

from 9 a.m. to 9:30 a.m. on November 17, 2021.

(4) Paragraph (a)(5) of this section will be enforced:

(i) From 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 7, 2021. If necessary due to inclement weather or other reason on October 7, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on October 11, 2021;

(ii) from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 11, 2021. If necessary due to inclement weather or other reason on October 11, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on October 13, 2021;

(iii) from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on November 11, 2021. If necessary due to inclement weather or other reason on November 11, 2021, it will be enforced from 6 a.m. to 7 a.m., from 8 a.m. to 9 a.m., and from 10 a.m. to 11 a.m. on November 15, 2021; and

(iv) from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 15, 2021. If necessary due to inclement weather or other reason on November 15, 2021, it will be enforced from 10 a.m. to 10:30 a.m., from 11 a.m. to 11:30 a.m., from 12 p.m. (noon) to 12:30 p.m., and from 1 p.m. to 1:30 p.m. on November 17, 2021.

(4) Paragraph (a)(6) of this section will be enforced:

(i) From 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 7, 2021. If necessary due to inclement weather or other reason on October 7, 2021, it will be enforced from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on October 11, 2021;

(ii) from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 11, 2021. If necessary due to inclement weather or other reason on October 11, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., from 5 p.m. to 5:30 p.m., from 6 p.m. to 6:30 p.m., and from 7 p.m. to 7:30 p.m. on October 13, 2021;

(iii) from 12 p.m. (noon) to 1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 11, 2021. If necessary due to inclement weather or other reason on November 11, 2021, it will be enforced from 12 p.m. (noon) to

1 p.m., from 2 p.m. to 3 p.m., and from 4 p.m. to 5 p.m. on November 15, 2021; and

(iv) from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., and from 5 p.m. to 5:30 p.m. on November 15, 2021. If necessary due to inclement weather or other reason on November 15, 2021, it will be enforced from 2 p.m. to 2:30 p.m., from 3 p.m. to 3:30 p.m., from 4 p.m. to 4:30 p.m., and from 5 p.m. to 5:30 p.m. on November 17, 2021.

Dated: June 10, 2021.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2021-12580 Filed 6-15-21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2021-0052; FRL-10023-82-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Emissions Statement Requirement for the 2015 Ozone National Ambient Air Quality Standard

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 Maryland. This revision fulfills Maryland's emissions statement requirement for the 2015 ozone national ambient air quality standard (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before July 16, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R03-OAR-2021-0052 at <https://www.regulations.gov>, or via email to talley.david@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](https://www.regulations.gov). For either manner of submission, 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, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For 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:

Adam Yarina, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-2108. Mr. Yarina can also be reached via electronic mail at yarina.adam@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2015, EPA revised the ozone NAAQS from 0.075 parts per million (ppm) to 0.070 ppm,¹ and subsequently designated the Baltimore, MD, Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE, and Washington, DC-MD-VA areas as Marginal Nonattainment for the 2015 ozone NAAQS on June 4, 2018.² These areas include the following Maryland counties: Anne Arundel, Baltimore, Baltimore City, Carroll, Harford, Howard, Cecil, Calvert, Charles, Frederick, Montgomery, and Prince George's counties.³ Section 182 of the CAA identifies plan submissions and requirements for ozone nonattainment areas. Specifically, section 182(a)(3)(B) requires that states develop and submit rules which establish annual reporting requirements for certain stationary sources. Sources that are within marginal (or worse) ozone nonattainment areas must annually report the actual emissions of nitrogen oxides (NO_x) and volatile organic compounds (VOC) to the state. However, states may waive reporting requirements for sources that emit under 25 tpy of NO_x and VOC if the state provides an inventory of emissions from such class or category of sources. See CAA section 182(a)(3)(B)(ii).

Additionally, Maryland is located in the ozone transport region (OTR)

¹ See 80 FR 65291.

² See 83 FR 25776.

