suspension of a Copyright Office electronic system, that has delayed the receipt by the Copyright Office of applications, fees, deposits, or any other materials, the Register shall publish an announcement of that determination, stating the date on which the disruption or suspension commenced. The announcement may, if appropriate, limit the means of delivery that are subject to relief pursuant to section 709. Following the cessation of the disruption or suspension of services, the Register shall publish an announcement stating the date on which the disruption or suspension has terminated, and may provide specific instructions on how to make a request under paragraph (b)(1) of this section.

(b) *Request for earlier filing date due to disruption*—(1) *When the Register has declared a disruption.* When the Register has made a declaration of disruption under paragraph (a) of this section, any person who, in compliance with any instructions provided by the Register, provides satisfactory evidence as described in paragraph (e) of this section that he or she attempted to deliver an application, fee, deposit, or other material to the Copyright Office, but that receipt by the Copyright Office was delayed due to a general disruption or suspension of postal or other transportation or communications services announced under paragraph (a), shall be assigned, as the date of receipt of the application, fee, deposit, or other material, the date on which the Register determines the material would have been received but for the disruption or suspension of services, so long as the application, fee, deposit, or other material was actually received in the Copyright Office within one month after the date the Register identifies pursuant to paragraph (a) of this section that disruption or suspension of services has terminated. Such requests should be mailed to the address specified in § 201.1(c)(1), or through any other delivery method the Register specifies in a published announcement under paragraph (a) of this section.

(2) *With respect to disruption affecting specific submission.* In the absence of a declaration of disruption under paragraph (a) of this section, any person who provides satisfactory evidence as described in paragraph (e) of this section that he or she physically delivered or attempted to physically deliver an application, fee, deposit, or other material to the Copyright Office, but that the Office did not receive that material or that it was lost or misplaced by the Office after its delivery to the Office, shall be assigned, as the date of receipt, the date that the Register determines that the material was received or would have been received. Such requests may be mailed to the address specified in § 201.1(c)(1), or through any other delivery method specified by the Copyright Office.

(c) *Timing.* (1) A request under paragraph (b)(1) of this section shall be made no earlier than the date on which the Register publishes the announcement under paragraph (a) of this section declaring that the disruption or suspension has terminated, and no later than one year after the publication of that announcement.

(2) A request under paragraph (b)(2) of this section shall be made no later than one year after the person physically delivered or attempted to physically deliver the application, fee, deposit, or other material to the Copyright Office.

(d) *Return of certificate.* In cases where a certificate of registration or a certificate of recordation has already been issued, the original certificate must be returned to the Copyright Office along with the request under paragraph (b) of this section.

(e) *Satisfactory evidence.* In all cases the Register shall have discretion in determining whether materials submitted with a request under paragraph (b) of this section constitute satisfactory evidence. For purposes of paragraph (b) of this section, satisfactory evidence may include:

(1) A receipt from the United States Postal Service indicating the date on which the United States Postal Service received material for delivery to the Copyright Office by means of first class mail, Priority Mail, or Express Mail;

(2) A receipt from a delivery service such as, or comparable to, United Parcel Service, Federal Express, or Airborne Express, indicating the date on which the delivery service received material for delivery to the Copyright Office; and

(i) The date on which delivery was to be made to the Copyright Office, or

(ii) The period of time (*e.g.,* overnight, or two days) from receipt by the delivery service to the date on which delivery was to be made to the Copyright Office;

(3) A statement under penalty of perjury, pursuant to 28 U.S.C. 1746, from a person with actual knowledge of the facts relating to the attempt to deliver the material to the Copyright Office, setting forth with particularity facts which satisfy the Register that in the absence of the general disruption or suspension of postal or other transportation or communications services, including a disruption or suspension of a Copyright Office electronic system, or but for the misdelivery, misplacement, or loss of materials sent to the Copyright Office, the material would have been received by the Copyright Office by a particular date; or

(4) Other documentary evidence which the Register deems equivalent to the evidence set forth in paragraphs (e)(1) and (2) of this section.

