

TABLE 1 TO § 165.1191

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7. San Francisco Independence Day Fireworks

Table with 2 columns: Field Name and Description. Fields include Sponsor, Event Description, Date, Location 1, Location 2, Regulated Area 1, and Regulated Area 2.

8. Fourth of July Fireworks, Berkeley Marina

Table with 2 columns: Field Name and Description. Fields include Sponsor, Event Description, Date, Location, and Regulated Area.

22. Monte Foundation Fireworks

Table with 2 columns: Field Name and Description. Fields include Sponsor, Event Description, Date, Location, and Regulated Area.

Dated: March 11, 2016
Gregory G. Stump,
Captain, U.S. Coast Guard, Captain of the
Port San Francisco.
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA-R04-OAR-2016-0018; FRL-9945-04-Region 4]

Air Plan Approval and Air Quality Designation; TN; Redesignation of the Shelby County 2008 8-Hour Ozone Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: On January 19, 2016, the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), Air Pollution

Control Division, submitted a request for the Environmental Protection Agency (EPA) to redesignate the portion of Tennessee that is within the Memphis, Tennessee-Mississippi-Arkansas (Memphis, TN-MS-AR) 2008 8-hour ozone nonattainment area (hereafter referred to as the "Tennessee portion of the Memphis, TN-MS-AR Area" or "Tennessee portion of the Area") to attainment for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS) and an associated State Implementation Plan (SIP) revision containing a maintenance plan and a base year emissions inventory for the Area. EPA is proposing to approve the base year emissions inventory for the Tennessee portion of the Area into the SIP; to determine that the Memphis, TN-MS-AR Area has attained the 2008 8-hour ozone NAAQS; to approve the State's plan for maintaining attainment of the 2008 8-hour ozone standard in the Area, including the motor vehicle emission budgets (MVEBs) for nitrogen oxides (NOx) and volatile organic compounds (VOC) for the year 2027 for

the Tennessee portion of the Area, into the SIP; and to redesignate the Tennessee portion of the Area to attainment for the 2008 8-hour ozone NAAQS. EPA is also notifying the public of the status of EPA's adequacy determination for the MVEBs for the Tennessee portion of the Memphis, TN-MS-AR Area.

DATES: Comments must be received on or before May 19, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2016-0018, at http://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is

considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, 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:** Jane Spann, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Spann can be reached by phone at (404) 562–9029 or via electronic mail at [spann.jane@epa.gov](mailto:spann.jane@epa.gov).

**SUPPLEMENTARY INFORMATION:**

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**I. What are the actions EPA is proposing to take?**

EPA is proposing to take the following four separate but related actions, one of which involves multiple elements: (1) To approve the base year emissions inventory for the 2008 8-hour ozone NAAQS for the Tennessee portion of the Area into the Tennessee SIP; (2) to determine that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS;<sup>1</sup> (3) to approve

<sup>1</sup> On August 27, 2015, EPA published a proposed rulemaking entitled “Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas Classified as Marginal for the 2008 Ozone National Ambient Air Quality Standards” where the Agency has proposed to determine that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS by the applicable attainment date of July 20, 2015, based on 2012–2014

Tennessee's plan for maintaining the 2008 8-hour ozone NAAQS (maintenance plan), including the associated MVEBs for the Tennessee portion of the Memphis, TN–MS–AR Area, into the SIP; and (4) to redesignate the Tennessee portion of the Memphis, TN–MS–AR Area to attainment for the 2008 8-hour ozone NAAQS. EPA is also notifying the public of the status of EPA's adequacy determination for the MVEBs for the Tennessee portion of the Memphis, TN–MS–AR Area. The Memphis, TN–MS–AR Area consists of all of Shelby County in Tennessee, all of Crittenden County in Arkansas, and a portion of DeSoto County in Mississippi. Today's proposed actions are summarized below and described in greater detail throughout this notice of proposed rulemaking.

Based on the 2008 8-hour ozone nonattainment designation for the Memphis, TN–MS–AR Area, Tennessee was required to develop a nonattainment SIP revision addressing certain Clean Air Act (CAA or Act) requirements. Specifically, pursuant to CAA section 182(a)(3)(B) and section 182(a)(1), the state was required to submit a SIP revision addressing emissions statements and emissions inventory requirements, respectively, for its portion of the Area. EPA approved the emissions statements requirements for the Tennessee portion of the Area into the SIP in a separate action. *See* 80 FR 11974 (March 5, 2015). Today, EPA is proposing to determine that the base year emissions inventory, as submitted in the State's January 19, 2016, SIP revision, meets the requirements of section 182(a)(1) of the CAA and proposing to approve this emissions inventory into the SIP.

EPA is making the preliminary determination that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS based on recent air quality data and proposing to approve Tennessee's maintenance plan for its portion of the Memphis, TN–MS–AR Area as meeting the requirements of section 175A (such approval being one of the CAA criteria for redesignation to attainment status). The maintenance plan is designed to keep the Memphis, TN–MS–AR Area in attainment of the 2008 8-hour ozone NAAQS through 2027. The maintenance plan includes 2027 MVEBs for NO<sub>x</sub> and VOC for the Tennessee portion of the Memphis, TN–MS–AR Area for transportation conformity purposes. EPA is proposing to approve these MVEBs and

monitoring data. *See* 80 FR 51992. Any final action on the August 27, 2015 proposed rule will occur in a separate rulemaking from today's proposed action.

incorporate them into the Tennessee SIP.

EPA also proposes to determine that the Tennessee portion of the Memphis, TN–MS–AR Area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA. Accordingly, in this action, EPA is proposing to approve a request to change the legal designation of Shelby County, as found at 40 CFR part 81, from nonattainment to attainment for the 2008 8-hour ozone NAAQS.

EPA is also notifying the public of the status of EPA's adequacy process for the 2027 NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the Memphis, TN–MS–AR Area. The Adequacy comment period began on January 27, 2016, with EPA's posting of the availability of Tennessee's submissions on EPA's Adequacy Web site (<http://www3.epa.gov/otaq/stateresources/transconf/currrips.htm#shelby-ctny>).

The Adequacy comment period for these MVEBs closed on February 26, 2016. No comments, adverse or otherwise, were received during the Adequacy comment period. Please see section VII of this proposed rulemaking for further explanation of this process and for more details on the MVEBs.

In summary, today's notice of proposed rulemaking is in response to Tennessee's January 19, 2016, redesignation request and associated SIP submission that address the specific issues summarized above and the necessary elements described in section 107(d)(3)(E) of the CAA for redesignation of the Tennessee portion of the Memphis, TN–MS–AR Area to attainment for the 2008 8-hour ozone NAAQS.

**II. What is the background for EPA's proposed actions?**

On March 12, 2008, EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm). *See* 73 FR 16436 (March 27, 2008). Under EPA's regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm. *See* 40 CFR 50.15. Ambient air quality monitoring data for the 3-year period must meet a data completeness requirement. The ambient air quality monitoring data completeness requirement is met when the average percent of days with valid ambient monitoring data is greater than 90 percent, and no single year has less than 75 percent data completeness as determined in Appendix P of part 50.

The Memphis, TN–MS–AR Area was designated nonattainment for the 2008 8-hour ozone NAAQS on May 21, 2012 (effective July 20, 2012) using 2008–2010 ambient air quality data. *See* 77 FR 30088. At the time of designation, the Memphis, TN–MS–AR Area was classified as a marginal nonattainment area for the 2008 8-hour ozone NAAQS. In the final implementation rule for the 2008 8-hour ozone NAAQS (SIP Implementation Rule),<sup>2</sup> EPA established ozone nonattainment area attainment dates based on Table 1 of section 181(a) of the CAA. This established an attainment date three years after the July 20, 2012, effective date for areas classified as marginal areas for the 2008 8-hour ozone nonattainment designations. Therefore, the Memphis, TN–MS–AR Area's attainment date is July 20, 2015.

### III. What are the criteria for redesignation?

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that: (1) The Administrator determines that the area has attained the applicable NAAQS; (2) the Administrator has fully approved the applicable implementation plan for the area under section 110(k); (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable federal air pollutant control regulations and other permanent and enforceable reductions; (4) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A; and (5) the state containing such area has met all requirements applicable to the area for purposes of redesignation under section 110 and part D of the CAA.

