

the Agency has preliminarily determined that it is not consistent with the requirements for SIP provisions under the CAA. EPA is further proposing to determine that the SIP revision does not correct the deficiencies identified in the June 12, 2015, SIP call. EPA is not reopening the 2015 SSM SIP Action and is only taking comment on whether this SIP revision is consistent with CAA requirements and whether it addresses the substantial inadequacy in the specific Georgia SIP provision identified in the 2015 SSM SIP Action.

If the Agency finalizes this disapproval, CAA section 110(c) would require EPA to promulgate a federal implementation plan within 24 months of the effective date of the final action unless EPA first approves a SIP revision that corrects the deficiencies identified in Section II of this NPRM within such time.<sup>14</sup>

#### IV. Statutory and Executive Order Reviews

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

The Proposed action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget for review.

##### B. Paperwork Reduction Act (PRA)

The proposed action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

##### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This action merely proposes to

<sup>14</sup> In addition to a requirement for EPA to promulgate a federal implementation plan, a final disapproval would trigger the offset sanction in CAA section 179(b)(2) 18 months after the effective date of a final disapproval, and the highway funding sanction in CAA section 179(b)(1) 24 months after the effective date of a final disapproval. Although the sanctions clock would begin to run from the effective date of a final disapproval, mandatory sanctions under CAA section 179 generally apply only in designated nonattainment areas. This includes areas designated as nonattainment after the effective date of a final disapproval. As discussed in the 2015 SSM SIP Action, EPA will evaluate the geographic scope of potential sanctions at the time it makes a determination that the air agency has failed to make a complete SIP submission in response to the 2015 SIP call, or at the time it disapproves such a SIP submission. The appropriate geographic scope for sanctions may vary depending upon the SIP provisions at issue. See 80 FR 33839, 33930. At this time, there are no nonattainment areas in Georgia.

disapprove a SIP submission as not meeting the CAA.

##### D. Unfunded Mandates Reform Act (UMRA)

The proposed 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. This proposed action imposes no enforceable duty on any State, local, or tribal governments or the private sector.

##### E. Executive Order 13132: Federalism

The proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

The proposed action does not have tribal implications as specified in Executive Order 13175. The proposed action does not apply on any Indian reservation land, any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply in this action.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definitions of “covered regulatory action” in section 2–202 of the Executive Order. This proposed action is not subject to Executive Order 13045 because it merely proposes to disapprove a SIP submission from Georgia as not meeting the CAA.

##### H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution and Use

The proposed 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

This proposed rulemaking does not involve technical standards.

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

EPA believes the human health or environmental risk address by this proposed action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This proposed action merely proposes to disapprove a SIP submission as not meeting the CAA.

##### List of Subjects in 40 CFR Part 52

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

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

Dated: November 21, 2022.

**Daniel Blackman,**

*Regional Administrator, Region 4.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R04–OAR–2022–0436; FRL–10401–01–R4]

#### Air Plan Approval; Georgia; Atlanta Area Limited Maintenance Plan for the 1997 8-Hour Ozone NAAQS

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Georgia, through the Georgia Environmental Protection Division (EPD), via a letter dated December 17, 2021. The SIP revision includes the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the Atlanta, Georgia Area (hereinafter referred to as the Atlanta Area or Area). The Area consists of 20 counties in Georgia: Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding, and Walton County. EPA is proposing to approve the LMP for the Area because the LMP provides for the maintenance of the 1997 8-hour ozone NAAQS within the Area through the end of the second 10-year portion of the

maintenance period. The effect of this action would be to make certain commitments related to maintenance of the 1997 8-hour ozone NAAQS in the Area federally enforceable as part of the Georgia SIP.

**DATES:** Comments must be received on or before December 28, 2022.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2022-0436 at <https://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 <https://www.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:**

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**I. Summary of EPA's Proposed Action**

In accordance with the Clean Air Act (CAA or Act), EPA is proposing to approve the Atlanta Area LMP for the 1997 8-hour ozone NAAQS that was submitted by Georgia EPD as a revision to the Georgia SIP on December 17, 2021. On April 15, 2004, the EPA Administrator signed a final rule announcing designations under the 8-hour ozone NAAQS. That action included the designation of the Atlanta Area as nonattainment for the 1997 8-hour ozone NAAQS. It was published April 30, 2004 and became effective June 15, 2004. *See* 69 FR 23857 (April 30, 2004). Subsequently, EPA approved a maintenance plan and redesignated the Atlanta Area attainment for the 1997 8-hour Ozone NAAQS. *See* 78 FR 72040 (December 2, 2013).

The Area LMP submitted by Georgia EPD on December 17, 2021, is designed to maintain the 1997 8-hour ozone NAAQS within the Atlanta Area through the end of the second 10-year portion of the maintenance period beyond redesignation. EPA is proposing to approve the LMP because it meets all applicable requirements under CAA sections 110 and 175A.

As a general matter, the Atlanta Area LMP builds upon controls and contingency provisions to maintain the 1997 8-hour ozone NAAQS during the second 10-year portion of the Area's maintenance period as the maintenance plan submitted by Georgia EPD for the first 10-year period.

**II. Background**

Ground-level ozone is formed when oxides of nitrogen (NO<sub>x</sub>) and volatile organic compounds (VOC) react in the presence of sunlight. These two pollutants, referred to as ozone precursors, are emitted by many types of pollution sources, including on- and off-road motor vehicles and engines, power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints. Scientific evidence indicates that adverse public health effects occur following exposure to ozone, particularly in children and in adults with lung disease. Breathing air containing ozone can reduce lung function and inflame airways, which can increase respiratory symptoms and aggravate asthma and other lung diseases.