(f) *Presumption of receipt.* For purposes of paragraph (b) of this section, the Register shall presume that but for the general disruption or suspension of postal or other transportation or communications services, including a disruption or suspension of a Copyright Office electronic system, or but for the misdelivery, misplacement, or loss of materials sent to the Copyright Office:

* * * * *

(4) Materials deposited with a delivery service such as, or comparable to, United Parcel Service, Federal Express, or Airborne Express, would have been received in the Copyright Office on the date indicated on the receipt from the delivery service;

(5) Materials submitted or attempted to be submitted through a Copyright Office electronic system would have been received in the Copyright Office on the date the attempt was made. If it is unclear when an attempt was made, the Register will determine the effective date of receipt on a case-by-case basis.

Dated: May 11, 2017.

Karyn Temple Claggett,

Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2017–10218 Filed 5–18–17; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–HQ–OAR–2012–0918; FRL–9962–89–OAR]

RIN 2060–AT44

Air Quality Designations for the 2012 Primary Annual Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) for Areas in Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is establishing air quality designations in the United States (U.S.)

for the 2012 primary annual fine particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) for the remaining undesignated areas in the state of Tennessee. When the EPA designated the majority of areas in the country in December 2014, and March 2015, the EPA deferred initial area designations for several locations, including all of the state of Tennessee except three counties in the Chattanooga area, because the EPA could not determine using available data whether the areas were meeting or not meeting the NAAQS. However, we believed that forthcoming data in 2015 would allow the EPA to make that determination. Tennessee has now submitted complete, quality-assured, and certified air quality monitoring data for 2015 for the areas identified in this document, and based on these data, the EPA is designating these areas as unclassifiable/attainment for the 2012 primary annual $PM_{2.5}$ NAAQS.

DATES: This final rule is effective on June 19, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2012–0918. All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or in hard copy at the EPA Docket Center, William Jefferson Clinton West Building, Room 3334, 1301 Constitution Avenue 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 Docket is (202) 566–1742.

In addition, the EPA has established a Web site for the rulemakings to initially designate areas for the 2012 primary annual $PM_{2.5}$ NAAQS at: *https://www3.epa.gov/pmdesignations/2012standards/index.htm.* This Web site includes the EPA's final $PM_{2.5}$ designations, as well as state and tribal initial recommendation letters, the EPA's modification letters, technical support documents, responses to comments and other related technical information.

FOR FURTHER INFORMATION CONTACT: For general questions concerning this action, please contact Carla Oldham, U.S. EPA, Office of Air Quality Planning and Standards, Air Quality Planning Division, C539–04, Research Triangle Park, North Carolina 27711, telephone (919) 541–3347, email at *oldham.carla@epa.gov.* The Region 4 contact is Madolyn Sanchez, U.S. EPA, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960, telephone (404) 562–9644, email at *sanchez.madolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 2012, the EPA promulgated a revised primary annual $PM_{2.5}$ NAAQS to provide increased protection of public health from fine particle pollution (78 FR 3086; January 15, 2013). In that action, the EPA strengthened the primary annual $PM_{2.5}$ standard from 15.0 micrograms per cubic meter ($\mu g/m^3$) to 12.0 $\mu g/m^3$, which is attained when the 3-year average of the annual arithmetic means does not exceed 12.0 $\mu g/m^3$. Section 107(d) of the Clean Air Act (CAA), 42 U.S.C. 7407(d), governs the process for initial area designations after the EPA establishes a new or revised NAAQS. Under CAA section 107(d), each governor is required to, and each tribal leader may, if they so choose, recommend air quality designations to the EPA by a date that cannot be later than 1 year after the promulgation of a new or revised NAAQS. The EPA considers these recommendations as part of its duty to promulgate the area designations and boundaries for the new or revised NAAQS. If, after careful consideration of these recommendations, the EPA believes that it is necessary to modify a state's recommendation and intends to promulgate a designation different from a state's recommendation, the EPA must notify the state at least 120 days prior to promulgating the final designation and the EPA must provide the state an opportunity to demonstrate why any proposed modification is inappropriate. These modifications may relate either to an area's designation or to its boundaries.