On April 16, 1992, EPA provided guidance on redesignation in the General Preamble for the

<sup>2</sup> This rule, entitled Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements and published at 80 FR 12264 (March 6, 2015), addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology (RACT), reasonably available control measures (RACM), major new source review (NSR), emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. This rule also addresses the revocation of the 1997 ozone NAAQS and the anti-backsliding requirements that apply when the 1997 ozone NAAQS are revoked.

Implementation of title I of the CAA Amendments of 1990 (57 FR 13498), and supplemented this guidance on April 28, 1992 (57 FR 18070). EPA has provided further guidance on processing redesignation requests in the following documents:

1. "Ozone and Carbon Monoxide Design Value Calculations," Memorandum from Bill Laxton, Director, Technical Support Division, June 18, 1990;
2. "Maintenance Plans for Redesignation of Ozone and Carbon Monoxide Nonattainment Areas," Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, April 30, 1992;
3. "Contingency Measures for Ozone and Carbon Monoxide (CO) Redesignations," Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, June 1, 1992;
4. "Procedures for Processing Requests to Redesignate Areas to Attainment," Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter referred to as the "Calcagni Memorandum");
5. "State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines," Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992;
6. "Technical Support Documents (TSDs) for Redesignation of Ozone and Carbon Monoxide (CO) Nonattainment Areas," Memorandum from G. T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, August 17, 1993;
7. "State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992," Memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, September 17, 1993;
8. "Use of Actual Emissions in Maintenance Demonstrations for Ozone and CO Nonattainment Areas," Memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, November 30, 1993;
9. "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994; and
10. "Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard," Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995.

### IV. Why is EPA proposing these actions?

On January 19, 2016, the State of Tennessee, through TDEC, requested that EPA redesignate the Tennessee portion of the Memphis, TN–MS–AR Area to attainment for the 2008 8-hour

ozone NAAQS and approve the associated SIP revision submitted on the same date. EPA's evaluation indicates that the entire Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS and that the Tennessee portion of the Memphis, TN–MS–AR Area meets the requirements for redesignation as set forth in CAA section 107(d)(3)(E), including the maintenance plan requirements under CAA section 175A and associated MVEBs. Also, based on Tennessee's January 19, 2016, submittal, EPA is proposing to determine that the base year emissions inventory, included in Tennessee's January 19, 2016, submittal, meets the requirements under CAA section 182(a)(1). Approval of the base year emissions inventory is a prerequisite to redesignating an ozone nonattainment area to attainment. As a result of these proposed findings, EPA is proposing to take the four related actions summarized in section I of this notice.

### V. What is EPA's analysis of the redesignation request and January 19, 2016, SIP submission?

As stated above, in accordance with the CAA, EPA proposes in today's action to: (1) Approve the 2008 8-hour ozone NAAQS base year emissions inventory for the Tennessee portion of the Area into the Tennessee SIP; (2) determine that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS; (3) approve the 2008 8-hour ozone NAAQS maintenance plan, including the associated MVEBs, into the Tennessee SIP; and (4) redesignate the Tennessee portion of the Memphis, TN–MS–AR Area to attainment for the 2008 8-hour ozone NAAQS.

#### A. Emission Inventory

Section 182(a)(1) of the CAA requires states to submit a comprehensive, accurate, and current inventory of actual emissions from all sources of the relevant pollutant or pollutants in each ozone nonattainment area. The section 182(a)(1) base year emissions inventory is defined in the SIP Requirements Rule as "a comprehensive, accurate, current inventory of actual emissions from sources of VOC and NO<sub>x</sub> emitted within the boundaries of the nonattainment area as required by CAA section 182(a)(1)." *See* 40 CFR 51.1100(bb). The inventory year must be selected consistent with the baseline year for an RFP plan as required by 40 CFR 51.1110(b),<sup>3</sup> and the inventory must

<sup>3</sup> 40 CFR 51.1110(b) states that "at the time of designation for the 2008 ozone NAAQS the baseline emissions inventory shall be the emissions

include actual ozone season day emissions as defined in 40 CFR 51.1100(cc) <sup>4</sup> and contain data elements consistent with the detail required by 40 CFR part 51, subpart A. See 40 CFR 51.1115(a), (c), (e). In addition, the point source emissions included in the inventory must be reported according to the point source emissions thresholds of the Air Emissions Reporting Requirements (AERR) in 40 CFR part 51, subpart A. See 40 CFR 51.1115(d).

Tennessee selected 2011 as the year for the CAA section 182(a)(1) emissions inventory which is the year corresponding with the first triennial inventory under 40 CFR part 51, subpart A. The emissions inventory is based on data developed and submitted by TDEC and Shelby County Health Department to EPA's 2011 National Emissions Inventory (NEI), and it contains data elements consistent with the detail required by 40 CFR part 51, subpart A. <sup>5</sup>

Tennessee's emissions inventory for its portion of the Area provides 2011 emissions data for NO<sub>x</sub> and VOCs for the following general source categories: Point, area, non-road mobile, and on-road mobile. A detailed discussion of the inventory development is located in Attachment VII to Tennessee's January 19, 2016, SIP submittal which is provided in the docket for this action. Table 1, below, provides a summary of the emissions inventory.

TABLE 1—2011 POINT, AREA, NON-ROAD MOBILE, AND ON-ROAD MOBILE SOURCES EMISSIONS FOR THE TENNESSEE PORTION OF THE MEMPHIS AREA  
[Tons per typical summer day]

County	Point		Area *		Non-road mobile **		On-road mobile	
	NO <sub>x</sub>	VOC	NO <sub>x</sub>	VOC	NO <sub>x</sub>	VOC	NO <sub>x</sub>	VOC
Shelby County .....	18.30	9.49	4.53	46.88	29.24	15.09	37.90	16.11

\* Includes Prescribed Burning.

\*\* Includes nonroad equipment, airports, Commercial Marine Vessels (CMVs), and locomotives.

The emissions inventory includes all anthropogenic VOC and NO<sub>x</sub> sources for Shelby County, Tennessee. NO<sub>x</sub> and VOC emissions were calculated for a typical summer July day, taking into account the seasonal adjustment factor for summer operations. More detail on the inventory emissions for individual sources categories is provided below and in Attachment VII to Tennessee's January 19, 2016, SIP submittal.

Point sources are large, stationary, identifiable sources of emissions that release pollutants into the atmosphere. The inventory contains point source emissions data for facilities located within Shelby County based on the Shelby County, Tennessee, Emissions Inventory Questionnaire (EIQ) which is an annual emissions inventory survey conducted by the Shelby County Health Department. Each facility was required to update the data through the EIQ with information for the requested year and return the updated data to Shelby County Health Department.

Area sources are small emission stationary sources which, due to their

large number, collectively have significant emissions (e.g., dry cleaners, service stations). Emissions for these sources were estimated by multiplying an emission factor by such indicators of collective emissions activity as production, number of employees, or population. These emissions were estimated at the county level. Tennessee submitted an inventory that it developed for the NEI in accordance with the AERR. Tennessee developed its inventory according to the current EPA emissions inventory guidance for area sources. <sup>6</sup>

On-road mobile sources include vehicles used on roads for transportation of passengers or freight. Tennessee developed its on-road emissions inventory using EPA's Motor Vehicle Emissions Simulator (MOVES) model with input data from the Memphis Metropolitan Planning Organization (MPO). <sup>7</sup> County level on-road modeling was conducted using county-specific vehicle population and other local data. Tennessee developed its inventory according to the current

EPA emissions inventory guidance for on-road mobile sources using MOVES version 2014.