Ozone exposure also has been associated with increased susceptibility to respiratory infections, medication use, doctor visits, and emergency department visits and hospital admissions for individuals with lung disease. Children are at increased risk

from exposure to ozone because their lungs are still developing and they are more likely to be active outdoors, which increases their exposure.<sup>1</sup>

In 1979, under section 109 of the CAA, EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. *See* 44 FR 8202 (February 8, 1979). On July 18, 1997, EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. *See* 62 FR 38856 (July 18, 1997).<sup>2</sup> EPA set the 8-hour ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set. EPA determined that the 8-hour ozone NAAQS would be more protective of human health, especially for children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. Effective June 15, 2004, EPA designated the Atlanta Area as nonattainment for the 1997 8-hour ozone NAAQS. *See* 69 FR 23858 (April 30, 2004). Similarly, on May 21, 2012, EPA designated areas as unclassifiable/attainment or nonattainment for the 2008 8-hour ozone NAAQS. Fifteen metro Atlanta counties were designated nonattainment for the 2008 ozone NAAQS: Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale. *See* 77 FR 30088 (May 21, 2012). EPA designated five other metro Atlanta counties as unclassifiable/attainment for the 2008 8-hour ozone NAAQS: Barrow, Carroll, Hall, Spalding, and Walton. These designations became effective on July 20, 2012. In addition, on June 4, 2018, EPA designated areas for the 2015 8-hour ozone NAAQS. Effective August 3, 2018, seven metro Atlanta counties were designated as nonattainment for the 2015 8-hour ozone NAAQS: Bartow,

<sup>1</sup> *See* "Fact Sheet, Proposal to Revise the National Ambient Air Quality Standards for Ozone," January 6, 2010, and 75 FR 2938 (January 19, 2010).

<sup>2</sup> In March 2008, EPA completed another review of the primary and secondary ozone NAAQS and tightened them further by lowering the level for both to 0.075 ppm. *See* 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone NAAQS and tightened them by lowering the level for both to 0.070 ppm. *See* 80 FR 65292 (October 26, 2015).

Clayton, Cobb, DeKalb, Fulton, Gwinnett and Henry. See 83 FR 25776 (June 4, 2018) and 40 CFR 81.311.

A state may submit a request that EPA redesignate a nonattainment area that is attaining a NAAQS, and, if the area has met other required criteria described in section 107(d)(3)(E) of the CAA, EPA may approve the area's redesignation to attainment.<sup>3</sup> One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the NAAQS for the period extending 10 years after redesignation, and it must contain such additional measures as necessary to ensure maintenance and such contingency provisions as necessary to assure that violations of the NAAQS will be promptly corrected. Eight years after the effective date of redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the NAAQS for an additional ten years pursuant to CAA section 175A(b) (*i.e.*, ensuring maintenance for 20 years after redesignation).

EPA has published long-standing guidance for states on developing maintenance plans, beginning with a 1992 memo referred to as the Calcagni memo.<sup>4</sup> The Calcagni memo provides that states may generally demonstrate maintenance by either performing air quality modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS or by showing that projected future emissions of a pollutant and its precursors will not exceed the level of emissions generated during a year when the area was attaining the NAAQS (*i.e.*, attainment year inventory). See Calcagni memo at page 9. EPA clarified in three subsequent guidance memos that certain areas could meet the CAA section 175A requirement to provide for maintenance by showing that the area was unlikely to violate the NAAQS in the future, using information such as the area's

<sup>3</sup> Section 107(d)(3)(E) of the CAA sets out the requirements for redesignating a nonattainment area to attainment. They include attainment of the NAAQS, full approval of the applicable SIP pursuant to CAA section 110(k), determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

<sup>4</sup> See John Calcagni, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards, "Procedures for Processing Requests to Redesignate Areas to Attainment," September 4, 1992 (Calcagni memo, available at <https://www.epa.gov/ground-level-ozone-pollution/procedures-processing-requests-redesignate-areas-attainment>).

design value<sup>5</sup> being well below the standard and the area having a historically stable design value.<sup>6</sup> EPA refers to a maintenance plan containing this streamlined demonstration as an LMP.

EPA has interpreted CAA section 175A as permitting the LMP option because section 175A of the Act does not define how areas may demonstrate maintenance, and in EPA's experience implementing the various NAAQS, areas that qualify for an LMP and have approved LMPs have rarely, if ever, experienced subsequent violations of the NAAQS. As noted in the LMP guidance memoranda, states seeking an LMP must still submit the other maintenance plan elements outlined in the Calcagni memo, including: an attainment emissions inventory, provisions for the continued operation of the ambient air quality monitoring network, verification of continued attainment, and a contingency plan in the event of a future violation of the NAAQS. Moreover, a state seeking an LMP must still submit its section 175A maintenance plan as a revision to its SIP, with all attendant notice and comment procedures. While the LMP guidance memoranda were originally written with respect to certain NAAQS,<sup>7</sup> EPA has extended the LMP interpretation of section 175A to other NAAQS and pollutants not specifically covered by the previous guidance memos. See, e.g., 79 FR 41900 (July 18, 2014) (approval of the second ten-year LMP for the Grant County 1971 SO<sub>2</sub> maintenance area).