On December 18, 2014, the Administrator of the EPA signed a final action promulgating initial designations for the 2012 primary $PM_{2.5}$ NAAQS based on 2011–2013-air quality monitoring data for the majority of the U.S., including areas of Indian country (80 FR 2206; January 15, 2015). In that action, the EPA also deferred initial area designations for several areas where available data, including air quality monitoring data, were insufficient to determine whether the areas met or did not meet the NAAQS, but where forthcoming data were likely to result in complete and valid air quality data sufficient to determine whether these areas meet the NAAQS. Accordingly, the EPA stated that it would use the additional time available as provided under section 107(d)(1)(B) of the CAA to assess relevant information and subsequently promulgate initial designations for the identified areas through a separate rulemaking action or actions. The deferred areas included the entire state of Tennessee, except three counties in the Chattanooga area; several areas in the state of Georgia, including two neighboring counties in the bordering states of Alabama and South Carolina; the entire state of Florida; and areas of Indian country located in these areas.

In separate actions published on April 15, 2015 (80 FR 18535), and September 6, 2016 (81 FR 61136), the EPA completed designations of unclassifiable/attainment for all remaining deferred areas in the state of Georgia (including two neighboring counties in the bordering states of Alabama and South Carolina) and 62 counties in the state of Florida, including areas of Indian country located in those areas.

II. Purpose and Designation Decisions Based on 2013–2015 Data

The purpose of this action is to announce and promulgate initial area designations of unclassifiable/attainment for the 2012 $PM_{2.5}$ NAAQS for the remaining 92 counties in the state of Tennessee.[1] All of the areas at issue in this action were initially deferred in the EPA's January 15, 2015, rulemaking.[2] Since then, the state of Tennessee submitted to the EPA complete, quality-assured, and certified air quality monitoring data from 2013–2015 for these deferred areas. These data provide the EPA with sufficient information to promulgate initial designations for the remaining undesignated areas in the state of Tennessee in this action. Air quality data collected and submitted to the EPA

[1] The 3 previously designated unclassifiable/attainment counties in the Chattanooga area are Hamilton County, Marion County and Sequatchie County.

[2] *See* also the technical support document for the deferred Tennessee areas in the rulemaking docket, document numbered EPA–HQ–OAR–2012–0918–0325.

for 2013–2015 for these areas indicate that the areas are attaining the 2012 $PM_{2.5}$ NAAQS and are not causing or contributing to a violation of the NAAQS in a nearby area. Therefore, the EPA is designating the remaining 92 undesignated counties in the state of Tennessee as unclassifiable/attainment. This designation is consistent with Tennessee's recommended area designations and boundaries for these areas for the 2012 $PM_{2.5}$ standard. The table at the end of this final rule (amendments to 40 CFR 81.343—Tennessee) lists all areas for which the EPA has promulgated an initial designation in Tennessee. There are no areas of Indian country covered by this action.

III. Environmental Justice Considerations

When the EPA establishes a new or revised NAAQS, the CAA requires the EPA to designate all areas of the U.S. as either nonattainment, attainment, or unclassifiable. The EPA provided a meaningful opportunity for members of the public to participate in the development of the 2012 primary annual $PM_{2.5}$ standard that underlies the present action, including conducting an outreach and information call with environmental justice organizations on August 9, 2012.

As part of the process of reviewing the PM air quality criteria and revising the primary annual $PM_{2.5}$ standard, the EPA identified persons from lower socioeconomic strata as an at-risk population for PM-related health effects. As a result, the EPA carefully evaluated the potential impacts on low-income and minority populations. Based on this evaluation and consideration of public comments, the EPA eliminated spatial averaging provisions as part of the form of the primary annual $PM_{2.5}$ standard in order to avoid potential disproportionate impacts on at-risk populations, including populations from lower socioeconomics strata. *See* 78 FR at 3267 (January 15, 2013).

This final action addresses designation determinations for certain areas in Tennessee based on that 2012 primary annual $PM_{2.5}$ standard. The CAA requires the EPA to determine through a designation process whether an area meets or does not meet any new or revised national primary or secondary ambient air quality standard. The promulgation of area designations facilitates public understanding and awareness of the air quality in an area. For this action, the complete and valid monitoring data from Tennessee indicate that all affected areas are meeting the NAAQS. Furthermore, no area affected by this action is contributing to a NAAQS violation in a nearby area.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is exempt from review by the Office of Management and Budget because it responds to the CAA requirement to promulgate air quality designations after promulgation of a new or revised NAAQS.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action fulfills the non-discretionary duty for the EPA to promulgate air quality designations after promulgation of a new or revised NAAQS and does not contain any information collection activities.