Non-road mobile sources include vehicles, engines, and equipment used for construction, agriculture, recreation, and other purposes that do not use roadways (e.g., lawn mowers, construction equipment, railroad locomotives, and aircraft). Tennessee calculated emissions for most of the non-road mobile sources using EPA's NONROAD2008a model <sup>8</sup> and developed its non-road mobile source inventory according to the current EPA emissions inventory guidance for non-road mobile sources. <sup>9</sup>

For the reasons discussed above, EPA has preliminarily determined that Tennessee's emissions inventory meets the requirements under CAA section 182(a)(1) and the SIP Requirements Rule for the 2008 8-hour ozone NAAQS. Approval of Tennessee's redesignation request is contingent upon EPA's final approval of the base year emissions inventory for the 2008 8-hour ozone NAAQS.

inventory for the most recent calendar year for which a complete triennial inventory is required to be submitted to EPA under the provisions of subpart A of this part. States may use an alternative baseline emissions inventory provided the state demonstrates why it is appropriate to use the alternative baseline year, and provided that the year selected is between the years 2008 to 2012. <sup>4</sup>

<sup>4</sup> "Ozone season day emissions" is defined as "an average day's emissions for a typical ozone season work weekday. The state shall select, subject to EPA approval, the particular month(s) in the ozone season and the day(s) in the work week to be represented, considering the conditions assumed in the development of RFP plans and/or emissions budgets for transportation conformity." See 40 CFR 51.1100(cc).

<sup>5</sup> Data downloaded from the EPA EIS from the 2011 NEI was subjected to quality assurance procedures described under quality assurance details under 2011 NEI Version 1 Documentation located at: <http://www.epa.gov/ttn/chief/net/2011inventory.html#inventorydoc>. The quality assurance and quality control procedures and measures associated with this data are outlined in the State's EPA-approved Emission Inventory Quality Assurance Project Plan.

<sup>6</sup> This guidance includes: *Procedures for the Preparation of Emission Inventories of Carbon Monoxide and Precursors of Ozone, Vol. 1*, EPA-450/4-91-016 (May 1991) and *Emissions Inventory Improvement Program (EIIP) Technical Report, Vol. 3, Area Sources* (Revised January 2001, updated April 2001).

<sup>7</sup> Tennessee used MOVES2014 technical guidance: *Using MOVES to Prepare Emission Inventories in State Implementation Plans and Transportation Conformity*, EPA-420-b-15-007 (January 2015).

<sup>8</sup> For consistency with the NEI, Tennessee included emissions data for aircraft, locomotive, and commercial marine vessels (CMV) by county. CMV emissions for 2011 were primarily based on EPA's 2011 NEI, U.S. Corps of Engineers' 2012 Waterborne Commerce, and 2012 survey of railroad companies operating in Shelby County.

<sup>9</sup> This guidance includes: *Procedures for Emission Inventory Preparation, Volume IV: Mobile Sources*, EPA-450/4-81-026d (December 1992).

*B. Redesignation Request and Maintenance Demonstration*

The five redesignation criteria provided under CAA section 107(d)(3)(E) are discussed in greater detail for the Area in the following paragraphs of this section.

**Criteria (1)—The Memphis, TN–MS–AR Area Has Attained the 2008 8-Hour Ozone NAAQS**

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the area has attained the applicable NAAQS. See CAA section 107(d)(3)(E)(i). For ozone, an area may be determined to be attaining the 2008 8-hour ozone NAAQS if it meets the 2008 8-hour ozone NAAQS, as determined in accordance

with 40 CFR 50.15 and appendix P of part 50, based on three complete, consecutive calendar years of quality-assured air quality monitoring data. To attain the NAAQS, the 3-year average of the fourth-highest daily maximum 8-hour average ozone concentrations measured at each monitor within an area over each year must not exceed 0.075 ppm. Based on the data handling and reporting convention described in 40 CFR part 50, appendix P, the NAAQS are attained if the design value is 0.075 ppm or below. The data must be collected and quality-assured in accordance with 40 CFR part 58 and recorded in EPA’s Air Quality System (AQS). The monitors generally should have remained at the same location for

the duration of the monitoring period required for demonstrating attainment.

In this action, EPA is preliminarily determining that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS. EPA reviewed ozone monitoring data from monitoring stations in the Memphis, TN–MS–AR Area for the 2008 8-hour ozone NAAQS for 2012–2014, and the design values for each monitor in the Area are less than 0.075 ppm. These data have been quality-assured, are recorded in AQS, and indicate that the Area is attaining the 2008 8-hour ozone NAAQS. The fourth-highest 8-hour ozone values at each monitor for 2012, 2013, 2014, and the 3-year averages of these values (*i.e.*, design values), are summarized in Table 2, below.

**TABLE 2—2012–2014 DESIGN VALUE CONCENTRATIONS FOR THE MEMPHIS, TN–MS–AR AREA**  
[ppm]

Location	Site	4th Highest 8-hour ozone value (ppm)			3-Year design values (ppm)
		2012	2013	2014	2012–2014
Shelby, TN .....	Frayser .....	0.083	0.069	0.067	0.073
Shelby, TN .....	Orgill Park .....	0.084	0.063	0.065	0.070
Shelby, TN .....	Shelby Farms .....	0.086	0.069	0.066	0.073
Crittenden, AR .....	Marion .....	0.079	0.067	0.067	0.071
DeSoto, MS .....	Hernando .....	0.075	0.065	0.067	0.069

The 3-year design value for 2012–2014 for the Memphis, TN–MS–AR Area is 0.073 ppm,<sup>10</sup> which meets the NAAQS. EPA has reviewed 2015 preliminary monitoring data for the Area and the preliminary data does not indicate a violation of the NAAQS.<sup>11</sup> In today’s action, EPA is proposing to determine that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS. EPA will not take final action to approve the redesignation if the 3-year design value exceeds the NAAQS prior to EPA finalizing the redesignation. As discussed in more detail below, Tennessee has committed to continue monitoring in this Area in accordance with 40 CFR part 58.

**Criteria (2)—Tennessee Has a Fully Approved SIP Under Section 110(k) for the Tennessee Portion of the Memphis, TN–MS–AR Area; and Criteria (5)—Tennessee Has Met All Applicable Requirements Under Section 110 and Part D of Title I of the CAA**

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the state has met all applicable requirements under section 110 and part D of title I of the CAA (CAA section 107(d)(3)(E)(v)) and that the state has a fully approved SIP under section 110(k) for the area (CAA section 107(d)(3)(E)(ii)). EPA proposes to find that Tennessee has met all applicable SIP requirements for the Tennessee portion of the Area under section 110 of the CAA (general SIP requirements) for purposes of redesignation. Additionally, EPA proposes to find that Tennessee has met all applicable SIP requirements for purposes of redesignation under part D of title I of the CAA in accordance with section 107(d)(3)(E)(v) and proposes to determine that the SIP is fully approved with respect to all requirements applicable for purposes of redesignation in accordance with section 107(d)(3)(E)(ii) contingent upon

approval of the 182(a)(1) base year emissions inventory for the 2008 8-hour ozone NAAQS for the Tennessee portion of the Area. In making these determinations, EPA ascertained which requirements are applicable to the Area and, if applicable, that they are fully approved under section 110(k). SIPs must be fully approved only with respect to requirements that were applicable prior to submittal of the complete redesignation request.

**a. The Tennessee Portion of the Memphis, TN–MS–AR Area Has Met All Applicable Requirements Under Section 110 and Part D of the CAA**

*General SIP requirements.* General SIP elements and requirements are delineated in section 110(a)(2) of title I, part A of the CAA. These requirements include, but are not limited to, the following: submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; implementation of a source permit program; provisions for the implementation of part C requirements (Prevention of Significant Deterioration

<sup>10</sup>The highest 3-year design value among the monitoring stations is the design value for the Area.

<sup>11</sup>This preliminary data is available at EPA’s air data Web site: [http://aqsdr1.epa.gov/aqsweb/aqstmp/airdata/download\\_files.html#Daily](http://aqsdr1.epa.gov/aqsweb/aqstmp/airdata/download_files.html#Daily).

(PSD)) and provisions for the implementation of part D requirements (NSR permit programs); provisions for air pollution modeling; and provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA has required certain states to establish programs to address the interstate transport of air pollutants. The section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that the CAA's interstate transport requirements should be construed to be applicable requirements for purposes of redesignation.

