA, Table 3–3; REA, Table 6–8). No simulated at-risk individuals were estimated to experience multiple such days (PA, section 3.2.4; REA, Table 6–9).

In considering the public health implications of the REA estimated occurrences of exposures of different magnitudes, the PA takes note of guidance from the ATS (Thurston et al., 2017). The 2010 ATS statement that was considered in the last review, is generally consistent with and supportive of the earlier statement (available at the time of the 2010 decision) and the 2010 judgments. Additionally, the CASAC has provided advice in the context of this SO2 NAAQS review, which is summarized in section II.D.2 below.

Further, while recognizing the differences between the current REA analyses and the 2009 REA analyses, implications of similar effects in previous NAAQS reviews.82

In so doing, the PA finds the REA exposure and risk estimates to indicate that the current standard is likely to provide a high level of protection from SO2-related health effects to at-risk populations of children and adults with asthma (PA, section 3.2.4). In summarizing these findings, the PA also notes the uncertainties in the REA results (summarized in section II.C.2 above) associated with the limited or lacking evidence from the controlled human exposure studies for some subgroups in these populations such as people with severe asthma and children younger than 12 years old (PA, section 3.2.4).

The PA additionally reflects on the key aspects of the 2010 decision that established the current standard, such as considerations of adversity of SO2-related effects to health, and also the public health implications of associated exposure and risk estimates for simulated at-risk populations. As an initial matter, the 2010 decision recognized that 5 to 10 minutes “exposure to SO2 concentrations as low as 200 ppb can result in adverse health effects in [people with asthma]” (75 FR 35546, June 22, 2010);83 this judgment was based on consideration of CASAC advice and EPA judgments in prior NAAQS reviews, as well as ATS guidance. Since the last review, the ATS has released an additional statement on adversity of air pollution, which is generally consistent with and supportive of the earlier statement (available at the time of the 2010 decision) and the 2010 judgments. Additionally, the CASAC has provided advice in the context of this SO2 NAAQS review, which is summarized in section II.D.2 below.

82 Judgments by the EPA across NAAQS reviews for various pollutants have particularly emphasized the protection of at-risk population members from multiple occurrences of exposures or effects of concern and from such effects of greater severity that have been documented to be accompanied by symptoms (75 FR 35520, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015).

83 The decision notice additionally stated that “[t]he Administrator notes that although these decrements in lung function have not been shown to be statistically significant at the group mean level, or to be frequently accompanied by respiratory symptoms, she considers effects associated with exposures as low as 200 ppb to be adverse in light of CASAC advice, similar conclusions in prior NAAQS reviews, and the ATS guidelines described in detail above” and that “[t]herefore, she has concluded it appropriate to place weight on the 200 ppb 5-minute benchmark concentration” (75 FR 35546, June 22, 2010).
Including the 2009 REA’s lack of an air quality scenario specific to the now-current standard in the last review, as well as uncertainties associated with such analyses, the PA notes a rough consistency of the associated estimates when considering the array of study areas in both reviews (PA, section 3.2.4). Overall, the PA finds the newly available quantitative analyses to comport with the conclusions reached in the last review regarding the control expected to be exerted by the now-current 1-hour standard on 5-minute exposures of concern (PA, section 3.2.4). With regard to the results for the REA in the last review (which were for a single-year simulation), the 2010 decision recognized those results for the area with the highest estimates and largest population (St. Louis) to indicate that a 1-hour standard of a magnitude between the two levels assessed in the 2009 REA (50 and 100 ppb) might be expected to protect more than 97% of children with asthma and (somewhat less than 100%) from experiencing exposures at or above a 200 ppb benchmark concentration. With more than 99% of that population group from experiencing exposures at or above a 400 ppb benchmark (75 FR 35546–47, June 22, 2010; 2009 REA, pp. B–62 and B–63). Single-year results in the current REA for the two study areas with the highest estimates (including the area with the most sizeable population, Indianapolis) indicate protection for the now-current standard of 75 ppb of approximately 98 to 99% of the populations of children with asthma from experiencing exposures at or above a 200 ppb benchmark concentration and 99.7% or more of the study area at-risk populations from exposures at or above 400 ppb (PA, sections 3.2.2.2 and 3.2.4; REA, Table 6–8). These and the similar estimates for a doubling or more in sRaw are of a magnitude roughly consistent with the level of protection that was described in establishing the now-current standard in 2010 (PA, section 3.1.1.2.4).84

Additionally, the 2010 decision also took note of the magnitude of the SO2 concentrations in ambient air in U.S. epidemiologic studies of associations between ambient air concentrations and emergency department visits or hospital admissions, for which the effect estimate remained positive and statistically significant in copollutant models with PM (PA, sections 3.1.1.2.4 and 3.2.4).85 No additional such studies are available in the current review, as summarized in section II.B.3 above (PA, section 3.2.1.3). Accordingly, in considering the main aspects of the decision in the last review, the PA finds the currently available information to be consistent with that on which the decision establishing the current standard was based (PA, section 3.2.4).

In considering potential public health implications of the current REA exposure and risk estimates for the three case studies, the PA recognizes the importance of these estimates to consideration of whether the currently available information calls into question the adequacy of public health protection afforded by the current standard. In so doing, the PA notes that the REA estimates for conditions associated with just meeting the current standard, are of particular importance to consideration of exposures and risks in areas still existing across the U.S. that have source and population characteristics similar to the study areas assessed, and with ambient concentrations of SO2 that just meet the current standard today or that will be reduced to do so at some period in the future. In this context, the PA takes note of the more than 24 million people with asthma currently in the U.S., including more than 6 million children, with potentially somewhat more than 100,000 living within 5 km of large86 sources of SO2 emissions (PA, sections 3.2.2.4 and 3.2.4).

The PA additionally takes note of the uncertainties or limitations of the current evidence base with regard to the exposure levels at which effects may be elicited in some groups (e.g., children with asthma and individuals with severe asthma), as well as the severity of the effects in those groups (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5–22 to 5–25). In so doing, the PA recognizes that the controlled human exposure studies, on which the depth of the general understanding of SO2-related health effects is based, are limited or lacking in providing information with regard to responses in people with more severe asthma or in children younger than 12 years (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5–22 to 5.25). Additional limitations in understanding relate to the potential for effects in some people with asthma exposed to concentrations below 200 ppb, as well as the potential for other air pollutants to affect responses to SO2 (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5–22 to 5–26). In light of these uncertainties, the PA additionally takes note of the REA results for the lowest benchmark concentration (100 ppb) that indicate that in some areas of the U.S. under air quality conditions that just meet the current standard, approximately 20% to just over 25% of children with asthma may experience one or more days per year, on average across a 3-year period, with a 5-minute exposure to concentrations at or above this benchmark while breathing at an elevated rate (PA, section 3.2.4 and Table 3–3; REA, Table 6–8). Based on such consideration of the evidence across the exposure concentrations studied and the exposure/risk information related to the lowest benchmark concentration, the PA finds that the combined consideration of the body of evidence and the quantitative exposure estimates continues to provide support for a standard as protective as the current one (PA, section 3.2.4).

The PA further recognizes that the EPA’s conclusions regarding the adequacy of the current standard depend in part on public health policy judgments identified above and judgments by the Administrator about the level of public health protection that is appropriate, allowing for an adequate margin of safety. In so doing, the PA takes note of the long-standing health effects evidence that documents the effects of SO2 exposures as short as a few minutes in people with asthma that are exposed while breathing at elevated rates and recognizes that such effects have been documented at the lowest concentration studied in exposure chambers with appropriate clean-air controls (PA, section 3.2.4). The PA additionally notes that it was recognized in the last review that such exposures can result in adverse health effects in people with asthma (75 FR 35546–47, June 22, 2010), and that there are limitations, and associated uncertainty, in the evidence available for the lower exposure concentration of 100 ppb (summarized in section II.B.3 above), as was the case in the last review. The PA further notes the indication of an appreciable reduction in the magnitude of the SO2-induced response in exercising people with asthma at this
lower exposure concentration compared with responses observed for exposures at 200 ppb (PA, sections 3.2.1.3, 3.2.1.4 and 3.2.4). Thus, in focusing on the potential for 5-minute exposures at and above 200 ppb, the PA takes note of the REA results that indicate the current standard may be expected to protect approximately 98% and nearly 99% of populations of children with asthma from experiencing any days with such exposures in the highest year and on average each year in a 3-year period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6–8). The PA additionally notes that the REA estimates indicate the current standard may be expected to protect more than 99% of children from experiencing any days with a 5-minute exposure of 300 ppb or higher, with the estimates for the 400 ppb benchmark indicating protection of at least 99.7% and 99.9% of children with asthma from experiencing any days with a 5-minute exposure of 400 ppb or higher in the highest year and in each year on average for a 3-year period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6–8). In considering these results, the PA notes the lesser severity of effects reported for exposures below 400 ppb than those at and above 400 ppb, which include larger decrements in lung function that are frequently accompanied by respiratory symptoms, facts given weight in establishing the current standard in 2010 (75 FR 35547, June 22, 2010). With regard to the potential for children to experience SO2-related lung function decrements in terms of air pollution in RAW, the PA takes note of the REA results that indicate the current standard may be expected to protect approximately 98.1% and nearly 98.7% from experiencing any days with such decrements, in the highest year of the 3-year period and in each year on average for the period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6–10). In light of ATS guidance, CASAC advice and EPA judgments in past NAAQS reviews, the PA finds these results to indicate the current standard may be expected to protect approximately 98% and nearly 99% of populations of children with asthma from experiencing any days with such exposures in the highest year and on average each year in a 3-year period, respectively (PA, sections 3.2.2.4 and 3.2.4). The quantitative exposure and risk estimates for conditions just meeting the current standard indicate a similar level of protection, for populations from respiratory effects considered to be adverse, as that indicated by the information considered in the decision for the 2010 review in establishing the now-current standard (PA, sections 3.2.2 and 3.2.4.). As in the last review, limitations and uncertainties are associated with the available information, as summarized in section 3.2.4 of the PA. Collectively, the PA finds that the evidence and exposure/risk based considerations provide the basis for its conclusion that consideration should be given to retaining the current standard, without revision (PA, section 3.2.4). Accordingly, and in light of this conclusion that it is appropriate to consider the current standard to be adequate, the PA did not identify any potential alternative standards for consideration in this review (PA, section 3.2.4).

2. CASAC Advice

In the current review of the primary standard for SO2, the CASAC has provided advice and recommendations in their review of drafts of the IRP, ISA, REA and PA, and of the REA Planning Document.

In their comments on the draft PA, the CASAC concurred with staff’s overall preliminary conclusions that “the current scientific literature does not support revision of the primary NAAQS for SO2,” additionally stating the following (Cox and Diez Roux, 2018b, p. 3 of letter).

The CASAC notes that the new scientific information in the current review does not lead to different conclusions from the previous review. Thus, based on review of the current state of the science, the CASAC supports retaining the current standard, and specifically notes that all four elements (indicator, averaging time, form, and level) should remain the same.

The CASAC further stated the following (Cox and Diez Roux, 2018b, p. 3 of letter).

With regard to indicator, SO2 is the most abundant of the gaseous SO2 species, because, as the PA states, “the available scientific information regarding health effects was overwhelmingly indexed by SO2,” it is the most appropriate indicator. The CASAC affirms that the one-hour averaging time will protect against high 5-minute exposures and reduce the number of instances where the 5-minute concentration poses risks to susceptible individuals. The CASAC concurs that the 99th percentile form is preferable to a 98th percentile form to limit the upper end of the distribution of 5-minute concentrations. Furthermore, the CASAC concurs that a three-year averaging time for the form is appropriate.

The choice of level is driven by scientific evidence from the controlled human exposure studies used in the previous NAAQS review, which show a causal effect of SO2 exposure on asthma exacerbations. Specifically, controlled five-minute average exposures as low as 200 ppb lead to adverse health effects. Although there is no definitive experimental evidence below 200 ppb, the monotonic dose-response suggests that susceptible individuals could be affected below 200 ppb. Furthermore, short-term epidemiology studies provide supporting evidence even though these studies cannot rule out the effects of co-exposures and are limited by the available monitoring sites, which do not adequately capture population exposures to SO2. Thus, the CASAC concludes that the 75 ppb average level, based on the three-year average of 99th percentile daily maximum one-hour concentrations, is protective and that levels above 75 ppb do not provide the same level of protection.

The comments from the CASAC also took note of the uncertainties that remain in this review. In so doing, it stated that the “CASAC notes that there are many susceptible subpopulations that have not been studied and which could plausibly be more affected by SO2 exposures than adults with mild to moderate asthma,” providing as examples people with severe asthma and obese children with asthma, and citing physiologic and clinical understanding (Cox and Diez Roux, 2018b, p. 3 of letter). The CASAC stated that “[i]t is plausible that the current 75 ppb level does not provide an adequate margin of safety in these groups,[h]owever because there is considerable uncertainty in quantifying the sizes of these higher risk subpopulations and the effect of SO2 on them, the CASAC
The CASAC comments additionally state that the draft PA “clearly identifies most of the key uncertainties, including uncertainties in dose-response” and that “[t]here are also some additional uncertainties that should be mentioned” (Cox and Diez Roux, 2018b, pp. 6–7 of Consensus Responses to Charge Questions). These are in a variety of areas including risk for various population groups, personal exposures to SO$_2$ and estimating short-term ambient air concentrations. The CASAC suggested research and data gathering in these and other areas that would inform the next SO$_2$ primary standard review (Cox and Diez Roux, 2018b, p. 6 of the Consensus Responses to Charge Questions).

3. Administrator’s Proposed Conclusions on the Current Standard

Based on the large body of evidence concerning the health effects and potential public health impacts of exposure to SO$_2$ in ambient air, and taking into consideration the attendant uncertainties and limitations of the evidence, the Administrator proposes to conclude that the current primary SO$_2$ standard provides the requisite protection of public health, including an adequate margin of safety, and should therefore be retained, without revision. In reaching these proposed conclusions, the Administrator has carefully considered the assessment of the available health effects evidence and conclusions contained in the ISA; the quantitative analyses in the REA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC (summarized in section II.D.2 above); and public comments received to date in this review.

In the discussion below, the Administrator considers first the evidence base on health effects associated with short-term exposure to SO$_2$, including the controlled human exposure studies that document respiratory effects in people with asthma exposed for as short as a few minutes while breathing at elevated rates and the relative lack of such information for some subgroups of this population, including young children and people with severe asthma. He additionally notes the available epidemiologic evidence that documents associations between short-term concentrations of SO$_2$ in ambient air and asthma-related health outcomes, particularly in children. Further, the Administrator considers the estimates of SO$_2$ exposures and risk in multiple study areas under air quality conditions just meeting the current standard (summarized in sections II.C and II.D.1 above), and the public health implications of those results. The Administrator additionally considers uncertainties in the evidence and the exposure/risk information, as a part of public health policy judgments essential to decisions regarding the adequacy of the protection provided by the standard, similar to the judgements made in establishing the current standard. He draws on the PA considerations, and PA conclusions in the current review, with which the CASAC has concurred, taking note of key aspects of the rationale presented for those conclusions.

Further, the Administrator considers the advice of the CASAC, including particularly its overall agreement with the PA conclusion that the current evidence and quantitative exposure and risk estimates provide support for retaining the current standard and the CASAC’s recommendation to retain all elements of the standard without revision (Cox and Diez Roux, 2018b).

With regard to the evidence base for SO$_2$, the Administrator first recognizes the long-standing evidence that has established the key aspects of the harmful effects of very short SO$_2$ exposures on people with asthma that are relevant to this review as they were relevant in 2010 when the current short-term standard was established. This evidence, drawn largely from the controlled human exposure studies, demonstrates that very short exposures (for as short as a few minutes) to less than 1000 ppb SO$_2$, while breathing at an elevated rate (such as while exercising), induces bronchoconstriction and related respiratory effects in people with asthma and supports identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA; 2008 ISA; U.S. EPA, 1994). The evidence base additionally includes epidemiologic studies that provide support for the conclusion of a causal relationship between short-term SO$_2$ exposures and respiratory effects for which the controlled human exposure studies are the primary evidence. The epidemiologic studies report positive associations of short-term (i.e., hourly or daily) concentrations of SO$_2$ in ambient air with asthma-related health outcomes, including hospital admissions and emergency department visits. In considering these epidemiologic studies in the context of the larger evidence base, the ISA recognizes that while these studies analyze hourly or daily metrics, there is the potential for shorter-term concentrations within the study areas to be playing a role in such associations. The ISA also notes associated uncertainties related to potential confounding from co-occurring pollutants such as PM, a chemical mixture including some components for which SO$_2$ is a precursor, and also related to exposure estimates and the ability of fixed-site monitors to adequately represent variations in personal exposure, particularly with regard to peak exposures, as summarized in section II.B.3 above (ISA, p. 5–37; PA, section 3.2.1.4).

With regard to the health effects evidence newly available in this review, the Administrator takes note of the PA finding that, while the health effects evidence, as assessed in the ISA, has been augmented with additional studies since the time of the last review, including more than 200 new health studies, the newly available evidence does not lead to different conclusions regarding the primary health effects of SO$_2$ in ambient air or regarding exposure concentrations associated with those effects. Nor does it identify different or additional populations at risk of SO$_2$-related effects. Thus, the Administrator recognizes that the health effects evidence available in this review is consistent with evidence available in the last review when the current standard was established and that this strong evidence base continues to demonstrate a causal relationship between relevant short-term exposures to SO$_2$ and respiratory effects, particularly with regard to effects related to asthma exacerbation in people with asthma. He also recognizes that the ISA conclusion on the respiratory concentrations at or above 1000 ppb (ISA, section 5.2.1.7).

Sulfur dioxide is a precursor to sulfate, which commonly occurs in particulate form (ISA, section 2.3; U.S. EPA, 2009, section 3.3.2 and Table 3–2).
effects caused by short-term exposures is based primarily on evidence from controlled human exposure studies, available at the time of the last review, that reported moderate or greater lung function decrements and respiratory symptoms in people with asthma exposed to SO\textsubscript{2} for 5 to 10 minutes while breathing at an elevated rate (ISA, section 5.2.1.9), and that the current 1-hour standard was established to provide protection from effects such as these (75 FR 35520, June 22, 2010). The Administrator further notes the control of peak 5-minute exposures that is provided by the current 1-hour standard, as indicated by the exposure analysis in the REA and air quality analyses in the PA (PA, chapter 2 and Appendix B). With regard to exposure concentrations of interest in this review, the Administrator takes particular note of the evidence from controlled human exposure studies that demonstrate the occurrence of lung function decrements, at times accompanied by respiratory symptoms, in subjects with asthma exposed for very short periods of time while breathing at elevated rates, focusing primarily on such study findings for which exposure concentration-specific data are available to the EPA for individual subjects (ISA, Table 5–2 and Figure 5–1, summarized in Table 3–1 of the PA).

These data demonstrate such effects related to asthma exacerbation in sensitive people with asthma exposed to SO\textsubscript{2} concentrations as low as 200 ppb. These data include limited evidence of respiratory symptoms accompanying the lung function effects at this exposure level (ISA, Table 5–2). The Administrator recognizes that both the percent of individuals experiencing lung function decrements and the severity of the decrements, as well as the frequency with which they are accompanied by symptoms, increase with increasing SO\textsubscript{2} concentrations across the range of exposure levels studied (ISA, Table 5–2; PA, section 3.2.1.3). For example, approximately 10% of study subjects experienced moderate or greater lung function decrements at 200 ppb, while at 300–400 ppb, as many as approximately 30% of subjects in some studies experienced such decrements. Further, at concentrations at or above 400 ppb, the moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5–2 and section 5.2.1).

In considering the potential public health significance of effects associated with SO\textsubscript{2} exposures, the Administrator further recognizes the greater significance accorded both to larger lung function decrements, which are more frequently documented at exposures above 200 ppb, and the potential for greater impacts of SO\textsubscript{2}-induced decrements in people with more severe asthma, as recognized in the ISA and by the CASAC (as summarized in section II.D.2 above). For example, he notes that the ATS indicated it to be appropriate to consider small lung function changes as adverse when they occur in individuals with pre-existing compromised function, “such as resulting from asthma, even without accompanying respiratory symptoms” (Thurston et al., 2017). Thus, with regard to the health effects evidence for SO\textsubscript{2}, the Administrator recognizes that health effects resulting from exposures at and above 400 ppb are appreciably more severe than those elicited by exposure to SO\textsubscript{2} concentrations as low as 200 ppb (and lower), and that health impacts of short-term SO\textsubscript{2} exposures (including those occurring at concentrations below 400 ppb) have the potential to be more significant in the subgroup of people with asthma that have more severe disease and for which the study data are more limited.

As at the time of the last review, the Administrator considers the health effects evidence in the context of the exposure and risk modeling, including key limitations and uncertainties, as summarized in the PA and section II.C.1 above (described in detail in the REA). In so doing, he recognizes such a context to be critical for SO\textsubscript{2}, for which health effects in people with asthma are linked to exposures during periods of elevated breathing rates, such as while exercising. Thus, population exposure modeling that takes activity levels into account is integral to consideration of population exposures compared to benchmark concentrations and of population risk of lung function decrements.

In considering the exposure and risk estimates, the Administrator recognizes that unlike the REA available in the last review, which analyzed single-year air quality scenarios for potential standard levels bracketing the now current level, the current REA assesses an air quality scenario for three years of air quality conditions that just meet the current standard, including its 3-year form. The other ways in which the current REA analyses are improved and expanded from those in the REA for the last review relate to improvements that have been made to models, model inputs and underlying databases. These improvements include the database, vastly expanded since the last review, of ambient air monitoring data for 5-minute concentrations. These data are available as a result of the monitoring data reporting requirement established in the last review to inform subsequent primary NAAQS reviews for SO\textsubscript{2} and the associated assessments of the protection provided from elevated short-term (5- to 10-minute exposure) SO\textsubscript{2} concentrations for people with asthma breathing at elevated rates (75 FR 35567–68, June 22, 2010). The current REA is additionally expanded from the prior one with regard to the number of study areas in that it now includes three urban areas, each with populations of more than 100,000 people, as contrasted to the single such area in the 2009 REA.

In considering the REA results for the benchmark comparisons for the three years analyzed in each of the three study areas, the Administrator notes the estimates of as many as 0.7% of children with asthma to experience a single day per year (on average across the 3-year period) with a 5-minute exposure at or above 200 ppb in a single year, while breathing at elevated rates, and as many as 2.2% in a single year. He additionally takes note of the REA findings that also estimate somewhat less than 0.1% of children with asthma to experience multiple days with such exposures in any one year. In turning to consideration of the REA estimates of lung function risk, the Administrator notes that as many as 1.9% of children with asthma are estimated to experience a day in a single year with an SO\textsubscript{2}-related doubling of sRaw, and as many as 1.3% per year on average across three years. He further takes note that as many as 1% of children with asthma may be estimated to experience multiple days in a single year (0.7% on average across multiple years) with a lung function decrement of such a magnitude, and as many as 0.3% (on average across multiple years) may be estimated to...
experience a day with at least a tripling in SO2 (as summarized in section II.C.3 above).

In considering the level of protection indicated by these estimates of exposure and risk under air quality conditions that just meet the current standard, the Administrator additionally recognizes the limitations in the available evidence base that contribute to uncertainties with regard to the risk estimates for lung function decrements in young children with asthma and in individuals of any age with severe asthma. While health effects study data are limited or lacking for these population groups, the ISA indicates a potential for these groups to experience somewhat greater health impacts than the populations studied (as summarized in section II.B above). In light of these limitations of the evidence and the potential articulated in the ISA for the risk to be greater for these groups for which the evidence is limited or lacking, the Administrator notes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified.

The Administrator additionally notes the PA consideration of the sizeable number of at-risk individuals living in locations near large SO2 emissions sources that may contribute to increased SO2 concentrations in ambient air. The information concerning population exposure characteristics such as the co-occurrence of elevated ambient air concentrations with areas of relatively higher population density is not available for all of these locations. Consideration of the population sizes in these areas and the potential for similarity of exposure characteristics in some of these areas to the study areas assessed in the REA (as summarized in section II.D.1 above) confirms the public health relevance of the REA results to this review of the current standard.

In considering the adequacy of the protection provided by the current standard, the Administrator notes the findings of the REA in light of considerations recognized above regarding the significance associated with different exposure benchmark concentrations and severity of lung function decrements, as well as the estimated frequency of occurrence of such concentrations and decrements under air quality conditions just meeting the current standard. Given the clear concentration-response relationship documented in the evidence for the key effects in people with asthma across the range of exposure concentrations studied, higher SO2 concentrations would be expected to contribute to greater severity and frequency in occurrence of responses in at-risk groups. Other considerations summarized above, include the strong evidence for lung function decrements in people with asthma exposed for just a few minutes while breathing at elevated rates (e.g., while exercising) to SO2 concentrations as low as 200 ppb, the public health implications of such exposures, and related considerations raised by the ATS in its statement on adverse effects of air pollution. Further, advice from the CASAC included its conclusion that the current evidence and exposure/risk information supports retaining the current standard and its associated caution as to uncertainty in the adequacy of the margin of safety provided by the current standard for less well studied yet potentially susceptible population groups. Based on all of these considerations, the Administrator gives weight to the PA findings, summarized in section II.D.1 above, that the current body of evidence, in combination with the exposure/risk information, does not support a primary standard that is less protective than the current standard. Thus, he proposes to conclude that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety.

Turning to consideration of the adequacy of protection provided by the current standard from effects associated with lower exposures, including those at or below 200 ppb, the Administrator considers the public health significance of the REA estimates for such effects, and of single (versus multiple) occurrences of exposures at or above the lower benchmark concentrations and associated lung function decrements, and the nature and magnitude of the various uncertainties that are inherent in the underlying scientific evidence and REA analysis. In so doing, the Administrator recognizes that our understanding of the relationships between the presence of a pollutant in ambient air and associated health effects is based on a broad body of information encompassing not only more established aspects of the evidence, but also aspects with which there may be substantial uncertainty. In the case of the primary SO2 standard review, he considers the increased uncertainty recognized in the PA with regard to characterization of the risk of lung function decrements (including their magnitude and prevalence, and the associated health significance) at exposure levels below those represented in the controlled human exposure studies and in populations potentially at risk but for which the evidence base is limited or lacking (PA, section 3.2.2.3; REA, section 5.3). He additionally considers the uncertainties recognized in the PA, and summarized in section II.B and II.D.1 above, regarding exposure measurement error and copollutant confounding in the epidemiologic evidence. In so doing, the Administrator recognizes that collectively, these aspects of the evidence and associated uncertainties support an acknowledgment that for SO2, as for other pollutants, the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

In considering the point at which health effects associated with lower levels of SO2 exposure become important from a public health perspective, the Administrator takes note of the PA consideration of the CASAC advice and EPA judgments in establishing the current standard in 2010, as well as the currently available information and commonly accepted guidelines or criteria within the public health community, including the ATS, an organization of respiratory disease specialists, for interpreting public health significance of moderate or greater lung function decrements, particularly when accompanied by respiratory symptoms, and their occurrence in a portion of the at-risk populations. In so doing, the Administrator additionally notes that the most recent ATS statement on adversity of air pollution is generally consistent with its prior statement that was referenced when the current standard was set (PA, section 3.2.1.5.). He also takes note of EPA judgments in prior NAAQS decisions for SOX and

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94 In conveying this caution related to such population groups, the CASAC additionally recognized there to be “considerable uncertainty” and concluded that “the CASAC does not recommend reconsideration of the level in order to provide a greater margin of safety” (Cox and Diez Roux, 2018, Consensus Responses, p. 5).