C. Regulatory Flexibility Act (RFA)

This designation action under CAA section 107(d) is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. Section 107(d)(2)(B) of the CAA explicitly provides that designations are exempt from the notice and comment provisions of the APA. In addition, designations under section 107(d) are not among the list of actions that are subject to the notice and comment procedures of CAA section 307(d).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action implements mandates specifically and explicitly set forth in the CAA for the 2012 $PM_{2.5}$ NAAQS (40 CFR 50.18). The CAA establishes the process whereby states take primary responsibility for developing plans, where required, to meet the 2012 $PM_{2.5}$ NAAQS.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have a 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.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Government

This action does not have tribal implications. It will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. Areas of Indian country are not being designated as part of this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. 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 a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this determination is contained in Section III of this preamble, ''Environmental Justice Considerations.''

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the U.S. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Judicial Review

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final

actions by the EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit: (i) When the agency action consists of ''nationally applicable regulations promulgated, or final actions taken by the Administrator,'' or (ii) when 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.''

This final action, in conjunction with the previous final actions designating areas across the U.S. for the 2012 annual $PM_{2.5}$ NAAQS, is ''nationally applicable'' within the meaning of section 307(b)(1). At the core of this final action is the EPA's interpretations of the definitions of nonattainment, attainment and unclassifiable under section 107(d)(1) of the CAA, and its application of those interpretations to areas across the country. For the same reasons, the Administrator is also determining that the final designations are of nationwide scope and effect for the purposes of section 307(b)(1). This is particularly appropriate because, in the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that an action is of ''nationwide scope or effect'' would be appropriate for any action that has a scope or effect beyond a single judicial circuit. H.R. Rep. No. 95–294 at 323, 324, *reprinted* in 1977 U.S.C.C.A.N. 1402–03. Here, the scope and effect of this final action extends to numerous judicial circuits since the designations relate to the designations for areas across the country. In these circumstances, section 307(b)(1) and its legislative history calls for the Administrator to find the action to be of ''nationwide scope or effect'' and for venue to be in the D.C. Circuit.

Thus, any petitions for review of final designations must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date final action is published in the **Federal Register**.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: May 10, 2017.

E. Scott Pruitt,

Administrator.

For the reasons set forth in the preamble, 40 CFR part 81 is amended as follows:

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 2. Section 81.343 is amended by revising the table entitled ''Tennessee—2012 Annual $PM_{2.5}$ NAAQS [Primary]'' to read as follows:

§ 81.343 Tennessee.

* * * * *

TENNESSEE—2012 ANNUAL $PM_{2.5}$ NAAQS

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Statewide:				
Anderson County		Unclassifiable/Attainment.		
Bedford County		Unclassifiable/Attainment.		
Benton County		Unclassifiable/Attainment.		
Bledsoe County		Unclassifiable/Attainment.		
Blount County		Unclassifiable/Attainment.		
Bradley County		Unclassifiable/Attainment.		
Campbell County		Unclassifiable/Attainment.		
Cannon County		Unclassifiable/Attainment.		
Carroll County		Unclassifiable/Attainment.		
Carter County		Unclassifiable/Attainment.		
Cheatham County		Unclassifiable/Attainment.		
Chester County		Unclassifiable/Attainment.		
Claiborne County		Unclassifiable/Attainment.		
Clay County		Unclassifiable/Attainment.		
Cocke County		Unclassifiable/Attainment.		
Coffee County		Unclassifiable/Attainment.		
Crockett County		Unclassifiable/Attainment.		
Cumberland County		Unclassifiable/Attainment.		
Davidson County		Unclassifiable/Attainment.		
Decatur County		Unclassifiable/Attainment.		
DeKalb County		Unclassifiable/Attainment.		
Dickson County		Unclassifiable/Attainment.		
Dyer County		Unclassifiable/Attainment.		
Fayette County		Unclassifiable/Attainment.		
Fentress County		Unclassifiable/Attainment.		
Franklin County		Unclassifiable/Attainment.		
Gibson County		Unclassifiable/Attainment.		
Giles County		Unclassifiable/Attainment.		
Grainger County		Unclassifiable/Attainment.		
Greene County		Unclassifiable/Attainment.		
Grundy County		Unclassifiable/Attainment.		
Hamblen County		Unclassifiable/Attainment.		
Hamilton County	April 15, 2015	Unclassifiable/Attainment.		
Hancock County		Unclassifiable/Attainment.		