In addition, EPA believes other section 110 elements that are neither connected with nonattainment plan submissions nor linked with an area's attainment status are not applicable requirements for purposes of redesignation. The area will still be subject to these requirements after the area is redesignated. The section 110 and part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request. This approach is consistent with EPA's existing policy on applicability (*i.e.*, for redesignations) of conformity and oxygenated fuels requirements, as well as with section 184 ozone transport requirements. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174–53176, October 10, 1996), (62 FR 24826, May 7, 2008); Cleveland-Akron-Lorain, Ohio, final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking at (60 FR 62748, December 7, 1995). *See also* the discussion on this issue in the Cincinnati, Ohio, redesignation (65 FR 37890, June 19, 2000), and in the Pittsburgh, Pennsylvania, redesignation (66 FR 50399, October 19, 2001).

*Title I, part D, applicable SIP requirements.* Section 172(c) of the CAA sets forth the basic requirements of

attainment plans for nonattainment areas that are required to submit them pursuant to section 172(b). Subpart 2 of part D, which includes section 182 of the CAA, establishes specific requirements for ozone nonattainment areas depending on the area's nonattainment classification. As provided in subpart 2, a marginal ozone nonattainment area, such as the Memphis, TN–MS–AR Area, must submit an emissions inventory that complies with section 172(c)(3), but the specific requirements of section 182(a) apply in lieu of the demonstration of attainment (and contingency measures) required by section 172(c). *See* 42 U.S.C. 7511a(a). A thorough discussion of the requirements contained in sections 172(c) and 182 can be found in the General Preamble for Implementation of Title I (57 FR 13498).

*Section 182(a) requirements.* Section 182(a)(1) requires states to submit a comprehensive, accurate, and current inventory of actual emissions from sources of VOC and NOx emitted within the boundaries of the ozone nonattainment area. Tennessee provided an emissions inventory for the Tennessee portion of the Area to EPA in a January 19, 2016, SIP submission. Specifically, Tennessee addressed this requirement by submitting a 2011 base year emissions inventory for the Tennessee portion of the Area. EPA is proposing approval of Tennessee's 2011 base year emissions inventory in this action (*see* Section V.A. above). Tennessee's section 182(a)(1) inventory must be approved before EPA can take final action to approve the State's redesignation request for the Tennessee portion of the Area.

Under section 182(a)(2)(A), states with ozone nonattainment areas that were designated prior to the enactment of the 1990 CAA amendments were required to submit, within six months of classification, all rules and corrections to existing VOC RACT rules that were required under section 172(b)(3) of the CAA (and related guidance) prior to the 1990 CAA amendments. The Tennessee portion of the Memphis, TN–MS–AR Area is not subject to the section 182(a)(2) RACT “fix up” because the Area was designated as nonattainment after the enactment of the 1990 CAA amendments.

Section 182(a)(2)(B) requires each state with a marginal ozone nonattainment area that implemented, or was required to implement, an inspection and maintenance (I/M) program prior to the 1990 CAA amendments to submit a SIP revision providing for an I/M program no less stringent than that required prior to the

1990 amendments or already in the SIP at the time of the amendments, whichever is more stringent. The Tennessee portion of the Memphis, TN–MS–AR Area is not subject to the section 182(a)(2)(B) because it was designated as nonattainment after the enactment of the 1990 CAA amendments and did not have an I/M program in place for ozone prior to those amendments.

Regarding the permitting and offset requirements of section 182(a)(2)(C) and section 182(a)(4), Tennessee currently has a fully approved part D NSR program in place. However, EPA has determined that areas being redesignated need not comply with the requirement that a NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR, because PSD requirements will apply after redesignation. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, “Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment.” Tennessee's PSD program will become applicable in the Memphis, TN–MS–AR Area upon redesignation to attainment.

Section 182(a)(3) requires states to submit periodic inventories and emissions statements. Section 182(a)(3)(A) requires states to submit a periodic inventory every three years. As discussed below in the section of this notice titled *Verification of Continued Attainment*, the State will continue to update its emissions inventory at least once every three years. Under section 182(a)(3)(B), each state with an ozone nonattainment area must submit a SIP revision requiring emissions statements to be submitted to the state by sources within that nonattainment area. Tennessee provided a SIP revision to EPA on January 5, 2015, addressing the section 182(a)(3)(B) emissions statements requirement, and on March 5, 2015, EPA published a direct final rule approving this SIP revision. *See* 80 FR 11974.

*Section 176 conformity requirements.* Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded, or approved under title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity)

as well as to all other federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with federal conformity regulations relating to consultation, enforcement, and enforceability that EPA promulgated pursuant to its authority under the CAA.

EPA interprets the conformity SIP requirements<sup>12</sup> as not applying for purposes of evaluating a redesignation request under section 107(d) because state conformity rules are still required after redesignation and federal conformity rules apply where state rules have not been approved. *See Wall v. EPA*, 265 F.3d 426 (6th Cir. 2001) (upholding this interpretation); *see also* 60 FR 62748 (December 7, 1995) (redesignation of Tampa, Florida). Nonetheless, Tennessee has an approved conformity SIP for the Tennessee portion of the Memphis, TN–MS–AR Area. *See* 78 FR 29027 (May 17, 2013). Thus, EPA proposes that the Tennessee portion of the Memphis, TN–MS–AR Area has satisfied all applicable requirements for purposes of redesignation under section 110 and part D of title I of the CAA contingent upon approval of the 182(a)(1) base year emissions inventory.

**b. The Tennessee Portion of the Memphis, TN–MS–AR Area Has a Fully Approved Applicable SIP Under Section 110(k) of the CAA**

EPA has fully approved the applicable Tennessee SIP for the Memphis, TN–MS–AR Area under section 110(k) of the CAA for all requirements applicable for purposes of redesignation except for the 182(a)(1) base year emissions inventory. EPA may rely on prior SIP approvals in approving a redesignation request (*see* Calcagni Memorandum at p. 3; *Southwestern Pennsylvania Growth Alliance v. Browner*, 144 F.3d 984, 989–90 (6th Cir. 1998); *Wall*, 265 F.3d 426) plus any additional measures it may approve in conjunction with a redesignation action (*see* 68 FR 25426 (May 12, 2003) and citations therein). Tennessee has adopted and submitted, and EPA has fully approved at various times, provisions addressing various SIP elements applicable for the ozone NAAQS. *See* 78 FR 14450 (March 6, 2013).

As indicated above, EPA believes that the section 110 elements that are neither

<sup>12</sup>CAA section 176(c)(4)(E) requires states to submit revisions to their SIPs to reflect certain federal criteria and procedures for determining transportation conformity. Transportation conformity SIPs are different from the MVEBs that are established in control strategy SIPs and maintenance plans.

connected with nonattainment plan submissions nor linked to an area's nonattainment status are not applicable requirements for purposes of redesignation. With the exception of the emissions inventory requirement, which is addressed in this action, EPA has approved all part D requirements applicable for purposes of this redesignation. As noted above, EPA has approved Tennessee's emissions statements SIP revisions under CAA section 182(a)(3)(B). *See* 80 FR 11974 (March 5, 2015).

**Criteria (3)—The Air Quality Improvement in the Memphis, TN–MS–AR Area Is Due to Permanent and Enforceable Reductions in Emissions Resulting From Implementation of the SIP and Applicable Federal Air Pollution Control Regulations and Other Permanent and Enforceable Reductions**

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP, applicable federal air pollution control regulations, and other permanent and enforceable reductions (CAA section 107(d)(3)(E)(iii)). EPA has preliminarily determined that Tennessee has demonstrated that the observed air quality improvement in the Memphis, TN–MS–AR Area is due to permanent and enforceable reductions in emissions resulting from federal measures and are not the result of weather conditions.<sup>13</sup> EPA does not have any information to suggest that the decrease in ozone concentrations in the Memphis, TN–MS–AR Area is due to unusually favorable meteorological conditions.

Federal measures enacted in recent years have resulted in permanent emission reductions. The federal measures that have been implemented include the following:

**Tier 2 vehicle and fuel standards.** Implementation began in 2004 and requires all passenger vehicles in any manufacturer's fleet to meet an average standard of 0.07 grams of NO<sub>x</sub> per mile.

<sup>13</sup>Tennessee compared ozone data on days with the highest 8-hour ozone maxima in 2005 and 2006 to ozone data on days of comparative weather conditions in 2012–2014. The weather parameters used in the comparison were maximum temperature, dew point depression, relative humidity, cloud cover, wind direction and wind speed. The ozone levels in 2005–2006 were considerably higher than the ozone levels during similar weather conditions in 2012–2014 indicating that emission reductions between 2006 and 2014 are the reason for the reduction in ozone levels. Details of the analysis are found in Attachment I to Tennessee's January 19, 2016, SIP submittal.