In this case, EPA is proposing to approve the Area's LMP for the 1997 8-hour ozone NAAQS because the State has made a showing, consistent with EPA's prior LMP guidance, that the Area's ozone concentrations are well below the 1997 8-hour ozone NAAQS and have been historically stable, and

<sup>5</sup> The ozone design value for a monitoring site is the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations. The design value for an ozone area is the highest design value of any monitoring site in the area.

<sup>6</sup> See "Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas" from Sally L. Shaver, Office of Air Quality Planning and Standards (OAQPS), dated November 16, 1994; "Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas" from Joseph Paisie, OAQPS, dated October 6, 1995; and "Limited Maintenance Plan Option for Moderate PM<sub>10</sub> Nonattainment Areas" from Lydia Wegman, OAQPS, dated August 9, 2001. Copies of these guidance memoranda can be found in the docket for this proposed rulemaking.

<sup>7</sup> The prior memos addressed: unclassifiable areas under the 1-hour ozone NAAQS, nonattainment areas for the PM<sub>10</sub> (particulate matter with an aerodynamic diameter less than 10 microns) NAAQS, and nonattainment for the carbon monoxide (CO) NAAQS.

that it has met the other maintenance plan requirements. Georgia EPD has submitted the LMP for the Atlanta Area to fulfill the second maintenance plan requirement in the Act. EPA's evaluation of the Area's LMP for the 1997 8-hour ozone NAAQS is presented below.

On April 4, 2012, Georgia EPD submitted to EPA a request to redesignate the Atlanta Area to attainment for the 1997 8-hour ozone NAAQS. This submittal included a plan to provide for maintenance of the 1997 8-hour ozone NAAQS in the Atlanta Area through 2024 as a revision to the Georgia SIP. EPA approved the Atlanta Area Maintenance Plan and the State's request to redesignate the Atlanta Area to attainment for the 1997 8-hour ozone NAAQS effective January 2, 2014. See 78 FR 72040 (December 2, 2013).

Under CAA section 175A(b), states must submit a revision to the first maintenance plan eight years after redesignation to provide for maintenance of the NAAQS for ten additional years following the end of the first 10-year period. EPA's final implementation rule for the 2008 8-hour ozone NAAQS revoked the 1997 8-hour ozone NAAQS and stated that one consequence of revocation was that areas that had been redesignated to attainment (*i.e.*, maintenance areas) for the 1997 NAAQS no longer needed to submit second 10-year maintenance plans under CAA section 175A(b). See 80 FR 12315 (March 6, 2015). On June 2, 2017, EPA redesignated 15 counties in metro Atlanta as attainment for the 2008 8-hour ozone NAAQS.<sup>8</sup> See 82 FR 25523 (June 2, 2017).

In *South Coast Air Quality Management District v. EPA*, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) vacated EPA's interpretation that, because of the revocation of the 1997 8-hour ozone NAAQS, second maintenance plans were not required for "orphan maintenance areas," *i.e.*, areas that had been redesignated to attainment for the 1997 8-hour ozone NAAQS maintenance areas and were designated attainment for the 2008 ozone NAAQS. *South Coast*, 882 F.3d 1138 (D.C. Cir. 2018). Thus, states with these "orphan maintenance areas" under the 1997 8-hour ozone NAAQS must submit maintenance plans for the second maintenance period. Accordingly, on December 17, 2021,

<sup>8</sup> The 15-county metro Atlanta region identified for the 2008 8-hour ozone NAAQS is comprised of Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale counties in Georgia.

Georgia submitted a second maintenance plan for the Atlanta Area that shows that the Area is expected to remain in attainment of the 1997 8-hour ozone NAAQS through January 2, 2034.

In recognition of the continuing record of air quality monitoring data showing ambient 8-hour ozone concentrations in the Area are below the 1997 8-hour ozone NAAQS, Georgia EPD chose the LMP option for the development of the Area's second 1997 8-hour ozone NAAQS maintenance plan. On December 17, 2021, Georgia EPD submitted the second 10-year 1997 8-hour ozone maintenance plan to EPA as a revision to the Georgia SIP.

**III. Georgia's SIP Submittal**

Georgia's December 17, 2021, submittal includes the LMP, air quality data, emissions inventory information, and an appendix. The submission also includes comments and responses between EPA and Georgia EPD and documentation of notice, hearing, and public participation prior to submission of the plan by Georgia EPD on December 17, 2021. It also includes an explanation that Georgia's LMP submittal for the remainder of the 20-year maintenance period for the Atlanta Area is in response to the D.C. Circuit Court's decision overturning aspects of EPA's Implementation Plan rule. In addition, the LMP went through interagency consultation to ensure transportation conformity.