TENNESSEE—2012 ANNUAL $PM_{2.5}$ NAAQS—Continued

[Primary]

Designated area [1]	Designation		Classification	
	Date [2]	Type	Date [2]	Type
Hardeman County		Unclassifiable/Attainment.		
Hardin County		Unclassifiable/Attainment.		
Hawkins County		Unclassifiable/Attainment.		
Haywood County		Unclassifiable/Attainment.		
Henderson County		Unclassifiable/Attainment.		
Henry County		Unclassifiable/Attainment.		
Hickman County		Unclassifiable/Attainment.		
Houston County		Unclassifiable/Attainment.		
Humphreys County		Unclassifiable/Attainment.		
Jackson County		Unclassifiable/Attainment.		
Jefferson County		Unclassifiable/Attainment.		
Johnson County		Unclassifiable/Attainment.		
Knox County		Unclassifiable/Attainment.		
Lake County		Unclassifiable/Attainment.		
Lauderdale County		Unclassifiable/Attainment.		
Lawrence County		Unclassifiable/Attainment.		
Lewis County		Unclassifiable/Attainment.		
Lincoln County		Unclassifiable/Attainment.		
Loudon County		Unclassifiable/Attainment.		
McMinn County		Unclassifiable/Attainment.		
McNairy County		Unclassifiable/Attainment.		
Macon County		Unclassifiable/Attainment.		
Madison County		Unclassifiable/Attainment.		
Marion County	April 15, 2015	Unclassifiable/Attainment.		
Marshall County		Unclassifiable/Attainment.		
Maury County		Unclassifiable/Attainment.		
Meigs County		Unclassifiable/Attainment.		
Monroe County		Unclassifiable/Attainment.		
Montgomery County		Unclassifiable/Attainment.		
Moore County		Unclassifiable/Attainment.		
Morgan County		Unclassifiable/Attainment.		
Obion County		Unclassifiable/Attainment.		
Overton County		Unclassifiable/Attainment.		
Perry County		Unclassifiable/Attainment.		
Pickett County		Unclassifiable/Attainment.		
Polk County		Unclassifiable/Attainment.		
Putnam County		Unclassifiable/Attainment.		
Rhea County		Unclassifiable/Attainment.		
Roane County		Unclassifiable/Attainment.		
Robertson County		Unclassifiable/Attainment.		
Rutherford County		Unclassifiable/Attainment.		
Scott County		Unclassifiable/Attainment.		
Sequatchie County	April 15, 2015	Unclassifiable/Attainment.		
Sevier County		Unclassifiable/Attainment.		
Shelby County		Unclassifiable/Attainment.		
Smith County		Unclassifiable/Attainment.		
Stewart County		Unclassifiable/Attainment.		
Sullivan County		Unclassifiable/Attainment.		
Sumner County		Unclassifiable/Attainment.		
Tipton County		Unclassifiable/Attainment.		
Trousdale County		Unclassifiable/Attainment.		
Unicoi County		Unclassifiable/Attainment.		
Union County		Unclassifiable/Attainment.		
Van Buren County		Unclassifiable/Attainment.		
Warren County		Unclassifiable/Attainment.		
Washington County		Unclassifiable/Attainment.		
Wayne County		Unclassifiable/Attainment.		
Weakley County		Unclassifiable/Attainment.		
White County		Unclassifiable/Attainment.		
Williamson County		Unclassifiable/Attainment.		
Wilson County		Unclassifiable/Attainment.		

[1] Includes areas of Indian country located in each county or area, if any, except as otherwise specified.
[2] This date is June 19, 2017, unless otherwise noted.

* * * * *

[FR Doc. 2017–10245 Filed 5–18–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule; further delay of effective date.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), referred to as the ''340B Drug Pricing Program'' or the ''340B Program.'' HRSA published a final rule on January 5, 2017, that set forth the calculation of the ceiling price and application of civil monetary penalties. The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. In accordance with a January 20, 2017, memorandum from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' HRSA issued an interim final rule that delayed the effective date of the final rule published in the **Federal Register** (82 FR 1210, (January 5, 2017)) to May 22, 2017. HHS invited commenters to provide their views on whether a longer delay of the effective date to October 1, 2017, would be more appropriate. After consideration of the comments received on the interim final rule, HHS is delaying the effective date of the January 5, 2017 final rule, to October 1, 2017.