95 Such populations include those for which the CASAC described there to be “considerable uncertainty” (Cox and Diez Roux, 2018, Consensus Responses, p. 5).

96 With regard to commonly accepted guidelines or criteria within the public health community, the PA considered statements issued by the ATS (as summarized in section II.D.1 above).
other pollutants that, consistent with these statements, have particularly emphasized the protection of at-risk population members from multiple occurrences of exposures or effects of concern and from such effects of greater severity or that have been documented to be accompanied by symptoms (75 FR 35520, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Together these factors inform the Administrator’s consideration in this review of public health implications of the exposure and risk estimates for air quality conditions just meeting the current primary SO₂ standard.

Thus, in considering the evidence and quantitative exposure and risk estimates available in this review with regard to the adequacy of public health protection provided by the current primary standard from respiratory effects associated with the lowest SO₂ exposure concentrations represented in the health effects evidence, the Administrator recognizes that, as noted in section II.A above, the final decision on such judgments is largely a public health policy judgment that draws upon scientific information and analyses about health effects and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information and analyses. These judgments are informed by the recognition, noted just above, that the available health effects evidence generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. Accordingly, the Administrator’s final decision requires judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn. As described in section I.A above, the Act does not require that primary standards be set at a zero-risk level. The NAAQS must be sufficient but not more stringent than necessary to protect public health, including the health of sensitive groups, with an adequate margin of safety.

In this light, the Administrator takes note of PA considerations regarding the REA results and the associated uncertainties (summarized in section II.C above), as well as the nature and magnitude of the uncertainties inherent in the scientific evidence upon which the REA is based. The Administrator finds such considerations collectively to be important to judgments such as the extent to which the exposure and risk estimates for air quality conditions that just meet the current standard in the three study areas indicate exposures and risks that are important from a public health perspective. In turning first to the REA estimates of the percent of children with asthma estimated to experience a day with a 5-minute SO₂ exposure, while breathing at elevated rates, above benchmark concentrations, the Administrator notes the very small percentage (no more than 0.3% in the highest year) of children with asthma estimated to experience a single day per year at/above the benchmark concentration of 400 ppb, an exposure level frequently associated with respiratory symptoms in controlled human exposure studies. In particular, he takes note of the fact that the REA results do not estimate any children in any of the three study areas to experience more than one such exposure in a year. The Administrator considers these results to represent a very high level of protection at least 99.7% protected from a single occurrence in the highest year and 100% protected from multiple occurrences) from the risk of respiratory effects that have been observed to occur in as many as approximately 25% of controlled human exposure study subjects with asthma exposed to 400 ppb while breathing at elevated rates, and that have frequently been accompanied by respiratory symptoms. The Administrator additionally notes the small percentage (no more than approximately 2% in the highest year) of children with asthma estimated to experience a single day with a 5-minute exposure at or above the lower exposure concentration of 200 ppb, and that less than 0.1% of that population group is estimated to experience more than a single such day in the highest year. In so doing, he recognizes, as did the Administrator in the last review, that effects resulting from this lower exposure concentration are appreciably less severe (e.g., in terms of prevalence of study subjects experiencing a tripling or more in sRaw as well as a 20% reduction in FEV₁) than those elicited by exposures at or above 400 ppb, and that they are less frequently accompanied by respiratory symptoms (ISA, Table 3–2 and Figure 5–1; PA, Table 3–1 and section 3.2.1.3).

The Administrator additionally considers the PA findings regarding the REA estimates of lung function risk in terms of lung function decrements as assessed using doubling and tripling of sRaw. The Administrator finds the REA estimates to indicate a high level of protection for children with asthma against the risk of lung function decrements, and particularly against the larger decrements (e.g., tripling in sRaw) and against multiple occurrences. The REA results for air quality conditions that just meet the current standard indicate, based on average estimates across the 3-year period, protection of more than 99.7% of children with asthma from experiencing a day per year with a SO₂-related tripling of sRaw and at least 99.8% from experiencing multiple such days per year. The results further indicate 99% or more of children with asthma to be protected from multiple days with a SO₂-related doubling of sRaw.

Taking the REA estimates of exposure and risk together, while recognizing the uncertainties associated with such estimates for the scenarios of air quality developed to represent conditions just meeting the current standard, the Administrator considers the current standard to provide a high degree of protection to at-risk populations from SO₂ exposures associated with health effects of public health concern, as indicated by the extremely low estimates of occurrences of exposures at or above 400 ppb (and at or above 300 ppb). He further considers the current standard to additionally provide a slightly lower, but still high, degree of protection for the appreciably less severe effects associated with lower exposures (i.e., at and below 200 ppb), for which public health implications are less clear. In considering the adequacy of protection provided by the current standard from these lower exposure concentrations, the Administrator additionally notes take of the array of limitations in the evidence summarized above with regard to characterizing the potential response of at-risk individuals to exposures below 200 ppb, which the PA indicates to be much reduced. He also notes the limitations in the evidence for population groups potentially at risk by virtue of which the evidence of risk is limited (PA, section 3.2.2.3; REA, section 5.3). Based on these and all of the above considerations, the Administrator proposes to conclude that a more stringent standard is not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act.

With regard to key aspects of the specific elements of the standard, the Administrator recognizes first the support in the current evidence base for

97 Such judgments are among those important to decisions on the adequacy of the margin of safety allowed by the current standard.
SO\textsubscript{2} as the indicator for SO\textsubscript{2}. In so doing, he notes the ISA conclusion that SO\textsubscript{2} is the most abundant of the SO\textsubscript{2} in the atmosphere and the one most clearly linked to human health effects, as described in the PA and summarized in sections II.B.1 and II.D.1 above. He additionally recognizes the control exerted by the 1-hour averaging time on 5-minute ambient air concentrations of SO\textsubscript{2} and the associated exposures of particular importance for SO\textsubscript{2}-related health effects. Lastly, with regard to form and level of the standard, the Administrator takes note of the REA results as discussed above and the level of protection that they indicate the elements of the current standard to provide. The Administrator additionally takes note of the CASAC support for retaining the current standard and the CASAC’s specific recommendation that all four elements should remain the same. Beyond his recognition of this support in the available information and in CASAC advice for the elements of the current standard, the Administrator has considered the elements collectively in evaluating the health protection afforded by the current standard, as described above.

Thus, based on consideration of the evidence and exposure/risk information available in this review with its attendant uncertainties and limitations and information that might inform public health policy judgments, as well as advice from the CASAC, including their concurrence with the PA conclusions that the current evidence does not support revision of the primary SO\textsubscript{2} standard, the Administrator further proposes to conclude that it is appropriate to retain the current standard without revision. The Administrator bases these proposed conclusions on consideration of the health effects evidence, including consideration of this evidence in the context of the quantitative exposure and risk analyses, recognizing the uncertainties associated with both. Inherent in the Administrator’s proposed conclusions are public health policy judgments, including those regarding the public health significance of the SO\textsubscript{2}-related effects estimated to occur in small portions of the at-risk populations under air quality conditions adjusted to just meet the current standard. In reaching his proposed conclusion on the adequacy of public health protection afforded by the existing primary standard, the Administrator recognizes that the Act requires primary standards to be requisite to protect public health with an adequate margin of safety, and neither more nor less stringent than necessary for this purpose (see generally, Whitman v. American Trucking Associations, 531 U.S. 457, 465–472, 475–76 [2001]). The Administrator also recognizes that the Act does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that avoids unacceptable risks to public health, even if the risk is not precisely identified as to nature or degree. The Administrator finds the current standard to provide such a level of public health protection. Thus, the Administrator proposes to conclude that the current primary SO\textsubscript{2} standard provides an adequate margin of safety against adverse effects associated with short-term exposures to SO\textsubscript{2} in ambient air. For these reasons, and all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence and REA results provide support for retaining the current standard, the Administrator proposes to conclude that the current primary SO\textsubscript{2} standard is requisite to protect public health with an adequate margin of safety from effects of SO\textsubscript{2} in ambient air and should be retained, without revision. The Administrator solicits comment on this proposed conclusion.

Having reached the proposed decision described here based on interpretation of the health effects evidence, as assessed in the ISA, and the quantitative analyses in the REA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC; public comments received to date in this review; and the public health policy judgments described above, the Administrator recognizes that other interpretations, assessments and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision, as described above. The EPA also solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at http://www2.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) determined that this action is a significant regulatory action and it was submitted to OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. Because this action does not propose to change the existing primary NAAQS for SO\textsubscript{2}, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. EPA has thus not prepared a Regulatory Impact Analysis for this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an E.O. 13771 regulatory action. There are no quantified cost estimates for this proposed action because EPA is proposing to retain the current standard.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA and this action proposes to retain the current primary SO\textsubscript{2} NAAQS without any revisions.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this action proposes to retain, without revision, existing national standards for allowable concentrations of SO\textsubscript{2} in ambient air as required by section 109 of the CAA. See also American Trucking Associations v. EPA, 175 F.3d 1027, 1044–45 (D.C. Cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), rev’d in part on other grounds, Whitman v. American Trucking Associations, 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small
governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. This action does not change existing regulations; it proposes to retain the current primary NAAQS for SO2 based on the Administrator’s conclusion that the existing standard protects public health, including the health of sensitive groups, with an adequate margin of safety. Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence and risk assessment information for this action, which focuses on children with asthma as a key at-risk population, is summarized in sections II.B and II.C above and described in the ISA and PA, copies of which are in the public docket for this action.

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

This action is not subject to Executive Order 13211, because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this document is to propose to retain the current primary SO2 NAAQS. This proposal does not change existing requirements. Thus, the EPA concludes that this proposal does not constitute a significant energy action as defined in Executive Order 13211.

J. National Technology Transfer and Advancement Act

This action does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation related to this is contained in section II above. The action proposed in this notice is to retain without revision the existing primary NAAQS for SO2 based on the Administrator’s conclusion that the existing standard protects public health, including the health of sensitive groups, with an adequate margin of safety. Executive Order 13175 does not apply to this action.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to “such other actions as the Administrator may determine.” Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.


E. Scott Pruitt,
Administrator.

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Part III

Securities and Exchange Commission

17 CFR Parts 230, 242, and 270
Covered Investment Fund Research Reports; Proposed Rule
I. Introduction and Background

A. Introduction

As directed by the Fair Access to Investment Research Act of 2017, we are proposing new rule 139b under the Securities Act of 1933 (the “Securities Act”). Proposed rule 139b includes certain conditions that, if satisfied, would provide that a broker’s or dealer’s (a “broker-dealer’s”) publication or distribution of a covered investment fund research report will be deemed for purposes of sections 2(a)(10) and 5(c) of the Securities Act of 1933 (the “Securities Act”) to be an offer for sale or offer to sell a security. 

1. Market Structure and Market Participants

A. Scope of Proposed Rule 139b


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covered investment fund, even if the broker-dealer is participating or may participate in a registered offering of the covered investment fund’s securities. Proposed rule 139b would establish a new safe harbor for unaffiliated broker-dealers’ publication or distribution of covered investment fund research reports similar to the existing safe harbor under rule 139 applicable to research reports about other issuers or their securities. We are also proposing new rule 24b–4 under the Investment Company Act of 1940 (the “Investment Company Act’’), which would exclude a covered investment fund research report from the filing requirements of section 24(b) of the Investment Company Act (or the rules and regulations thereunder), except to the extent that such report is otherwise not subject to the content standards in self-regulatory organization (“SRO”) rules related to research reports, including those contained in the rules governing communications with the public regarding investment company research reports, or substantially similar equivalent rules.

This proposed rule would have the effect of reducing the filing requirements currently applicable to certain communications that, by operation of the FAIR Act and proposed rule 139b, would now be deemed “covered investment fund research reports.” Additionally, in light of the proposal of rule 139b, we are proposing a conforming amendment to rule 101 of Regulation M. This amendment would permit certain participants, such as brokers or dealers, to publish or disseminate any information, opinion, or recommendation relating to a covered security if the conditions of proposed rule 139b (or, alternatively, the conditions of rule 139 or rule 139 under the Securities Act) are satisfied. The proposed conforming amendment is intended to align the treatment of research under proposed rule 139b with the treatment of research under rules 138 and 139 for purposes of Regulation M.

Rule 139 currently provides a safe harbor for the publication or distribution of research reports concerning one or more issuers by a broker-dealer participating in a registered offering of one of the covered issuers’ securities. Specifically, rule 139 provides that a broker-dealer’s publication or distribution of research reports—whether about a particular issuer or multiple issuers, including within the same industry—that satisfy certain conditions under the rule are “deemed for purposes of sections 2(a)(10) and 5(c) of the [Securities] Act not to constitute an offer for sale or offer to sell.” A broker-dealer’s publication or distribution of a research report in reliance on rule 139 would therefore not be deemed to constitute an offer that otherwise could be a non-conforming prospectus in violation of section 5 of the Securities Act. Although the Commission has previously requested comment as to whether to extend rule 139 to cover investment company research reports, the rule’s safe harbor currently is not available for a broker-dealer’s publication or distribution of research reports pertaining to specific registered investment companies or business development companies.

B. FAIR Act

The FAIR Act directs us to propose and adopt rules amendments that would extend the current safe harbor available under rule 139 to a “covered investment fund research report.” The FAIR Act also directs that these amendments shall be “upon such terms, conditions, or requirements as the Commission may determine necessary or appropriate in the public interest, for the protection of investors.”

3 See infra text accompanying notes 32–34 (discussing our general approach in modeling proposed rule 139b after rule 139 [17 CFR 230.139], and noting that we propose this approach in furtherance of the FAIR Act’s directive to revise rule 139 to extend the current safe harbor available under rule 139 to broker-dealers’ publication or distribution of covered investment fund research reports); see also proposed addition to rule 139(a) (“For purposes of the [FAIR Act], a safe harbor has been established for covered investment fund research reports, and the specific terms of that safe harbor are set forth in Rule 139b.”).

4 See infra notes 11–15 and accompanying text.

5 15 U.S.C. 80a–1 et seq.

6 As discussed below, we are proposing this rule pursuant to section 2(b)(4) of the FAIR Act (mandating that the Commission shall provide that a covered investment fund research report shall not be subject to section 24(b) of the Investment Company Act of 1940 (15 U.S.C. 80a–24(b)) or the rules and regulations thereunder, except to the extent that such report may still be subject to such section and the rules and regulations thereunder to the extent that it is otherwise not subject to the content standards in the rules of any self-regulatory organization related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar equivalent rules). See infra section II.B.1.

7 See infra notes 184–187 and accompanying text.
investors, and for the promotion of capital formation.”\(^\text{17}\) Under the FAIR Act, a “covered investment fund research report” is generally a research report published or distributed by a broker-dealer about a covered investment fund or any of the covered investment fund’s securities.\(^\text{18}\) The term “covered investment fund” under the FAIR Act includes registered investment companies and business development companies.\(^\text{19}\) The term also includes other persons issuing securities in an offering registered under the Securities Act (i) whose securities are listed for trading on a national securities exchange, (ii) whose assets consist primarily of commodities, currencies, or derivative instruments that reference commodities or currencies or interests in the foregoing, and (iii) whose registration statement reflects that its securities are purchased or redeemed, subject to certain conditions or limitations, for a ratable share of its assets (such exchange-listed funds or trusts, “commodity- or currency-based trusts or funds”).\(^\text{20}\) However, a “covered investment fund research report” excludes research reports published or distributed by the covered investment fund itself, any affiliated investment fund, or any broker-dealer that is an investment adviser (or an affiliated person of the investment adviser) to the covered investment fund.\(^\text{21}\)

The FAIR Act directs us to address the application of certain aspects of current rule 139 to covered investment fund research reports. For example, one of the conditions for using the rule 139 safe harbor for research reports about a specific issuer is that the broker-dealer’s publication or distribution of the research report must “not represent the initiation of publication of research reports about such issuer or its securities or reinitiation of such publication following discontinuation of publication of such research reports.”\(^\text{22}\) Because many covered investment funds continuously offer their shares for sale (as opposed to engaging in an offering over a discrete period of time), it is difficult for a broker-dealer participating in such a continuous offering to satisfy this condition. In light of this, the FAIR Act prescribes that our extension of the rule 139 safe harbor, with respect to research reports in an offering of covered investment funds that are in “substantially continuous distribution,” cannot be conditioned on whether the broker-dealer’s publication or distribution of such research reports constitutes initiation or reinitiation of research about the covered investment fund or its securities.\(^\text{23}\)

The FAIR Act also permits us to impose conditions on covered investment fund research reports that are similar to the conditions imposed under rule 139.\(^\text{24}\) We may set a minimum public float requirement for covered investment funds but may not require a minimum public float that is greater than what is required under rule 139 (currently, $75 million).\(^\text{25}\) Similarly, we may set a reporting history requirement for covered investment funds, but may not require a reporting history period for longer than what is required under rule 139 (currently, the 12 months preceding the time of the broker-dealer’s first reliance on the rule 139 safe harbor).\(^\text{26}\) Moreover, as noted above, we may impose additional conditions that we determine to be necessary or appropriate in the public interest, for the protection of investors, and for the promotion of capital formation.\(^\text{27}\)

Finally, the FAIR Act includes provisions concerning the ability of SROs to impose requirements on the use and filing of covered investment fund research reports.\(^\text{28}\) First, the FAIR Act directs us to provide that covered investment fund research reports will not be subject to section 24(b) of the Investment Company Act and the rules and regulations thereunder,\(^\text{29}\) except to the extent that such reports are otherwise not subject to the content standards in the rules of any SRO related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.\(^\text{30}\) The FAIR Act also requires us to provide that SROs: (i) Cannot prohibit the ability of a broker-dealer to publish or distribute a covered investment fund research report, or (ii) Cannot set conditions that would result in the publication of non-substantially similar research reports.\(^\text{31}\)

\(^{17}\) See id.

\(^{18}\) See id. at section 2(f)(3). But see infra note 21 and accompanying text (noting that the definition of “covered investment fund research report” includes research reports published or distributed by the covered investment fund or any affiliate of the covered investment fund, or any research report published or distributed by any broker or dealer that is an investment adviser (or an affiliated person of an investment adviser) for the covered investment fund).

\(^{19}\) See id. at section 2(f)(2)(A).

\(^{20}\) See id. at section 2(f)(2)(B).

\(^{21}\) The FAIR Act definition of “covered investment fund research report” uses the term “affiliate” in connection with a covered investment fund and “affiliated person” in connection with an investment adviser. See section 2(f)(3) of the FAIR Act.

The FAIR Act includes a definition for the term “affiliate.” See supra note 17 and accompanying text. Because the FAIR Act directs the Commission to revise rule 139 under the Securities Act, we interpret the reference to the term “affiliate” in the definition of “covered investment fund research report” to refer to the term “affiliate” as it would be interpreted under rule 139, which we believe is by reference to rule 405 under the Securities Act. (We believe this to be the case because, for example, rule 139 is available for research reports regarding issuers that register their securities on Form S–3 or Form F–3 or that meet the minimum float provisions of General Instruction I.B.1 of such forms. See rule 139(a)(1)(i)(A)(1)(i). General Instruction I.B.1, in turn, refers to the definition of “affiliate” in Securities Act rule 405.) Under rule 405, the term “affiliated” means an affiliate of, or person affiliated with, specified persons that directly or indirectly own, control, or own indirectly through one or more intermediaries, control or is controlled by, or is under common control with, the person specified. See rule 405 under the Securities Act (17 CFR 230.405). The FAIR Act defines “affiliated person” as having the same meaning given the term in section 2(a) of the Investment Company Act. See section 2(f)(1) of the FAIR Act. Section 2(f)(1) of the Investment Company Act defines an “affiliated person” as: (A) Any person directly or indirectly owning, controlling, or holding with power to vote, five percentum or more of the outstanding voting securities of such other person; (B) any person five percentum or more of whose outstanding voting securities are owned directly or indirectly, controlled, or held with power to vote by such other person; (C) any person directly or indirectly controlling, controlled by, or under common control with, such other person; (D) any officer, director, partner, cotainer, employee of such other person; (E) if such other person is an investment company, any investment adviser thereof or any member of an advisory board thereof; and (F) if such other person is an unincorporated entity, by not having a board of directors, the predecessor thereof. See rule 139(a)(1)(i)(iii) [17 CFR 230.139(a)(1)(i)(iii)].

\(^{22}\) See section 2(b)(1) of the FAIR Act.

\(^{23}\) See infra notes 25–27.
research report solely because the broker-dealer is participating in a registered offering or other distribution of any securities of the covered investment fund; and (ii) cannot prohibit the ability of a broker-dealer to participate in a registered offering or other distribution of securities of the covered investment fund solely because the broker-dealer has published or distributed a research report about that covered investment fund or its securities.31

II. Discussion

In the sections that follow, we discuss in detail the scope and conditions of proposed rule 139b, the operation and effect of proposed rule 24b-4,32 and the proposed conforming amendment to rule 101 of Regulation M.

Proposed rule 139b’s framework is modeled after and generally tracks rule 139. However, proposed rule 139b differs from rule 139 in certain respects. Some of these differences are specifically directed or contemplated by the FAIR Act.33 Other differences, while not specifically directed by the FAIR Act, clarify and tailor the provisions of rule 139 more directly or specifically to the context of broker-dealers’ publication or distribution of covered investment fund research reports.34 For the reasons described below, we believe that the provisions of proposed rule 139b that differ from the provisions of rule 139, and that are not specifically contemplated in the FAIR Act, are necessary or appropriate in the public interest, for the protection of investors, and for the promotion of capital formation.

A. Scope of Proposed Rule 139b

Proposed rule 139b would establish a safe harbor for the publication or distribution of “covered investment fund research reports” by unaffiliated broker-dealers (as described below) participating in a securities offering of a “covered investment fund.” Under the safe harbor, such publication or distribution would be deemed to constitute an offer for sale or offer to sell the covered investment fund’s securities for purposes of sections 2(a)(10) and 5(c) of the Securities Act. The safe harbor would be available even if the broker-dealer is participating or may participate in a registered offering of the covered investment fund’s securities.

We are proposing to define the term “covered investment fund research report,” as well as the “covered investment fund” and “research report” components of this definition.

1. Definition of “Covered Investment Fund Research Report”

   Under the FAIR Act, the term “covered investment fund research report” means a research report published or distributed by a broker or dealer about a covered investment fund or any security issued by the covered investment fund, but does not include a research report to the extent that the research report is published or distributed by the covered investment fund or any affiliate of the covered investment fund, or any research report published or distributed by any broker or dealer that is an investment adviser (or an affiliated person of an investment adviser) for the covered investment fund (the “affiliation exclusion”).35 Proposed rule 139b incorporates the same definition as is set forth in the FAIR Act.36

   The FAIR Act’s affiliation exclusion prohibits two separate categories of research reports from being deemed to be “covered investment fund research reports” that a broker-dealer may publish or distribute under the contemplated safe harbor. The first category covers research reports published or distributed by the covered investment fund or any affiliate of the covered investment fund. We believe this exclusion would prevent such persons from indirectly using the safe harbor to avoid the applicability of the Securities Act prospectus requirements and other provisions applicable to written offers by such persons.

   The second category covers research reports published or distributed by any broker or dealer that is an investment adviser (or an affiliated person of an investment adviser) for the covered investment fund. This second exclusion addresses the concern that a broker-dealer that is a fund’s adviser or an affiliated person of a fund’s adviser may have financial incentives that could give rise to a conflict of interest. For example, a broker-dealer that is an affiliated person of a fund’s adviser may have an incentive to promote the covered investment fund’s securities relative to other securities because sales of the covered investment fund’s securities would benefit not only the fund, but also could benefit the broker-dealer.37 This second exclusion therefore helps to establish a certain level of independence in the activity of publishing and distributing covered investment fund research reports and therefore could help mitigate these potential conflicts of interest.

   We believe that it would be inappropriate for any person covered by the affiliate exclusion, or for any person acting on its behalf, to publish or distribute a research report indirectly that the person could not publish or distribute directly under the proposed rule.38 For example, if a broker-dealer were to publish or distribute a research report that included materials that were specifically authorized or approved by a person covered by the affiliate exclusion, expressly for the purpose of inclusion in a research report, this could inappropriately circumvent the affiliate exclusion in proposed rule 139b. In this case, the person covered by the affiliate exclusion would be publishing or distributing communications indirectly through the third-party broker-dealer that otherwise would have to be included in a statutory prospectus meeting the requirements of section 10 of the Securities Act. One of the factors to consider in evaluating whether a research report has been published or

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31 See section 2(b)(3) of the FAIR Act.32 This discussion appears in section II.D infra.33 See, e.g., infra section II.A.1 (discussing the “affiliation exclusion” [defined below]).34 See, e.g., infra section II.B.1.a (discussing reporting history and timeliness requirements for issuer-specific reports).35 See section 2(f)(3) of the FAIR Act.36 See proposed rule 139b(c)(3); see also supra note 21 (discussing the terms “affiliate” and “affiliated person” in the FAIR Act definition of “covered investment fund research report”); proposed rule 139b(c)(5) (defining the term “investment adviser” for purposes of the proposed rule).37 We note that broker-dealers may have incentives to recommend certain covered investment funds to clients even when the broker-dealer is not the fund’s investment adviser (or an affiliated person of the investment adviser). For example, when a covered investment fund’s investment adviser has entered into revenue sharing arrangements with a broker-dealer, the broker-dealer may have incentives to recommend to its clients the purchase of this fund’s securities relative to the securities of other covered investment funds (whose investment advisers have not entered into revenue sharing agreements with the broker-dealer). We also note that certain covered investment fund research reports also may be subject to additional rules and regulations under the federal securities laws, as well as certain SRO rules, that are designed to help address certain conflicts of interest and abuses identified with analyst research. See, e.g., Sarbanes-Oxley Act of 2002, Public Law 107–204, 116 Stat. 745 (2002) ("Sarbanes-Oxley Act"), Regulation AC, and FINRA rules 2110, 2241, 2242. The Sarbanes-Oxley Act, Regulation AC, and a global research analyst settlement required structural changes and increased disclosures in communications with certain institutions identified with analyst research. See section 501 of the Sarbanes-Oxley Act; Regulation Analyst Certification, Securities Act Release No. 8193 (Feb. 20, 2003) [68 FR 9481 (Feb. 27, 2003) ("Regulation AC adopting Release"); Global Research Analyst Settlement, Litigation Release No. 18438 (Oct. 31, 2003) ("Lit. Rel. No. 18438"); 2010 Modifications to Global Research Analyst Settlement, Litigation Release No. 21457 (Mar. 19, 2010) ("Lit. Rel. No. 21457").38 See, e.g., section 48(a) of the Investment Company Act [15 U.S.C. 80a–47(a)]; section 208(d) of the Investment Advisers Act of 1940 [15 U.S.C. 80b–8(d)].
distributed by a person covered by the affiliate exclusion is the extent of such person’s involvement in the preparation, distribution, or publication of the research report.

39 Such determinations would necessarily be based on the extent to which a person covered by the affiliate exclusion, or any person acting on its behalf, has been involved in the preparation of the information or explicitly or implicitly endorsed or approved the information. The Commission has referred to these as the entanglement theory and the adoption theory, respectively, and these are helpful guideposts in establishing whether a research report about a covered investment fund may be deemed published or distributed by the fund. See Securities Offering Reform, Securities Act Release No. 8591 [July 19, 2005] [70 FR 44722 {Aug. 3, 2005}] (“Securities Offering Reform Adopting Release”) (noting that “[[i]liability under the entanglement theory depends upon the level of pre-publication involvement in the preparation of the information”). See “Use of Electronic Media, Securities Act Release No. 7856 [Apr. 28, 2000] [65 FR 25843 (May 4, 2000)] (interpretive release on the use of electronic media); Asset-Backed Securities, Securities Act Release No. 8518 (Dec. 22, 2004) [70 FR 1506 (Jan. 5, 2005)] (adopting asset-backed securities regulations).