³ See 40 CFR 81.321.

established by Congress in section 184 of the CAA. Pursuant to section 184(b)(2), any stationary source that emits or has the potential to emit at least 50 tons per year (tpy) of VOC shall be considered a major stationary source and subject to the requirements which would be applicable to major stationary sources if the area were classified as a moderate nonattainment area. See CAA section 184. Thus, states within the OTR are subject to certain plan requirements in CAA section 182(b) applicable to moderate nonattainment areas. Also, section 182(f)(1) of the CAA requires that the plan provisions required for major stationary sources of VOC also apply to major stationary sources of NO_x for states with moderate (or worse) ozone nonattainment areas. A major stationary source of NO_x is defined as a stationary facility or source of air pollutants which directly emits or has the potential to emit 100 tpy or more of NO_x. See CAA section 302(j). Because Maryland is in the OTR, stationary sources located in attainment areas in Maryland and which emit above 50 tpy of VOC or 100 tpy of NO_x are considered major sources and also subject to the requirements of major stationary sources in moderate (or worse) nonattainment areas, including the emissions statement submission required by CAA section 182(a)(3)(B). See CAA sections 182(f) and 184(b)(2).

On July 6, 2020, the State of Maryland, through the Maryland Department of the Environment (MDE), submitted a SIP revision to satisfy the emissions statement requirement of CAA section 182(a)(3)(B) for the 2015 ozone NAAQS.

II. Summary of SIP Revision and EPA Analysis

On October 12, 1994 (59 FR 51517), EPA first approved Maryland's SIP submittal satisfying CAA section 182(a)(3)(B) and has approved submissions for section 182(a)(3)(B) for each succeeding revision of the ozone NAAQS. Maryland's emissions reporting requirements are codified in Code of Maryland Regulations (COMAR) 26.11.01.05–1 "Emissions Statements." COMAR 26.11.01.05–1 requires sources that emit above specified thresholds of NO_x or VOC to submit an emissions statement to the State. The emissions threshold for reporting varies according to the county in which the source is located. The statement must be submitted by a certified individual who can verify the source's actual emissions.

COMAR 26.11.01.05–1.A(1) requires a person who owns or operates any installation, source, or premises that emits 25 tons or more of NO_x or VOC

during a calendar year and is located in Baltimore City or the counties of Anne Arundel, Baltimore, Calvert, Carroll, Cecil, Charles, Frederick, Harford, Howard, Kent, Montgomery, Prince George's, or Queen Anne's to submit an emissions statement to the state. These counties are included in various ozone nonattainment areas. See 40 CFR 81.321. Per CAA section 182(a)(3)(B)(ii), states may waive this requirement for sources that emit less than 25 tpy of NO_x or VOC if the state provides an inventory of emissions from such class or category of sources as required by CAA sections 172(c)(3) and 182(a)(3)(B).⁴

COMAR 26.11.01.05–1 also requires a person who owns or operates any installation, source, or premises that emits 50 tons or more of VOC or 100 tons or more of NO_x during a calendar year to submit an emissions statement if they are located in the following counties: Allegany, Caroline, Dorchester, Garrett, St. Mary's, Somerset, Talbot, Washington, Wicomico, or Worcester Counties. These counties are designated attainment/unclassifiable for the 2015 ozone NAAQS but within the OTR; therefore, sources in attainment areas for the 2015 ozone NAAQS that emit 50 tpy or more of VOC or 100 tpy or more of NO_x are considered major sources and subject to the requirements for major stationary sources applicable to moderate nonattainment areas. Because the requirements for moderate nonattainment areas include all the requirements for marginal areas, major sources in these areas are also subject to the emission statement submission requirement specified in CAA section 182(a)(3)(B).⁵

In Maryland's July 6, 2020 SIP submittal, Maryland states that the existing COMAR 26.11.01.05–1 "Emissions Statements" continues to satisfy section 182(a)(3)(B) for the 2015 ozone NAAQS because Maryland has not made any changes since EPA's prior approval and COMAR 26.11.01.05–1 meets the CAA requirements for emission statements.⁶ EPA is proposing to find that COMAR 26.11.01.05–1 continues to satisfy CAA section 182(a)(3)(B) because the existing rule is

applicable to the entire State of Maryland and requires stationary sources that emit NO_x or VOC to submit an emissions statement to the State detailing the sources' emissions. EPA finds that Maryland's emissions thresholds for stationary sources that are required to submit an emissions statement meet CAA requirements in sections 182 (plan submissions and requirements for ozone nonattainment areas) and 184 (OTR requirements).⁷ Therefore, EPA has determined that COMAR 26.11.01.05–1, which is currently in the Maryland SIP, is appropriate to address the emissions statement requirement in section 182(a)(3)(B) and is proposing to approve this SIP revision. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