The Atlanta LMP for the 1997 8-Hour ozone NAAQS includes same or similar emission reduction strategies as the first 10-year Maintenance Plan, as well as additional emissions reduction measures to provide for the maintenance of the 1997 8-hour ozone NAAQS through January 2, 2034. Specifically, the measures upon which the second 10-year LMP for the Area rely include the following SIP-approved Georgia Rules: 391-3-1-.02(2)(yy)—Emissions of Nitrogen Oxides from Major Sources; 391-3-1-.02(2)(jjj)—NO<sub>x</sub> Emissions from Electric Utility Steam Generating Units; 391-3-1-.02(2)(lll)—NO<sub>x</sub> Emissions from Fuel-Burning Equipment; 391-3-1-.02(2)(rrr)—NO<sub>x</sub> from Small Fuel-Burning Equipment; 391-3-20—Vehicle Emissions Inspection and Maintenance Program; and 391-3-1-.02(12)—Cross-State Air Pollution Rule (CSAPR) NO<sub>x</sub> Annual Trading Program. The Area's LMP also relies on continued implementation of Federal measures (e.g., Onboard Refueling Vapor Recovery for Light Duty Vehicles; Architectural and Industrial Maintenance Coatings; Automobile Refinishing; National Emission Standards for Hazardous Air

Pollutants (the majority of which are for VOC); Phase II Acid Rain Program for NO<sub>x</sub>; Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements (65 FR 6697); Tier 3 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements (79 FR 23414); and CSAPR).

**IV. EPA's Evaluation of Georgia's SIP Submittal**

EPA has reviewed the Area's LMP which is designed to maintain the 1997 8-hour ozone NAAQS within the Area through the end of the 20-year period beyond redesignation, as required under CAA section 175A(b). The following is a summary of EPA's interpretation of the section 175A requirements<sup>9</sup> and EPA's evaluation of how each requirement is met.

*A. Attainment Emissions Inventory*

For maintenance plans, a state should develop a comprehensive, accurate inventory of actual emissions for an attainment year to identify the level of emissions which is sufficient to maintain the NAAQS. A state should develop this inventory consistent with EPA's most recent guidance on emissions inventory development. For ozone, the inventory should be based on typical summer day emissions of VOC and NO<sub>x</sub>, as these pollutants are precursors to ozone formation. The Atlanta LMP includes an ozone attainment inventory for the Area generated from the data EPA made available from the 2014 National Emissions Inventory (NEI) and that Georgia represents as 2014 summer tons.<sup>10</sup> Table 1 presents a summary of the inventory for 2014 contained in the LMP.

**TABLE 1—2014 NO<sub>x</sub> AND VOC EMISSIONS BY SECTOR (SUMMER TONS) IN THE ATLANTA AREA**

Sector	2014	
	NO <sub>x</sub>	VOC
Fire .....	1	4
Nonpoint .....	3,228	22,991
Nonroad .....	6,502	8,478
Onroad .....	27,684	13,868
Point .....	7,189	2,582
<b>Total</b> <sup>11</sup> .....	<b>44,604</b>	<b>47,923</b>

<sup>9</sup> See Calcagni memo, pages 7–13.  
<sup>10</sup> Georgia defines summer tons as the total cumulative emissions from May through September.  
<sup>11</sup> The totals represented in the table may be slightly different than the inventories in the LMP based on rounding convention.

The Emissions Inventory section of the LMP for the Atlanta Area describes the methods, models, and assumptions used to develop the attainment inventory. These estimates were derived from emission values provided by EPA for use in developing maintenance plans for the 1997 8-hour ozone NAAQS.<sup>12</sup> For the Atlanta Area, Georgia EPD used the emissions summaries generated by EPA from the 2014 NEI, version 2 (2014NEIv2).<sup>13</sup>

Based on review of the methods, models, and assumptions used by Georgia EPD to develop the VOC and NO<sub>x</sub> estimates, EPA proposes to find that the Area's LMP includes a comprehensive, reasonably accurate inventory of actual ozone precursor emissions in attainment year 2014, and proposes to conclude that the plan's inventories are acceptable for the purposes of a subsequent maintenance plan under CAA section 175A(b).

*B. Maintenance Demonstration*

The maintenance demonstration requirement is considered to be satisfied in an LMP if the state can provide sufficient weight of evidence indicating that air quality in the area is well below the level of the NAAQS, that past air quality trends have been shown to be stable, and that the probability of the area experiencing a violation over the second 10-year maintenance period is low.<sup>14</sup> These criteria are evaluated below with regard to the Atlanta Area.

**1. Evaluation of Ozone Air Quality Levels**

To attain the 1997 8-hour ozone NAAQS, the three-year average of the fourth-highest daily maximum 8-hour average ozone concentrations (design value) at each monitor within an area must not exceed 0.08 ppm. Based on the rounding convention described in 40 CFR part 50, appendix I, the NAAQS is attained if the design value is 0.084 ppm (84 parts per billion or "ppb")<sup>15</sup> or below. EPA has evaluated the quality assured and certified 2018–2020

<sup>12</sup> U.S. EPA, "1997 Ozone NAAQS Air Quality Monitoring and Modeling Data" downloaded from [https://www.epa.gov/sites/production/files/2018-11/ozone\\_1997\\_naaqs\\_air\\_qual\\_monitoring\\_and\\_modeling\\_data\\_nov\\_19\\_2018\\_1.xlsx](https://www.epa.gov/sites/production/files/2018-11/ozone_1997_naaqs_air_qual_monitoring_and_modeling_data_nov_19_2018_1.xlsx), accessed April 2020.

<sup>13</sup> U.S. EPA, "Air Emissions Modeling, 2014 Version 7.1 Platform," is available from <https://www.epa.gov/air-emissions-modeling/2014-version-71-platform>, accessed April 2020 (note that the version 7 platform, which included 2028 projections is not available on EPA's website).

