Subpart PP—South Carolina

■ 5. In § 52.2120(e), amend the table by adding a new entry for ''110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS'' at the end of the table to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(e) * * *

Provision	State effective date	EPA approval date	Explanation
*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2015 8-Hour Ozone NAAQS.	9/7/2018	12/2/2021, [Insert citation of publication]	Addressing Prongs 1 and 2 of section 110(a)(2)(D)(i)(I) only.

[FR Doc. 2021–26144 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

EPA–R04–OAR–2020–0428; FRL–8911–02–R4]

Air Plan Approval; TN; Montgomery County Limited Maintenance Plan for the 1997 8-Hour Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a state implementation plan (SIP) revision submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), Air Pollution Control Division, on June 23, 2020. The SIP revision includes the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the Montgomery County, Tennessee portion of the Clarksville-Hopkinsville Area (hereinafter referred to as the ''Montgomery County Area'' or ''Area''). The Clarksville-Hopkinsville Area is comprised of Montgomery County, Tennessee, and Christian County, Kentucky. EPA is approving Tennessee's LMP for the Montgomery County Area because it provides for the maintenance of the 1997 8-hour ozone NAAQS within the Montgomery County 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 Montgomery County Area federally enforceable as part of the Tennessee SIP.

DATES: This rule is effective January 3, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R04–OAR–2020–0428. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials can either be retrieved electronically via *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at *larocca.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, under section 109 of the Clean Air Act (CAA or Act), 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).[1] 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 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. On April 15, 2004, EPA designated the Clarksville-Hopkinsville Area, which included Montgomery County, Tennessee, and Christian County, Kentucky, as nonattainment for the 1997 8-hour ozone NAAQS, and the designation became effective on June 15, 2004. *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. EPA designated Montgomery County as unclassifiable/attainment for the 2008 8-hour ozone NAAQS. This designation became effective on July 20, 2012. *See* 77 FR 30088 (May 21, 2012). In addition, on November 16, 2017, areas were designated for the 2015 8-hour ozone NAAQS. The Montgomery County Area was designated attainment/unclassifiable for the 2015 8-hour ozone NAAQS, with an effective date of January 16, 2018. *See* 82 FR 54232 (November 16, 2017).

A state may submit a request to redesignate a nonattainment area that is attaining a NAAQS to attainment, and, if the area has met other required criteria described in section 107(d)(3)(E) of the CAA, EPA may approve the

[1] 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).

redesignation request.[2] 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 ten 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.[3] 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 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 design value [4] being significantly below the standard and the area having a historically stable design value.[5] 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,[6] EPA has extended the LMP interpretation of section 175A to other NAAQS and pollutants not specifically covered by the previous guidance memos.[7]

In a notice of proposed rulemaking (NPRM), published on September 23, 2021 (86 FR 52864), EPA proposed to approve Tennessee's LMP because the State 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 that it met the other maintenance plan requirements. The details of Tennessee's submission and the rationale for EPA's action are explained in the NPRM. Comments on the September 23, 2021, NPRM were due on or before October 25, 2021. EPA did not receive any comments on the September 23, 2021, NPRM.

II. Final Action

EPA is taking final action to approve the Montgomery County Area LMP for the 1997 8-hour ozone NAAQS, submitted by TDEC on June 23, 2020, as a revision to the Tennessee SIP. EPA is approving the Montgomery County Area LMP because it includes a sufficient update of the various elements of the 1997 8-hour ozone NAAQS Maintenance Plan approved by EPA for the first 10-year portion of the maintenance period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions) and retains the relevant provisions of the SIP under sections 110(k) and 175A of the CAA.

EPA also finds that the Montgomery County Area qualifies for the LMP option and that the Montgomery County Area LMP is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Clarksville-Hopkinsville Area over the second 10-year maintenance period (*i.e.,* through 2025).

III. 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 approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

[2] 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.

[3] John Calcagni, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards (OAQPS), ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' September 4, 1992 (Calcagni memo).

[4] 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.

[5] See ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas,'' from Sally L. Shaver, OAQPS, November 16, 1994; ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas,'' from Joseph Paisie, OAQPS, October 6, 1995; and ''Limited Maintenance Plan Option for Moderate PM_{10} Nonattainment Areas,'' from Lydia Wegman, OAQPS, August 9, 2001. Copies of these guidance memoranda can be found in the docket for this rulemaking.

[6] The prior memos addressed: Unclassifiable areas under the 1-hour ozone NAAQS, nonattainment areas for the PM_{10} (particulate matter with an aerodynamic diameter less than 10 microns) NAAQS, and nonattainment for the carbon monoxide (CO) NAAQS.

[7] *See, e.g.,* 79 FR 41900 (July 18, 2014) (approval of the second ten-year LMP for the Grant County 1971 SO_2 maintenance area).

• 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).

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.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental Protection, Air Pollution Control, Incorporation by Reference, Intergovernmental Relations, Nitrogen Oxides, Ozone, Reporting and Recordkeeping Requirements, Volatile Organic Compounds.

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.2220 amend the table in paragraph (e) by adding, at the end of the table, the entry ''1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area'' to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
*	*	*	*	*
1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area.	Montgomery County	6/10/2020	12/2/2021, [Insert citation of publication].	

* * * * *

[FR Doc. 2021–26143 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB27

National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: On April 4, 2018, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend the National Vaccine Injury Compensation Program (VICP or Program) Vaccine Injury Table (Table), consistent with the statutory requirement to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant women. Specifically, the Secretary sought public comment regarding how the addition of this new category should be formatted on the Table. Through this final rule, the Secretary amends the Table to add ''and/or pregnant women'' after ''children'' to the existing language in Item XVII as proposed in the NPRM. This change will apply only to petitions for compensation under the VICP filed after the effective date of this final rule.

DATES: This rule is effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa-10 *et seq.*), established the VICP, a Federal compensation program for individuals thought to be injured by certain vaccines. The statute governing the VICP has been amended several times since 1986 and will be hereinafter