38 We request comment on the proposed definition of “covered investment fund research report.”

• Should we define “covered investment fund research report” as specified in the FAIR Act, as proposed? Why or why not? What modifications, if any, to this definition do commenters recommend? Solely for purposes of the proposed affiliate exclusion, should we use a definition of “affiliate” that differs from the definition of this term in rule 405 under the Securities Act? If so, should we interpret the term “affiliate” in this context to mean an “affiliated person” as defined in the Investment Company Act? If not, what other definition should we use?

• Should we include a provision in rule 139b specifying that the affiliate exclusion terminate the safe harbor unavailable if a broker-dealer were to publish or distribute a research report that includes materials that were specifically authorized or approved by a person covered by the affiliate exclusion (or a person acting on its behalf) for purposes of inclusion in a research report? Why or why not? If not, is the guidance discussed above on this point appropriate and helpful to the public in understanding the proposed affiliate exclusion? Is there any other guidance that we should provide that would be helpful to promote clarity with respect to the proposed affiliate exclusion?

• Broker-dealers may have incentives—in particular, arising from the compensation arrangements between registered investment companies and their distributing broker-dealers—to recommend certain covered investment funds to clients even when the broker-dealer is not the fund’s investment adviser (or an affiliated person of the investment adviser). While certain covered investment fund research reports may be subject to additional rules and regulations under the federal securities laws, as well as certain SRO rules, that are designed to help address certain conflicts of interest, these additional rules and regulations would not necessarily be applicable with respect to all covered investment fund research reports under proposed rule 139b. Moreover, while these rules and regulations address conflicts of interest, certain of the conflicts they address may not be prevalent in the investment company context (e.g., FINRA rules 2241 and 2242, addressing, among other things, investment-banking-related conflicts). Are we correct in thinking there are conflicts of interest that could arise with respect to broker-dealers’ publication or distribution of covered investment fund research reports (in particular, research reports about registered investment company issuers) that would not be mitigated by proposed rule 139b’s exclusion of research reports published or distributed by a broker-dealer that is an investment adviser for the covered investment fund (or an affiliated person of the adviser)? If not, why not? If so, how should we address these conflicts? Should we add restrictions or conditions to the safe harbor to further mitigate potential conflicts? If so, what types of additional restrictions or conditions would be appropriate? For example, should we require a broker-dealer to describe in a research report the revenue-sharing or other distribution arrangements it has with a covered investment fund as a condition to relying on the proposed safe harbor? Should the existence of a revenue-sharing agreement or other particular type of distribution arrangement disqualify a broker-dealer from being able to publish or distribute a research report about a covered investment fund in reliance on the proposed safe harbor? If so, what types and why?

• Alternatively, should we require broker-dealers that rely on proposed rule 139b to maintain policies and procedures designed to mitigate conflicts that are raised by the distribution of covered investment funds (in particular, covered investment funds that are registered investment companies) and not addressed by the Commission’s rules or SRO rules (such as FINRA rules 2241 and 2242)? To the extent that Commission and SRO rules do not require disclosure of conflicts of interest in covered investment fund research reports, should we require broker-dealers that rely on the proposed rule 139b safe harbor to disclose conflicts of interest in a salient way in covered investment fund research reports? If so, what should the content and format requirements be with respect to such disclosure?

2. Definition of “Research Report”

We are proposing to define the term “research report” in rule 139b as a written communication, as defined in rule 405 under the Securities Act, that includes information, opinions, or recommendations with respect to securities of an issuer or an analysis of a security or an issuer, whether or not it provides information reasonably sufficient upon which to base an investment decision.

Rule 405 defines “written communication” to mean that “[j]except as otherwise specifically provided or the context otherwise requires, a written communication is any communication that is written, printed, a radio or television broadcast, or a graphic communication as defined in [rule 405].” 17 CFR 230.405.

Rule 139 defines “research report” to mean a “written communication,” as defined in rule 405, that includes information, opinions, or recommendations with respect to securities of an issuer or an analysis of a security or an issuer, whether or not it provides information reasonably sufficient upon which to base an investment decision.” See rule 139(d) [17 CFR 230.139(d)]. Rule 139 defines “research report” to mean “a written communication,” as defined in rule 405, that includes information, opinions, or recommendations with respect to securities of an issuer or an analysis of a security or an issuer, whether or not it provides information reasonably sufficient upon which to base an investment decision.” See rule 139(d) [17 CFR 230.139(d)]. A “written communication,” as defined in rule 405, includes a “graphic communication,” as further defined in rule 405, a “graphic communication” includes all forms of electronic media, including electronic communications except those, which at the time of the communication, originate in real-time to a live audience and does not originate in recorded form or otherwise as a graphic communication, although it is transmitted through graphic means. See rule 405 [17 CFR 230.405].
the same meaning as the definition of “research report” in the FAIR Act. Second, we believe that proposing a definition of “research report” in rule 139b that is identical to the existing definition of “research report” in rule 139 would reduce potential interpretive confusion for market participants who are familiar with the rule 139 definition. The FAIR Act defines the term “research report” as having the meaning given to that term under section 2(a)(3) of the Securities Act but specifies that the term “shall not include an oral communication.” 47 Section 2(a)(3) of the Securities Act, in turn, defines “research report” to mean “a written, electronic, or oral communication that includes information, opinions, or recommendations with respect to securities of an issuer or an analysis of a security or an issuer, whether or not it provides information reasonably sufficient upon which to base an investment decision.”

The proposed rule 139b definition of “research report” tracks the FAIR Act definition of “research report,” except that while it does include “electronic communications,” it does not expressly reference that term. For the following reasons, we believe that this difference would have no effect on the types of communications that would qualify as research reports under the proposed safe harbor. Current Commission rules make clear that all electronic communications (other than telephone and other live communications) are graphic and, therefore, written communications for purposes of the Securities Act. Therefore, the proposed rule 139b definition’s reference to a “written communication,” as defined in rule 405, would include a “graphic communication,” which in turn would include electronic communications (other than telephone and other live communications).

46 See infra notes 49–50 and accompanying text.
47 See section 2(18) of the FAIR Act.
49 See Securities Offering Reform Adopting Release, supra note 39, at nn.96–97 and accompanying text; infra note 50. Among other things, the Securities Offering Reform Adopting Release amended the definition of “research report” in rule 139 to make clear that it continues to apply to information, opinions, or recommendations contained in written communications. See id., at text following n.363.

As the Commission noted in the Securities Offering Reform Adopting Release, the intention of the proposed rule 139b definition of “research report,” as defined in rule 405, which definition in turn incorporates the term “graphic communication”).

By using the same definition of “research report” in rule 139 and proposed rule 139b we avoid creating ambiguity that may result if market participants are unable to understand, based on the text of the rules, that the term “research report,” though defined in two different ways, would be interpreted identically.

We request comment on the proposed definition of “research report.”

• Should we use the definition of “research report” in rule 139 as we have proposed rather than as specified in the FAIR Act? Is our proposed approach appropriate? Is defining “research report” as proposed consistent with section 2(f)(6) of the FAIR Act? Would the proposed definition of “research report” have the intended result of assuring that the definitions of “research report” under the FAIR Act and rule 139b would be interpreted identically? Why or why not?

• What, if any, additional modifications to the proposed definition of “research report” would promote clarity? Should we incorporate any additional modifications to the proposed definition for any other purpose?

3. Definition of “Covered Investment Fund”

The FAIR Act defines the term “covered investment fund” to include registered investment companies, business development companies, and certain commodity- or currency-based trusts or funds.51 We are proposing to define the term “covered investment fund” in rule 139b in substantially the same manner as the FAIR Act, with the addition that we propose to specify in this definition that the term “investment company” includes “a series or class thereof.”

We request comment on the proposed definition of “covered investment fund.”

• Should we define “covered investment fund” substantially the same as this term is defined in the FAIR Act as proposed? Why or why not? Should we specify in the definition, as proposed, that the term “investment company” includes a “series or class thereof”? What modifications, if any, to this definition do commenters recommend?

• Are there any types of funds, trusts, or other pooled investment vehicles that would not be included within the proposed definition of “covered investment fund” that we should consider including within the definition? If so, why?

4. Non-Exclusivity of Safe Harbor

Broker-dealers publishing or distributing research reports for some covered investment funds, such as commodity- or currency-based trusts or funds that have a class of securities registered under the Exchange Act, may be able to rely on existing rule 139.53 We do not intend for proposed rule 139b to preclude a broker-dealer from relying on existing rule 139 where appropriate. In order to clarify that a broker-dealer may rely on existing research safe harbors, proposed rule 139b provides that the rule does not affect the availability of any other exemption or exclusion from sections 2(a)(10) or 5(c) of the Securities Act that may be available to a broker-dealer.54 A broker-dealer therefore would be able to rely on proposed rule 139b to publish or distribute a covered investment fund research report or could choose to rely instead on any other available exemption or exclusion from sections 2(a)(10) or 5(c) of the Securities Act.

52 See supra note 49 (discussing the current definition of “research report” in rule 139, which references a “written communication” as defined in rule 405, which definition in turn incorporates the term “graphic communication”).
53 See supra notes 19–20 and accompanying text. Based on the definition in section 2(2) of the FAIR Act, the term “covered investment fund” would not include an investment company that is registered solely under the Investment Company Act, such as certain master funds in a master-feeder structure. See id.
54 See proposed rule 139b(c)(2). This approach reflects the approach taken in other Commission rules that define the term “fund” to include a separate entity that is an investment company. See, e.g., rule 22c–4(a)(4) under the Investment Company Act [17 CFR 270.22c–4(a)(4)]; rule 22c–11(a)(3)(v)(A) under the Investment Company Act [17 CFR 270.22c–11(a)(3)(v)(A)] (effective Nov. 19, 2018).
including those provided by rules 137, 138, and 139, as applicable.

We request comment on the non-exclusivity provision in proposed rule 139b:

• Should other exemptions, exclusions, or safe harbors from sections 2(a)(10) or 5(c) of the Securities Act for research reports, such as rules 137, 138, or 139, continue to be available to broker-dealers as proposed? Why or why not? Should we make any additional clarifications? If so, what clarifications should we make?

B. Conditions for the Safe Harbor

The Commission has previously acknowledged the value of research reports in providing the market and investors with information about reporting issuers.  To mitigate the risk of research reports being used to circumvent the prospectus requirements of the Securities Act, the Commission has placed conditions on a broker-dealer’s publication or distribution of research reports. Under rule 139, these conditions include restrictions on who may rely on the rule and on the issuers to which the research may relate, as well as a requirement that such reports be published in the regular course of a broker-dealer’s business. These conditions vary depending on whether a research report covers a specific issuer (“issuer-specific research reports”) or a substantial number of issuers in an industry or sub-industry (“industry research reports”).

Consistent with the FAIR Act’s directive to revise rule 139 to extend the rule’s safe harbor to covered investment fund research reports, proposed rule 139b seeks to address concerns that could accompany broker-dealers’ publication or distribution of these research reports. Rule 139b proposes conditions for both issuer-specific research reports and industry research reports that must be satisfied in order for a broker-dealer to rely on the safe harbor. The conditions are intended to track the conditions already in place under rule 139 to the extent practicable. We believe that any deviations from the requirements of rule 139 are consistent with the FAIR Act’s directives.

Tracking the requirements in rule 139 to the extent practicable also provides efficiencies for broker-dealers familiar with the requirements of rule 139.

1. Issuer-Specific Research Reports

a. Reporting History and Timeliness Requirements

In order for a broker-dealer to include a covered investment fund in a research report published or distributed in reliance on the proposed safe harbor, we propose that the fund must meet certain reporting history requirements. Specifically, we are proposing that any such covered investment fund must have been subject to relevant requirements under the Investment Company Act and/or the Exchange Act to file certain periodic reports for at least 12 calendar months prior to a broker-dealer’s reliance on proposed rule 139b (note 39).

Specifically, covered investment funds that are registered investment companies would need to have been subject to the reporting requirements of the Investment Company Act for a period of at least 12 calendar months prior to reliance on the proposed rule and to have filed in a timely manner all required reports, as applicable, on Forms N–CSR, N–SAR, N–Q, N–PORT, N–MFP, and N–CEN during the immediately preceding 12 months. If the covered investment fund is not a registered investment company, it would need to have been subject to the reporting requirements under section 13 or 15(d) of the Exchange Act for a period of at least 12 calendar months and to have filed all required reports in a timely manner on Forms 10–K and 10–Q and 20–F during the immediately preceding 12 months.

The proposed reporting history requirements are consistent with current rule 139. The timeliness

55 17 CFR 230.137.
56 See Securities Offering Reform Adopting Release, supra note 39.
57 For example, the Commission has recognized that, for companies that are well-followed, the research-report-related rules “enhance the efficiency of the markets by allowing a greater number of research reports to provide a continuous flow of essential corporate information into the marketplace.” See Research Reports, Securities Act Release No. 6550 (Sept. 19, 1984) [49 FR 37569 (Sept. 23, 1984)] (“1984 Adopting Release”).
58 See supra note 13 and accompanying text (noting that the rule 139 safe harbor permits a broker-dealer to publish or distribute a research report without this publication or distribution being deemed to constitute an offer that otherwise could be a non-conforming prospectus in violation of section 5 of the Securities Act).
59 See, also, e.g., Securities Offering Reform Adopting Release, supra note 39 (discussing how the Sarbanes-Oxley Act, Regulation AC, and a global research analyst settlement required structural changes and increased disclosures in the early 2000s in connection with certain abuses identified with analyst research); discussion at supra note 37 (discussing certain rules and regulations under federal securities laws, as well as certain SRO rules, that are designed to help address certain conflicts of interest and abuses identified with analyst research).
60 Many research reports that broker-dealers publish or distribute in reliance on the rule 139 safe harbor may also be subject to other federal securities rules and regulations under the Exchange Act and SRO rules governing their content and use. See supra note 57.
61 Proposed rule 139b(a)(1)(1).
As the Commission has previously recognized in the context of Form S–3 and F–3 issuers, satisfaction of the applicable reporting history and public float requirements suggests the presence of a sufficiently broad market following for the issuer’s securities and, consequently, an adequate mix of information to inform investors as to material risks.75 Consistent with this view, we believe the proposed reporting history and timely reporting requirements would facilitate investors’ analysis of issuer-specific covered investment fund research reports and aid them in making informed investment decisions.76 The Commission believes that it is appropriate to require a 12-month reporting history for covered investment fund issuers that may be included in issuer-specific research reports, rather than a shorter duration.77 As under rule 139, this approach would provide investors with publicly-available information about the issuers included in a research report for a full year. The proposed approach also has the benefit of maintaining consistency between rule 139b and the long-established reporting history conditions of rule 139.78

We recognize, however, that in the context of covered investment funds that are open-end registered investment companies, use of a reporting history of only 12 months could result in certain performance and other information that may be relevant to investors not yet being available in the fund’s prospectus at the time the broker-dealer publishes or distributes a research report on that fund. This is because the disclosure requirements for a registered investment company, or a series thereof, are based in part on how long the fund has been operational. For example, for a newly-registered covered investment fund that is an open-end registered investment company, a bar chart pursuant to Item 4 of Form N–1A is not required to be included in the fund’s prospectus until the fund has been operational for one full calendar year.79 We note, however, that other information for such a fund, such as principal investment strategies and estimated expenses, would be available at the time the fund launches. We request comment below on whether—and if so, how—the proposed reporting history and timeliness requirements could be more tailored to covered investment funds.

We request comment on the proposed reporting history and timeliness requirements.

• Are the proposed reporting requirements an appropriate condition for issuer-specific covered investment fund research reports whose publication or distribution would be required to appear in reports filed on Form N–Q or 20–F for the immediately preceding 12 calendar months, and issuers that are not registered investment companies must have timely filed reports on Forms N–CSR, N–SAR, N–PORT, N–MFP, and N–CEN, as applicable,60 for the immediately preceding 12 calendar months, and issuers that are not registered investment companies must have timely filed reports on Forms 10–K and 10–Q or 20–F for the immediately preceding 12 calendar months, in order to be included in a research report for whose publication or distribution the proposed safe harbor would be available. Should we require a different set of periodic reports to be timely filed, other than what we propose? For example, should the requirement be based on a limited subset of the reports? Why or why not?

b. Minimum Public Market Value Requirement

In order for broker-dealers to use the proposed rule 139b safe harbor to publish or distribute issuer-specific research reports, we also are proposing that the covered investment fund that is the subject of a report must satisfy a minimum public market value threshold at the date of reliance on the proposed rule (the “minimum public market value requirement”). Specifically, we are proposing that the aggregate market value of a covered investment fund,61 or the net asset value in the case of a registered open-end investment company (other than an exchange-traded fund), be required to be at least $100 million.62
There are various requirements and considerations under the proposed rule 139b, including:

1. Minimum public float and aggregate market value requirements generally track the minimum public float and aggregate market value requirements under rule 139, modified as appropriate to apply to covered investment fund issuers. As discussed above, the FAIR Act specifically permits us to set a minimum public float requirement for covered investment funds, as long as the minimum public float is not greater than what is required by rule 139.

2. Market value requirements under rule 139b, net asset value and aggregate market value would be the common equity share price). The proposed minimum public market value requirement generally tracks the minimum public float and aggregate market value requirements under rule 139, modified as appropriate to apply to covered investment fund issuers.

3. The proposed public market value requirement is designed to protect investors by evaluating research reports on covered investment funds with a relatively small amount of total assets, and hence a limited market following. We believe that it is appropriate to include a $75 million public market value requirement for issuers that may include in issuer-specific research reports, rather than some lower threshold. The proposed minimum public market value threshold is the same as the parallel threshold in rule 139, which we believe would increase compliance efficiencies among broker-dealers relying on the rule 139 and proposed rule 139b safe harbors.

4. The proposed rule also would provide an exception for issuers that are not actively traded (such as non-traded closed-end funds and non-traded business development companies), we anticipate that, for purposes of rule 139a, net asset value and aggregate market value would be calculated based on the fund’s publicly-disclosed share price (for non-traded business development companies, this would be the common equity share price).

5. We request comment on the proposed minimum public market value requirement.

6. Distribution of covered investment funds, and “net asset value” in the case of a registered open-end investment company (other than an ETF)? Should the proposed requirement instead refer to “net asset value” for ETFs? Is there another measure of market value that is more appropriately tailored for covered investment fund research reports?

7. Should we include different or more specific instructions about how covered investment funds would aggregate market value and net asset value? For example, should we specify that an ETF’s aggregate market value be calculated with reference to the definition of “market price” in Form N–1A rather than General Instruction B.1 of Form S–3? Should we include more specific instructions about how a covered investment fund that is not actively traded should aggregate market value and net asset value?

8. Would the proposed minimum public market value requirement promote the dissemination into the market of an appropriate amount of research about covered investment funds? Conversely, would it unduly impede analyst coverage of covered investment fund issuers, and could this in turn affect the market following for these issuers? Is the approach we are proposing consistent with section 2(b)(2)(B) of the FAIR Act?

9. Regular-Course-Of-Business Requirement

The proposed rule also would condition eligibility for the safe harbor on a broker-dealer’s publication or distribution of research reports “in the regular course of its business” (the “regular-course-of-business” requirement).

Although the proposed regular-course-of-business requirement is generally similar to the existing provisions of rule 139, it differs in one way:
respect as required by the FAIR Act. Rule 139 provides, in addition to the requirement that a broker-dealer “publish[] or distribute[] research reports in the regular course of its business,” that such publication or distribution may not represent either the initiation of publication of research reports about the issuer or its securities or the re-initiation of such publication following a discontinuation thereof (the “initiation or reinitiation” requirement).96 The FAIR Act, however, provides that the safe harbor shall not apply the “initiation or reinitiation” requirement to a report concerning a covered investment fund with a class of securities “in substantially continuous distribution.”97 Proposed rule 139b reflects this requirement by incorporating the “initiation or reinitiation” requirement from current rule 139 but specifying that it applies only to research reports regarding a covered investment fund that does not have a class of securities in substantially continuous distribution.98 Determining whether a class of securities is in substantially continuous distribution would be based on an analysis of the relevant facts and circumstances. We request comment below on whether there are any types of covered investment funds or classes of securities that raise particular questions as to the presence or absence of a “substantially continuous distribution.” We also request comment as to whether market participants would benefit from further Commission guidance on this point.

Since rule 139 was first adopted, the regular-course-of-business requirement has been a condition for a broker-dealer’s publication or distribution of research reports in reliance on the rule.99 We believe requiring that research reports be published or distributed in the regular course of a broker-dealer’s business, consistent with the requirements of rule 139, could reduce the potential that covered investment fund research reports will be used to circumvent the prospectus requirements of the Securities Act. Moreover, we are concerned about certain potential consequences of broker-dealers’ ability, under proposed rule 139b, to publish or distribute communications as research reports that have traditionally been viewed by the investing public as advertisements or sales material related to registered investment companies or business development companies. The safe harbor provided under rule 139 is currently not available for a broker-dealer’s publication or distribution of research reports pertaining to specific registered investment companies or business development companies.100 Therefore, a research report about a covered investment fund that is a registered investment company currently must comply with the requirements of Securities Act rule 482.101 Given the definition of “research report” under the FAIR Act,102 however, certain communications that are currently treated as covered investment fund advertisements under Securities Act rule 482 also could fall under the proposed rule 139b definition of “research report.”

Investors, particularly retail investors, may be unaware of the differences in regulatory status and purpose among the various types of communications regarding registered investment companies and business development companies. This may result in investors not being able to readily discern what constitutes a research report and what constitutes an advertisement about these issuers. Context helps investors evaluate and weigh the information presented to them. For example, investors likely know that advertising directly promotes sales of a particular product. A broker-dealer publishing or distributing a research report on the other hand, may do so with multiple purposes for multiple audiences. While a research report may have the effect of promoting sales of the securities of the issuer that the research report features, it may serve a number of market functions as well, such as promoting market trading, educating a particular audience, or providing a service to clients.103 We believe that broker-dealers that publish or distribute research reports in the regular course of business are more likely to publish analysis that investors recognize as research. For example, these broker-dealers are more likely to have compliance structures in place, with relevant policies and procedures, governing their publication of research and (as applicable) their distribution of registered investment company advertisements. Similarly, if a broker-dealer were to publish or distribute research reports in the regular course of its business, the broker-dealer may be more likely to have a research department with research analysts who regularly cover particular issuers or industries. This commitment in resources and infrastructure makes it more likely that the market recognizes the broker-dealer as a provider of research-related communications. A research report published or distributed by a research analyst in the research department at a broker-dealer that regularly covers that issuer or industry would therefore be a factor indicating that the regular-course-of-business requirement has been satisfied for purposes of proposed rule 139b.104 Additional factors may include whether the broker-dealer maintains policies and procedures governing its research protocols and whether the broker-dealer regularly publishes or distributes research on any other type of company or business other than covered investment funds.

We request comment on the proposed regular-course-of-business requirement.

- Is the proposed regular-course-of-business requirement appropriate in the context of covered investment fund research reports?
- Would the proposed regular-course-of-business requirement allow an appropriate flow of analyst-generated information to the market?
- Should we define “regular course of business” in proposed rule 139b more specifically in the context of research reports on registered investment companies or business development companies? Today, due to the unavailability of rule 139, we understand that broker-dealers are generally not in the business of publishing and distributing what we consider issuer-specific research reports on registered investment companies or business development companies (although some broker-dealers have

96 Rule 139(a)(1)(ii) [17 CFR 230.139(a)(1)(ii)].
97 Section 2(b)(1) of the FAIR Act.
98 See proposed rule 139b(a)(1)(ii).
100 See supra notes 11–15 and accompanying text.
101 17 CFR 230.482. An investment company advertisement that complies with rule 482 is deemed to be a section 10(b) prospectus (also known as an “advertising prospectus” or “omitting prospectus”) for purposes of section 5(b)(1) of the Securities Act. As a section 10(b) prospectus, an investment company advertisement is subject to liability under section 12(a)(2) of the Securities Act, as well as the antifraud provisions of the federal securities laws.
102 Section 2(0)(6) of the FAIR Act.
103 See infra section III.C.1.b.
104 We believe it is appropriate to include the regular-course-of-business requirement because it is important that the broker-dealer have a history of publishing or distributing a particular type of research. If a broker or dealer begins publishing research about a different type of security around the time of a public offering of an issuer’s security and does not have a history of publishing research on those types of securities, such publication or distribution could be viewed as a way to provide information about the publicly-offered securities in circumvention of the provisions of section 5 of the Securities Act. See Securities Offering Reform Adopting Release, supra note 39.
published and distributed communications styled as “research reports” in compliance with rule 482, and some broker-dealers have published and distributed research reports on other issuers in reliance on the rule 139 safe harbor). Does this raise questions as to how to apply a regular-course-of-business requirement to research reports regarding these issuers that we should address in the proposed rule or through additional Commission guidance? If so, what further definitions or guidance should we consider? Would the proposed regular-course-of-business requirement promote the publication or distribution of research reports on covered investment funds that investors recognize as research?

- What facts and circumstances suggest that a covered investment fund has a class of securities in “substantially continuous distribution”? Are there any types of covered investment funds that raise specific questions about whether or not they have a class of securities in substantially continuous distribution, either generally or in particular circumstances? For example, do all open-end management investment companies, and those closed-end interval funds that make periodic repurchase offers pursuant to rule 23c–3, have a class of securities in substantially continuous distribution, while other closed-end investment companies do not? Why or why not?

- Are there other types of funds with a class of securities in substantially continuous distribution, or are there specific circumstances that should definitively constitute substantially continuous distribution? Would market participants benefit from Commission guidance as to how one would make a determination that a covered investment fund has a class of securities in substantially continuous distribution?

- Alternatively, should we define the term “substantially continuous distribution” in rule 139b, and if so, how? Should this definition include certain types of funds (e.g., open-end management investment companies, closed-end interval funds that make periodic repurchase offers pursuant to rule 23c–3, and other types of funds that are engaged in continuous offerings pursuant to Securities Act rule 415(a)(1)(ix) or others that conduct continuous offerings as shelf takedowns pursuant to rule 415(a)(1)(x))? If so, what funds and under what circumstances? Are there any specific factors that we should incorporate in proposed rule 139b in order to determine whether a covered investment fund is in substantially continuous distribution?

- Because a safe harbor is generally not currently available for broker-dealers’ publication or distribution of covered investment fund research reports,103 should the proposed regular-course-of-business requirement be modified to address how broker-dealers that have not previously published or distributed research reports could satisfy this requirement? If we were to modify the proposed regular-course-of-business requirement to incorporate factors indicating that a broker-dealer has created a history of publishing or distributing research reports in the regular course of business, what should these factors be, and why? Alternatively, should rule 139b provide a “start-up” period to allow broker-dealers to establish a regular course of business of publishing research reports? For example, should the rule provide that a broker-dealer that could not satisfy the regular-course-of-business requirement pose challenges for broker-dealers that had not previously published research reports because of the absence of an applicable safe harbor? If we do not modify the proposed requirement in this way, should we provide further guidance regarding broker-dealers that have not previously published or distributed research reports?

- Should the proposed regular-course-of-business requirement incorporate any more specific requirements regarding the person(s) preparing a covered investment fund research report (e.g., a requirement that the person who prepares the research report must be employed by the broker-dealer to prepare research in the normal course of his or her duties)?