<sup>14</sup> See footnote 6.  
<sup>15</sup> EPA set the 1997 8-hour ozone NAAQS in ppm. To convert ppm to ppb the decimal is moved three places to the right (i.e., 0.084 ppm is equal to 84 ppb). Georgia EPD provided the values in ppb for easy reference.

monitoring data (which was the most recent quality assured and certified data at the time of submission) and determined that the 2018–2020 design value for the Area is 70 ppb, or 83 percent of the level of the 1997 8-hour ozone NAAQS. In addition, EPA evaluated the quality assured and certified 2019–2021 monitoring data (which is the most recent quality assured and certified monitoring data) and determined that the 2019–2021 design value for the Area is 68 ppb, or 81 percent of the level of the 1997 8-hour ozone NAAQS. Consistent with

prior guidance, EPA believes that if the most recent air quality design value for the area is at a level that is well below the NAAQS (e.g., below 85 percent of the NAAQS, or in this case below 71 ppb), then EPA considers the state to have met the section 175A requirement for a demonstration that the area will maintain the NAAQS for the requisite period. Such a demonstration assumes continued applicability of prevention of significant deterioration requirements and any control measures already in the SIP, and that Federal measures will remain in place through the end of the

second 10-year maintenance period, absent a showing consistent with section 110(l) that such measures are not necessary to assure maintenance.

Table 2 presents the design values for each monitor in the Atlanta Area over the 2009–2021 period.<sup>16</sup> As shown in Table 2, all sites have been below the level of the 1997 8-hour ozone NAAQS since the 2008–2010 design value, and the most current design value for each monitoring site is below 85 percent of the NAAQS, consistent with prior LMP guidance.

TABLE 2—1997 8-HOUR OZONE NAAQS DESIGN VALUES (ppb) AT MONITORING SITES IN THE ATLANTA AREA FOR THE 2009–2021 TIME PERIOD

Location	County	AQS site ID	2007–2009 DV	2008–2010 DV	2009–2011 DV	2010–2012 DV	2011–2013 DV	2012–2014 DV	2013–2015 DV	2014–2016 DV	2015–2017 DV	2016–2018 DV	2017–2019 DV	2018–2020 DV	2019–2021 DV
Kennesaw .....	Cobb .....	13–067–0003	80	76	78	77	73	I	I	I	67	66	65	62	61
Newnan (Discontinued)	Coweta ...	13–077–0002	77	68	67	66	62	60	62	66	63	D	D	D	D
Dawsonville .....	Dawson ..	13–085–0001	73	71	68	67	64	64	64	65	65	65	64	61	60
South DeKalb .....	DeKalb ...	13–089–0002	86	79	77	80	75	72	67	71	71	69	69	67	67
Douglasville .....	Douglas ..	13–097–0004	79	75	74	75	71	67	66	68	69	67	67	64	66
United Avenue .....	Fulton .....	13–121–0055	86	80	80	83	80	76	73	75	75	73	73	70	68
Gwinnett .....	Gwinnett	13–135–0002	81	74	75	78	77	72	69	72	71	69	66	66	66
McDonough .....	Henry .....	13–151–0002	87	79	78	82	80	77	71	74	71	70	69	67	66
Yorkville (Discontinued)	Polk .....	13–223–0003	74	70	71	72	69	64	62	63	D	D	D	D	D
Georgia Station CASTNET.	Pike .....	13–231–9991	ND	ND	ND	ND	72	69	66	68	67	I	I	I	61
Conyers .....	Rockdale	13–247–0001	85	78	75	79	77	77	72	74	69	70	68	67	65

I: Indicates that a monitor did not collect a valid three-year design value due to incomplete data.

D: Indicates that a monitor was approved by EPA to discontinue operation in the Georgia ambient air monitoring network plan.

ND: Prior to 2011, CASTNET sites did not provide regulatory ozone data for comparisons to the NAAQS. Starting in 2011, CASTNET sites were upgraded to meet all requirements of 40 CFR part 58 and provide ozone data for NAAQS comparisons.

The bolded numbers are the design values for the Atlanta Area for the three-year time periods.

Therefore, the Atlanta Area is eligible for the LMP option, and EPA proposes to find that the long record of monitored ozone concentrations that attain the NAAQS, together with the continuation of existing VOC and NO<sub>x</sub> emissions control programs, adequately provide for the maintenance of the 1997 8-hour ozone NAAQS in the Area through the second 10-year maintenance period and beyond.

## 2. Stability of Ozone Levels

As discussed above, the Atlanta Area has maintained air quality below the 1997 8-hour ozone NAAQS over the past twelve design values. Additionally, the design value data shown within Table 2 of this document illustrates that ozone levels have been relatively stable over this timeframe, with an overall downward trend. For example, the data within Table 2 of this document

indicates that the largest, year over year change in design value presented was 8 ppb for the Atlanta Area, which occurred between the 2009 design value and 2010 design value at monitor 13–151–0002 (McDonough), representing approximately a 9 percent decrease.

Furthermore, overall trend in design values for the Area between 2009–2021 indicates decreases in the monitored ozone concentrations. See, e.g., Table 2, of this document. The Atlanta Area monitor that most frequently measured the highest design value in the area, monitor 13–121–0055 (United Avenue), displayed a decreasing trend over this period from 86 ppb to 68 ppb, a 21 percent decrease.

The downward trend in ozone levels, coupled with the relatively small, year-over-year variation in ozone design values, makes it reasonable to conclude that the Atlanta Area will not exceed the

1997 8-hour ozone NAAQS during the second 10-year maintenance period.