Additionally, in January 2006, the sulfur content of gasoline was required to be on average 30 ppm which assists in lowering the NO<sub>x</sub> emissions. EPA expects that these standards will reduce NO<sub>x</sub> emissions from vehicles by approximately 74 percent by 2030, translating to nearly 3 million tons annually by 2030.<sup>14 15</sup>

**Heavy-duty gasoline and diesel highway vehicle standards.** EPA issued this rule in January 2001 (66 FR 5002). This rule includes standards limiting the sulfur content of diesel fuel, which went into effect in 2004. A second phase took effect in 2007, which further reduced the highway diesel fuel sulfur content to 15 ppm, leading to additional reductions in combustion NO<sub>x</sub> and VOC emissions. EPA expects that this rule will achieve a 95 percent reduction in NO<sub>x</sub> emissions from diesel trucks and buses and will reduce NO<sub>x</sub> emissions by 2.6 million tons by 2030 when the heavy-duty vehicle fleet is completely replaced with newer heavy-duty vehicles that comply with these emission standards.<sup>16</sup>

**Large non-road diesel engines rule.** This rule was promulgated in 2004 and was phased in between 2008 through 2014. This rule reduces the sulfur content in the nonroad diesel fuel and reduces NO<sub>x</sub>, VOC, particulate matter, and carbon monoxide emissions. These emission reductions are federally enforceable. EPA issued this rule in June 2004, which applies to diesel engines used in industries such as construction, agriculture, and mining. It is estimated that compliance with this rule will cut NO<sub>x</sub> emissions from non-road diesel engines by up to 90 percent nationwide.

**Nonroad spark-ignition engines and recreational engines standards.** The nonroad spark-ignition and recreational engine standards, effective in July 2003, regulate NO<sub>x</sub>, hydrocarbons, and carbon monoxide from groups of previously unregulated nonroad engines. These engine standards apply to large spark-ignition engines (*e.g.*, forklifts and airport ground service equipment), recreational vehicles (*e.g.*, off-highway motorcycles and all-terrain-vehicles), and recreational marine diesel engines sold in the United States and imported after the effective date of these

<sup>14</sup>EPA, Regulatory Announcement, EPA420–F–99–051 (December 1999), available at: <http://www.epa.gov/tier2/documents/f99051.pdf>.

<sup>15</sup>The Memphis Area MPO estimates for Shelby County alone emission reductions of 2.05 tons per day (tpd) for NO<sub>x</sub> (a 4.7 percent reduction) and 0.54 tpd for VOCs (3 percent reduction) from 2009 to 2012. TDEC notes that this occurred when the vehicle miles traveled (VMT) increased by 9.3 percent.

<sup>16</sup>66 FR 5002, 5012 (January 18, 2001).

standards. When all of the nonroad spark-ignition and recreational engine standards are fully implemented, an overall 72 percent reduction in hydrocarbons, 80 percent reduction in NO<sub>x</sub>, and 56 percent reduction in carbon monoxide emissions are expected by 2020. These controls reduce ambient concentrations of ozone, carbon monoxide, and fine particulate matter.

*National program for greenhouse gas (GHG) emissions and fuel economy standards.* The federal GHG and fuel economy standards apply to light-duty cars and trucks in model years 2012–2016 (phase 1) and 2017–2025 (phase 2). The final standards are projected to result in an average industry fleet-wide level of 163 grams/mile of carbon dioxide which is equivalent to 54.5 miles per gallon if achieved exclusively through fuel economy improvements. The fuel economy standards result in less fuel being consumed, and therefore less NO<sub>x</sub> emissions released.

EPA proposes to find that the improvements in air quality in the Memphis, TN–MS–AR Area are due to real, permanent and enforceable reductions in NO<sub>x</sub> and VOC emissions resulting from the federal measures discussed above.

Criteria (4)—The Tennessee Portion of the Memphis, TN–MS–AR Area Has a Fully Approved Maintenance Plan Pursuant to Section 175A of the CAA

For redesignating a nonattainment area to attainment, the CAA requires EPA to determine that the area has a fully approved maintenance plan pursuant to section 175A of the CAA (CAA section 107(d)(3)(E)(iv)). In conjunction with its request to redesignate the Tennessee portion of the Memphis, TN–MS–AR Area to attainment for the 2008 8-hour ozone NAAQS, TDEC submitted a SIP revision to provide for the maintenance of the 2008 8-hour ozone NAAQS for at least 10 years after the effective date of redesignation to attainment. EPA has made the preliminary determination that this maintenance plan meets the requirements for approval under section 175A of the CAA.

a. What is required in a maintenance plan?

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must

submit a revised maintenance plan which demonstrates that attainment will continue to be maintained for the remainder of the 20-year period following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures as EPA deems necessary to assure prompt correction of any future 2008 8-hour ozone violations. The Calcagni Memorandum provides further guidance on the content of a maintenance plan, explaining that a maintenance plan should address five requirements: The attainment emissions inventory, maintenance demonstration, monitoring, verification of continued attainment, and a contingency plan. As is discussed more fully below, EPA has preliminarily determined that Tennessee's maintenance plan includes all the necessary components and is thus proposing to approve it as a revision to the Tennessee SIP.

b. Attainment Emissions Inventory

As discussed above, EPA is proposing to determine that the Memphis, TN–MS–AR Area has attained the 2008 8-hour ozone NAAQS based on quality-assured monitoring data for the 3-year period from 2012–2014, and is continuing to attain the standard based on preliminary 2015 data. Tennessee selected 2012 as the base year (*i.e.*, attainment emissions inventory year) for developing a comprehensive emissions inventory for NO<sub>x</sub> and VOC, for which projected emissions could be developed for 2017, 2020, and 2027. The attainment inventory identifies a level of emissions in the Area that is sufficient to attain the 2008 8-hour ozone NAAQS. Tennessee began development of the attainment inventory by first generating a baseline emissions inventory for the State's portion of the Memphis, TN–MS–AR Area. The State projected summer day emission inventories using projected rates of growth in population, traffic, economic activity, and other parameters. In addition to comparing the final year of the plan (2027) to the base year (2012), Tennessee compared interim years to the baseline to demonstrate that these years are also expected to show continued maintenance of the 2008 8-hour ozone standard.

The emissions inventory is composed of four major types of sources: Point, area, on-road mobile, and non-road mobile. Complete descriptions of how the State developed these inventories are located in Attachment I of the January 19, 2016, SIP submittal.

Point source emissions are tabulated from data collected by direct on-site measurements of emissions or from mass balance calculations utilizing approved emission factors. The 2012 base year inventory contains point source emissions data for facilities located within Shelby County. Each facility was required to update the data through the EIQ with information for the requested year and return the updated data to Shelby County Health Department. The point source emissions inventory for Shelby County is located in the docket for today's action. For each projected year's inventory for 2017, 2020, and 2027, the State projected point source emissions using growth factors developed from the United States Department of Energy's 2014 Annual Energy Outlook (AEO) projections and the University of Tennessee, Data Center 2014 Econometric Model Forecast. A conservative value of 1 was substituted for all negative growth factors. Growth factors used for this analysis include fuel consumption, employment, and population changes.

Emissions for area sources were estimated by multiplying an emission factor by such indicators of collective emissions activity as production, number of employees, or population. These emissions were estimated at the county level. Tennessee used a similar method to that used to develop the 2011 emissions inventory. For each projected year's inventory, emission factors are used to determine area source emissions. Tennessee developed its inventory according to the current EPA emissions inventory guidance for area sources.<sup>17</sup>

Tennessee developed its 2012 on-road emissions inventory using EPA's MOVES2014 model with input data from the MPO.<sup>18</sup> County level on-road modeling was conducted using county-specific vehicle population and other local data. Tennessee developed its inventory according to the current EPA emissions inventory guidance for on-road mobile sources using MOVES2014. The MOVES2014 model includes the VMT as an input file and can directly output the estimated emissions. For each projected year's inventory,

<sup>17</sup> This guidance includes: *Procedures for the Preparation of Emission Inventories of Carbon Monoxide and Precursors of Ozone, Vol. 1*, EPA-450/4-91-016 (May 1991) and *Emissions Inventory Improvement Program (EIIP) Technical Report, Vol. 3, Area Sources* (Revised January 2001, updated April 2001).