2. Industry Research Reports

Our proposed conditions for industry research reports parallel those set forth in rule 139 and are intended to provide appropriate parameters to address the risk of circumvention of the prospectus requirements of the Securities Act.106

a. Reporting Requirement

Under the proposed safe harbor, each covered investment fund included in an industry research report must be subject to the reporting requirements of section 30 of the Investment Company Act (or, for covered investment funds that are not registered investment companies under the Investment Company Act, the reporting requirements of section 13 or section 15(d) of the Exchange Act). This proposed reporting requirement generally tracks an existing requirement for industry research reports under rule 139107 but has been modified so that it would be applicable to industry research reports that include covered investment fund issuers. Like the parallel provision of rule 139, the proposed reporting requirement helps assure that there is publicly available information about the relevant issuers and that investors are able to use such information in making their investment decisions.

We request comment on the reporting requirement in proposed rule 139b.

- Is the proposed reporting requirement appropriate? Why or why not?

- As discussed above, proposed rule 139b’s framework, including its scope and conditions, generally tracks rule 139.108 Therefore, as in rule 139, the conditions applicable to industry and issuer-specific research reports differ. For example, as proposed, rule 139b (like rule 139) would not require the issuers included in an industry research report to satisfy the minimum market value thresholds discussed in section II.B.1.b above. Is there any reason we should extend all of the conditions for issuer-specific research reports (or a subset of these conditions, to the extent they are not already reflected in proposed rule 139b) to industry reports, even if this approach would diverge from the approach taken in rule 139? Are the concerns underlying the proposed conditions for broker-dealers’ publication or distribution of covered investment fund research reports the same for issuer-specific research reports and industry research reports? Are there any other concerns specific to industry research reports that we should consider?

b. Regular-Course-of-Business Requirement

We are also proposing that a broker-dealer be required to publish or distribute research reports in the regular course of its business in order to rely on the proposed safe harbor.109

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103 See supra notes 11–15 and accompanying text.
104 See supra notes 57–58 and accompanying text; see also paragraph accompanying notes 32–34.
105 See supra notes 11–15 and accompanying text.
106 See supra paragraph accompanying notes 32–34.
107 See rule 139(a)(2)(i) [17 CFR 230.139(a)(2)(i)] (“The issuer is required to file reports pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 or satisfies the conditions in the paragraphs of §240.139(b) of this section.”).
108 See supra paragraph accompanying notes 32–34.
109 Proposed rule 139b(a)(2)(iv) (the broker or dealer publishes or distributes research reports in the regular course of its business and, at the time
proposed regular-course-of-business requirement for industry research reports similarly applies to issuer-specific research reports, and it also tracks an existing requirement for industry research reports under rule 139.111

Like the parallel provision in rule 139, the proposed regular-course-of-business requirement for industry research reports includes a “similar information” requirement. To satisfy this requirement, at the time a broker-dealer publishes or distributes an industry research report, the broker-dealer would have to include similar information, in similar reports, about the issuer covered in the industry report or its securities.112 However, unlike rule 139, we are proposing that the “similar information” requirement apply only to circumstances in which a broker-dealer is publishing or distributing a research report regarding a covered investment fund that does not have a class of securities in substantially continuous distribution. As discussed above, the FAIR Act provides that the safe harbor shall not apply the “initiation or reinitiation” requirement to a research report concerning a covered investment fund with a class of securities “in substantially continuous distribution.” 113 We believe that the proposed “similar information” requirement is akin to the proposed “initiation or reinitiation” requirement, in that both would have the effect of limiting a broker-dealer’s ability to rely on the proposed safe harbor to publish or distribute a research report about a particular covered investment fund if the broker-dealer had not previously published research on that issuer. Therefore, as in the proposed “initiation or reinitiation” requirement, we are proposing to exclude covered investment funds from the “similar information” requirement if they have a class of securities in substantially continuous distribution.114

As discussed above, we believe that the proposed regular-course-of-business requirement could reduce the possibility that broker-dealers’ publication or distribution of covered investment fund research reports may be used to circumvent the prospectus requirements of the Securities Act. We also believe that broker-dealers that publish or distribute research reports in the regular course of business are more likely to publish reports incorporating analysis that investors recognize as research and to have appropriate compliance structures in place governing their publication of research.115 We continue to believe, in the context of proposed rule 139b as well as in rule 139, that a regular-course-of-business requirement is equally appropriate for issuer-specific research reports and industry research reports.

We request comment on the proposed regular-course-of-business requirement.

• Is the proposed regular-course-of-business requirement appropriate? Why or why not?
• In the context of covered investment fund research reports, would the proposed “similar information” requirement unduly restrict broker-dealers’ ability to rely on the proposed safe harbor? Why or why not?
• Would any of the questions, concerns, or issues discussed above with respect to the proposed regular-course-of-business requirement in the context of issuer-specific research reports be equally applicable in the context of industry research reports? Why or why not?

c. Content Requirements for Industry Research Reports

The proposed rule would also condition eligibility for the safe harbor for industry research reports on certain content requirements. Specifically, under the proposed rule, industry research reports either must include similar information about a substantial number of covered investment fund issuers of the same type or investment focus (the “industry representation requirement”), or alternatively contain a comprehensive list of covered investment fund securities currently recommended by the broker or dealer (the “comprehensive list requirement”).117

Industry Representation Requirement

The proposed industry representation requirement imposes a requirement similar to one contained in rule 139 to covered investment fund research reports.118 The Commission has stated that “where a publication covers a broad range of companies in an industry and is issued not on a sporadic but on a regular schedule, the possibility that such a publication could condition the market is lessened.” 119 Furthermore, the possibility of market conditioning is lessened “where research reports discussing the registrant contain similar information, opinions or recommendations with respect to a substantial number of other companies in the registrant’s industry.” 120 We believe that these observations are applicable today in the context of covered investment fund industry research reports, and therefore we propose that rule 139b include an industry representation requirement.

Accordingly, we are proposing to replicate the language from rule 139’s industry representation requirement in rule 139b, with modifications designed to apply the language to the covered investment fund context. Under rule 139’s corresponding requirement, an industry research report must include “similar information with respect to a substantial number of issuers in the issuer’s industry or sub-industry.” 121 When this section of rule 139 first was proposed, the Commission explained that the term “industry” in this context refers to a broad category of similar businesses, such as the airline or steel
industries. In adopting the rule, the Commission added “sub-industry” to the rule text in order to clarify that the safe harbor would apply to research reports covering a smaller number of companies in a particular industry. While operating companies are typically grouped based on their business category, entities that are included in the definition of “covered investment fund” are typically grouped based either on their type or investment focus. Therefore, the proposed industry representation requirement would require an industry research report to include similar information about a substantial number of issuers either of the same type (e.g., ETFs or mutual funds that are large cap funds, bond funds, balanced funds, money market funds, etc.) or investment focus (e.g., primarily invested in the same industry or sub-industry, or the same country or geographic region). We believe that this proposed requirement tracks rule 139 to the extent practicable and appropriate.

Comprehensive List Requirement

Under the proposed rule, a broker-dealer’s publication or distribution of an industry research report that conforms to the comprehensive list requirement, rather than the industry representation requirement, also would be eligible for the rule’s safe harbor. Rule 139 contains a similar provision, and we are proposing to replicate the language from rule 139’s comprehensive list requirement in rule 139b, with some modifications owing to the difference in context and the FAIR Act’s affiliate exclusion.

Like the proposed industry representation requirement, the proposed comprehensive list requirement is designed to result in industry research reports that cover a broad range of investment companies or securities. We are proposing that a comprehensive list of recommended issuers appearing in an industry research report could not include any covered investment fund issuer that is an affiliate of the broker-dealer, or for which the broker-dealer serves as investment adviser (or is an affiliated person of the investment adviser), as this could implicate the proposed industry representation requirement. As discussed in the context of the proposed industry representation requirement, we believe that including a broad range of issuers in a research report lessens concerns over market conditioning. At the same time, the proposed comprehensive list requirement would permit a different presentation of research about multiple covered investment funds than the industry representation requirement would permit. We understand that the two types of presentations could serve different research needs.

We request comment on the proposed content requirements for industry research reports.

- Are the proposed industry representation requirement and the proposed comprehensive list requirement appropriate? Why or why not?
- How would the publication or distribution of industry research reports help investors, and do commenters anticipate that industry research reports would be published or distributed more or less frequently than issuer-specific research reports? Do commenters anticipate that broker-dealers would be more likely to publish or distribute industry research reports that comply with the industry representation requirement, or alternatively the comprehensive list requirement, or both, in relying on the proposed rule 139b safe harbor?
- Are there other conditions that we should consider in addition to the proposed industry representation requirement and the proposed comprehensive list requirement? For example, should we require that there be a minimum number of funds included in an industry research report for it to qualify under the industry representation requirement, particularly in light of the fact that there may be only a few funds that track a particular sub-industry or geographic region or country? If so, what should that minimum number be? Is there another approach to industry research report content requirements that would be more appropriately tailored to covered investment fund research reports?
- The proposed industry representation requirement would be based on the “type” or “investment focus” of the issuers covered in the research report. Are these the appropriate terms to achieve comparisons of similar entities in industry research reports? Why or why not? Are there other more appropriate terms that could be used to specify subsets of covered investment funds that would be included in industry research reports (e.g., category, asset class, strategy, topic, or investment policy)? Should we include more specific definitions for the terms “type” and “investment focus” in rule 139b, and if so, what should these definitions be? Should we instead identify categories that can qualify for the industry report provisions, such as “legal structure” (e.g., ETF, mutual fund, business development company, interval fund), “asset class” (e.g., international equity, domestic fixed income, domestic fixed income), “investment focus” (e.g., sector, industry, sub-industry, geographic region), or “strategy” (e.g., passive, active, market-cap-weighted, smart beta, capital preservation, capital appreciation)?

The proposed comprehensive list requirement would require the research report to contain a list of covered investment funds that are “currently recommended” by the broker-dealer. Is it clear what is meant by the terms “comprehensive list” and “currently recommended” under proposed rule 139b? Would broker-dealers seeking to rely on the proposed safe harbor understand that we interpret these terms in the context of rule 139b to have the same meaning as they do in the context of rule 139? For example, would the term “currently recommended” be interpreted as meaning “available for sale by the broker-dealer,” or a “buy” recommendation by the broker-dealer, or something else? Should we further define either of the terms “comprehensive list” or “currently recommended”? The proposed comprehensive list requirement would require the research report to contain a list of covered investment funds that are “currently recommended” by the broker-dealer. Is it clear what is meant by the terms “comprehensive list” and “currently recommended” under proposed rule 139b? Would broker-dealers seeking to rely on the proposed safe harbor understand that we interpret these terms in the context of rule 139b to have the same meaning as they do in the context of rule 139? For example, would the term “currently recommended” be interpreted as meaning “available for sale by the broker-dealer,” or a “buy” recommendation by the broker-dealer, or something else? Should we further define either of the terms “comprehensive list” or “currently recommended”? The proposed comprehensive list requirement would require the research report to contain a list of covered investment funds that are “currently recommended” by the broker-dealer. Is it clear what is meant by the terms “comprehensive list” and “currently recommended” under proposed rule 139b? Would broker-dealers seeking to rely on the proposed safe harbor understand that we interpret these terms in the context of rule 139b to have the same meaning as they do in the context of rule 139? For example, would the term “currently recommended” be interpreted as meaning “available for sale by the broker-dealer,” or a “buy” recommendation by the broker-dealer, or something else? Should we further define either of the terms “comprehensive list” or “currently recommended”? The proposed comprehensive list requirement would require the research report to contain a list of covered investment funds that are “currently recommended” by the broker-dealer. Is it clear what is meant by the terms “comprehensive list” and “currently recommended” under proposed rule 139b? Would broker-dealers seeking to rely on the proposed safe harbor understand that we interpret these terms in the context of rule 139b to have the same meaning as they do in the context of rule 139? For example, would the term “currently recommended” be interpreted as meaning “available for sale by the broker-dealer,” or a “buy” recommendation by the broker-dealer, or something else? Should we further define either of the terms “comprehensive list” or “currently recommended”?
recommended” as they appear in rule 139b (or, within rule 139b, as these terms apply to certain types of covered investment funds such as registered investment companies), and if so, how?

- Do commenters anticipate that, if a broker-dealer were to rely on the proposed rule 139b safe harbor to publish or distribute research reports that meet the proposed comprehensive list requirement, there would be a sufficient number of “currently recommended” covered investment funds to produce an appropriately broad array of funds included in the report given the affiliate exclusion?

- We are proposing that a comprehensive list could not include any covered investment fund issuer that is an affiliate of the broker-dealer, or for which the broker-dealer serves as investment adviser (or is an affiliated person of the investment adviser), as this could implicate the proposed affiliate exclusion. Should rule 139b instead provide that a comprehensive list of recomme ned issuers could include issuers that are affiliates of the broker-dealer that is publishing or distributing the research report under certain circumstances? If so, what information, if any, should a broker-dealer be permitted to include about affiliated issuers such that the list can be described as “comprehensive” while continuing to address the goals of the affiliate exclusion? For example, should the rule provide that those issuers could be included in a comprehensive list if the research report were to identify which issuers are in the list, if any, were affiliated with the broker-dealer? In addition, or in the alternative, should we permit these issuers to be included in a comprehensive list if disclosure about the affiliated issuers were limited, for example, to basic identifying information such as the name of the covered investment fund, its type and investment focus, and its ticker symbol (if applicable)? As another example, should the rule require that if a comprehensive list includes affiliated issuers and includes performance information as to performance, such information must be presented in accordance with rule 482 in order to address the concern that the broker-dealer may be incentivized to present more favorably the performance of its affiliated covered investment funds?133

d. Presentation Requirement for Industry Research Reports

Proposed rule 139b also would condition the safe harbor for industry research reports on a presentation requirement. Under the proposed rule, analysis of any covered investment fund issuer or its securities included in an industry research report could not be given materially greater space or prominence in the publication than that given to any other covered investment fund issuer or its securities.134

The proposed presentation requirement tracks a parallel “no greater space or prominence” requirement in rule 139.135 The Commission has stated that the “no greater space or prominence” language is necessary to mitigate the risk of conditioning the market136 but also that the materiality standard within this presentation requirement provides flexibility.137 We believe that the concerns underlying the rule 139 presentation requirements apply equally in the context of covered investment fund research reports. We believe that, if the proposed rule were to permit a broker-dealer to rely on the safe harbor even if it were to publish or distribute an industry research report that gives materially greater space or prominence to one issuer than to others, this would create an avenue for circumventing the conditions associated with issuer-specific research reports. The industry should already be familiar with this long-established and well-understood condition, and therefore we believe implementing a similar presentation condition for industry research reports on covered investment funds would be straightforward.

We request comment on the proposed presentation requirement for industry research reports.

- Is the proposed presentation requirement appropriate for covered investment fund industry research reports? Why or why not?

- Is the proposed presentation requirement sufficiently clear? Should we provide guidance as to what compliance with this requirement would entail?

- Would this requirement unduly restrict design flexibility for research reports, or impede broker-dealers’ ability to provide material information in research reports?

- Should we consider additional presentation requirements for covered investment fund research reports? Is there another approach that would be more appropriately tailored?

C. Presentation of Performance Information in Research Reports About Registered Investment Companies

Specific statutory provisions and rules apply to advertising the performance of registered investment companies.138 An advertisement about a covered investment fund that is a registered investment company is deemed a section 10(b) prospectus (also known as an “advertising prospectus” or “omitting prospectus”) for purposes of section 5(b)(1) of the Securities Act so long as it complies with rule 482.139 Therefore, under the current regulatory framework, a broker-dealer’s publication or distribution of a research report that complies with the requirements of rule 482 would not be deemed a non-conforming prospectus in violation of section 5 of the Securities Act.140

Given the breadth of the definition of “research report” under the FAIR Act (and the definition of “research report” that we propose under rule 139b), certain communications by broker-dealers that historically have been treated as advertisements for registered investment companies under rule 482 now could be considered covered investment fund research reports subject to the proposed rule 139b safe harbor.141 Among other things, rule 482 requires standardized presentation of performance data included in registered open-end investment company

133 See supra section 9.
134 Proposed rule 139b(a)(2)(iii).
135 Rule 139(a)(2)(iv) [17 CFR 230.139(a)(2)(iv)].
137 Id.
138 See, e.g., section 24(g) of the Investment Company Act [15 U.S.C. 80a–24(g)] (directing the Commission to adopt rules or regulations that permit registered investment companies to use prospectus data in covered investment fund sales literature); section 5(b)(1) of the Securities Act [15 U.S.C. 77c(b)(1)] (prohibiting misrepresentations or omissions of material fact in sales literature); rule 24b–1 under the Investment Company Act 17 CFR 24b–1 (requiring that, in order not to be misleading, investment company sales literature must include certain information, including with respect to performance information by incorporating certain related provisions of rule 482 of the Securities Act); rule 156 of the Securities Act 17 CFR 156 (providing guidance on what statements or omissions of material fact may be misleading in investment company sales literature); rule 482 of the Securities Act 17 CFR 482 (setting forth that for an investment company advertisement to be deemed a prospectus under section 10(b) of the Securities Act, it must meet certain requirements thereunder, including with respect to standardized performance information presentation).
139 See supra note 101 and accompanying text.
140 See supra notes 13, 101 and accompanying text. FINRA content standards also would generally require a member’s publication or distribution of such a communication (to the extent it presents performance data as permitted by rule 4621) to include certain of the standardized performance information specified under rule 482. See FINRA rule 2210(d)(5)(A).
141 See supra note 102 and accompanying text.
advertisements. Alternatively, if other performance measures are presented, they must be accompanied by certain standardized performance data. Because a broker-dealer’s publication or distribution of a covered investment fund research report under proposed rule 139b would be deemed not to constitute an offer for purposes of sections 2(a)(10) and 5(c) of the Securities Act, a covered investment fund research report would no longer need to be deemed to be a section 10(b) prospectus (such as an advertising prospectus under rule 482) for purposes of section 5(b)(1) of the Securities Act. In addition, some communications that previously were considered supplemental sales literature that must be accompanied or preceded by a statutory prospectus under rule 34b–1 under the Investment Company Act now could be considered covered investment fund research reports (which need not be preceded or accompanied by a statutory prospectus). Rule 34b–1 incorporates many of the rule 482 requirements relating to performance disclosure and makes these requirements applicable to supplemental sales literature. We are concerned that this shift in regulatory treatment of research reports about registered investment companies could result in investor confusion if a communication were not easily recognizable as research as opposed to an advertising prospectus or supplemental sales literature. Although there are multiple provisions in proposed rule 139b that aim to limit the risk that broker-dealers could use the proposed safe harbor to circumvent the prospectus requirements of the Securities Act, there could be circumstances where, under the proposed rule, broker-dealers could publish or distribute communications that historically have been viewed as registered investment company advertisements or selling materials. Research reports published under rule 139 are not required to present performance information in any particular fashion. To the extent the rules we are proposing today diverge from rule 139, these differences are designed to implement the FAIR Act or tailor existing provisions of rule 139 to the context of covered investment fund research reports. Therefore, unlike registered open-end investment company advertisements that must comply with the requirements of Securities Act rule 482, covered investment fund research reports would not be required to present investment performance data in a standardized manner. However, we have long recognized that investors tend to consider investment performance to be a particularly significant factor in evaluating or comparing investment companies. The Commission has previously identified a number of circumstances in which performance could be disclosed in a misleading manner. If a broker-dealer publishes or distributes a covered investment fund research report in reliance on the safe harbor—and presents performance information in a manner inconsistent with rule 482—retail investors could be confused about the comparability of the performance to that presented in the prospectuses, sales literature, and advertisements of the fund and its competitors. In addition, the possibility exists that the requirements of rule 482 or rule 34b–1 could be circumvented by recasting registered investment company advertisements or selling materials as research reports. We request comment below as to whether, in light of these concerns, it would be appropriate to require that covered investment fund research reports that include performance information present the information in accordance with the requirements in rule 482 or rule 34b–1.

In addition, all covered investment fund research reports under the proposed safe harbor would remain subject to the antifraud provisions of the federal securities laws. The Commission has previously articulated guidance on factors to be weighed in considering whether statements involving a material fact in registered investment company advertisements and sales literature, which are also subject to the antifraud provisions of the federal securities laws, could be misleading. This guidance provided factors to be weighed when determining whether fund performance in sales literature is adequately disclosed. The guidance factors in rule 156 are subject to the requirements of Regulation AC. Similarly, covered investment fund research reports that meet the definition of “research report” in FINRA rule 2241 or the definition of “debt research report” in FINRA rule 2242 would be subject to the content requirements in those rules as applicable. See supra note 58; infra section II.D.1.

As the Commission has previously noted “[a]lthough there are many factors other than performance that an investor should consider in deciding whether to invest in a particular fund, many investors consider performance to be one of the most significant factors when evaluating mutual funds.” Amendments to Investment Company Advertising Rules, Securities Act Release No. 8101 (May 17, 2002) [67 FR 36712 (May 24, 2002)] (“Amendments to Investment Company Advertising Rules, Securities Act Release No. 8101”). See supra note 58; infra section II.D.1.

See supra notes 142–143 and accompanying text.

As proposed, rule 34b–1 provides that any advertisement, pamphlet, circular, form letter, or other sales literature addressed to or intended for distribution to prospective investors that is required to be filed with the Commission by section 24(b) of the Investment Company Act will have omitted to state a fact necessary in order to make the statements made therein not materially misleading unless it includes certain specified information.

See supra note 58; infra section II.D.1 (affiliate exclusion) and II.B.1.c (regular course of business requirement). Certain covered investment fund research reports that meet the definition of “research report” in Regulation AC would be

142 See rule 482(d)(1)–(4) (for open-end investment companies other than money market funds) and rule 482(e) (for money market funds).

143 See rule 482(d)(5). These other performance measures are not subject to any prescribed method of computation, but must reflect all elements of return and be accompanied by quotations of standardized measures of total return as provided for in paragraphs (d)(3) and (d)(4) of the rule. Rule 482(d)(5) also includes other requirements for the inclusion of non-standardized performance data, such as presentation and prominence requirements.

144 See supra notes 142–143 and accompanying text.

145 Amended at various times by SEC Release Nos. 34b–1(b)(1)–(2).

146 See, e.g., supra notes I.A.1 (affiliate exclusion) and II.B.1.c (regular course of business requirement). Certain covered investment fund research reports that meet the definition of “research report” in Regulation AC would be


148 The guidance factors in rule 156 are subject to the requirements of Regulation AC. Similarly, covered investment fund research reports that meet the definition of “research report” in FINRA rule 2241 or the definition of “debt research report” in FINRA rule 2242 would be subject to the content requirements in those rules as applicable. See supra note 58; infra section II.D.1.

149 See supra notes 142–143 and accompanying text.

150 Additional conditions that might lessen potential investor confusion are if a research report that presents performance information other than in accordance with the provisions of rule 482 were to: 1) adequately explain how the performance presentation differs from that which would be required under rule 482, and/or 2) include a statement noting that the document is a research report, and is not an investment company advertisement that is subject to the requirements of rule 482. We request comment on these and other conditions below.

151 See section 21c(1) of the FAIR Act (stating that nothing in the Act shall be construed as in any way limiting the applicability of the antifraud or antimisrepresentation provisions of the Federal securities laws and rules adopted thereunder to a covered investment fund research report, including section 17 of the Securities Act of 1933 (15 U.S.C. 77q), section 34(b) of the Investment Company Act of 1940 (15 U.S.C. 80a–33(b)), and sections 9 and 10 of the Securities Exchange Act of 1934 (15 U.S.C. 78i, 78j)).


153 See Amendments to Investment Company Advertising Rules, supra note 152.

154 Rule 156(b) under the Securities Act provides guidance factors concerning misleading statements in investment company sales literature including: (i) Statements and omissions generally (including in light of general economic or financial conditions or circumstances), (ii) representations about past or future investment performance, and (iii) statements involving a material fact about an investment company’s characteristics or attributes.
informative in evaluating whether any presentations of registered investment company performance in these research reports could be misleading because they reflect principles (such as providing information to investors that is informative and that does not create unrealistic investor expectations) that would help guide this analysis.

Rule 139 provides an instruction on the use of projections of an issuer’s sales and earnings. This instruction provides that a projection “constitutes the use of projections of an issuer’s sales or earnings in reliance on rule 482.” We request comment on whether we should adopt any additional conditions in rule 139b or issue guidance to help mitigate the potential for investor confusion regarding research reports about registered investment companies.

- Do commenters anticipate that certain issuer-specific covered investment fund research reports could be confused with registered investment company advertisements and sales materials? If so, what additional conditions could prevent investor confusion, including, for example, legends?

- If commenters anticipate that certain covered investment fund research reports could be confused with registered investment company advertisements and sales materials, what additional conditions or guidance factors would help mitigate investor confusion? For example, should we incorporate any of the rule 156 guidance factors, which are weighed in considering whether statements in investment company sales literature could be misleading? Why or why not?

Alternatively, should we provide any additional guidance regarding considerations to be weighed in considering whether statements in registered investment companies (including any performance information presented in these research reports) could be misleading? Should any additional guidance be limited either to issuer-specific research reports or to industry research reports?

- Do commenters anticipate that broker-dealers would include performance information in covered investment fund research reports about registered open-end investment companies in a manner inconsistent with the requirements for the presentation of total return or yield in rule 482 (“non-482 performance information”)? We request that commenters provide specific examples of non-482 performance information that they would consider using in a research report about an open-end investment company, and why they would use this information.

- What, if any, risks could result from including non-482 performance information in covered investment fund research reports about registered open-end investment companies? For example, would the variability of non-482 performance information result in investor confusion? Would the inclusion of non-482 performance information result in any of the concerns that the provisions of rule 482 are meant to address, such as disclosing performance without providing adequate disclosure of unusual circumstances that have contributed to performance; without providing adequate disclosure of the performance period (including information about current performance); or without disclosing important context that would permit an investor to evaluate performance (such as the fact that the performance is based on selective dates or time periods)? Would the ability of a covered investment fund to include non-482 performance information incentivize broker-dealers to recast registered investment company advertisements or selling materials as research reports that they could publish or distribute under proposed rule 139b, instead of meeting the requirements of rule 482? To what extent would any such risks be mitigated by regulations that are currently in effect, for example, the rule 156 guidance factors discussed above, or other factors (such as the applicable content standards in SRO rules, such as FINRA rule 2210)? If we were to permit non-482 performance information to appear in covered investment fund research reports about registered open-end investment companies, as proposed, what benefits could result? Would any benefits of the ability to include the non-482 performance information be diminished if the broker-dealer were also required to include the standardized information required by rule 482?

- If commenters anticipate that the potential risks of including non-482 performance information in covered investment fund research reports would outweigh the benefits, what action should we take to mitigate these risks? Would these risks be mitigated if we were to incorporate any of the requirements of rule 482 directly into rule 139b? Why or why not? If so,
which requirements? For example, should we incorporate a provision in rule 139b stating that, where a registered open-end investment company’s total return or yield is presented in a covered investment fund research report, the presentation must be consistent with the requirements for the presentation of total return or yield in rule 482? Should we include in rule 139b only certain of the requirements in rule 482, as those listed in paragraphs (d)(5) and (e) of rule 482 for the presentation of other, non-482 conforming performance information measures? 

- Should we incorporate a requirement in rule 139b relating to the timeliness of performance data about registered investment companies, similar to timeliness of performance requirements for advertising prospectuses under rule 482 or supplemental sales literature under rule 34b–1? If so, why? Would unaffiliated broker-dealers have any difficulty obtaining this information in order to comply with such a requirement? Would the inclusion of performance data in covered investment fund research reports entail the same concerns about timeliness that rules 482 and rule 34b–1 are designed to address? Why or why not?