## 3. Projected Emissions

Although under the LMP option there is no requirement to project emissions over the maintenance period, Georgia EPD provided VOC and NO<sub>x</sub> emissions for 2014 and 2028. The year 2014 was selected as a baseline for the projection.<sup>17</sup> Projected emissions data for the year 2028 were obtained from EPA, and Georgia presented an inventory that reflects projected NO<sub>x</sub> and VOC summer tons for the Area.<sup>18 19</sup>

The emissions projection shows that between 2014 and 2028, total VOC emissions are estimated to fall by 27 percent in the Atlanta Area. The emissions projection trends show that between 2014 and 2028, total NO<sub>x</sub> emissions are estimated to fall by 58 percent in the Atlanta Area. These

<sup>16</sup> Georgia EPD provided monitoring data for years 2009 through 2020. The values can be found on Page 12 of the submittal. The monitoring data shows the general downward trend in design values at the monitoring sites.

<sup>17</sup> See [https://www.epa.gov/sites/default/files/2018-11/documents/ozone\\_1997\\_naaqs\\_lmp\\_resource\\_document\\_nov\\_20\\_2018.pdf](https://www.epa.gov/sites/default/files/2018-11/documents/ozone_1997_naaqs_lmp_resource_document_nov_20_2018.pdf).

<sup>18</sup> See <https://www.epa.gov/air-emissions-modeling/2014-2016-version-7-air-emissions-modeling-platforms>. EPA's emissions projections to 2028 were made from the 2011 NEI, as that iteration of the NEI was the most recently available version when the projection work was performed. Although this projection does not correspond exactly with the end of the second ten-year maintenance period, it provides additional support for EPA's proposed

finding that the Area will maintain the NAAQS due to its low and historically stable design values. See the Emissions Inventory section of the LMP for additional information regarding the 2028 projections.

<sup>19</sup> Georgia defines summer tons as the total cumulative emissions from May through September.

projected declining emissions trends further support the proposed conclusion that it is unlikely that the Areas would violate the 1997 8-hour ozone NAAQS in the future. Table 3 presents a summary of projected emissions for 2028 contained in the maintenance plan.<sup>20</sup>

TABLE 3—PROJECTED 2028 NO<sub>x</sub> AND VOC EMISSIONS BY SECTOR (SUMMER TONS) IN THE ATLANTA AREA

Sector	2028	
	NO <sub>x</sub>	VOC
Fire .....	6	15
Nonpoint .....	2,554	20,552
Nonroad .....	4,131	7,098
Onroad .....	7,995	4,982
Point .....	4,221	2,156
Total <sup>21</sup> .....	18,907	34,803

### C. Monitoring Network and Verification of Continued Attainment

EPA periodically reviews the ozone monitoring network that Georgia EPD operates and maintains in accordance with 40 CFR part 58. Georgia EPD submits an annual ambient air monitoring network plan to EPA after the plan is made available for public inspection and comment, as required by 40 CFR 58.10. EPA has reviewed and approved the 2021 Georgia Ambient Air Monitoring Network Plan (“2021 Annual Network Plan”), which includes an ozone network for the Atlanta Area that meets the requirements of 40 CFR part 58.<sup>22</sup>

To verify the attainment status of the Area over the maintenance period, the maintenance plan should contain provisions for continued operation of an appropriate, EPA-approved monitoring network in accordance with 40 CFR part 58. As noted above, Georgia EPD’s monitoring network in the Area has been approved by EPA in accordance with 40 CFR part 58, and the State has committed to continue to maintain a network in accordance with EPA requirements. EPA proposes to find that Georgia EPD’s monitoring network is adequate to verify continued attainment of the 1997 8-hour ozone NAAQS in the Area.

### D. Contingency Plan

Section 175A(d) of the CAA requires that a maintenance plan include contingency provisions. The purpose of such contingency provisions is to prevent future violations of the NAAQS or to promptly remedy any NAAQS violations that might occur during the maintenance period.

The Atlanta Area LMP contingency plan includes tracking and triggering mechanisms to determine when control measures are needed, and a process for developing and adopting appropriate control measures. There are two potential triggers for the contingency plan. The Tier I trigger will be any 8-hour ozone monitoring reading exceeding 84 ppb at an ambient monitoring station located in the Atlanta Area or periodic emissions inventory updates<sup>23</sup> that reveal excessive or unanticipated growth greater than 10 percent in either NO<sub>x</sub> or VOC emissions over the attainment inventory for the Atlanta Area. The Tier II trigger will be any recorded violation of the 1997 8-hour ozone NAAQS at any of the ambient monitoring stations in the Atlanta Area. Upon either the Tier I or Tier II triggers being activated, Georgia EPD will commence analyses to determine what additional measures, if any, will be necessary to attain or maintain the ozone standard. If activation of either trigger occurs, the plan provides a regulatory adoption process for revising emission control strategies. If Georgia’s analysis determines that the Atlanta Area is the source of emissions that contribute to a violation, the State will evaluate those measures as specified in Section 172 of the CAA for control options as well as other available measures. Georgia will implement necessary controls as expeditiously as possible, and at least one contingency measure will be implemented within 24 months after the determination, based on quality-assured ambient data, that a violation has occurred. The Georgia EPD will begin initial analysis of possible contingency measures within 6 months of the trigger occurring.<sup>24</sup>

EPA proposes to find that the contingency provisions in Georgia’s second maintenance plan for the 1997 8-hour Ozone NAAQS meet the

requirements of the CAA section 175A(d).