<sup>18</sup> Tennessee used MOVES2014 technical guidance: *Using MOVES to Prepare Emission Inventories in State Implementation Plans and Transportation Conformity*, EPA-420-b-15-007 (January 2015).

Tennessee calculated the on-road mobile sources emissions by running the MOVES mobile model for the future year with the projected VMT to generate emissions that take into consideration expected federal tailpipe standards, fleet turnover, and new fuels.

Non-road mobile sources include non-road equipment, airport, commercial marine vessels, and locomotives. The majority of the non-road mobile emissions in the U.S. are from the non-road equipment segment (*i.e.*, agricultural equipment, construction equipment, lawn and garden equipment, and recreational vehicles, such as boats and jet-skis). Tennessee calculated emissions for most of the non-road

mobile sources using EPA's NONROAD2008a model within EPA's MOVES2014 model and developed its non-road mobile source inventory according to the current EPA emissions inventory guidance for non-road mobile sources.<sup>19</sup>

c. Maintenance Demonstration

The maintenance plan associated with the redesignation request includes a maintenance demonstration that:

- (i) Shows compliance with and maintenance of the 2008 8-hour ozone NAAQS by providing information to support the demonstration that current and future emissions of NO<sub>x</sub> and VOC

remain at or below 2012 emissions levels.

(ii) Uses 2012 as the attainment year and includes future emissions inventory projections for 2017, 2020, and 2027.

(iii) Identifies an "out year" at least 10 years after the time necessary for EPA to review and approve the maintenance plan. Per 40 CFR part 93, NO<sub>x</sub> and VOC MVEBs were established for the last year (2027) of the maintenance plan (see section VI below).

(iv) Provides actual (2012) and projected emissions inventories, in tons per summer day (tpsd), for the Tennessee portion of the Memphis, TN-MS-AR Area, as shown in Tables 3 and 4, below.

TABLE 3—ACTUAL AND PROJECTED AVERAGE SUMMER DAY NO<sub>x</sub> EMISSIONS (TPD) FOR THE TENNESSEE PORTION OF THE MEMPHIS, TN-MS-AR AREA

Sector	2012	2017	2020	2027
Point Area	13.87	13.45	8.34	8.43
Non-road	4.11	4.18	4.24	4.33
On-road	35.93	32.09	30.57	29.77
	61.56	31.30	22.42	12.51
Total	115.47	81.01	65.56	55.05

TABLE 4—ACTUAL AND PROJECTED AVERAGE SUMMER DAY VOC EMISSIONS (TPD) FOR THE TENNESSEE PORTION OF THE MEMPHIS, TN-MS-AR AREA

Sector	2012	2017	2020	2027
Point Area	9.30	6.64	6.22	6.24
Non-road	44.04	45.33	45.53	46.30
On-road	28.44	21.32	19.76	19.33
	19.01	11.22	8.75	5.81
Total	100.79	84.51	80.26	77.69

Tables 3 and 4 summarize the 2012 and future projected emissions of NO<sub>x</sub> and VOC from the Tennessee portion of the Memphis, TN-MS-AR Area. In situations where local emissions are the primary contributor to nonattainment, such as the Memphis, TN-MS-AR Area if the future projected emissions in the nonattainment area remain at or below the baseline emissions in the nonattainment area, then the related ambient air quality standard should not be exceeded in the future. Tennessee has projected emissions as described previously and determined that emissions in the Tennessee portion of the Memphis, TN-MS-AR Area will remain below those in the attainment year inventory for the duration of the maintenance plan.

As discussed in section VI of this proposed rulemaking, a safety margin is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the level of emissions during one of the years in which the area met the NAAQS. Tennessee selected 2012 as the attainment emissions inventory year for the Tennessee portion of the Memphis, TN-MS-AR Area. Tennessee calculated safety margins in its submittal for 2027. The State has allocated a portion of the 2027 safety margin to the 2027 MVEBs for the Memphis, TN-MS-AR Area.

TABLE 5—SAFETY MARGINS FOR THE TENNESSEE PORTION OF THE MEMPHIS, TN-MS-AR AREA

Year	VOC (tpd)	NO <sub>x</sub> (tpd)
2027	23.10	60.42

The State has decided to allocate a portion of the available safety margin to the 2027 MVEBs to allow for unanticipated growth in VMT, changes and uncertainty in vehicle mix assumptions, etc., that will influence the emission estimations. Tennessee has allocated 49.04 tpd of the NO<sub>x</sub> safety margin to the 2027 NO<sub>x</sub> MVEB and 13.19 tpd of the VOC safety margin to the 2027 VOC MVEB. After allocation of the available safety margin, the remaining safety margin is 11.38 tpd for

<sup>19</sup>This guidance includes: *Procedures for Emission Inventory Preparation, Volume IV: Mobile Sources*, EPA-450/4-81-026d (December 1992).

NO<sub>x</sub> and 9.91 tpd for VOC. This allocation and the resulting available safety margin for the Tennessee portion of the Memphis, TN–MS–AR Area are discussed further in section VI of this proposed rulemaking along with the MVEBs to be used for transportation conformity proposes.

#### d. Monitoring Network

There currently are five monitors measuring ozone in the Memphis, TN–MS–AR Area, of which three are in the Tennessee portion of the Memphis, TN–MS–AR Area. Tennessee has committed to continue operation of the monitors in the Tennessee portion of the Memphis, TN–MS–AR Area in compliance with 40 CFR part 58 and has thus addressed the requirement for monitoring. Arkansas and Mississippi have made similar commitments in their maintenance plans. EPA approved Tennessee's monitoring plan on October 26, 2015. EPA approved Arkansas' monitoring plan on November 16, 2015, and approved Mississippi's monitoring plan on October 6, 2015.

#### e. Verification of Continued Attainment

TDEC has the legal authority to enforce and implement the maintenance plan for the Tennessee portion of the Area. This includes the authority to adopt, implement, and enforce any subsequent emissions control contingency measures determined to be necessary to correct future ozone attainment problems.

Additionally, under the AERR, TDEC is required to develop a comprehensive, annual, statewide emissions inventory every three years that is due twelve to eighteen months after the completion of the inventory year. Tennessee will update the AERR inventory every three years beginning no later than the 2015 emission season and will use the updated emissions inventory to track progress of the maintenance plan.

#### f. Contingency Measures in the Maintenance Plan

Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to assure that the state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the contingency measures to be adopted, a schedule and procedure for adoption and implementation, and a time limit for action by the state. A state should also identify specific indicators to be used to determine when the contingency measures need to be implemented. The maintenance plan must include a requirement that a state

will implement all measures with respect to control of the pollutant that were contained in the SIP before redesignation of the area to attainment in accordance with section 175A(d).

In the January 19, 2016, submittal, Tennessee commits to continuing existing programs and commits to implement programs and measures depending upon emission inventory and air quality monitoring results. The contingency plan included in the submittal includes a triggering mechanism to determine when contingency measures are needed and a process of developing and implementing appropriate control measures.

The primary trigger is activated when emissions or ambient air monitoring data indicates possible future ozone levels violating the 2008 8-hour ozone NAAQS but an actual violation of the 2008 8-hour ozone NAAQS has not yet occurred. This will occur if the certified triennial emissions inventory of VOCs or NO<sub>x</sub> (summer season tons per day) exceeds the 2012 base year attainment inventory by ten percent or more and any area monitor has recorded at least one exceedance of the ozone NAAQS according to certified data during the most recent monitoring season. The Shelby County Health Department will then conduct an investigation lasting no longer than three months into the possible causes. The results will be reported to EPA and TDEC. If the data is valid and not due to unusual circumstances, the Shelby County Health Department will seek to expand voluntary programs<sup>20</sup> and develop regulations as appropriate following consultation with EPA and TDEC. Proof of regulation adoption will be sent to EPA within nine months and implementation of regulations will occur within 18 to 24 months after monitoring data is certified. Possible contingency measures include, but are not limited to:

- Programs or incentives to decrease motor vehicle use;
- Programs to require additional emissions reductions on stationary sources;

- Restrictions of certain roads or lanes for, or construction of such roads or lanes for use by, passenger buses or high-occupancy vehicles;

- Employer-based transportation incentive plans; and

- Additional programs for new construction of paths for use by pedestrian or non-motorized vehicles when economically feasible and in the public interest.