- Alternatively, should we incorporate a provision in rule 139b requiring that a research report must include certain disclosures or disclaimers when performance information about registered open-end investment companies is presented as non-482 performance information? For example, should we require that a research report about a registered investment company must incorporate disclosure stating that the document is a research report and is not subject to the Commission’s regulations applicable to sales and advertising? If a covered investment fund research report about a registered open-end investment company includes non-482 performance information, should we require that the research report must disclose the website address for that registered open-end investment company (including a hyperlink for research reports in electronic format), to facilitate investor access to total return or yield disclosure that is presented in a manner consistent with the requirements in rule 482?

Should we require that the methodology used to calculate the registered open-end investment company’s total return or yield be disclosed, if the research report includes non-482 performance information?

- Should we include an instruction in rule 139b on the use of projections that is similar to the instruction on the use of projections in rule 139? Why or why not? If we were to include such an instruction, would the instruction in rule 139 be appropriate to include in rule 139b, or should it be modified in any way? As discussed above, we recognize that the guidance factors set forth under rule 156 of the Securities Act address future investment performance, and similarly, certain SRO rules that would apply to covered investment fund research reports prohibit the prediction or projection of performance.166

D. Role of Self-Regulatory Organizations

1. SRO Content Standards and Filing Requirements for Covered Investment Fund Research Reports

SRO Content Standards

The FAIR Act contemplates that SRO content standards applicable to research reports would apply to covered investment fund research reports.167 Specifically, the FAIR Act provides that, unless covered investment fund research reports are subject to the content standards in the rules of any SRO related to research reports, these research reports may still be subject to the filing requirements of section 24(b) of the Investment Company Act for the review of investment company sales literature.168 As discussed in more detail below, we are proposing rule 24b–4 to implement this provision of the FAIR Act. Proposed rule 24b–4 provides that a covered investment fund research report about a registered investment company will not be subject to section 24(b) of the Investment Company Act (or the rules and regulations thereunder), except to the extent the research report is otherwise not subject to the content standards in SRO rules related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.169

Currently, the SRO content standards relevant to communications that would be considered covered investment fund research reports under proposed rule 139b include the applicable content standards of FINRA rules 2210, 2241(c)(1), and 2242(c)(1).170 FINRA’s rule governing communications with the public (FINRA rule 2210) contains general content standards that apply broadly to member communications, including broker-dealer research reports. These general content standards require, among other things, that all member communications “must be based on principles of fair dealing and good faith, must be fair and balanced, and must provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry or service.”

The FAIR Act does not explicitly refer to specific content standards in SRO rules. It refers more generally to “the content standards in the rules of any self-regulatory organization related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.” In order to provide clarity and facilitate consistent and predictable application of proposed rule 24b–4, we interpret section 2(b)(4) of the FAIR Act as

166 See supra paragraph accompanying notes 156–158.

167 See section 2(b)(4) of the FAIR Act (A covered investment fund research report shall not be subject to section 24(b) of the Investment Company Act of 1940 (15 U.S.C. 80a–24(b)) or the rules and regulations thereunder, except that such report may still be subject to such section and the rules and regulations thereunder, except that such report may still be subject to such section and the rules and regulations thereunder to the extent that it is otherwise not subject to the content standards in the rules of any self-regulatory organization related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.).

168 As discussed in more detail below, we are proposing rule 24b–4 to implement this provision of the FAIR Act. Proposed rule 24b–4 provides that a covered investment fund research report about a registered investment company will not be subject to section 24(b) of the Investment Company Act (or the rules and regulations thereunder), except to the extent the research report is otherwise not subject to the content standards in SRO rules related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.

169 See infra note 174 (discussing the scope of these rules in more detail, including noting that the scope of certain provisions of FINRA rule 2210, and the scope of FINRA rules 2241(c)(1) and 2242(c)(2) generally, apply only to a certain subset of communications that would be considered covered investment fund research reports under proposed rule 139b).

170 See FINRA rule 2210(d)(1).

171 See FINRA rule 2210(d)(1)(A). FINRA rule 2210’s general content standards also provide, among other things, that FINRA members may not “make any false, exaggerated, unwarranted, promissory or misleading statement or claim in any communication” nor “publish, circulate or distribute any communication that the member knows or has reason to know contains any untrue statement of a material fact or is otherwise false or misleading.” See FINRA rule 2210(d)(1)(B).

172 Section 2(b)(4) of the FAIR Act.
excluding covered investment fund research reports from section 24(b) of the Investment Company Act so long as they continue to be subject to the general content standards in FINRA rule 2210(d)(1) (or substantially similar SRO rules). Accordingly, by operation of proposed rule 24b–4, covered investment fund research reports under proposed rule 139b that otherwise would be subject to section 24(b) of the Investment Company Act would not be subject to that section so long as they remain subject to the general content standards of FINRA rule 2210(d)(1).\textsuperscript{174} This interpretation is consistent with our belief that it is important for SRO content standards to continue to apply to covered investment fund research reports, especially if, as discussed below, research reports about registered investment companies would no longer be required to be filed pursuant to section 24(b) of the Act or rule 497 under the Securities Act,\textsuperscript{175} and therefore would no longer be subject to routine review.\textsuperscript{176}

Filing Requirements for Covered Investment Fund Research Reports

The FAIR Act, as implemented by proposed rule 24b–4, would modify the filing requirements that currently apply to certain broker-dealer communications regarding registered investment companies. As discussed above, research reports about registered investment companies have historically not been included within the scope of rule 139.\textsuperscript{177} Therefore, a research report or other communication about a covered investment fund that is a registered investment company, particularly one that contains performance information, would ordinarily have to comply with rule 482.\textsuperscript{178} Today, registered investment company sales literature, including rule 482 omitting prospectus advertisements, are required to be filed with the Commission under section 24(b) of the Investment Company Act\textsuperscript{179} and rule 497 under the Securities Act.\textsuperscript{180} Rule 24b–3 under the Investment Company Act and rule 497(i) deem these materials to have been filed with the Commission if filed with FINRA.\textsuperscript{181}

As discussed in the Economic Analysis below, we anticipate that certain communications that historically have been treated as investment company sales literature, including rule 482 “omitting prospectus” advertisements, would be published or distributed by a broker-dealer as covered investment fund research reports pursuant to the rule 139b safe harbor.\textsuperscript{182} Such communications that previously had been subject to the filing requirements of section 24(b) no longer would be subject to these requirements by operation of proposed rule 24b–4 because they would be subject to the general content standards of FINRA rule 2210(d)(1).\textsuperscript{183}

FINRA rule 2210 requires the filing of certain communications, including retail communications that promote or recommend a specific registered investment company or family of registered investment companies.\textsuperscript{184} However, FINRA provides a number of exclusions from the filing requirements.\textsuperscript{185} For example, with respect to research reports (as that term is defined in FINRA rule 2241),\textsuperscript{186} FINRA currently excludes from filing those that concern only securities that are listed on a national securities exchange, other than research reports required to be filed with the Commission pursuant to section 24(b) of the Investment Company Act.\textsuperscript{187}

Because covered investment fund research reports would no longer be required to be filed with the Commission pursuant to section 24(b),\textsuperscript{188} these reports may be distributed without regard to certain SRO filing requirements. The following discussion is intended to provide context for the discussion of the filing requirements in the context of the proposed rule 24b–4, including the SEC’s ongoing analysis of potential FINRA requirements.

\textsuperscript{174} A subset of communications that would fall within the definition of “covered investment fund research report” under proposed rule 139b also would be subject to additional content-related requirements under FINRA rules that are applicable to certain research reports, but that are more narrowly scoped and concern the general content standards of FINRA rule 2210(d)(1). However, under our interpretation, whether or not these additional content standards apply to any given covered investment fund research report would not determine the applicability of section 24(b) to that research report under proposed rule 24b–4. A different interpretation could lead to results that we believe would conflict with section 21b(b) of the FAIR Act (i.e., if only communications that are subject to additional FINRA content standards discussed in this section (e.g., those applicable to retail communications) were excluded from section 24(b) filing requirements).

\textsuperscript{175} See infra discussion at notes 177–181 and accompanying text.

\textsuperscript{176} Broker-dealer communications that are excluded from, or otherwise not subject to FINRA’s filing requirements may still be reviewed by FINRA, for example, through examinations, targeted sweeps or spot-checks. FAIR Act section 2(c)(2) provides that nothing in the Act shall be construed as in any way limiting “the authority of any self-regulatory organization to examine or supervise a member’s practices in connection with such member’s publication or distribution of a covered investment fund research report for compliance with applicable provisions of the Federal securities laws or self-regulatory organization rules related to research reports, including those contained in rules governing communications with the public.” See also, e.g., FINRA rule 2210(c)(6) (“In addition to the foregoing requirements, each member’s written [including electronic] communications may be subject to a spot-check procedure. Upon written request from [FINRA, retail regulation], each member must submit the material requested in a spot-check procedure within the time frame specified by the Department.”).

\textsuperscript{177} See supra notes 11–15 and accompanying text.

\textsuperscript{178} See supra discussion at notes 177–181 and accompanying text.

\textsuperscript{179} See supra notes 11–15 and accompanying text.

\textsuperscript{180} A communication that previously had been subject to the filing requirements of rule 497 also would no longer be subject to the rule 497 filing requirements if it were published or distributed by a broker-dealer as a covered investment fund research report, because it would no longer be considered to be a section 10(b) prospectus. See supra paragraph accompanying notes 141–146.

\textsuperscript{181} See FINRA rule 2210(c)(3) (broker-dealers must file, within 10 business days of first use or publication of a covered investment fund research report, a notice to the Department that they will or have ceased to distribute such a report, and if they distribute such a report, a statement to the Department that they have registered or recommend a specific registered investment company or family of registered investment companies). See generally, FINRA rule 2210(c)(1)–(3). In addition to these FINRA filing requirements, as discussed above, such communications would be required to be filed with the Commission (and are deemed to have been filed with the Commission if filed with FINRA). See supra notes 179–181 and accompanying text.


proposed rule 24b–4 could have the effect of narrowing the types of communications that would be filed with FINRA (under current FINRA rule 2210) regarding registered investment companies.

We note, however, that the FAIR Act’s rules of construction provide that the Act shall not be construed as limiting the authority of an SRO to require the filing of communications with the public if the purpose of such communications “is not to provide research and analysis of covered investment funds.” Therefore, even if the exclusion of covered investment fund research reports from the provisions of section 24(b) affects the applicability of the filing requirements or exclusions under FINRA rule 2210 with respect to covered investment fund research reports, it would not affect FINRA’s authority to require the filing of a communication that is included in the FAIR Act’s definition of “covered investment fund research report” but whose purpose is not to provide research and analysis. In addition, a covered investment fund research report would continue to be subject to FINRA recordkeeping requirements applicable to communications with the public, even if the broker-dealer would not be required to file the research report with FINRA or the Commission.188

We request comment on issues relating to SRO content standards for covered investment fund research reports.

• Should we implement FAIR Act section 2(b)(4) through proposed rule 24b–4? Are there any modifications to the proposed rule that we should consider?

• Do commenters believe that we should incorporate any of the SRO content standards currently applicable to research reports into rule 139b? If so, which ones and why?

2. SRO Limitations

The FAIR Act directs us to provide that SROs may not maintain or enforce any rule that would (i) prohibit the ability of a member to publish or distribute a covered investment fund research report solely because the member has published or distributed a covered investment fund research report about such covered investment fund or its securities.190 These limitations on an SRO and any rules relating to research reports that an SRO might adopt would not affect the safe harbor provided by proposed rule 139b. To provide additional context for the proposed safe harbor, however, and in light of Congress’s direction that we provide these limitations in implementing the rulemaking required by the FAIR Act, we have set forth these SRO limitations in proposed rule 139b.191

E. Conforming Amendment

Rule 101 of Regulation M under the Exchange Act192 prohibits any person who participates in a distribution from attempting to induce others to purchase securities covered by the rule during a specified period. It provides an exception for certain research activities—namely, the publication or dissemination of any information, opinion, or recommendation—if the conditions of Securities Act rule 138 or rule 139 are satisfied. In light of our proposal of Securities Act rule 139b, we are proposing a corresponding change to the exception contained within rule 101(b)(1) of Regulation M to permit the publication or dissemination of any information, opinion, or recommendation so long as the conditions of proposed rule 139b are satisfied. The proposed conforming amendment is intended to align the treatment of research under proposed rule 139b with the treatment of research under rules 138 and 139 for purposes of Regulation M.

In the absence of the conforming amendment, rule 101 could prevent the publication or dissemination of a covered investment fund research report under the proposed rule 139b safe harbor by a broker-dealer that is participating in a distribution that is covered by Regulation M. We believe that such a result would be contrary to the mandate of the FAIR Act. As such, the proposed conforming amendment is intended to harmonize treatment of research under the Securities Act and Exchange Act rules.

We request comment on the proposed conforming amendment to Regulation M.

• Is the proposed conforming amendment appropriate?

• Are there other conforming amendments to Regulation M or any of our other rules appropriate for consideration based on the FAIR Act? If so, what rules should be amended and why?

III. Economic Analysis

A. Introduction

We are mindful of the costs and benefits of our rules. Section 2(b) of the Securities Act, section 3(f) of the Exchange Act, and section 2(c) of the Investment Company Act state that when the Commission is engaged in rulemaking under such titles and is required to consider whether an action is necessary or appropriate in (or, with respect to the Investment Company Act, consistent with) the public interest, the Commission shall consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.193 Additionally, Exchange Act section 23(a)(2) requires us, when making rules or regulations under the Exchange Act, to consider, among other matters, the impact that any such rule or regulation would have on competition and states that the Commission shall not adopt any such rule or regulation which would impose a burden on competition that is not necessary or appropriate in furtherance of the Exchange Act.194

The economic analysis proceeds as follows. We begin with a discussion of the baseline used in the analysis. We then discuss the proposed rules’ costs and benefits, as well as their effects on efficiency, competition, and capital formation compared to the baseline. Where possible, we attempt to quantify the economic effects we discuss. However, we cannot produce reasonable estimates for most of the effects. In such cases we instead provide qualitative economic assessments.

B. Baseline

The Commission’s economic analysis evaluates the costs and benefits of the proposed rule relative to a baseline that represents the best assessment of relevant markets and market participants in the absence of the proposed rule. In this section, we begin by characterizing the relevant market structure and participants.195 We then

188 See section 2(c)(2) of the FAIR Act.
189 See FINRA rule 2210(b)(4)(A) (requiring members to maintain all retail communications and institutional communications for the retention period required by Exchange Act rule 17a–4(b) and in a format and media that comply with Exchange Act rule 17a–4).
189 See proposed rule 139b(b).
190 Section 2(b)(3) of the FAIR Act.
191 See proposed rule 139b(b).
195 To characterize the baseline, we rely on data from year-end 2017 where possible; however, in some cases, timing issues related to data availability require us to rely on data from prior periods.
proceed to describe the relevant regulatory structure.

1. Market Structure and Market Participants

The proposed rules would directly affect broker-dealers, but their indirect effects would extend to covered investment funds, other producers of research on covered investment funds, and consumers of information about covered investment funds. The proposed rules, through their effects on capital formation, may also affect securities issuers more broadly. See infra section III.C.5.

The “covered investment fund” definition in the FAIR Act and proposed rule 139b has the effect of capturing five common types of investment vehicles: Mutual funds, ETFs, certain currency and commodity exchanged traded products (“ETPs”), closed-end funds, and BDCs. As shown in Figure 1, the universe of covered investment funds is large. At the end of 2017, there were 11,924 such entities, including 9,564 mutual funds, 1,629 ETFs and ETPs, 596 closed-end funds, and 135 BDCs. The total public market value of covered investment funds exceeds $20 trillion. Of this total, $17 trillion is held through shares issued by open-end mutual funds, $3 trillion through shares of ETFs and ETPs, $317 billion through shares of closed-end funds, and $27 billion through shares of BDCs.

Figure 1: Numbers of publicly-traded covered investment funds, by type and year. Counts based on CRSP mutual fund database, CRSP monthly stock file, and Commission’s listing of BDC registrants; see supra note 199. BDC data begins in 2013.

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196 See supra section II.A.3.


198 See supra note 199. Market value of BDC shares based on information obtained from Compustat and Audit Analytics.
Covered investment fund shares represent a significant fraction of investment assets held by U.S. residents. Approximately one-third of U.S. corporate equity issues, one-quarter of U.S. municipal securities, one-fifth of corporate debt, one-fifth of U.S. commercial paper, and one-tenth of U.S. treasury and agency securities are held through covered investment funds.\footnote{See Investment Company Institute, 2017 Investment Company Fact Book (2017), available at http://www.icifactbook.org/ (“ICI Fact Book”).} Mutual funds comprise the bulk (84\%) of covered investment funds.\footnote{See supra note 200.} Nearly half of U.S. households hold mutual fund shares\footnote{See Investment Company Institute, Ownership of Mutual Funds, Shareholder Sentiment, and Use of the internet (2017), available at https://www.icfi.org/pdf/per23-07.pdf.} and the vast majority (89\%) of mutual fund shares are held through retail accounts (\textit{i.e.} accounts of retail investors, or households).\footnote{Percentage by value. See ICI Fact Book, supra note 201, at 30. Excluding money market funds ("MMF"), mutual fund shares held in retail accounts make up an even larger fraction (95\%) of mutual fund shares.} Consequently, at least 75\% of the public market value of all covered investment funds are held through retail accounts.

By analyzing institutional holdings from year-end 2016 Form 13F filings we estimate that across ETF and ETPs, the mean institutional holding\footnote{We calculated “institutional holding” as the sum of shares held by institutions (as reported on Form 13F filings) divided by shares outstanding (as reported in CRSP).} was 50\%.\footnote{Year-end 2016 Form 13F filings were used to estimate institutional ownership. Closed-end funds were matched to reported holdings based on CUSIP. We note that there are long-standing questions around the reliability of data obtained from 13F filings. See Anne M. Anderson, & Paul Brockman, Form 13F (Mis)Filings, SSRN Scholarly Paper.} For BDCs, we estimate the mean institutional holding was 33\%, while for closed-end funds, we estimate the mean institutional holding was 23\%. Based on these figures, we further estimate that shares representing 87\% of the public market value of all covered investment funds are held through retail accounts.\footnote{Staff calculated the percentage of net asset value held by institutions reported on Form 13F for ETFs, ETPs and BDCs as public market value of shares held by institutions divided by public market value of all shares. Mutual funds shares are generally not required to be reported on Form 13F. We estimate institutional ownership of non-MMF mutual funds using ICI Fact Book estimate (95\%). See supra note 204 and accompanying text.}

As depicted in Figure 3, the covered investment fund market is dynamic. In Form 13F (Mis)Filings, SSRN Scholarly Paper, Rochester, NY: Social Science Research Network (Oct. 15, 2016), available at https://papers.ssrn.com/abstract=2809128. See also Securities and Exchange Commission, Office of Inspector General, Office of Audits, Review of the SEC’s Section 13(f) Reporting Requirements (2010).
2017, 638 covered investment funds were created, while 853 were closed or merged into other covered investment funds.\(^{208}\)

**Covered Investment Funds: Entries and Exits**

Numbers of covered investment funds coming into existence (+) and exiting the market (-) each year.

![Graph showing entries and exits of covered investment funds](image)

**Figure 3: Entries and exits of covered investment funds.** Counts based on CRSP mutual fund database, CRSP monthly stock file, and Commission’s listing of BDC registrants; see supra note 199. BDC data begins in 2013.

We are requesting comments on our characterization of the covered investment fund market and data to help us further describe this market and current market practices.

- Do commenters agree with our characterization of the covered investment fund market? Do commenters agree with our characterization of ownership patterns? Are there ways to improve our estimates?
- Do commenters believe that our estimates of institutional ownership of covered investment funds are accurate? If not, are there ways to improve our estimates? Do commenters believe that our estimates of institutional ownership of different types of covered investment fund shares (e.g., mutual funds, ETFs, ETPs, BDCs) include shares held in street name where the beneficial owners are retail investors?
- Do commenters believe that our estimates of institutional holdings of covered investment funds represent securities held for investment or securities held for other purposes (e.g., market-making inventory, proprietary trading)?

**b. Broker- Dealers**

The broker-dealers directly affected by the proposed rules are those who participate in registered offerings of covered investment funds while at the same time publishing or distributing information about those funds. The Commission does not have comprehensive data on the number or characteristics of broker-dealers currently publishing and distributing communications about covered investment funds, the extent of their communications, and their distribution arrangements with covered investment funds. Therefore we rely on inferences based on the data that are available\(^{209}\) and make certain assumptions when characterizing the baseline.

We believe that broker-dealers that do not derive revenues from the distribution of covered investment funds are less likely to be directly

\(^{208}\) See supra note 199.

\(^{209}\) We rely here primarily on broker-dealers' quarterly FOCUS reports.
affected by the proposed rules.\textsuperscript{210} As discussed above, registered investment companies represent the vast majority of covered investment funds.\textsuperscript{211} Broker-dealers report revenues from the distribution of investment company shares in regulatory filings,\textsuperscript{212} and we use this to estimate broker-dealers’ revenues from distribution of covered investment funds. We estimate that for the 3,882 broker-dealers active in 2017, revenues related to distribution of covered investment funds exceeded $28 billion, or 9% of total broker-dealers’ revenues. Of these 3,882 broker-dealers, 1,417 reported revenues from the distribution of investment company shares. These 1,417 “affected” broker-dealers accounted for 74% of total broker-dealer revenues and 59% of total broker-dealer assets.\textsuperscript{213} As shown in Figure 4, among the affected broker-dealers, the importance of revenues from the distribution of covered investment funds varies widely.\textsuperscript{214} However, in aggregate, these revenues accounted for 13% of affected broker-dealers’ total revenues.\textsuperscript{215} For comparison, among the affected broker-dealers, revenues from brokerage trading commissions and account management accounted for 9%, and 20% of total revenues, respectively, while revenues from proprietary trading and underwriting accounted for 4% and 8% of total revenues, respectively.

We are seeking comment on our assumptions used in characterizing this market.

- Do commenters agree with our estimates of the immediately-affected broker-dealers based on revenue from sales of investment company shares? If not, what other proxy would be more appropriate?

c. Research on Covered Investment Funds

The Commission does not have comprehensive data on broker-dealers that publish or distribute research reports on entities that would be included within the definition of “covered investment fund” under proposed rule 139b.\textsuperscript{216} The Commission estimates that in 2017, there were 1,417 broker-dealers that reported revenues from the distribution of covered investment funds.\textsuperscript{217} We assume that these broker-dealers would have incentives to publish or distribute research reports about covered investment funds. However, due to the large number of covered investment funds, we do not expect that many broker-dealers’ in-house research departments (if they have such broker-dealers that reported revenues from the distribution of covered investment funds are currently more active in the marketing of covered investment funds would be more affected.\textsuperscript{214} This suggests that the degree to which the “affected” broker-dealers are affected by the proposed rule will also vary widely.

\textsuperscript{215} Estimation is based on staff analysis of FOCUS filings.

\textsuperscript{216} See supra section III.B.1.b.

\textsuperscript{217} See id.
entities that would be considered "covered investment funds," but that do not need to comply with the requirements of rule 482 (e.g., commodity- or currency-based trusts or funds). Third, for those communications that are currently filed as rule 482 advertising prospectuses or rule 34b–1 supplemental sales literature, we are uncertain what percentage of these communications brokers dealers would continue to structure as rule 482 advertising prospectuses or rule 34b–1 supplemental sales literature, as opposed to publishing or distributing them as covered investment fund research reports under the proposed rule 139b safe harbor.

We have also analyzed the number of "research reports" as defined under FINRA rules 2241 and 2242 that FINRA staff reviewed in 2017. However, for reasons discussed below, we also believe that these data have limited value in assessing the number of covered investment fund research reports whose publication or distribution could be eligible for the safe harbor under proposed rule 139b. FINRA reviewed 354 filings in 2017 that were identified as "research reports" as defined in FINRA rules 2241 and 2242. However, the definitions of "research report" and "debt research report" under FINRA rules 2241 and 2242, respectively, do not correspond in every respect to the term "research report" as defined in the FAIR Act and proposed rule 139b.

Under FINRA rule 2241, the term "research report" includes any written communication that includes an analysis of equity securities (other than mutual fund securities) and that provides information reasonably sufficient upon which to base an investment decision.224 Under FINRA rule 2242, the term "debt research report" includes any written communication that includes an analysis of a debt security and that provides information reasonably sufficient upon which to base an investment decision.225 Also, unlike the definition of "research report" in FINRA rule 2241, the FAIR Act and proposed rule 139b definitions of "research report" would include communications about mutual funds. Thus, while the number of "research reports" as defined in FINRA rules 2241 and 2242 that FINRA staff has historically reviewed provides an estimate of a subset of communications currently being styled as research reports whose publication or distribution could be eligible for the proposed rule 139b safe harbor, this number would represent only a small portion of the complete universe of research reports whose publication or distribution could be eligible for this safe harbor. We also understand that the reported number of "research reports" as defined in FINRA rules 2241 and 2242 that FINRA staff has historically reviewed also could relate to research reports for securities products other than entities that would be considered "covered investment funds" (e.g., certain stocks, bonds, or master limited partnership interests).

In addition to broker-dealers, various firms that are independent of the offering process currently provide data and analysis on different subsets of the covered investment fund universe (e.g., through subscription services or through licensing agreements with broker-dealers). Because data and analysis provided by these firms play an important role in investors’ information environment under the baseline, these firms would be affected by changes to the competitive environment resulting from the proposed rules.226 We understand that communications styled as research reports on covered investment funds distributed by broker-dealers may rely on information obtained from these independent sources. In particular, we understand that information that is commonly provided by these independent firms may include: (1) Information obtained from regulatory filings, such as narrative descriptions of fund objectives, information about key personnel, performance history, fees, and top holdings; (2) statistics and other information derived from public, proprietary, and licensed data sources, such as risk exposures (e.g., geographic, sectoral), quantitative characteristics (e.g., beta, correlations, tracking error), and peer group; and (3) fund ratings. The fund ratings that independent firms may provide are generally based on methodologies proprietary to each firm.227

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218 See supra note 174 and accompanying text.
219 See supra note 101.
220 Based on staff analysis of FOCUS filings, we estimate that as of year-end 2016, there were 3,882 registered broker-dealers, 3,755 of which were members of FINRA.
221 See supra note 181 and accompanying text.
222 Under rule 34b–1, “sales literature” required to be filed by section 24(b) shall have omitted to state a fact necessary in order to make the statement material by not materially misleading unless the sales literature includes certain specified information. See rule 34b–1 (17 CFR 270.34b–1); see also supra notes 144–145 and accompanying text.
223 Of the 47,707 filings subject to rule 482, 229 were also subject to rule 34b–1. These 229 are not included in the 8,528 figure. Statistics provided by FINRA.
224 See FINRA rule 2241(a)(11).
225 See FINRA rule 2242(a)(3).
226 See supra note 44 and accompanying text.
We are seeking comment on our characterization of the market for research reports on covered investment funds.

- What other data are available on broker-dealers’ current publication or distribution of research reports on entities that would be included within the definition of “covered investment fund” under proposed rule 139b? On the scope of their coverage? On their consumers?
- Do commenters agree with our characterization of the data and analysis on covered investment funds that is provided by independent (non-broker-dealer) research firms? Are there significant gaps or limitations to the information and analysis on covered investment funds provided by such firms?