### E. Conclusion

EPA proposes to find that the Atlanta LMP for the 1997 8-hour ozone NAAQS includes an approvable update of the various elements (including attainment inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions) of the initial EPA-approved Maintenance Plan for the 1997 8-hour ozone NAAQS. EPA also proposes to find that the Atlanta Area qualifies for the LMP option and adequately demonstrates maintenance of the 1997 8-hour ozone NAAQS through the documentation of monitoring data showing maximum 1997 8-hour ozone levels well below the NAAQS, historically stable design values, and low probability that the Area will experience a violation over the second 10-year maintenance period. EPA believes the Atlanta LMP for the 1997 8-hour ozone NAAQS, which retains all existing control measures, is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Area over the second maintenance period (*i.e.*, through January 2, 2034), and thereby satisfies the requirements for such plans under CAA section 175A(b). EPA is therefore proposing to approve Georgia’s December 17, 2021, submission of the Area’s LMP for the 1997 8-hour ozone NAAQS as a revision to the Georgia SIP.

### V. Transportation Conformity and General Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations or delay timely attainment of the NAAQS. See CAA 176(c)(1)(A) and (B). EPA’s transportation conformity rule at 40 CFR part 93, subpart A, requires that transportation plans, programs, and projects conform to SIPs, and that it establishes the criteria and procedures for determining whether they conform. The conformity rule generally requires a demonstration that emissions from the Regional Transportation Plan (RTP) and the Transportation Improvement Program (TIP) are consistent with the motor vehicles emissions budget (MVEB) contained in the control strategy SIP revision or maintenance plan. See 40 CFR 93.101, 93.118, and 93.124. A MVEB is defined as “the portion of the total allowable emissions defined in the submitted or approved control strategy implementation plan revision or maintenance plan for a

<sup>20</sup> The inventory documentation for this platform can be found here: <https://www.epa.gov/air-emissions-modeling/2011-version-63-platform>.

<sup>21</sup> The totals represented in the table may be slightly different than the inventories in the LMP based on rounding convention.

<sup>22</sup> The letter approving the network plan is in the docket for this proposed rulemaking.

<sup>23</sup> The Air Emissions Reporting Rule (AERR) requires state and local agencies to collect and submit criteria pollutant emissions data to EPA’s Emissions Inventory System (EIS) according to the schedule in 40 CFR 51.30.

<sup>24</sup> See the Contingency Plan Section of the LMP for further information regarding the contingency plan, including measures that Georgia will consider for adoption if any of the triggers are activated.

certain date for the purpose of meeting reasonable further progress milestones or demonstrating attainment or maintenance of the NAAQS, for any criteria pollutant or its precursors, allocated to highway and transit vehicle use and emissions.” See 40 CFR 93.101.

Under the conformity rule, LMP areas may demonstrate conformity without a regional emissions analysis. See 40 CFR 93.109(e). EPA made findings that the MVEBs in the first 10-years of the 1997 8-hour ozone maintenance plan for the Atlanta Area were adequate for transportation conformity purposes. In a **Federal Register** action published on December 2, 2013, EPA notified the public of the adequacy finding for the Atlanta Area through a final rule; the adequacy determination for Atlanta Area became effective on January 2, 2014. See 78 FR 72040.<sup>25</sup>

After approval of or an adequacy finding for the LMP, there is no requirement to meet the “budget test” for motor vehicle emissions pursuant to the transportation conformity rule for the respective maintenance area. All actions that would require a transportation conformity determination for the Atlanta Area under EPA’s transportation conformity rule provisions are considered to have already satisfied the regional emissions analysis and “budget test” requirements in 40 CFR 93.118 as a result of EPA’s adequacy finding for the LMP. See 69 FR 40004 (July 1, 2004). The Atlanta 2008 and 2015 NAAQS Areas need to continue to meet all applicable requirements of the transportation conformity regulations, including the need for a regional emissions analysis and comparison of the results of the regional emissions analysis to the applicable MVEB for the 2008 8-hour ozone NAAQS. The 2008 8-hour ozone NAAQS MVEBs will be used to demonstrate conformity for the 2015 8-hour ozone NAAQS until MVEBs for the 2015 8-hour ozone NAAQS are deemed adequate or approved.

However, because LMP areas are still maintenance areas, certain aspects of transportation conformity determinations still will be required for transportation plans, programs, and projects. Specifically, for such determinations, RTPs, TIPs, and transportation projects still will have to demonstrate that they are fiscally constrained (40 CFR 93.108), meet the criteria for consultation (40 CFR 93.105) and Transportation Control Measure

implementation in the conformity rule provisions (40 CFR 93.113), as well as meet the hot-spot requirements for projects (40 CFR 93.116).<sup>26</sup> Additionally, conformity determinations for RTPs and TIPs must be determined no less frequently than every four years, and conformity of plan and TIP amendments and transportation projects is demonstrated in accordance with the timing requirements specified in 40 CFR 93.104. Finally, in order for projects to be approved they must come from a currently conforming RTP and TIP. See 40 CFR 93.114 and 93.115.

#### VI. Proposed Action

Under sections 110(k) and 175A of the CAA and for the reasons set forth above, EPA is proposing to approve the Atlanta LMP for the 1997 8-hour ozone NAAQS, submitted by Georgia EPD on December 17, 2021, as a revision to the Georgia SIP. EPA is proposing to approve the LMP because the LMP includes an acceptable update of the various elements of the 1997 8-hour ozone NAAQS Maintenance Plan approved by EPA for the first 10-year period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions), and retains the relevant provisions of the SIP.