III. Proposed Action

EPA is proposing to approve the May 12, 2020 Maryland SIP revision, submitted on July 6, 2020, certifying that Maryland's existing SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA for the 2015 ozone NAAQS.

IV. Statutory and Executive Order Reviews

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

⁴ The Maryland Department of the Environment has previously formally submitted base year 2017 emissions inventories for: The Baltimore, MD 2015 Ozone NAAQS Nonattainment Area; the Cecil County, MD 2015 Ozone NAAQS Nonattainment Area; and the Washington DC–MD–VA 2015 Ozone NAAQS Nonattainment Area.

⁵ See CAA sections 182(f) and 184(b)(2).

⁶ See 59 FR 51517 (October 12, 1994).

⁷ See also "Guidance on the Implementation of an Emission Statement Program (July 1992)."

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

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

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

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

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

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

In addition, this proposed rulemaking, which proposes to approve Maryland's certification that Maryland's SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: May 28, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–11924 Filed 6–15–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906–AB25

Proposed Rescission of Executive Order 13937, “Executive Order on Access to Affordable Life-Saving Medications”

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

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (HHS) proposes to rescind the final rule entitled “Implementation of Executive Order on Access to Affordable Life-Saving Medications,” published in the December 23, 2020, **Federal Register**. HHS is proposing the rescission due to undue administrative costs and burdens that implementation would impose on health centers. In particular, the final rule would require health centers to create and sustain new practices necessary to determine patients' eligibility to receive certain drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program, resulting in reduced resources available to support critical services to their patients—including those who use insulin and injectable epinephrine. These challenges would be significantly exacerbated by the multitude of demands on health centers related to the COVID–19 pandemic. HHS is seeking public comment on this notice of proposed rulemaking (NPRM). As Executive Order 13937 remains in effect, should the final rule be rescinded, other implementation approaches will be considered to effectuate the Executive Order.

DATES: Written comments and related material to this proposed rule must be received to the online docket via <https://www.regulations.gov> on or before July 16, 2021.

ADDRESSES: Comments must be identified by HHS Docket No. HRSA–2021–0003 and submitted electronically to the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments and attachments will be posted to the docket unchanged. Because your comments will be made public, you are solely responsible for ensuring that your comments do not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's

Social Security number, or confidential business information. Additionally, if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted.

FOR FURTHER INFORMATION CONTACT:

Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; email: jjoseph@hrsa.gov; telephone: 301–594–4300; fax: 301–594–4997.

SUPPLEMENTARY INFORMATION:

I. Background

HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** on September 28, 2020 (85 FR 60748), and a final rule on December 23, 2020 (85 FR 83822) entitled, “Implementation of Executive Order on Access to Affordable Life-Saving Medications.” This rule established a new requirement directing all health centers receiving grants under section 330(e) of the Public Health Service (PHS) Act (42 U.S.C. 254b(e)) that participate in the 340B Program (42 U.S.C. 256b), to the extent that they plan to make insulin and/or injectable epinephrine available to their patients, to provide assurances that they have established practices to provide these drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program (plus a minimal administration fee) to health center patients with low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or who have no health insurance.

Pursuant to the January 20, 2021, memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” and OMB Memorandum M–21–14, the effective date of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule, published in the December 23, 2020, **Federal Register** (85 FR 83822), was delayed from January 22, 2021, to March 22, 2021 (86 FR 7069), to give HHS officials the opportunity for further review and consideration of the rule.

On March 11, 2021 (86 FR 13872), HHS published a proposed rule to further delay the effective date of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule. On March 22, 2021, the effective date of the