2. Regulatory Structure

a. Current Legal and Regulatory Framework Applicable to Statements Included in Covered Investment Fund Research Reports

As discussed above, the rule 139 safe harbor is currently not available for broker-dealers that publish or distribute research reports about most covered investment funds. A broker-dealer’s publication or distribution of a covered investment fund research report could therefore be deemed to constitute an offer that otherwise could be a non-conforming prospectus whose use in the offering may violate section 5 of the Securities Act.230 We understand that some broker-dealers currently publish and distribute communications styled as “research reports” regarding covered investment funds in compliance with rule 482 under the Securities Act.231 Unlike research reports covered under the rule 139 safe harbor, broker-dealers’ publication or distribution of rule 482 advertisements could subject the broker-dealer to liability under section 12(a)(2) of the Securities Act.232 In addition, rule 482 advertisements are subject to requirements on the standardized presentation of performance information.233 Additionally, certain SRO rules governing content standards may apply to communications that would be considered covered investment fund research reports under proposed rule 139b or advertisements styled as “research reports” under rule 482. These include FINRA rule 2210 which contains general content standards that apply broadly to member communications.234 In addition, covered investment fund research reports pertaining to funds other than open-end registered investment companies that are not listed or traded on an exchange (i.e., ETFs, ETPs, closed-end funds, and BDCs) may be subject to FINRA rules 2241 and 2242 governing content standards of “research reports”, as defined by FINRA.235 Exposure to liability under section 12(a)(2) of the Securities Act, rule 482 requirements on the standardized presentation of performance information, and the various aforementioned FINRA rules impose costs on broker-dealers. These include conduct costs resulting from additional liability (e.g. foregoing publication of certain reports), and compliance costs associated with the relevant content standards. We are not able to quantify these costs and are seeking comments on our characterization of these costs:

- What do commenters view as the most significant costs associated with distributing and publishing research reports on covered investment funds under existing regulation? Can commenters quantify these costs?

232 Section 12(a)(2) provides express remedies to the person purchasing the security (i.e., a private right of action) for material misstatements and omissions made by any seller of the security. It also provides a different standard for claims for damages than under Exchange Act rule 10b-5, which requires proof of reliance in the representations made. See 15 U.S.C. 77l(a)(2); see also rule 10b-5 [17 CFR 240.10b-5].

233 Research reports that are published or distributed as rule 34b-1 supplemental sales literature also would be subject to requirements relating to the standardized presentation of performance information, because rule 34b-1 incorporates many of the rule 482 requirements relating to performance disclosure. See supra notes 231, 145.

234 See FINRA rule 2210(d)(1).

235 See supra note 174 (discussing the scope of these rules in more detail, including noting that the scope of FINRA rules 2241(c)(1) and 2242(c)(2) generally apply only to a subset of communications that would be considered covered investment fund research reports under proposed rule 139b).

b. Current Filing Requirements

As discussed above, the rule 139 safe harbor currently is not available for broker-dealers’ publication and distribution of research reports about specific registered investment companies and BDCs.236 Therefore, a research report or other communication about a covered investment fund that is a registered investment company would have to comply with the requirements of Securities Act rule 482.237 Today, registered investment company sales material, including rule 482 “omitting prospectus” advertisements as well as supplemental sales literature,238 are required to be filed with the Commission under section 24(b) of the Investment Company Act.239 Broker-dealers that are FINRA members are also subject to certain additional filing requirements under current FINRA rule 2210.240

C. Costs and Benefits

In this section, we first consider the overarching costs and benefits associated with the FAIR Act’s statutory mandates. Second, we evaluate the costs and benefits of the specific proposed provisions and their relation to the overarching considerations resulting from the statutory mandate. Next, we discuss the effects on efficiency, competition, and capital formation of the proposed rules. We conclude with a discussion of alternatives considered.

1. FAIR Act Statutory Mandate

a. Benefits

We believe that the proposed expansion of the rule 139 safe harbor (as mandated by the FAIR Act) will generally reduce broker-dealers’ costs of publishing and distributing research reports about covered investment funds. These cost reductions are expected because under the proposed rules a broker-dealer could publish or distribute covered investment fund…

236 See supra note 15.

237 See FINRA rule 2210(d)(5) (providing that non-money market fund open-end management company performance data as permitted by rule 482 in retail communications and correspondence must disclose standardized performance information and, to the extent applicable, certain sales charge and expense ratio information); see also supra note 178.

238 See supra note 231.

239 Rule 24b–3 under the Investment Company Act deems these materials to have been filed with the Commission if filed with FINRA. See supra note 29.

240 FINRA rule 2210’s filing requirements include a number of exclusions, including an exclusion for certain research reports, except that broker-dealers are required to file research reports with FINRA if they are also required to be filed with the Commission pursuant to section 24(b) of the Investment Company Act. See supra notes 167–169, and accompanying text.
research reports without reliance on rule 482 or rule 34b–1 and without being required to file these reports under section 24(b) of the Investment Company Act and the rules and regulations thereunder.241 Broker-dealers publishing or distributing covered investment fund research reports in reliance on the expanded safe harbor would not be subject to the liability provisions of section 12(a)(2) of the Securities Act,242 the content requirements of rule 482 or rule 34b–1, or the filing requirements of section 24(b) of the Investment Company Act.243 Thus, they would be expected to incur lower costs associated with liability under section 12(a)(2), lower conduct costs, and lower compliance costs (including fewer content and filing requirements).244 Because of these cost reductions, we expect publication and distribution of such reports to increase. First, we expect that certain broker-dealers that had previously published and distributed communications under rule 482 that could be styled as “research reports” would aim to meet the conditions of the expanded safe harbor and increase their supply of covered investment fund research as a result. Second, we expect some broker-dealers that have previously not published or distributed such reports (due to the activity being deemed too costly or subject to too many restrictions), to begin doing so. We believe that the aforementioned effects will generally benefit broker-dealers and advisers to covered investment funds if, as we expect, they increase broker-dealers’ sales of covered investment funds.

Because there is limited historical experience dealing specifically with broker-dealers’ research reports on covered investment funds, there is little in the way of direct empirical evidence on the value of such reports to investors. Prior research on the informativeness of broker-dealers’ research on operating companies suggests that broker-dealers can research production that positively contributes to the information content of market prices,245 and—perhaps more importantly—that broker-dealers may enjoy a comparative advantage in its production.246 However, other studies have questioned the investment value of such research to investors247 or its continued relevance.248

We are cautious in drawing implications from these findings to broker-dealers’ research on covered investment funds. While analysts researching operating companies generally endeavor to identify mispricing—to forecast the idiosyncratic component of firms’ future returns—brokers researching covered investment funds represent portfolios of securities, and many covered investment funds are priced at net asset value (“NAV”).249 Although individual securities within a covered investment fund’s portfolio may be (broker-dealers’ research analysts’ upgrades (downgrades) elicit positive (negative) price reactions, respectively). See also Scott E. Stiel, The Anatomy of the Performance of Buy and Sell Recommendations, 51 Financial Analysts Journal 5, 25–39 (Sept. 1, 1995) (broker-dealers’ research provides new information particularly for smaller firms, where information is less generally available). See also Kent L. Womack, Do Brokerage Analysts’ Recommendations Have Investment Value?, 51 The Journal of Finance 1, 137–167 (1996) (price reactions are permanent and exhibit post-announcement drift).


249 Closed-end funds, for example, are not priced on a NAV basis and their (mis-) pricing has long served as a puzzle in the finance literature. See, e.g., Charles M.C. Lee, Andrei Schleifer, & Richard H. Thaler, Investor Sentiment and the Closed-End Fund Puzzle, 46 The Journal of Finance 1 (Mar. 1991). Similar pricing issues may arise in BDCs, individually viewed as “mispriced” by a research analyst, diversification effects will tend to drown out such effects at the fund level and minimize idiosyncratic variation in investors’ return on their investment in the fund. Therefore, any “investment value”250 of research on covered investment funds would likely be rooted in analysts’ ability to predict broader market movements. Such ability is generally believed to be rather rare.251 We therefore believe that the value to investors of information in broker-dealer research reports will largely be limited to the synthesis or discovery of factual information about fund characteristics, fees, or other transactions costs. For example, investors may find analysts’ views of a fund’s management, objectives, risk exposures, tracking error, volatility, tax efficiency, fees, or other fund characteristics to be valuable. Such analysis could be valuable a source of information for investors evaluating relative fund performance.252

We believe that the availability of information available to potential investors of covered investment funds would increase as a result of broker-dealers’ increased publication and distribution of covered investment fund research reports. The proposed rules will also allow for greater flexibility in the type of information that broker-dealers may communicate to customers.253 To the extent that this new information is valuable, it will benefit investors by providing them with additional information to help shape investment decisions. Finally, we believe that important negative information about a covered investment fund, such as high fees, high risk exposure, or an inefficient portfolio strategy will be more likely to be publicized as a result of increased competition among information providers, with attendant benefits to investors.254

We request comment generally on the benefits that we anticipate may arise.

241 See supra section I.D.1.

242 See supra note 232.

243 See supra section I.D.1.

244 We note, however, that we would not expect any lower costs of compliance for any research reports that currently are structured as rule 34b–1 supplemental sales literature (and are not rule 482 advertising prospectuses), because supplemental sales literature is not an “offer” to which prospectus liability under section 12(a)(2) of the Securities Act would attach.

245 See, e.g., Brad M. Barber, Reuven Lehavy, & Brett Trueman, Ratings changes, ratings levels, and the predictive value of analysts’ recommendations, 39 Financial Management 2, 533–553 (2010)


248 Currently such communications would be subject to rule 482 requirements, including standards on the presentation of performance information. See supra section II.C.

from proposed rule 139b and proposed rule 24b-4 as a result of the FAIR Act’s statutory mandate.

- Do commenters generally agree with our assessment of the cost reductions that we expect to result from the proposed rules?
- To what extent would broker-dealers rely on the proposed rule 139b safe harbor to publish or distribute communications that are currently structured as rule 482 advertising prospectuses or rule 34b-1 supplemental sales literature? What would motivate broker-dealers to instead use the proposed rule 139b safe harbor? For example, would broker-dealers expect to incur significantly lower legal and compliance costs and lower costs related to potential litigation due to covered investment fund research reports’ lack of prospectus liability under section 12(a)(2) of the Securities Act under the safe harbor? Alternatively, would the primary cost savings arise in other ways (for example, because of lower investment fund research report requirements where FINRA and NYSE rules have failed to manage in an adequate or appropriate manner).

b. Costs

Prior experience and academic research suggests that, unchecked, broker-dealers’ conflicts of interest can lead to bias in research reports, and that such bias has the potential to adversely affect investor welfare.256

255 See Amirrakhsh Dugar & Siva Nathan, The Effect of Investment Banking Relationships on Financial Analysts’ Earnings Forecasts and Investment Recommendations, 12 Contemporary Accounting Research 1, 131–166 (Sept. 1, 1993) (“Dugar and Nathan Article”) (affiliated analysts issue more optimistic earnings forecasts and investment recommendations about companies with which their firms had an investment banking relationship).

256 See also Siva Nathan, Affiliated Analysts in Investment Banking, 25 Journal of Accounting and Economics 1, 101–127 (Feb. 26, 1998) (“Lin and Nichols Article”) (affiliated analysts are more optimistic in their long-term growth forecasts and investment recommendations).


258 See also Patricia M. Dechow, Amy P. Hutton & Richard C. Sloan, The Relation between Analysts’ Forecasts of Long-Term Earnings Growth and Stock Price Performance Following Equity Offerings, 17 Contemporary Accounting Research 1, 1–32 (Mar. 1, 2000). See also Lit. Rel. No. 18438, supra note 261 (stating that the SEC has approved a $1.4 billion global settlement of FINRA rule 2241 by mitigating FINRA rule 2241(b)(2)(C), (E), (F), and (K). Additionally, section 501(a)(2) of Regulation AC (17 CFR 242.501(a)(2)) requires specific disclosure regarding research analyst compensation in order to mitigate the conflicts of interest that can arise based on analyst compensation arrangements.

259 Such conflicts arise from conflicts of interest that can arise from conflicts of interest arising from compensation arrangements involving research analyst issuing research reports covered by FINRA rule 2241 and mitigated by FINRA rule 2241(b)(2)(C), (E), (F), and (K). Additionally, section 501(a)(2) of Regulation AC (17 CFR 242.501(a)(2)) requires specific disclosure regarding research analyst compensation in order to mitigate the conflicts of interest that can arise based on analyst compensation arrangements.

260 For example, although it is prohibited conduct, a broker-dealer may have a financial incentive to provide coverage for, or to promote, a fund based on an understanding that the fund will participate in offerings underwritten by the broker-dealer. See, e.g., FINRA rule 2241(b)(2)(H) (requiring that a member’s written policies and procedures must be reasonably designed to, among other things, “prevent the use of research reports or research analysts to manipulate or condition the market or favor the interests of the member”): see also NASD Fines U.S. Bancorp Piper Jaffray and Managing Director $300,000, FINRA News Release (June 25, 2002) available at http://www.finra.org/newsroom/2002/nasd-fines-us-bancorp-piper-jaffray-and-managing-director-300000 (announcing settlement with U.S. Bancorp Piper Jaffray and one of its managing directors). The NASD found that the firm violated a NASD (now FINRA) rule requiring all firms and associated persons to adhere to high standards of commercial honor and just and equitable principles of trade when it threatened to discontinue research coverage of a company if the company did not select it as lead underwriter for an upcoming offering). But see also note 43.
that such conflicts of interest could result in actions that negatively impact information communicated to investors are mitigated by the fact that a broker-dealer will bear the costs of such actions, but generally may be unable to fully appropriate the benefits.

It is difficult for us to quantify the aforementioned costs in the context of this proposal. We are not aware of any studies directly examining the role that this proposal. We are not aware of any studies directly examining the role that such conflicts may play in broker-dealers’ research reports on covered investment funds in U.S. markets, or of any data that would support a quantitative analysis of an expanded safe harbor in this context. As with the potential benefits discussed above, we are limited to characterizing the potential costs qualitatively. While we believe that expanding the rule 139 safe harbor to broker-dealers’ publication or distribution of covered investment fund research reports has the potential to impose costs on retail investors, existing regulations, specific provisions of the rules that we are proposing, and certain market mechanisms would reduce such costs.

(1) Existing Regulation

Rules and regulations have been implemented to address potential conflicts of interest that may arise with broker-dealers specifically in the context of research reports. As discussed in detail above, the definition of “research report” for purposes of Regulation AC and FINRA rule 2241 is narrower than the definition of “research report” for purposes of the FAIR Act and proposed rule 139b. However, to the extent a research report meets both the definition of a research report under Regulation AC, Regulation AC would be applicable to that research report (and, if it meets the definition of "research report" in FINRA rule 2241, FINRA rule 2241 also would apply if the research report otherwise were within the scope of rule 2241). These rules may help promote objective and reliable research. Additionally, as described above, FINRA rule 2210 contains general content standards that apply broadly to member communications, including broker-dealer research reports. These general content standards require, among other things, that all member communications "must be based on principles of fair dealing and good faith, must be fair and balanced, and must provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry or service." 

If a broker-dealer recommends a covered investment fund to its customers, additional obligations under the federal securities laws and FINRA rules would apply. As a general matter, broker-dealers must deal with their customers fairly—and, as part of that obligation, have a reasonable basis for any recommendation. Furthermore, when making recommendations, broker-dealers may be generally liable under the antifraud provisions if they do not give “honest and complete information” or disclose any material adverse facts or conflicts of interest, including any economic self-interest.

(2) Market Mechanisms

We believe that by facilitating production of information on covered investment funds, the FAIR Act’s mandates will contribute to competition among information providers, which we believe can mitigate the effects of conflicts of interest on research reports. With respect to broker-dealers’ research on operating companies, analysts’ career concerns

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267 For example, if a broker-dealer firm publishes biased research about a fund, some of the gains (i.e., compensation from sales of that fund) may accrue to other broker-dealer firms (i.e., other broker-dealer firms that distribute the same fund) while the costs of the research costs, litigation risk, and risk of regulatory action) will be borne entirely by the broker-dealer firm that published the biased research. Authors have examined the impact of conflicts of interest on mutual fund research in China, providing evidence consistent with bias arising from conflicts of interest in that market, though differences between Chinese and U.S. markets and corresponding regulatory frameworks make it difficult to apply inferences drawn from experience in Chinese markets to U.S. markets. See Y. Zhang, Q. Yuan & J. Zhang, Blurred stars: Mutual fund ratings in the shadow of conflicts of interest, Journal of Banking & Finance 60, 284–295 (2015).

267 See infra section III.C.2.

267 See supra note 37.

267 See infra notes 11, 21, 43, and 174.
have also been found to have similar effects, and, in principle, broker-dealers’ reputations could as well. However, we do not believe that analyst career concerns or broker-dealer reputation will play as significant a role in the context of covered investment fund research reports. Research reports about operating companies have traditionally been provided to institutional investors as part of a bundle of services provided by full-service brokerages. In this setting, broker-dealers benefit from institutional customers that are willing to pay for broker-dealers’ additional services. They are also generally capable of producing similar reports, and so can evaluate the quality of broker-dealers’ research. Thus, institutional investors can provide market discipline; broker-dealers’ provision of low-quality or misleading information could plausibly be discovered and lead to the loss of valuable customer relationships. We do not believe that similar mechanisms would be as effective in the covered investment fund context. We expect broker-dealers to publish and distribute covered investment fund research reports on funds that they distribute to their customers. With retail investors, information asymmetries are greater: retail investors do not generally possess the capabilities to replicate an analyst report or evaluate its quality. Moreover, the problem of evaluating the performance of analysts is harder in the context of covered investment funds. Because institutional investors are not major investors in covered investment funds, we believe they are unlikely to provide market discipline in this context, and we do not believe that individual retail investors could be similarly effective in this role. Thus, we believe that in the context of covered investment fund research reports, providing market discipline would largely fall on retail investors’ investment advisers.

We also acknowledge that bias resulting from conflicts of interest need not adversely impact investors if investors disregard, disbelieve, or de-bias the recommendations of conflicted analysts. We believe, however, that retail investors who are primary clientele for covered investment funds are less likely to be aware of potential bias in analysts’ recommendations.284 They may fail to de-bias or otherwise condition their trades based on the credibility of the recommendation,285 and could thus be

284 Traditional analyst research reports on operating companies largely focus on firm-specific factors, and thus are more akin to “stock picking” than “market timing”: they attempt to forecast the idiosyncratic component of firms’ future returns. Covered investment fund research reports represent portfolios of securities and diversification effects reduce the amount of idiosyncratic variation in their returns. Thus, abstracting from fees, “fund picking” is more akin to “market timing” than “stock picking.”

285 Market timing is a skill that is relatively rare and econometrically difficult to detect. See, e.g., Kent Daniel, Mark Grinblatt, Sheridan Titman & Russ Wermers, Measuring Mutual Fund Performance with Characteristic-Based Benchmarks, 52 The Journal of Finance 3, 1035–1058 (July 1997).

286 See supra note 3.III.B.1.a.


288 See Dugan and Nathan Article, supra note 255.

289 See supra section III.B.1.a.

290 See supra section III.B.1.c.


292 See Michaely and Womack Article, supra note 255.

293 See supra section III.B.2.

294 See supra paragraph accompanying notes 32–34.

295 See supra section II.F.

296 See supra section III.B.1.a.

297 See Mikhail Walther and Willis Article, supra note 295. See also Malmendier and Shanthikumar Article, supra note 285. See also Amanda Cranston, Boris Groysberg & Paul Healy, Which Types of Analyst Firms Are More Optimistic?, 41 Journal of Accounting and Economics 1, 119–146 (Apr. 1, 2006) (finding that analysts at retail brokerage firms are more optimistic than those serving only institutional investors).


an affiliate of a covered investment fund (or is an investment adviser or an affiliated person of the investment adviser to a covered investment fund), would not be eligible for the safe harbor of proposed rule 139b when publishing or distributing a research report about that covered investment fund. The economic benefit of the affiliate exclusion is that it reduces the potential for retail investors to receive research reports containing information that was published, distributed, authorized, or approved by persons whose financial incentives create the greatest conflicts of interest. The primary cost of the affiliate exclusion will be borne by broker-dealers that both distribute covered investment funds and act as investment advisers to such funds (or do so through affiliated persons). These broker-dealers will be unable to provide research reports to their customers on funds that they (or their affiliated persons) advise. In addition, we believe that smaller broker-dealers, and broker-dealers without significant research departments and who would want to rely on pre-publication materials distributed by a covered investment fund, its adviser, or affiliated persons, would also be significantly affected by the proposed rules.

We expect covered investment funds and their investment advisers to engage in a broad range of marketing activities to support the distribution of fund shares (particularly in the case of redeemable securities such as those issued by mutual funds), and that funds and their advisers prepare and distribute materials to distributing broker-dealers intended to increase sales. As discussed in section II.A.1, we note that, if a broker-dealer were to publish or distribute a research report that were to include pre-publication materials that were specifically authorized or approved by a person covered by the affiliate exclusion for purposes of inclusion in a research report, this could inappropriately circumvent the affiliate exclusion. This guidance reduces the potential for retail investors to receive research reports containing materials from persons whose financial incentives create the greatest conflicts of interest.

The proposed affiliate exclusion is also likely to limit the benefits of the proposed rule for certain broker-dealers. Many broker-dealers distributing covered investment fund securities do not have sizeable research departments, and we understand that very few broker-dealers operate at a scale that would allow for comprehensive coverage of the covered investment funds that they distribute. The proposed affiliate exclusion could have the effect of limiting broker-dealers’ ability and willingness to publish and distribute research reports about the funds they distribute: in order to rely on the rule to publish or distribute a covered investment fund research report, these broker-dealers would need to conduct their own research in-house or to rely on independent third-party service providers for their information.

We are also seeking commenters’ views on our analysis:

- Will the proposed affiliate exclusion reduce the potential for investors to receive research reports that were affected by significant conflicts of interest?
- Will smaller broker-dealers, or broker-dealers without significant research departments, be most impacted by the proposed affiliate exclusion (and our guidance on the proposed affiliate exclusion)? If not, which broker-dealers would be most affected, and why?
- Are there additional benefits associated with the content and presentation standards that we have not considered?
- Are there additional costs associated with content and presentation requirements that we have not considered?

b. Regular-Course-of-Business Requirement

Under proposed rule 139b, research reports (both issuer-specific research reports and industry research reports) would need to be published or distributed by the broker-dealer in the “regular course of its business” in order to rely on the safe harbor. For issuers that do not have a class of securities in “substantially continuous distribution,” issuer-specific research reports that represent the initiation of publication of research reports about the issuer’s or its securities or reinitiation following discontinuation of publication of such research reports would be deemed to not satisfy the regular-course-of-business requirement. The regular-course-of-business requirement being proposed under rule 139b is similar to that of rule 139, except that, as directed by the FAIR Act, rule 139b specifies that the “initiation or reinitiation requirement” only applies to research reports regarding a covered investment fund that does not have a class of securities in substantially continuous distribution.

Given the breadth of the definition of “research report” under the FAIR Act (and the definition of “research report” that we propose under rule 139b), certain communications that are currently treated as covered investment fund advertisements under Securities Act rule 482 could fall under the proposed rule 139b definition of “research report.” Investors, particularly retail investors, may be unaware of the differences in regulatory status and purpose among the various types of communications regarding registered investment companies and business development companies. This may result in investors not being able to readily discern what constitutes a research report and what constitutes an advertisement about these issuers.

We believe that broker-dealers that publish or distribute research reports in the regular course of business are more likely to publish analysis that investors recognize as research. Therefore, we expect this requirement to benefit investors by reducing opportunities for communications published or distributed under the safe harbor to cause confusion about their intended purpose. However we also believe that establishing whether a research report is published in the “regular course of business” could, in practice, prove uniquely challenging in the covered investment funds context.

First, in the context of covered investment funds, the distinction between communications intended as sales materials and those intended as research could be difficult to discern. Research reports about debt and equity securities have traditionally been provided to institutional customers as part of the broker-dealer’s collection of services. Institutional customers are generally capable of producing similar reports, and so can more readily evaluate the quality of broker-dealers’

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304 See supra sections II.B.1.c and II.B.2.b.
305 See supra note 96 and accompanying text.
306 See section 2(b)(1) of the FAIR Act; see also supra discussion at note 98.
307 See supra note 102 and accompanying text.
308 See supra paragraph accompanying note 103.
309 See supra paragraph accompanying note 104.
310 See supra requests for comment in section II.B.1.c (requesting comment on the application of the regular-course-of-business requirement in the context of broker-dealers’ publication or distribution of covered investment fund research reports and unique concerns relevant to this context e.g., whether the proposed requirement should be modified to address broker-dealers that have not previously published or distributed covered investment fund research reports).
311 See Mehran and Stulz Article, supra note 283.
research. In these circumstances, broker-dealers have a compelling business rationale for producing high-quality research as distinct from sales materials. In contrast, we expect covered investment fund research reports to be produced by broker-dealers that distribute covered investment funds to retail customers. With retail investors, information asymmetries are greater: retail investors do not generally possess the capabilities to produce an analyst report or evaluate its quality, and some may have difficulty differentiating between research and sales literature. Moreover, the problem of evaluating the performance of research analysts is harder in the context of covered investment funds. Thus, we believe that cultivating a reputation for high-quality research is less likely to serve as the primary business rationale for broker-dealers’ publication and distribution of research reports on covered investment funds. Rather, we expect that facilitating the marketing of covered investment funds to customers (so as to increase revenues derived from distribution arrangements) will motivate these activities. In this setting, the distinction between different types of communications is not as clear.

Second, we note that the information environment surrounding covered investment funds further complicates establishing whether publishing research reports about covered investment funds is undertaken in the regular course of business. In the context of research reports about operating companies, a research analyst “following” an operating company continually monitors the company so as to provide timely forecasts and recommendations. Because of differences in the nature of covered investment funds and operating companies, we believe that the same is less likely to hold for a research analyst “following” a covered investment fund. We believe that the opportunities for acquiring idiosyncratic information relevant to future returns of covered investment funds are generally more limited: Covered investment funds represent portfolios of securities and diversification effects reduce the value of idiosyncratic (i.e., firm-specific) information. Consequently, we expect research analysts “following” covered investment funds to focus instead on information related to fund characteristics (e.g., fees, portfolio composition, or index tracking strategy) and on developments at the sector- or macro-level. Because we do not expect the arrival of such information to be as frequent, we expect that the inclusion of new analysis in research reports about covered investment funds could be more rare than in the context of operating company research reports. Consequently, the publication or distribution of covered investment fund research reports could occur relatively infrequently, or could be driven largely by market-wide factors. This could make it more difficult to establish whether a covered investment fund research report is published in the regular course of business. Due to the aforementioned distinctions in the information environment and business rationale, we believe that the regular-course-of-business requirement in the context of proposed rule 139b may be more challenging to apply in practice than the regular-course-of-business requirement in the context of rule 139. Accordingly, the potential benefits of this requirement in proposed rule 139b may be limited. The effects of the regular-course-of-business requirement would be clearer in cases where, in the case of issuer-specific research reports, the proposed bright-line “initiation or reinitiation” requirement applies (i.e., where the covered investment fund does not have a class of securities in substantially continuous distribution). For such cases, the regular-course-of-business requirement as proposed would condition the availability of the covered investment fund research report not representing the initiation or reinitiation of coverage by the broker-dealer publishing or distributing said research report. As the universe of covered investment funds is dominated by funds with a class of securities that could be considered to be in substantially continuous distribution, the bright-line test of the regular course of business requirement would impact only a small subset of funds.