DATES: As of May 19, 2017, the effective date of the final rule published in the **Federal Register** (82 FR 1210, (January 5, 2017)) is further delayed to October 1, 2017.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

In September 2010, HHS published an advanced notice of proposed rulemaking (ANPRM) in the **Federal Register**, ''340B Drug Pricing Program Manufacturer Civil Monetary Penalties'' (75 FR 57230, (September 20, 2010)). HHS subsequently published a notice of proposed rulemaking (NPRM) in June 2015 to implement civil monetary penalties (CMPs) for manufacturers who knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis; and to establish the requirement that a manufacturer charge a $.01 (penny pricing policy) for drugs when the ceiling price calculation equals zero (80 FR 34583, (June 17, 2015)). The public comment period closed August 17, 2015, and HRSA received 35 comments. After review of the initial comments, HHS reopened the comment period (81 FR 22960, (April 19, 2016)) to invite additional comments on the following areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers use when estimating the ceiling price for a new covered outpatient drug; and the definition of the ''knowing and intentional'' standard to be applied when assessing a CMP for manufacturers that overcharge a covered entity. The comment period closed May 19, 2016, and HHS received 72 comments.

On January 5, 2017, HHS published a final rule in the **Federal Register** (82 FR 1210, (January 5, 2017)) and comments from both the NPRM and the reopening notice were considered in the development of the final rule. The provisions of that rule were to be effective March 6, 2017; however, HHS issued a subsequent final rule (82 FR 12508, (March 6, 2017)) delaying the effective date to March 21, 2017, in accordance with a January 20, 2017 memorandum from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review.'' [1] In the January 5, 2017 final rule, HHS recognized that the effective date fell during the middle of a quarter and stakeholders needed time to adjust systems and update their policies and procedures. As such, HHS stated that it intended to enforce the requirements of the final rule at the start of the next quarter, which began April 1, 2017.

After further consideration and to provide affected parties sufficient time to make needed changes to facilitate compliance, and because there were questions raised, HHS issued an interim final rule (82 FR 14332, (March 20, 2017)) to delay the effective date of the final rule to May 22, 2017, and solicited additional comment on whether that date should be further delayed to October 1, 2017. HHS received a number of comments on the interim final rule both supporting and opposing the delay of the effective date to May 22, 2017, or alternatively to October 1, 2017. After careful consideration of the comments received, HHS has decided to delay the effective date of the January 5, 2017 final rule to October 1, 2017. As the effective date of the final rule has been changed to October 1, 2017, enforcement will be correspondingly delayed to October 1, 2017. HHS continues to believe that the delay of the effective date provides regulated entities sufficient time to implement the requirements of the rule.

Section 553(d) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) requires that Federal agencies provide at least 30 days after publication of a final rule in the **Federal Register** before making it effective, unless good cause can be found not to do so. HHS finds that there is good cause for making this final rule effective less than 30 days after publication in the **Federal Register** given that failure to do so would result in the final rule published on January 5, 2017, going into effect for several weeks, before having a delayed effective date of October 1, 2017. To preclude this uncertainty in the marketplace and to ease the burdens on all stakeholders, HHS believes that a clear effective date is an important goal and one that becomes particularly important when it is paired with potential civil monetary penalties. The additional time provided to the public before the rule takes effect constitutes an extra quarter and will assist stakeholders in preparing to comply with these new program requirements.

II. Analysis and Responses to Public Comments

In the interim final rule, we solicited comments regarding whether HHS should delay the January 5, 2017 final rule to May 22, 2017, or alternatively to October 1, 2017. We received a broad range of 51 comments from covered entities, manufacturers, and groups representing these stakeholders. In this final rule, we will only be responding to comments related to whether HHS should delay the January 5, 2017 final rule to May 22, 2017, or to October 1, 2017. Comments that raised issues beyond the narrow scope of the interim final rule, including comments related to withdrawal of the rule or comments related to policy matters, were not

[1] See: *https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.*