The secondary trigger is a violation of the 2008 8-hour ozone NAAQS (*i.e.*, when the three-year average of the 4th highest values is equal to or greater than 0.076 ppm at a monitor in the Area). The trigger date will be when a monitored violation of the 2008 ozone NAAQS occurs in the nonattainment area according to certified data during the most recent monitoring season. The Shelby County Health Department will then conduct an investigation lasting no longer than three months into the possible causes. The results will be reported to TDEC and EPA. If the data is valid, further action is required, and the Shelby County Health Department will seek to expand voluntary programs and develop regulations for submission to the Shelby County Commission or Tennessee State Air Board. Proof of adoption of such regulations will be submitted to EPA within nine months after the end of the investigation. Control measures will be implemented within 18 to 24 months after verification of a monitored violation by certified data. In addition to the measures stated for the primary trigger, the following measures may also be implemented if there is a secondary trigger of a violation of the standard:

- A RACT regulation for legacy major sources of NO<sub>x</sub> emissions in Shelby County; and

- Adoption of all industrial and commercial VOC controls as provided in final EPA-approved Control Technology Guidelines through the date of the recorded violation.

EPA preliminarily concludes that the maintenance plan adequately addresses the five basic components of a maintenance plan: The attainment emissions inventory, maintenance demonstration, monitoring, verification of continued attainment, and a contingency plan. Therefore, EPA proposes to find that the maintenance plan SIP revision submitted by Tennessee for the State's portion of the Area meets the requirements of section 175A of the CAA and is approvable.

<sup>20</sup> If the State adopts a voluntary emission reduction measure as a contingency measure necessary to attain or maintain the NAAQS, EPA will evaluate approvability in accordance with relevant Agency guidance regarding the incorporation of voluntary measures into SIPs. *See, e.g.*, Memorandum from Richard D. Wilson, Acting Administrator for Air and Radiation, to EPA Regional Administrators re: Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs) (October 24, 1997); EPA, Office of Air and Radiation, Incorporating Emerging and Voluntary Measures in a State Implementation Plan (SIP) (September 2004).

**VI. What is EPA’s analysis of Tennessee’s proposed NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the area?**

Under section 176(c) of the CAA, new transportation plans, programs, and projects, such as the construction of new highways, must “conform” to (*i.e.*, be consistent with) the part of the state’s air quality plan that addresses pollution from cars and trucks. Conformity to the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS or any interim milestones. If a transportation plan does not conform, most new projects that would expand the capacity of roadways cannot go forward. Regulations at 40 CFR part 93 set forth EPA policy, criteria, and procedures for demonstrating and assuring conformity of such transportation activities to a SIP. The regional emissions analysis is one, but not the only, requirement for implementing transportation conformity. Transportation conformity is a requirement for nonattainment and maintenance areas. Maintenance areas are areas that were previously nonattainment for a particular NAAQS but have since been redesignated to attainment with an approved maintenance plan for that NAAQS.

Under the CAA, states are required to submit, at various times, control strategy SIPs and maintenance plans for nonattainment areas. These control strategy SIPs (including RFP and attainment demonstration requirements) and maintenance plans create MVEBs for criteria pollutants and/or their precursors to address pollution from cars and trucks. Per 40 CFR part 93, a MVEB must be established for the last year of the maintenance plan. A state may adopt MVEBs for other years as well. The MVEB is the portion of the total allowable emissions in the maintenance demonstration that is allocated to highway and transit vehicle use and emissions. See 40 CFR 93.101. The MVEB serves as a ceiling on emissions from an area’s planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993, Transportation Conformity Rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and how to revise the MVEB.

After interagency consultation with the transportation partners for the Memphis TN–MS–AR Area, Tennessee has developed MVEBs for NO<sub>x</sub> and VOC for the Tennessee portion of the Area. Tennessee developed these MVEBs, as

required, for the last year of its maintenance plan, 2027. The 2027 MVEBs reflect the total projected on-road emissions for 2027, plus an allocation from the available NO<sub>x</sub> and VOC safety margins. Under 40 CFR 93.101, the term “safety margin” is the difference between the attainment level (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The safety margin can be allocated to the transportation sector; however, the total emissions must remain below the attainment level. The NO<sub>x</sub> and VOC MVEBs and allocation from the safety margin were developed in consultation with the transportation partners and were added to account for uncertainties in population growth, changes in model vehicle miles traveled, and new emission factor models. The NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the Area are identified in Table 6, below.

**TABLE 6—TENNESSEE PORTION OF THE AREA NO<sub>x</sub> AND VOC MVEBS (TPD)\***

	2027
NO <sub>x</sub> Base Emissions .....	12.51
NO <sub>x</sub> Safety Margin Allocated to MVEB .....	49.04
NO <sub>x</sub> MVEB .....	61.56
VOC Base Emissions .....	5.81
VOC Safety Margin Allocated to MVEB .....	13.19
VOC MVEB .....	19.01

\*The MVEBs do not total the sum of the base emissions and safety margins due to rounding convention.

As mentioned above, Tennessee has chosen to allocate a portion of the available safety margin to the NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the Area. This allocation is 49.04 tpd and 13.19 tpd for NO<sub>x</sub> and VOC, respectively. Thus, the remaining safety margins for 2027 are 11.38 tpd and 9.91 tpd NO<sub>x</sub> and VOC, respectively.

Through this rulemaking, EPA is proposing to approve the MVEBs for NO<sub>x</sub> and VOC for 2027 for the Tennessee Portion of the Area because EPA has preliminarily determined that the Area maintains the 2008 8-hour ozone NAAQS with the emissions at the levels of the budgets. Once the MVEBs for the Tennessee Portion of the Area are approved or found adequate (whichever is completed first), they must be used for future conformity determinations.

**VII. What is the status of EPA’s adequacy determination for the proposed NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the area?**

When reviewing submitted “control strategy” SIPs or maintenance plans containing MVEBs, EPA may affirmatively find the MVEB contained therein adequate for use in determining transportation conformity. Once EPA affirmatively finds the submitted MVEB is adequate for transportation conformity purposes, that MVEB must be used by state and federal agencies in determining whether proposed transportation projects conform to the SIP as required by section 176(c) of the CAA.

EPA’s substantive criteria for determining adequacy of a MVEB are set out in 40 CFR 93.118(e)(4). The process for determining adequacy consists of three basic steps: Public notification of a SIP submission, a public comment period, and EPA’s adequacy determination. This process for determining the adequacy of submitted MVEBs for transportation conformity purposes was initially outlined in EPA’s May 14, 1999, guidance, “Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.” EPA adopted regulations to codify the adequacy process in the Transportation Conformity Rule Amendments for the “New 8-Hour Ozone and PM<sub>2.5</sub> National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas; Transportation Conformity Rule Amendments—Response to Court Decision and Additional Rule Change,” on July 1, 2004 (69 FR 40004). Additional information on the adequacy process for transportation conformity purposes is available in the proposed rule entitled, “Transportation Conformity Rule Amendments: Response to Court Decision and Additional Rule Changes,” 68 FR 38974, 38984 (June 30, 2003).

As discussed earlier, Tennessee’s maintenance plan includes NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the Memphis TN–MS–AR Area for 2027, the last year of the maintenance plan. EPA reviewed the NO<sub>x</sub> and VOC MVEBs through the adequacy process. The NO<sub>x</sub> and VOC MVEBs for the Tennessee portion of the area were open for public comment on EPA’s adequacy Web site on January 27, 2016, found at: <http://www3.epa.gov/otaq/stateresources/transconf/cursips.htm#shelby-tn>. The EPA public comment period on adequacy for the 2027 MVEBs for the Tennessee portion of the Area closed on February

26, 2016, and no comments, adverse or otherwise, were received.