We are also seeking commenters’ views on our analysis:

- Is our assessment of the difficulties associated with establishing whether research reports about covered investment funds are published in the regular course of business accurate? If not, what factors will be indicative of the regular-course-of-business requirement having been satisfied?
- Are there additional benefits associated with this requirement that we have not considered?
- Are there additional costs associated with this requirement that we have not considered?

c. Reporting History and Minimum Market Value Requirements for Issuers Appearing in Issuer-Specific Research Reports

Under proposed rule 139b, a broker-dealer’s publication or distribution of issuer-specific research reports would not qualify for the safe harbor unless the covered investment fund included in the report satisfies a minimum public market value threshold of $75 million. Issuers would also be required to have been subject to the reporting requirements of the Investment Company Act (for covered investment funds that are registered investment companies) or the reporting requirements under section 13 or 15(d) of the Exchange Act (for covered investment funds that are not registered investment companies) for a period of at least 12 calendar months prior to reliance on the proposed rule as well as to have timely filed all required reports during the preceding 12 months.

The covered investment funds market is dynamic. In 2016, more than six hundred covered investment funds entered the market, while more than seven hundred exited. The entry and exit of covered investment funds creates a situation in which a younger covered investment fund may not be widely followed by market participants.

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312 See id; see also Malmendier and Shanthikumar Article, supra note 285.
313 See supra notes 279–281.
314 See Mehran and Stulz Article, supra note 283.
315 Traditional analyst research reports on operating companies largely focus on firm-specific factors, and thus are more akin to “stock picking” than “market timing”: they attempt to forecast the idiosyncratic component of firms’ future returns. Covered investment funds represent portfolios of securities and diversification effects reduce the amount of idiosyncratic variation in their returns. Thus, abstracting from fees, “fund picking” is more akin to “market timing” than “stock picking.” Market timing is a skill that is relatively rare and economically difficult to detect. See, e.g., Kent Daniel, Mark Grinblatt, Sheridan Titman & Russ Wermers, Measuring Mutual Fund Performance with Characteristic-Based Benchmarks, 52 The Journal of Finance 3, 1035–1058 (July 1997).
316 The regular course of business requirement generically would require “research reports” to be published or distributed in the regular course of a broker-dealer’s business and would not be limited to covered investment fund research reports. We request comment about what the regular course of business requirement means in the context of covered investment fund research reports. See supra section II.B.1.c. (requests for comments).
317 See supra notes 250 – 251 and accompanying text.
318 See supra note 98 and accompanying text.
319 See proposed rule 139b(a)(1)(II)(B).
320 Including Forms N-CSR, N-SAR, N-Q, N-PRT, N-MFP, and N-CEN as applicable for registered investment companies, and Forms 10-K, 10-Q, and 20-F as applicable for covered investment funds that are not registered investment companies. See proposed rule 139b(a)(1)(II)(A).
321 See supra section III.B.1.a.
322 In contrast, there were fewer than one hundred U.S. IPOs for operating companies in 2016.
Thus, for covered investment funds, the universe of young—and potentially less-followed—issuers is large. Moreover, securities issued by covered investment funds may not be subject to significant levels of market scrutiny. Unlike securities issued by operating companies (that generally have diverse groups of investors, including institutional investors, money managers, arbitrages, activist investors, and short sellers), covered investment funds are primarily held by retail investors. As covered investment fund shares are not a major cogwheel of institutional investors’ portfolios, we believe that they are less likely to garner widespread attention from the types of sophisticated institutional investors most capable of subjecting them to scrutiny.

We believe that in the context of covered investment funds, where we expect limited market discipline from institutional investors and where large numbers of new funds are created each year, the information available to investors could be sparse. In such an environment, a single “research report” about a covered investment fund could have a disproportionate effect on retail investors’ beliefs about the fund and—in the case of a biased research report—have a negative effect on investor welfare. We believe that conditioning the availability of the safe harbor on the aforementioned reporting history and market valuation requirements would help restrict the availability of the safe harbor in situations where we expect the information environment to be most limited: for new funds and for funds with niche markets. Moreover, we believe modeling the reporting history and minimum public market valuation requirements on those in rule 139 reduces regulatory complexity and opportunities for investor confusion.

Because young and small covered investment funds are relatively common, the costs associated with these conditions on the availability of a safe harbor may be significant. In particular, as shown in Table 1, the $75 million minimum public market valuation condition would limit the availability of the safe harbor with respect to broker-dealers’ publication or distribution of research reports for approximately one-third of all covered investment funds. Research reports about nearly half of extant ETFs, ETPs and BDCs would not qualify for the safe harbor. Availability of the safe harbor would be least impacted for research reports on open-end mutual funds and closed-end funds.

Although young and small funds represent a very small fraction of covered investment fund assets, they are relatively large in number. Because nearly one-third of covered investment funds would not satisfy the eligibility criteria for the proposed safe harbor, we believe that those funds would be less likely to receive coverage by broker-dealers insofar as the inability to rely on the proposed safe harbor reduces broker-dealers’ willingness to publish and distribute research reports.

Table 1—Covered Investment Funds With Public Market Value Less Than $75 Million, and the Fraction of Covered Investment Fund Assets Held by These Funds. For Each Covered Investment Fund Type, We Report the Percentage of Funds of That Type With a Public Market Value Below $75 Million and the Percentage of Covered Investment Fund Assets Held in Funds With Public Market Values Below $75 Million. Mutual Fund, ETF, and ETP Statistics Based on Data From CRSP Mutual Fund Database (2017Q3), Closed-End Fund Statistics Based on Data From CRSP Monthly Stock File (Dec. 2017). BDC Statistics Based on Commission’s Listing of Registered BDCs, and Regulatory Filings (2016) Compiled by Compustat and Audit Analytics

<table>
<thead>
<tr>
<th>Covered investment fund type</th>
<th>Funds with public market value &lt;$75 million</th>
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<tbody>
<tr>
<td></td>
<td>Number of funds (%)</td>
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<tr>
<td>Open-end</td>
<td>30</td>
</tr>
<tr>
<td>Closed-end</td>
<td>12</td>
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<tr>
<td>ETFs and ETPs</td>
<td>41</td>
</tr>
<tr>
<td>BDC</td>
<td>42</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
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Notes:

326 41% of ETF and ETPs and 42% of BDCs have public market valuations less than $75 million. See Table 1.

327 30% of open-end mutual funds and 12% of closed-end funds have public market valuations less than $75 million. See Table 1.

328 See Table 1.

329 Propose rule 139(b)(2)(ii). As discussed previously, each issuer included in an issuer-specific research report also would be required to be subject to these reporting requirements, as well as the requirement to have filed in a timely manner all of the periodic reports required to be filed during the preceding 12 months. See supra section II.B.1.a. We note that this condition limits industry reports published or distributed in reliance on rule 139b to covered investment funds that file their reports pursuant to section 30 of the Investment Company Act or section 13 or section 15(d) of the Exchange Act.

We are also seeking commenters’ views on our analysis:

- Are there additional benefits associated with these requirements that we have not considered?
- Are there additional costs associated with these requirements that we have not considered?

d. Reporting Requirement for Issuers Appearing in Industry Reports

Under proposed rule 139b an industry research report could only include covered investment funds that are required to file reports pursuant to section 30 of the Investment Company Act (or, for covered investment funds that are not registered investment companies under the Investment Company Act, required to file reports pursuant to section 13 or section 15(d) of the Exchange Act). As discussed above, these proposed conditions generally track parallel conditions under rule 139, but have been modified so that they would be applicable with respect to covered investment fund issuers. We do not expect these conditions to have economic effects beyond marginally improving economic efficiency by more closely aligning regulations with their intended context.

We are also seeking commenters’ views on our analysis:

- Are there additional benefits associated with these requirements that we have not considered?
- Are there additional costs associated with these requirements that we have not considered?

e. Content and Presentation Requirements for Industry Research Reports

Under proposed rule 139b, the content and presentation standards for industry research reports of rule 139 would be tailored to the context of covered investment funds. Under proposed rule 139b (and rule 139), issuers appearing in industry research reports are subject to fewer conditions than issuers that are subjects of issuer-specific research reports. We believe that in the absence of content and presentation requirements such as those
we propose today, an industry research report could be used to circumvent the conditions associated with the safe harbor available for issuer-specific research reports. We therefore believe that the proposed content and presentation standards have benefits similar to those of the parallel content and presentation requirements in rule 139, and provide meaningful limits for issuer-specific research reports. 331

We believe the compliance costs imposed by these requirements on the production of industry research reports would be low, particularly as broker-dealers are already familiar with similar conditions in rule 139, making implementation of presentation conditions for industry research reports on covered investment funds less burdensome.

We are also seeking commenters’ views on our analysis:

• Do commenters believe that there are there additional benefits associated with the content and presentation standards that we have not considered?
• Do commenters agree with our assessment of the compliance costs? Are there certain types of broker-dealers for which these compliance costs will be higher (or lower)?

3. Proposed Rule 24b–4

Proposed rule 24b–4 would exclude a covered investment fund research report from the coverage of section 24(b) of the Investment Company Act and the rules and regulations thereunder, except to the extent that such report is not subject to the content provisions of SRO rules related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards. As discussed above, this proposed rule is meant to implement section 2(b)(4) of the FAIR Act, which we interpret to exclude covered investment fund research reports from section 24(b) of the Investment Company Act so long as they continue to be subject to the general content standards in FINRA rule 2210(d)(1). 332 For covered investment fund research reports that are published or distributed by FINRA member firms, all such research reports would be subject to the content standards of FINRA rule 2210(d)(1), and thus we would interpret these research reports to be excluded from the Commission’s filing requirements under the proposed rule. 333

As discussed above, where covered investment fund research reports would no longer be required to be filed with the Commission pursuant to section 24(b), proposed rule 24b–4 could have the effect of narrowing the types of communications regarding registered investment companies that would be filed with FINRA (under current FINRA rule 2210). 334 However, we believe that administrative processes related to handling regulatory reviews of communications subject to filing requirements impose costs on broker-dealers, which in turn can reduce their willingness to publish and distribute such communications. Consequently, although we do not believe that limiting these filing requirements as required by the FAIR Act represents a first-order economic effect of the proposed rules, we believe that doing so will reduce administrative costs for broker-dealers publishing or distributing covered investment fund research reports. At the same time, as discussed above, we believe that eliminating these filing requirements may have the result that some communications that are currently subject to FINRA’s filing requirements would no longer be subject to routine review. 335 While these communications may still be reviewed by FINRA—for example, through examinations, targeted sweeps, or spot-checks—we believe that an effect of the FAIR Act, as implemented through proposed rule 24b–4, may be to reduce the monitoring by FINRA and the Commission of broker-dealers’ communications with customers for compliance with the applicable rules and regulations. 336

We are seeking comments on the costs and benefits of proposed rule 24b–4:

• Do commenters agree with our characterization of the costs and benefits? Are there additional costs and benefits that we should consider?
• Do commenters expect non-FINRA member firms to publish or distribute covered investment fund research reports that would not be subject to the content standards of FINRA rule 2210(d)(1)?

4. Proposed Amendment to Rule 101 of Regulation M

As discussed above, rule 101 of Regulation M prohibits a person who participates in a distribution from attempting to induce others to purchase securities covered by the rule during a specified period. 337 However, rule 101 provides an exception for research activities that satisfy the conditions of Securities Act rule 138 or rule 139. The proposed conforming amendment would expand this exception to include research activities that satisfy the conditions of proposed rule 139b. We believe that broker-dealers would generally be unable to make use of the proposed rule 139b safe harbor absent the proposed conforming amendment. Consequently, we do not consider its effects separately.

5. Effects on Efficiency, Competition, and Capital Formation

The primary effects on economic efficiency and capital formation resulting from proposed rules 139b and 24b–4 obtain from the statutory mandates of the FAIR Act. Because financial intermediaries such as broker-dealers are generally assumed to possess some comparative advantage in the production of information about securities, efficiency considerations would—in the absence of significant market imperfections—dictate that broker-dealers should be active in the production of such information. To the extent that the increase in broker-dealers’ production of research reports about covered investment funds—that we expect to occur as a result of the FAIR Act’s statutory mandates—is valuable to investors, we expect it to increase allocative efficiency, with attendant positive consequences on capital formation. As noted earlier, the existence of the safe harbor could provide increased opportunities for broker-dealers to publish and distribute research on funds from which they derive financial benefits. 338 To the extent that this could limit the value investors derive from research reports that broker-dealers publish and distribute, any potential gains to efficiency and improvements to capital formation could be reduced (or eliminated).

Beyond the aforementioned broader effects on efficiency and capital formation resulting from the FAIR Act’s statutory mandates, we believe that the specific conditions on the availability of the safe harbor in proposed rule 139b

331 See supra notes 118–119, and paragraph accompanying note 136.
332 See supra note 174 and accompanying text.
333 See id.
334 See id.
335 See supra section II.D.1.
336 But see supra note 188 and accompanying text (noting that the FAIR Act’s rules of construction provide that the Act shall not be construed as limiting the authority of an SRO to require the filing of communications with the public if the purpose of such communications “is not to provide research and analysis of covered investment funds”); see also section 2(c)(2) of the FAIR Act.
337 See supra section I.E.
338 See supra section III.C.1.a.
339 See supra section III.C.1.b.
will generally further economic efficiency and facilitate capital formation by reducing the potential for retail investors to receive research reports whose publication or distribution may be motivated by these financial incentives that could cause a conflict of interest. We believe that the affiliate exclusion and related guidance will have the largest impact because it addresses the greatest conflicts of interests in this context: Those arising from broker-dealers in investment advisory relationships.\(^{340}\) In addition, we believe that the Commission’s various tailoring of the proposed rules to the covered investment fund context will yield marginal efficiency improvements from reductions in regulatory ambiguity.

With respect to competition, we believe that expansion of the rule 139 safe harbor will increase competition in the market for research reports on covered investment funds. Under the baseline, the market for research reports on covered investment funds is dominated by a small number of independent research firms, with few broker-dealers producing original research about such funds.\(^{341}\) We believe that the availability of the safe harbor will encourage some broker-dealers to publish proprietary research on covered investment funds. However, due to the high costs associated with maintaining research departments capable of covering the large covered investment fund universe,\(^{342}\) we believe that most broker-dealers will continue to rely on content licensed from independent firms.\(^{343}\) We also believe that there are competitive implications stemming from the guidance we have given to address possible circumvention of the proposed affiliate exclusion.\(^ {344}\) This guidance may have the effect of placing smaller broker-dealers—who may not operate at a scale large enough to sustain a research department—at a competitive disadvantage. These smaller broker-dealers may find that they are unable to compete with larger broker-dealers in the provision of “original” research about covered investment funds.

We are seeking comments on our analysis of the proposed rules’ effects on efficiency, competition, and capital formation:

- Are there other significant effects on efficiency, competition, or capital formation that we have not considered?
- What competitive effects, if any, would the proposed reporting history and minimum market value requirements have on smaller covered investment funds? Do commenters believe these requirements would adversely affect the type and amount of analysis available to investors on these funds?

6. Alternatives Considered

We considered several alternative approaches to implementing the FAIR Act mandates that could satisfy the requirements of the FAIR Act. We summarize these here.

\(^{340}\) See supra section III.C.2.a.

\(^{341}\) See supra section III.B.1.c.

\(^{342}\) See supra section III.B.1.a.

\(^{343}\) We expect that broker-dealers that choose to publish research on covered investment funds will generally not license it to their competitors.

\(^{344}\) See supra section III.C.2.a.

\(^{345}\) See supra section II.B.1.b.

\(^{346}\) See supra section III.C.2.c.
Alternative Minimum Public Market Value Thresholds
Percentage of covered investment funds with a public market value (2016) below a given threshold.

We have considered a range of alternative minimum public market values thresholds. Figure 5 plots the percentage of covered investment funds whose public market valuations would fall under each alternative threshold. As shown in the figure, material increases in the availability of the safe harbor are only achievable through large reductions to the threshold. This is due to large numbers of funds being very small: as shown in Figure 6, over 600 covered investment funds have a public market valuation of $5 million or less. However, we do not believe that a significantly lower threshold would be effective at promoting investor protection because, as discussed above in section III.C.2.c, we expect the information environment to be more limited for smaller funds than for larger funds.

Figure 5: Percentage of covered investment funds with a public market value (2016) below a given threshold.
The FAIR Act prevents us from conditioning the availability of the safe harbor on a minimum public market value requirement that is greater than what is required under rule 139.\textsuperscript{347} This effectively prevents us from conditioning the availability of the safe harbor for research reports on the subject covered investment fund having a public float of more than $75 million. Consequently, we do not consider higher minimum public market value thresholds. We seek information from commenters to assist us in assessing the economic impacts of a lower minimum threshold.

- Would a public float threshold of less than $75 million for covered investment funds appropriately exclude those funds with a market following that is too small to permit investors to evaluate covered investment fund research reports? What factors should govern such an alternative threshold and where should it be set?

b. Conditions on Issuers Appearing in Industry Research Reports

(1) Applying Uniform Conditions on Issuers Appearing in Issuer-Specific and Industry Research Reports

With respect to conditions affecting the availability of the safe harbor for industry research reports, we considered applying to industry research reports the same requirements as would apply to issuer-specific research reports. As with the restrictions on issuer-specific research reports, similarly restricting industry research reports could help ensure that funds included in research reports are well-followed, and could restrict the availability of the safe harbor in situations where we expect the information environment to be most limited: for new funds and for funds with niche markets.

In the context of research reports about covered investment funds, cost-benefit considerations for including additional conditions on industry reports differ slightly from those that apply in the context of traditional research reports about equity and debt securities. In the context of research reports about equity and debt securities, analysis of an industry, in the case of operating companies, may require the discussion of specific firms within that industry. For example, a discussion about a mature industry (e.g., automobiles) may require discussion of a disruptive new entrant (e.g., autonomous vehicle start-up). In the context of the rule 139 safe harbor, the new entrant may not satisfy the

\textsuperscript{347} See supra note 25 and accompanying text.
reporting history and minimum float requirements. This would reasonably prevent an issuer-specific research report about the new entrant from qualifying for the safe harbor. However, it would not further the goal of facilitating coverage of the industry to limit the safe harbor for industry reports to reports that do not discuss the new entrant: analysis of the industry may require discussion of specific issuers that would not qualify for inclusion in issuer-specific research reports.

In the context of covered investment funds, a similar rationale would not apply as broadly. The proposed rule 139b content requirements for industry research reports would reference covered investment fund issuers of the same “type” or investment focus, rather than the issuers’ “industry or sub-industry” (i.e., a broad category of similar businesses). Although it is clear that an industry research report about some covered investment fund types (e.g., emerging growth bonds) may have reasons to include a discussion of issuers that may not be eligible for inclusion in issuer-specific reports (e.g., best-performing new fund), it is not clear that such reasons would rise to the level of requiring the discussion of such issuers. Unlike the effects of an operating company issuer’s on its “industry,” the effects of a covered investment fund issuer on its fund “type” is very limited.

(2) Allowing Affiliates To Appear in Comprehensive List of Recommended Issuers

We considered providing that a comprehensive list of recommended issuers may include issuers that are affiliates of the broker-dealer that is publishing or distributing the research report under certain circumstances, including: If affiliates were identified; if disclosure about the affiliated issuers were limited; or if any performance information included in a list that includes affiliated issuers were presented in accordance with rule 482. Generally, we believe that including such provisions would benefit broker-dealers that play a significant role both as investment advisers to, and as distributors of, covered investment funds. However, as discussed above, we believe that broker-dealers publishing or distributing research reports about affiliated funds would have the potential for the most significant conflicts of interest. Moreover, permitting affiliated funds to be included in such comprehensive lists could result in confusion: broker-dealers would be able to offer recommendations for affiliated funds in industry research reports, but there would be no safe harbor enabling them to publish or distribute issuer-specific research reports (which could provide the basis for such recommendations) as a result of the affiliate exclusion.

In proposed rule 139b, we have chosen not to incorporate these alternative conditions on issuers appearing in industry research reports. As discussed above, we are proposing that a comprehensive list of recommended issuers appearing in an industry research report could not include any covered investment fund that is an affiliate of the broker-dealer, or for which the broker-dealer serves as investment adviser (or is an affiliated person of the investment adviser), as this could implicated the proposed affiliate exclusion. However we are seeking comment on the economic effects of such alternative conditions.

• Do commenters believe that the value of industry research reports about covered investment funds would be adversely affected if discussion of funds not satisfying the conditions applicable to issuer-specific research reports was precluded? If so, under what circumstances?
  • Do commenters believe that the value of industry research reports about covered investment funds would be improved if different conditions were applied to issuers appearing in such reports? If so, which conditions?

• Do commenters believe that allowing affiliated funds to appear in comprehensive lists of recommended issuers would have additional costs or benefits?
  • Do commenters believe that conflicts of interests resulting from an advisory relationship would be likely to affect industry research reports featuring a comprehensive list?

• Do commenters believe that allowing the inclusion of affiliated funds in industry research reports featuring a comprehensive list, when proposed rule 139b would not permit a broker-dealer relying on the safe harbor to publish or distribute an issuer-specific research report about an affiliated fund, would result in investor confusion?

C. Approach to Regular-Course-of-Business Requirement

As discussed in section III.B.3.b, in principle we expect a regular-course-of-business requirement to reduce opportunities for the safe harbor to be used in ways that lead to investor confusion. However, we also believe that in the context of covered investment funds, establishing whether a report is published in the “regular course of business” could present more challenges than in the rule 139 context of research reports about the securities of operating companies. Thus, we considered various alternative approaches to the proposed regular-course-of-business requirements.

Specifically, we have considered that this requirement be defined more specifically to address, for example, circumstances in which a broker-dealer has not previously published or distributed research reports. For example, we considered whether rule 139b should provide a “start-up” period to allow broker-dealers to establish a regular course of business of publishing research reports. We have also considered requiring that the regular-course-of-business requirement incorporate more specific requirements regarding the persons preparing such reports (e.g., that they must be employed by a broker-dealer to prepare such research in the regular course of his or her duties).

Conditioning availability of the safe harbor on a broker-dealer’s having published research reports for a given period of time, or on the broker-dealer having operated for some amount of time, could lead to the publication of reports that are more likely to be recognized as research. Moreover, we believe that broker-dealers with a longer operating history and those who have published research reports—relying on the existing rule 139 safe harbor or otherwise without relying on the safe harbor—will have made greater investments in their reputations. Such investments increase the reputational costs associated with the publication of research reflecting conflicts of interest, which as discussed above could mitigate the effects of conflicts of interest on research reports.

352 See supra section II.B.2.b.
353 See supra section II.B.2.c [requests for comments].
354 See id.
355 See id.
356 See id.
357 See id.
358 See Cheimanur and Fulghieri Article, supra note 282; see also supra section III.C.1.b. However, we note that the efficacy of an institutional reputation mechanism has not found empirical support in related settings. See Fang and Yasuda Article, supra note 281 (where sell-side research analysts’ reputation mitigates manifestation of conflicts of interest from underwriting relationships, while institutional reputation does not).

359 See supra note 130 and accompanying text.
In proposed rule 139b, we have chosen not to incorporate these alternative approaches to the regular-course-of-business requirement. While we note the potential benefits of the approaches outlined above in enhancing the value that covered investment fund research reports may provide investors, we also understand that these alternatives may restrict the flow of relevant information to investors, and we are not proposing more prescriptive approaches to the regular-course-of-business requirement at this time. However, we are seeking comment on the economic effects of such alternative conditions.

- Do commenters believe that these alternative approaches to the regular-course-of-business requirement would result in additional costs and benefits that we have not considered? What is the magnitude of these costs and benefits?

d. Presentation of Performance Information

Given the definition of “research report” under the FAIR Act (and the definition of “research report” that we propose under rule 139b), certain communications by broker-dealers that historically have been treated as advertisements for registered investment companies under rule 482 now could be distributed as covered investment fund research reports under the proposed rule 139b safe harbor. Rule 482 imposes restrictions on the presentation of performance data included in registered open-end investment company advertisements. A covered investment fund research report that is published or distributed by a broker-dealer in reliance on the proposed rule 139b safe harbor would not need to adhere to rule 482’s requirements.

We have also considered the alternative approach of incorporating certain performance presentation standards of rule 482 and/or the guidance factors of rule 156 (concerning misleading statements in investment company sales literature) in the text of rule 139b. We also considered incorporating certain performance presentation requirements for when other performance measures that are not subject to any prescribed method of communication appear in covered investment fund research reports.

We also considered requiring that the methodology used to calculate the registered investment company’s total return or yield be disclosed if these performance measures are not presented in a research report in a manner that is consistent with the requirements in rule 482. We also considered requirements relating to nonrecurring fees and requirements on the timeliness of performance data similar to the requirements for these items in rule 482.

We also considered incorporating the factors set forth in rule 156 (or a subset thereof) into the rule. We also considered a requirement in proposed rule 139b to incorporate general narrative disclosure into a research report about a registered investment company, aimed at reducing potential investor confusion. For example, we could have required such research reports to incorporate a legend stating that the document is a research report and is not subject to the Commission’s regulations applicable to sales and advertising. We also could have required such a research report to incorporate similar disclosure without requiring that it be structured as a legend (which would require the disclosure of similar concepts but would not require any particular wording).

A main benefit associated with an alternative incorporating some or all of the aforementioned provisions into proposed rule 139b is reduced potential for confusion between (i) registered investment company advertisements and selling materials covered by rule 482 and (ii) advertisements or selling materials being recast as research reports. Additionally, incorporating some or all of the aforementioned provisions into proposed rule 139b would reduce potential for investor confusion resulting from divergent standards in the presentation of performance data.

Because fees can represent a significant drag on investment returns, because different performance measures may be more or less favorable at different times, and because retail investors are known to be sensitive to past performance data,
we believe that the manner in which past performance data is presented can be an important factor driving investors’ investment decisions. As discussed above, even unaffiliated broker-dealers may have incentives, stemming from funds’ distribution arrangements, to promote a covered investment fund, or to promote certain funds over others.\textsuperscript{373} When broker-dealers publish or distribute research reports on covered investment funds, their choices with respect to how fees are disclosed, which performance measures are quoted, and for what time periods could be affected by these considerations. This in turn can adversely affect investors, particularly non-sophisticated investors. To the extent that any of the alternative approaches discussed above would limit opportunities for selective performance disclosure, this would curtail opportunities to circumvent the requirements of rule 482.

If opportunities for selective performance disclosure were limited, this also could reduce investor confusion, because there would be fewer opportunities for the performance disclosure in registered investment company advertisements and research reports to diverge. There also could be less potential for investor confusion when comparing research reports about different covered investment funds, or obtained from different broker-dealers. These results would benefit investors. The extent of the benefit would depend on these measures’ effectiveness in ensuring consistent disclosure and/or alerting investors to factors that could influence their understanding of the disclosure in a research report. The extent of the benefit also would depend on the audience who will be reading research reports about registered investment companies. As discussed above, we assume that retail investors would generally be less likely to be able to identify sources of bias (and disregard or discount bias) in communications about covered investment funds than institutional investors and therefore could benefit from limitations on selective performance disclosure.\textsuperscript{374}

The most significant costs associated with this alternative would likely result from its effect on the content of broker-dealers’ research reports. An alternative that limits the prominence afforded to performance measures that are calculated using a methodology that differs from that required under rule 482 could adversely affect broker-dealers’ ability to provide valuable analysis. For example, a broker-dealer who wishes to center its analysis on a fund’s risk-adjusted returns would be limited in how such information could be presented in the report even though certain audiences for research reports could consider this information to be particularly relevant. Investors’ access to potentially relevant and useful analysis could be limited by alternatives such as those discussed in this section. We believe that broker-dealers’ direct compliance costs under these alternative provisions would generally be minimal. For example, if we were to incorporate rule 482’s requirements on the presentation of performance data into proposed rule 139b, we expect that broker-dealers that publish research reports would have processes and systems that could produce charts and tables of the rule-specified performance measures using timely data.\textsuperscript{375}

In proposed rule 139b, we have chosen not to incorporate additional provisions relating to the presentation of performance data, as this approach promotes flexibility for broker-dealers to make different types of information and analysis available to investors. We are seeking commenters’ views on these alternative provisions.