EPA also finds that the Atlanta Area, a former nonattainment area for the 1997 8-hour ozone NAAQS, qualifies for the LMP option and, therefore, the Area’s LMP adequately demonstrates maintenance of the 1997 8-hour ozone NAAQS through documentation of monitoring data showing maximum 1997 8-hour ozone levels well below the NAAQS and continuation of existing control measures. EPA believes the Area’s 1997 8-Hour Ozone LMP to be sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS over the second 10-year maintenance period (which extends through January 2, 2034), and thereby satisfies the requirements for such a plan under CAA section 175A(b).

#### VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 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. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

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

- Is certified as not having significant economic impacts on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandates or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

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

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

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

This SIP revision is not proposed 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 in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and

<sup>25</sup> EPA approved the MVEBs on December 2, 2013. See 78 FR 72040. The approval was made through a final rule and became effective on January 2, 2014.

<sup>26</sup> A conformity determination that meets other applicable criteria in Table 1 of paragraph (b) of the section (§ 93.109(e)) is still required, including the hot-spot requirements for projects in CO, PM<sub>10</sub>, and fine particulate matter (PM<sub>2.5</sub>) areas.

recordkeeping requirements, Volatile organic compounds.

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

**Daniel Blackman,**

*Regional Administrator, Region 4.*

[FR Doc. 2022-25585 Filed 11-25-22; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

#### 42 CFR Part 1001

#### Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts

**AGENCY:** Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department).

**ACTION:** Notification of intent to develop regulations.

**SUMMARY:** In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this annual notification solicits proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.

**DATES:** To ensure consideration, public comments must be received no later than 5 p.m. on January 27, 2023.

**ADDRESSES:** In commenting, please refer to file code OIG-1122-N. Because of staff and resource limitations, we cannot accept comments by fax transmission. You may submit comments in one of two ways (no duplicates, please):

1. *Electronically.* You may submit comments electronically at <https://www.regulations.gov>. Follow the "Submit a comment" instructions and refer to file code OIG-1122-N.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: OIG, Regulatory Affairs, HHS, Attention: OIG-1122-N, Room 5527, Cohen Building, 330 Independence Avenue SW, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, please see the

**SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Susan Edwards, (202) 619-0335.

**SUPPLEMENTARY INFORMATION:** Inspection of Public Comments: All comments

received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>.

### I. Background

#### A. OIG Safe Harbor Provisions

Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b)), the Federal anti-kickback statute, provides for criminal penalties for whoever knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward, among other things, referrals for or purchases of items or services reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act (42 U.S.C. 1320a-7b(f)). The offense is classified as a felony and is punishable by a fine of up to \$100,000 and imprisonment for up to 10 years. Violations of the Federal anti-kickback statute also may result in the imposition of civil monetary penalties under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729-33).

Because of the broad reach of the statute, stakeholders expressed concern that some relatively innocuous business arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress enacted section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93 (note to section 1128B of the Act; 42 U.S.C. 1320a-7b), which requires the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be subject to sanctions under the Federal anti-kickback statute, even though they potentially may be capable of inducing referrals of business for which payment may be made under a Federal health care program. Since July 29, 1991, there has been a series of final regulations published in the **Federal Register** establishing safe harbors to protect various payment and business practices.<sup>1</sup> These safe harbor provisions

<sup>1</sup> See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil

have been developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements."<sup>2</sup> Health care providers and others may voluntarily seek to comply with the conditions of an applicable safe harbor so that they have the assurance that their payment or business practice will not be subject to sanctions under the Federal anti-kickback statute. The safe harbor regulations promulgated by OIG are found at 42 CFR part 1001.

#### B. OIG Special Fraud Alerts

OIG periodically issues Special Fraud Alerts to give continuing guidance to health care industry stakeholders about practices that OIG considers to be suspect or of particular concern.<sup>3</sup> Special Fraud Alerts encourage industry compliance by giving stakeholders guidance that can be applied to their own practices. OIG Special Fraud Alerts are published in the **Federal Register**, on OIG's website, or both, and are intended for extensive distribution.

In developing Special Fraud Alerts, OIG relies on several sources and consults directly with experts in the subject field including those within OIG, other agencies of HHS, other Federal and State agencies, and those in the health care industry.

#### C. Section 205 of the Health Insurance Portability and Accountability Act of 1996

Section 205 of HIPAA, Public Law 104-191, and section 1128D of the Act (42 U.S.C. 1320a-7d), requires the Department to develop and publish an annual notification in the **Federal Register** formally soliciting proposals for developing additional or modifying existing safe harbors to the Federal anti-kickback statute and for issuing Special Fraud Alerts.

In developing or modifying safe harbors under the Federal anti-kickback statute, and in consultation with the Department of Justice, OIG thoroughly reviews the range of factual circumstances that may receive protection by the proposed or modified safe harbor. In doing so, OIG seeks to identify and develop safe harbors that protect beneficial and innocuous arrangements and safeguard Federal

Monetary Penalty Rules Regarding Beneficiary Inducements, 85 FR 77684 (Dec. 2, 2020).

<sup>2</sup> Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 FR 35952, 35958 (July 29, 1991).

<sup>3</sup> See, e.g., Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies (July 20, 2022), <https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf>.