EPA intends to make its determination on the adequacy of the 2027 MVEBs for the Tennessee portion of the Area for transportation conformity purposes in the near future by completing the adequacy process that was started on January 27, 2016. After EPA finds the 2027 MVEBs adequate or approves them, the new MVEBs for NO<sub>x</sub> and VOC must be used for future transportation conformity determinations. For required regional emissions analysis years for 2027 and beyond, the applicable budgets will be the new 2027 MVEBs established in the maintenance plan.

### VIII. What is the effect of EPA's proposed actions?

EPA's proposed actions establish the basis upon which EPA may take final action on the issues being proposed for approval today. Approval of Tennessee's redesignation request would change the legal designation of Shelby County, Tennessee, in the Memphis TN-MS-AR Area, found at 40 CFR part 81, from nonattainment to attainment for the 2008 8-hour ozone NAAQS. Approval of Tennessee's associated SIP revision would also incorporate a plan for maintaining the 2008 8-hour ozone NAAQS in the Tennessee portion of the Area through 2027 and a section 182(a)(1) base year emissions inventory into the Tennessee SIP for the Area. The maintenance plan establishes NO<sub>x</sub> and VOC MVEBs for 2027 for the Tennessee portion of the Area and includes contingency measures to remedy any future violations of the 2008 8-hour ozone NAAQS and procedures for evaluation of potential violations. Additionally, EPA is notifying the public of the status of EPA's adequacy determination for the newly-established NO<sub>x</sub> and VOC MVEBs for 2027 for the Tennessee portion of the Area.

### IX. Proposed Actions

EPA is proposing to take four separate but related actions regarding the redesignation request and associated SIP revision for the Tennessee portion of the Memphis TN-MS-AR Area for the 2008 8-hour ozone NAAQS. First, EPA is proposing to approve Tennessee's section 182(a)(1) base year emissions inventory for the 2008 8-hour ozone standard for the Tennessee portion of the Area into the SIP.

Second, EPA is proposing to determine that the Memphis, TN-MS-AR Area has attained the 2008 8-hour ozone NAAQS based on complete, quality-assured and certified monitoring

data for the 2012-2014 monitoring period. Preliminary 2015 data in AQS indicates that the Area is continuing to attain the 2008 8-hour ozone NAAQS.

Third, EPA is proposing to approve the maintenance plan for the Tennessee portion of the Area, including the NO<sub>x</sub> and VOC MVEBs for 2027, into the Tennessee SIP (under CAA section 175A). The maintenance plan demonstrates that the Area will continue to maintain the 2008 8-hour ozone NAAQS.

Finally, EPA is proposing to approve Tennessee's redesignation request for the 2008 8-hour ozone NAAQS for the Tennessee portion of the Area contingent upon approval of the 182(a)(1) base year emissions inventory for the Tennessee portion of the Area.

As part of today's action, EPA is also describing the status of its adequacy determination for the NO<sub>x</sub> and VOC MVEBs for 2027 in accordance with 40 CFR 93.118(f)(1). Within 24 months from the effective date of EPA's adequacy determination for the MVEBs or the effective date for the final rule for this action, whichever is earlier, the transportation partners will need to demonstrate conformity to the new NO<sub>x</sub> and VOC MVEBs pursuant to 40 CFR 93.104(e)(3).

If finalized, approval of the redesignation request would change the official designation of Shelby County, Tennessee in the Tennessee portion of the Memphis TN-MS-AR Area for the 2008 8-hour ozone NAAQS from nonattainment to attainment, as found at 40 CFR part 81.

### X. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, 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, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, these proposed actions merely propose to approve state law as meeting Federal requirements

and do not impose additional requirements beyond those imposed by state law. For this reason, these proposed actions:

- Are 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);

- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Are 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.*);

- Do 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);

- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Are not economically significant regulatory actions based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Are not significant regulatory actions subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Are 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

- Will not have disproportionate human health or environmental effects under Executive Order 12898 (59 FR 7629, February 16, 1994).

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 as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

### List of Subjects

#### 40 CFR Part 52

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

**40 CFR Part 81**

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

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

Dated: April 8, 2016.

**Heather McTeer Toney,**

*Regional Administrator, Region 4.*

[FR Doc. 2016-08796 Filed 4-18-16; 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; Reopening of Comment Period**

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** This document reopens the comment period for the June 17, 2015, proposed rule entitled “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.” The comment period for the proposed rule, which ended on August 17, 2015, is reopened for 30 days.

**DATES:** The comment period for the proposed rule published on June 17, 2015 (80 FR 34583), is reopened and ends on May 19, 2016.

**ADDRESSES:** In commenting, please refer to the Regulatory Information Number (RIN) 0906-AA89, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions. The first is the preferred method.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow instructions for submitting comments. This is the preferred method for the submission of comments.

- *Email:* [340BCMPNPRM@hrsa.gov](mailto:340BCMPNPRM@hrsa.gov). Include 0906-AA89 in the subject line of the message.

- *Mail:* Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All submitted comments will be available to the public in their entirety.

**FOR FURTHER INFORMATION CONTACT:** CAPT Krista Pedley, Director, OPA,

HSB, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

**SUPPLEMENTARY INFORMATION:** On June 17, 2015, the Department of Health and Human Services (HHS) published a proposed rule in the **Federal Register** (80 FR 34583) entitled, “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation” that would set forth the calculation of the ceiling price and application of civil monetary penalties for section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” In light of the comments received, HHS is reopening the comment period for 30 days for the purpose of inviting public comments on several specific areas, summarized below. Comments may be submitted on any aspect of the proposed rule, not just those areas specifically addressed below. Commenters do not need to resubmit comments previously submitted, as all previous comments are currently under review and will be considered prior to the finalization of the proposed rule.

#### **Ceiling Price for a Covered Outpatient Drug Exception**

In the June 17, 2015, notice of proposed rulemaking (80 FR 34583), HHS proposed that when the calculation of the 340B ceiling price resulted in an amount less than \$0.01, the ceiling price would be \$0.01 per unit of measure (hereinafter, penny pricing). In the notice of proposed rulemaking (NPRM), we recognized that it was not reasonable for a manufacturer to set the ceiling price at \$0.00 per unit of measure. HHS received a number of comments supporting and opposing the penny pricing proposal.

Commenters suggested a number of alternatives to penny pricing, including: The federal ceiling price, the most recent positive ceiling price from previous quarters, and nominal sales price. Some commenters stated that the federal ceiling price, which is the basis for prices paid by certain federal government programs, would be a viable alternative. Other commenters suggested that charging a ceiling price from previous quarters in which the ceiling price was greater than \$0.00 would be reasonable. Finally, several commenters suggested that nominal pricing, which is a term used in the Medicaid Drug Rebate Program, would be more appropriate. Other commenters suggested that manufacturers should be able to utilize any other reasonable alternative.

Given these comments, HHS is considering whether any of these alternatives or other alternatives not raised by the commenters, alone or in combination, would be more appropriate than the penny pricing proposal and whether to revise the proposed regulatory text in 42 CFR 10.10(b). As the NPRM did not indicate that alternatives to the penny pricing proposal would be considered, and given the number of comments on this issue, HHS is reopening the comment period specifically to invite comments on whether we should adopt an alternative policy to penny pricing. By reopening the comment period as to this specific issue, all parties will have an opportunity to express their views on penny pricing and other alternatives prior to finalization of the proposed rule.

#### **New Drug Price Estimation**

In the NPRM, HHS proposed that manufacturers estimate the ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and provide HRSA an estimated ceiling price for each of the first three quarters the drug is available for sale. HHS also proposed that, beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in proposed 42 CFR 10.10(a). Under the proposed rule, the actual ceiling price for the first three quarters must also be calculated and manufacturers would be required to provide a refund or credit to any covered entity which purchased the covered outpatient drug at a price greater than the calculated ceiling price. HHS proposed that any refunds or credits owed to a covered entity must be provided by the end of the fourth quarter. HHS received numerous comments supporting and opposing the various components of its proposal on new drug price estimation.

Several commenters supported a specific methodology for calculating new drug prices, which included setting the price of the new covered outpatient drug as wholesale acquisition cost (WAC) minus the applicable rebate percentage (*i.e.*, 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics and OTCs). Commenters argued that this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable ceiling price. We are seeking comment on this specific methodology for the estimation of a new covered outpatient drug pricing and at which