- Do commenters believe that the safe harbor under proposed rule 139b would be used to publish or distribute communications that have traditionally been considered registered investment company advertisements or sales materials subject to rule 482? To what extent? If not, why not? Would this practice to be more prevalent for certain types of broker-dealers or research reports about certain types of registered investment companies? Do commenters believe that imposing additional requirements on the presentation of performance information in research reports that are published or distributed in reliance on the proposed rule 139b safe harbor would result in additional costs and benefits that we have not considered? What is the magnitude of these costs and benefits? If we were to issue guidance relating to the presentation of performance in research reports about registered investment companies that are published or distributed in reliance on the proposed rule 139b safe harbor, would this result in additional costs and benefits that we have not considered? What is the magnitude of these costs and benefits?

\textsuperscript{376} We believe that most broker-dealers that would publish such reports are currently distributing advertisement under rule 482, which are subject to similar requirements. See supra section II.D.1.

IV. Paperwork Reduction Act

We do not believe that the proposed rules would impose any new “collections of information” as defined by the Paperwork Reduction Act of 1995 (“PRA”), 44 U.S.C. 3501 et seq. If we were to adopt rule 139b, what would they create any new filing, reporting, recordkeeping, or disclosure reporting requirements.\textsuperscript{377} Accordingly, we are not submitting the proposed rules to the Office of Management and Budget for review under the PRA.\textsuperscript{377} We request comment on whether our conclusion that there are no collections of information is correct.

V. Regulatory Flexibility Act Analysis

This Initial Regulatory Flexibility Act Analysis has been prepared in accordance with section 3 of the Regulatory Flexibility Act (“RFA”).\textsuperscript{378} It relates to proposed rule 139b, proposed rule 24b–4, and proposed revisions to the rules under the Securities Act and the Exchange Act to implement the FAIR Act.

A. Reasons for, and Objectives of, the Proposed Action

Proposed rule 139b provides that, if certain conditions are satisfied, a broker-dealer’s publication or distribution of a covered investment fund research report would be deemed for purposes of sections 2(a)(10) and 5(c) of the Securities Act not to constitute an offer for sale or offer to sell a security that is the subject of an offering of the covered investment fund, even if the broker-dealer is participating or may participate in a registered offering of the covered investment fund’s securities. Proposed rule 24b–4 provides that a covered investment fund research report about a registered investment company will not be subject to section 24(b) of the Investment Company Act (or the rules and regulations thereunder), except to the extent the research report is otherwise not subject to the content standards in SRO rules related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards. The

\textsuperscript{373} See supra section III.C.1.b.

\textsuperscript{374} But see discussion infra in this section III.C.6.d, discussing the potential benefits of allowing non-standardized information in the total mix of information available to investors, particularly for sophisticated investors.

\textsuperscript{375} As discussed above, certain communications that previously would have been treated as rule 482 advertising prospectuses or rule 34b–1 supplemental sales literature could be considered covered investment fund research reports subject to the proposed rule 139b safe harbor, which could result in a reduction in the information collection burdens for rules 482 and 34b–1. In connection with an extension of a currently approved collection for rules 482 and 34b–1, the Commission will adjust the burdens associated with these collections of information, as appropriate.

\textsuperscript{376} 44 U.S.C. 3507(d) and 5 CFR 1220.11.

\textsuperscript{377} See 5 U.S.C. 603.
proposed revision to paragraph (a) of rule 139 would clarify that rule 139 does not affect the availability of any other exemption or exclusion from sections 2(a)(10) or 5(c) of the Securities Act that may be available to a broker-dealer (as provided, for example, by the provisions of rule 139a or proposed 139b). The proposed revision to rule 101 under Regulation M would be a conforming amendment intended to harmonize treatment of research under the Securities Act and Exchange Act rules by permitting distribution participants under Regulation M, such as brokers-dealers, to publish or disseminate any information, opinion, or recommendation relating to a covered security if the conditions of rule 138, rule 139, or proposed rule 139b under the Securities Act are met. The proposed rules and proposed rule revisions would implement the directives under the FAIR Act to extend the current safe harbor available under rule 139 to broker-dealers’ publication or distribution of covered investment fund research reports. The reasons for, and objectives of, the proposed rules and proposed rule revisions are discussed in more detail in section II above.

B. Legal Basis

We are proposing the rules contained in this document under the authority set forth in the Securities Act, particularly sections 6, 7, 8, 10, 17(a), 19(a), and 28 thereof [15 U.S.C. 77a et seq.]; the Exchange Act, particularly, sections 2, 3, 9(a), 10, 11A(c), 12, 13, 14, 15, 17(a), 23(a), 30, and 36 thereof [15 U.S.C. 78a et seq.]; the Investment Company Act, particularly, sections 6, 23, 24, 30, and 38 thereof [15 U.S.C. 80a et seq.]; and the FAIR Act, particularly, section 2 thereof.

C. Small Entities Subject to the Proposed Rules

The proposed rules would affect broker-dealers that publish or distribute covered investment fund research reports. As such, broker-dealers that are small entities would be affected by the proposed rules. A broker-dealer is a small entity if it has total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to §240.17a-5(d), and it is not affiliated with any person (other than a natural person) that is not a small business or small organization. As of December 31, 2017, the Commission estimates that there were approximately 1,042 broker-dealers that would be considered small entities as defined above. To the extent a small broker-dealer would participate in the activity of publishing or distributing covered investment fund research reports and would seek to rely on the proposed rule 139b safe harbor, it may be affected by our proposal. Generally, we believe larger broker-dealers engage in these activities, but we request comment on whether and how the rules we are proposing today would affect small broker-dealers. We also request comment on the number of small entities that would be impacted by our proposal, including any available empirical data.

D. Reporting, Recordkeeping and Other Compliance Requirements

We believe that there are no reporting, recordkeeping and other compliance requirements with respect to proposed rule 139b and the proposed revision to Regulation M. As such, we believe that there are no attendant costs and administrative burdens for small entities associated with these activities, as they relate to proposed rule 139b and the proposed revision to Regulation M.

Proposed rule 139b would extend the safe harbor under current rule 139 to broker-dealers’ publication or distribution of covered investment fund research reports. As discussed above, rule 139 currently is not available for a broker-dealer’s publication or distribution of research reports about registered investment companies and business development companies. Instead, we understand that a research report or other communication about a covered investment fund that is a registered investment company would ordinarily have to comply with the requirements of Securities Act rule 482. As a result of the FAIR Act, however, communications that historically have been treated as covered investment fund advertisements under rule 482 now could fall under the proposed rule 139b definition of “research report.”

As discussed above, section 24(b) of the Investment Company Act requires registered open-end investment companies to file sales literature addressed to or intended for distribution to prospective investors with the Commission. Section 2(b)(4) of the FAIR Act directs the Commission to provide that a covered investment fund research report shall not be subject to section 24(b) of the Investment Company Act or the rules and regulations thereunder, except that such report may still be subject to 24(b) and the rules and regulations thereunder if it is otherwise not subject to the content standards in the rules of any SRO related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.

Today, registered investment company sales literature, including rule 482 advertisements, are required to be filed with the Commission under section 24(b) of the Investment Company Act. These filings are typically done by broker-dealers’ compliance staff. The Commission proposes to implement section 2(b)(4) of the FAIR Act via proposed rule 24b–4,2 which provides that a covered investment fund research report about a registered investment company shall not be subject to section 24(b) of the Investment Company Act (or the rules and regulations thereunder), unless the research report is not otherwise subject to the content standards in SRO rules related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards. We interpret section 2(b)(4) of the FAIR Act as excluding covered investment fund research reports from section 24(b) of the Investment Company Act so long as they continue to be subject to the general content standards in FINRA rule 2210(d)(1), described above (or substantially similar SRO rules). Thus, covered investment fund research reports, by operation of proposed rule 24b–4, would no longer be subject to...
filing requirements under section 24(b) because they would be subject to the general content standards of FINRA rule 2210(d)(1). Proposed rule 24b–4 would affect broker-dealers that, in lieu of a safe harbor such as that proposed to be provided by rule 139b, would have published or distributed communications styled as “research reports” in compliance with rule 482, which communications would be required to be filed with the Commission subject to section 24(b) of the Investment Company Act. As such, we believe that the administrative costs of broker-dealers that previously filed these communications pursuant to section 24(b) of the Investment Company Act would be reduced. However, large and small broker-dealers would not be affected differently by proposed rule 24b–4.

We encourage written comments regarding this analysis. We solicit comments as to whether the proposed regulation could have an effect that we have not considered. We request that commenters describe the nature of any impact on small entities and provide empirical data to support the extent of the impact.

E. Duplicative, Overlapping, or Conflicting Federal Rules

Although broker-dealers would be unable to rely on the rule 139 safe harbor in publishing or distributing certain communications that could be considered covered investment fund research reports, the existing rule 139 safe harbor may be available for their publication or distribution of research reports for certain covered investment funds, such as commodity- or currency-based trusts or funds that have a class of securities registered under the Exchange Act. As discussed above, the FAIR Act directs us to propose and adopt rule amendments that would extend the current safe harbor available under rule 139 to “covered investment fund research reports.” Proposed rule 139b, which is intended to implement the FAIR Act’s directives, includes all of the entities in the definition of “covered investment fund” that are specified in the FAIR Act’s parallel definition (including some types of entities where, if a broker-dealer were to publish or distribute a research report about that entity, the rule 139 safe harbor could already be available). As a result, in certain circumstances, a broker-dealer publishing or distributing a covered investment fund research report could rely either on rule 139 or proposed rule 139b. In light of this, we have clarified in proposed rule 139b that it provides a non-exclusive safe harbor, and we propose to amend rule 139 to include similar language regarding the non-exclusivity of the safe harbor available under rule 139. Thus, a broker-dealer would be able to rely on proposed rule 139b to publish or distribute a covered investment fund research report, or could choose to rely instead on any other available exemption or exclusion from sections 2(a)(10) or 5(c) of the Securities Act, including those provided by rules 137, 138, and 139, so long as the applicable conditions are satisfied.

F. Significant Alternatives

The RFA directs us to consider significant alternatives that would accomplish the Commission’s stated objectives, while minimizing any significant adverse impact on small entities. In connection with the proposals, we considered the following alternatives: (i) Establishing different compliance or reporting requirements that take into account the resources available to small entities; (ii) exempting broker-dealers that are small entities from certain proposed conditions that must be satisfied in order for the proposed rule 139b safe harbor to be available (e.g., the extent to which the proposed regular-course-of-business requirements would apply to small broker-dealers); (iii) clarifying, consolidating, or simplifying the conditions that must be satisfied for the proposed rule 139b safe harbor to be available for broker-dealers that are small entities; and (iv) using performance rather than design standards.

We do not believe that establishing different compliance and reporting requirements or timetables for broker-dealers that are small entities, or exempting broker-dealers that are small entities from certain proposed conditions, would permit us to achieve our stated objectives. We have considered a variety of approaches to achieve our regulatory objectives and the directives of the FAIR Act. We do not believe that the proposed rules would impose any significant new compliance obligations, because the proposed rules generally reduce the restrictions regarding communications that would be considered covered investment fund research reports.

As discussed above, the FAIR Act directs us to extend the current safe harbor available under rule 139 to broker-dealers’ publication or distribution of covered investment fund research reports, and thus proposed rule 139b’s framework, including its scope and conditions, is modeled after and generally tracks rule 139. Rule 139 does not incorporate conditions that would affect the availability of the rule’s safe harbor differently for broker-dealers that are small (versus large) entities. We likewise do not believe it is necessary or appropriate that proposed rule 139b incorporate conditions that would affect the availability of the proposed rule’s safe harbor differently based on whether a broker-dealer is a small entity. We have considered whether a different regular-course-of-business requirement would help mitigate investor confusion in the case of covered investment fund research reports about registered investment companies, as discussed in more detail above. This could have had the effect of limiting the availability of the proposed rule 139b safe harbor to certain broker-dealers, which in turn could have direct or indirect effects on the availability of the safe harbor to smaller broker-dealers. However, for the reasons discussed above, we are not proposing a regular-course-of-business requirement, in either the proposed rule 139b provisions on issuer-specific research reports or the proposed provisions on industry reports, other than a requirement that tracks the provisions of rule 139 (modified as directed by the FAIR Act).

Nor do we believe that clarifying, consolidating, or simplifying the proposed amendments for small entities would satisfy those objectives. Because proposed rule 139b’s framework (including its scope and conditions) is modeled after and generally tracks rule 139, proposed rule 139b like rule 139 does not treat small broker-dealers differently than large broker-dealers, including by clarifying, consolidating, or simplifying any conditions. Our proposal includes specific requests for comment on whether clarifications to certain proposed rule provisions are necessary or appropriate, and the comments we receive in response could, in certain circumstances, indirectly affect our approach to small entities. For example, we request comment about whether the proposed regular-course-of-business requirement should be

389 See supra section II.D.1.
390 See generally supra section II.A.4.
391 See supra section II.A.3.
392 See supra notes 11–15 and accompanying text.
393 See supra section II.A.4.
394 See supra section II.D.1.
395 See supra paragraph accompanying notes 32–34.
396 See supra section III.C.6.c.
397 See id.
398 See generally supra section II.
modified to address newly-established broker-dealers (which are likely to be small entities).\textsuperscript{399} We also recognize that the guidance that we provide in this release—which is meant to clarify certain of the provisions of the proposed rule—could indirectly affect small entities, and we request comment on the effects of this guidance on small entities. For example, we request comment about whether smaller broker-dealers, or broker-dealers without significant research departments, be most impacted by our guidance on the proposed affiliate exclusion.\textsuperscript{400}

Further, with respect to using performance rather than design standards, the proposed rule generally uses performance standards for all broker-dealers relying on the proposed rule, regardless of size. We believe that providing broker-dealers with the flexibility with respect to the design of covered investment fund research reports that they may publish or distribute in reliance on the proposed rule is appropriate in light of the diversity of entities included in the universe of covered investment funds. We also believe that this approach is appropriate in light of the diverse methodologies that might be taken with respect to research about these entities (particularly because the term “research report” in the FAIR Act and the proposed rule is defined broadly, as discussed above\textsuperscript{401}). However, we note that the proposed rule also uses design standards with respect to certain of its conditions (e.g., the conditions relating to reporting history and minimum public market value that apply to issuers that could appear in an issuer-specific research report). These are substantially similar to design standards used in rule 139, and they would apply with respect to the research reports published or distributed by all broker-dealers relying on the proposed rule, regardless of their size.\textsuperscript{402} For the reasons discussed above, we believe that this use of design standards is appropriate for the furtherance of investor protection, and to help ensure that the proposed rule is not used to circumvent the prospectus requirements of the Securities Act.\textsuperscript{403}

As we consider the comments we receive on our proposal, we will consider the available information to determine whether greater flexibility is warranted, consistent with investor protections.

\textbf{G. General Request for Comment}

The Commission requests comments regarding this analysis. We request comment on the number of small entities that would be subject to the proposed rules and whether the proposed rules would have any effects that have not been discussed. We request that commenters describe the nature of any effects on small entities subject to the proposed rules and provide empirical data to support the nature and extent of such effects.

\textbf{VI. Small Business Regulatory Enforcement Fairness Act}

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (“SBREFA”),\textsuperscript{404} the Commission must advise OMB whether a proposed regulation constitutes a “major” rule. Under SBREFA, a rule is considered “major” where, if adopted, it results in or is likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers or individual industries; or
- Significant adverse effects on competition, investment, or innovation.

We request comment on whether our proposal would be a “major rule” for purposes of SBREFA. We solicit comment and empirical data on:

- The potential effect on the U.S. economy on an annual basis;
- Any potential increase in costs or prices for consumers or individual industries; and
- Any potential effect on competition, investment, or innovation.

Commenters are requested to provide empirical data and other factual support for their views to the extent possible.

\textbf{VII. Statutory Authority}

We are proposing the rules contained in this document under the authority set forth in the Securities Act, particularly sections 4, 7, 8, 10, 17(a), 19(a), and 28 thereof [15 U.S.C. 77a et seq.]; the Exchange Act, particularly, sections 2, 3, 9(a), 10, 11A(c), 12, 13, 14, 15, 17(a), 23(a), 30, and 36 thereof [15 U.S.C. 78a et seq.]; the Investment Company Act, particularly, sections 6, 23, 24, 30, and 38 thereof [15 U.S.C. 80a et seq.]; and the FAIR Act, particularly, section 2 thereof.

\textbf{List of Subjects}

\textit{17 CFR Part 230}

Advertising, Confidential business information, Investment companies, Reporting and recordkeeping requirements, Securities.

\textit{17 CFR Part 242}

Brokers, Fraud, Reporting and recordkeeping requirements, Securities.

\textit{17 CFR Part 270}

Confidential business information, Fraud, Investment companies, Life insurance, Reporting and recordkeeping requirements, Securities.

\textbf{Text of Proposed Rules and Amendments}

For the reasons set out in the preamble, title 17, chapter II of the Code of the Federal Regulations is proposed to be amended as follows.

\textbf{PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933}

\begin{itemize}
\item 1. The authority citation for part 230 continues to read, in part, as follows:
\textit{Authority:} 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77h, 77i, 77j, 77k, 77t, 77u, 77v, 77w, 78a, 78b, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78p, 78q–7 note, 78t, 78v, 78w(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.
\end{itemize}

\begin{itemize}
\item 2. Amend § 230.139 by revising the introductory text of paragraph (a) to read as follows:
\end{itemize}

\textbf{§ 230.139 Publications or distributions of research reports by brokers or dealers distributing securities.}

\begin{itemize}
\item (a) Registered offerings. Under the conditions of paragraph (a)(1) or (2) of this section, a broker’s or dealer’s publication or distribution of a research report about an issuer or any of its securities shall be deemed for purposes of sections 2(a)(10) and 5(c) of the Act not to constitute an offer for sale or offer to sell a security that is the subject of an offering pursuant to a registration statement that the issuer proposes to file, or has filed, or that is effective, even if the broker or dealer is participating or will participate in the registered offering of the issuer’s securities. For purposes of the Fair Access to Investment Research Act of 2017 [Pub. L. 115–66, 131 Stat. 1196 (2017)], a safe harbor has been established for covered investment fund research reports, and the specific terms of that safe harbor are set forth in § 230.139b.
\end{itemize}
§ 230.139b  Publications or distributions of covered investment fund research reports by brokers or dealers distributing securities.

(a) Registered offerings. Under the conditions of paragraph (a)(1) or (2) of this section, the publication or distribution of a covered investment fund research report by a broker or dealer that is not an investment adviser to the covered investment fund and is not an affiliated person of the investment adviser to the covered investment fund shall be deemed for purposes of sections 2(a)(10) and 5(c) of the Act not to constitute an offer for sale or offer to sell a security that is the subject of an offering pursuant to a registration statement of the covered investment fund that is effective, even if the broker or dealer is participating or may participate in the registered offering of the covered investment fund’s securities. This section does not affect the availability of any other exemption or exclusion from sections 2(a)(10) or 5(c) of the Act available to the broker or dealer.

(1) Issuer-specific research reports. (i) At the date of reliance on this section: (A) The covered investment fund: (1) Has been subject to the reporting requirements of section 30 of the Investment Company Act of 1940 (the “Investment Company Act”) (15 U.S.C. 80a-29) for a period of at least 12 calendar months and has filed in a timely manner all of the reports required, as applicable, to be filed for the immediately preceding 12 calendar months on Forms N–CSR (§§ 249.331 and 274.128 of this chapter), N–SAR (§§ 249.330 and 274.101 of this chapter), N–Q (§§ 249.332 and 274.130 of this chapter), N–PORT (§ 274.150 of this chapter), N–MFP (§ 274.201 of this chapter), and N–CEN (§§ 249.330 and 274.101 of this chapter) pursuant to section 30 of the Investment Company Act; or

(2) If the covered investment fund is not a registered investment company under the Investment Company Act, has been subject to the reporting requirements of section 13 or section 15(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) (15 U.S.C. 78m or 78d) for a period of at least 12 calendar months and has filed in a timely manner all of the reports required to be filed for the immediately preceding 12 calendar months on Forms 10–K (§ 249.310 of this chapter) and 10–Q (§ 249.308a of this chapter), or 20–F (§ 249.220f of this chapter) pursuant to section 13 or section 15(d) of the Exchange Act; and

(b) The aggregate market value of voting and non-voting common equity hold by non-affiliates of the covered investment fund, or, in the case of a registered open-end investment company (other than an exchange-traded fund) its net asset value (subtracting the value of shares held by affiliates), equals or exceeds the aggregate market value specified in General Instruction I.B.1 of Form S–3; and

(ii) The broker or dealer publishes or distributes research reports in the regular course of its business and, in the case of a research report regarding a covered investment fund that does not have a class of securities in substantially continuous distribution, such publication or distribution does not represent the initiation of publication of research reports about such covered investment fund or its securities or reinitiation of such publication following discontinuation of publication of such research reports.

(2) Industry reports. (i) The covered investment fund is subject to the reporting requirements of section 30 of the Investment Company Act (15 U.S.C. 80a–29) or, if the covered investment fund is not a registered investment company under the Investment Company Act, is subject to the reporting requirements of section 13 or section 15(d) of the Exchange Act (15 U.S.C. 78m or 78d); and

(ii) The research report: (A) Includes similar information with respect to a substantial number of covered investment fund issuers of the issuer’s type (e.g., money market fund, bond fund, balanced fund, etc.), or investment focus (e.g., primarily invested in the same industry or sub-industry, or the same country or geographic region); or

(B) Contains a comprehensive list of covered investment fund securities currently recommended by the broker or dealer (other than securities of a covered investment fund that is an affiliate of the broker or dealer, or for which the broker or dealer serves as investment adviser (or for which the broker or dealer is an affiliated person of the investment adviser));

(iii) The analysis regarding the covered investment fund issuer or its securities is given no materially greater space or prominence in the publication than that given to other covered investment fund issuers or securities; and

(iv) The broker or dealer publishes or distributes research reports in the regular course of its business and, at the time of the publication or distribution of the research report (in the case of a research report regarding a covered investment fund that does not have a class of securities in substantially continuous distribution), is including similar information about the issuer or its securities in similar reports.

(b) Self-regulatory organization rules. A self-regulatory organization shall not maintain or enforce any rule that would prohibit the ability of a member to publish or distribute a covered investment fund research report solely because the member is also participating in a registered offering or other distribution of any securities of such covered investment fund; or to participate in a registered offering or other distribution of securities of a covered investment fund solely because the member has published or distributed a covered investment fund research report about such covered investment fund or its securities. For purposes of section 19(b) of the Exchange Act (15 U.S.C. 78s(b)), this paragraph (b) shall be deemed a rule under that Act.

(c) Definitions. For purposes of this section:

(1) “Affiliated person” has the meaning given the term in section 2(a) of the Investment Company Act.

(2) “Covered investment fund” means:

(i) An investment company (or a series or class thereof) registered under, or that has filed an election to be treated as a business development company under, the Investment Company Act and that has filed a registration statement under the Act for the public offering of a class of its securities, which registration statement has been declared effective by the Commission; or

(ii) A trust or other person: (A) Issuing securities in an offering registered under the Act and which class of securities is listed for trading on a national securities exchange;

(B) The assets of which consist primarily of commodities, currencies, or derivative instruments that reference commodities or currencies, or interests in the foregoing; and

(C) That provides in its registration statement under the Act that a class of its securities are purchased or redeemed, subject to conditions or limitations, for a ratable share of its assets.

(3) “Covered investment fund research report” means a research report published or distributed by a broker or dealer about a covered investment fund or any securities issued by the covered investment fund, but does not include a research report to the extent that the research report is published or distributed by the covered investment fund.
fund or any affiliate of the covered investment fund, or any research report published or distributed by any broker or dealer that is an investment adviser (or any affiliated person of an investment adviser) for the covered investment fund.

(4) “Exchange-traded fund” has the meaning given the term in General Instruction A to Form N–1A (§§ 239.15A and 274.11A of this chapter).

(5) “Investment adviser” has the meaning given the term in section 2(a) of the Investment Company Act.

(6) “Research report” means a written communication, as defined in § 230.405 that includes information, opinions, or recommendations with respect to securities of an issuer or an analysis of a security or an issuer, whether or not it provides information reasonably sufficient upon which to base an investment decision.

4. Effective May 1, 2020, amend § 230.139b by removing “N–Q (§§ 249.332 and 274.130 of this chapter),” in paragraph (a)(1)(i)(A)(1).

PART 242—REGULATIONS M, SHO, ATS, AC, NMS, AND SBSR AND CUSTOMER MARGIN REQUIREMENTS FOR SECURITY FUTURES

5. The authority citation for part 242 continues to read as follows:

Authority: 15 U.S.C. 77g, 77q(a), 77s(a), 78b, 78c, 78g(c)(2), 78i(a), 78j, 78k–1(c), 78l, 78m, 78n, 78o(b), 78o(c), 78o(g), 78q(a), 78q(b), 78q(h), 78w(a), 78dd–1, 78mm, 80a–23, 80a–29, and 80a–37.

6. Section 242.101 is amended by revising paragraph (b)(1) to read as follows:

§ 242.101. Activities by distribution participants.

(b) * * * * * *(1) Research. The publication or dissemination of any information, opinion, or recommendation, if the conditions of § 230.138, § 230.139, or § 230.139b of this chapter are met; or *

PART 270—RULE AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

7. The authority citation for part 270 continues to read, in part, as follows:


8. Add § 270.24b–4 to read as follows:

§ 270.24b–4 Filing copies of covered investment fund research reports.

A covered investment fund research report, as defined in paragraph (c)(3) of § 230.139b of this chapter under the Securities Act of 1933 (15 U.S.C. 77a et seq.), of a covered investment fund registered as an investment company under the Investment Company Act, shall not be subject to section 24(b) of the Act or the rules and regulations thereunder, except that such report shall be subject to such section and the rules and regulations thereunder to the extent that it is otherwise not subject to the content standards in the rules of any self-regulatory organization related to research reports, including those contained in the rules governing communications with the public regarding investment companies or substantially similar standards.

By the Commission.


Brent J. Fields,
Secretary.

[FR Doc. 2018–11497 Filed 6–7–18; 8:45 am]

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<td>This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at <a href="http://www.archives.gov/federal-register/laws">http://www.archives.gov/federal-register/laws</a>. The text of laws is not published in the Federal Register but may be ordered in “slip law” (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO’s Federal Digital System (FDsys) at <a href="http://www.gpo.gov/fdsys">http://www.gpo.gov/fdsys</a>. Some laws may not yet be available.</td>
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**S. 292/P.L. 115–180**  
Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018 (June 5, 2018; 132 Stat. 1382)

**S. 1282/P.L. 115–181**  
To redesignate certain clinics of the Department of Veterans Affairs located in Montana. (June 5, 2018; 132 Stat. 1391)

**S. 2372/P.L. 115–182**  

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