

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

[EPA–R06–OAR–2011–0513; FRL–10014–60–Region 6]

#### Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; New Mexico and Albuquerque-Bernalillo County, New Mexico; Control of Emissions From Existing Other Solid Waste Incineration Units

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

**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** In this supplemental notice of proposed rulemaking, the Environmental Protection Agency (EPA) is supplementing the proposal published on January 15, 2020, and pursuant to the Federal Clean Air Act (CAA or the Act), the EPA is notifying the public that we have received CAA section 111(d)/129 negative declarations from New Mexico and Albuquerque-Bernalillo County, New Mexico, for existing incinerators subject to the Other Solid Waste Incineration units (OSWI) emission guidelines (EG). The information provided in the negative declaration letter previously submitted by New Mexico on October 11, 2007, and addressed in our January 15, 2020 proposal, was clarified and reaffirmed in a June 15, 2020, negative declaration letter from New Mexico. The negative declarations from New Mexico and Albuquerque-Bernalillo County, New Mexico, certify that incinerators subject to the OSWI EG and the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdictions of New Mexico and Albuquerque-Bernalillo County. The EPA is supplementing our previous proposal and proposing to accept the negative declarations and amend the Code of Federal Regulations (CFR) in accordance with the requirements of the CAA.

**DATES:** Written comments must be received on or before October 28, 2020.

**ADDRESSES:** Submit your comments, identified by Docket No. EPA–R06–OAR–2011–0513, at <https://www.regulations.gov> or via email to [ruan-lei.karolina@epa.gov](mailto:ruan-lei.karolina@epa.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The 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. The 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 Karolina Ruan Lei, (214) 665–7346, [ruan-lei.karolina@epa.gov](mailto:ruan-lei.karolina@epa.gov). For 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>.

**Docket:** The index to the docket for this action is available electronically at [www.regulations.gov](http://www.regulations.gov). While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.*, CBI).

**FOR FURTHER INFORMATION CONTACT:** Karolina Ruan Lei, EPA Region 6 Office, Air and Radiation Division—State Planning and Implementation Branch, (214) 665–7346, [ruan-lei.karolina@epa.gov](mailto:ruan-lei.karolina@epa.gov). Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office will be closed to the public to reduce the risk of transmitting COVID–19. We encourage the public to submit comments via <https://www.regulations.gov>, as there will be a delay in processing mail and no courier or hand deliveries will be accepted. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

**SUPPLEMENTARY INFORMATION:** Throughout this document wherever “we,” “us,” or “our” is used, we mean the EPA.

### I. Background

#### A. Rulemaking History

On January 15, 2020, we published a direct final rule and accompanying proposed rule notifying the public that we had received CAA section 111(d)/129 negative declarations from New Mexico and Albuquerque-Bernalillo County for existing OSWI (85 FR 2316). These negative declarations certify that existing OSWI subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the specified jurisdictions in New Mexico. The direct final rule was published without prior proposal because we anticipated no adverse comments. We

stated in the direct final rule that if we received relevant adverse comments by February 14, 2020, we would publish a timely withdrawal in the **Federal Register**. We received a relevant adverse comment on the direct final rule, and we withdrew the direct final rule on March 23, 2020. We will address all comments received on the original proposal and on this supplemental proposal in our final action.

This supplemental notice of proposed rulemaking (SNPRM) supplements the proposal published on January 15, 2020, where we proposed to notify the public that we received CAA section 111(d)/129 negative declarations from New Mexico and Albuquerque-Bernalillo County, New Mexico, for existing OSWI; these negative declarations certify that existing OSWI subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the specified jurisdictions in New Mexico. In order to reaffirm and clarify the prior negative declaration, New Mexico submitted a revised negative declaration for incinerators subject to the OSWI EG by letter dated June 15, 2020; this letter clarifies that incinerators (including OSWI and air curtain incinerators (ACI)) subject to the OSWI EG do not exist within its air quality jurisdiction. In this SNPRM, we are appropriately expanding the inclusion of the facilities addressed in the negative declarations from New Mexico and Albuquerque-Bernalillo County from “existing OSWI” to “incinerators subject to the OSWI EG”. The term “incinerators subject to the OSWI EG” is more technically and legally accurate as all facilities affected by the OSWI EG are required to be addressed in state plans and negative declarations. The Albuquerque-Bernalillo County negative declaration letter that was submitted on December 13, 2006, appropriately addressed the subject facilities. Details on CAA sections 111(d) and 129, the OSWI EG, and the negative declarations submitted by New Mexico and Albuquerque-Bernalillo County, can be found in the following subsections.

#### B. Clean Air Act Sections 111(d) and 129

Sections 111(d) and 129 of the CAA require states to submit plans to control certain pollutants (designated pollutants) at existing solid waste combustor facilities (designated facilities) whenever standards of performance have been established under section 111(b) for new sources of the same type, and the EPA has established emission guidelines for such existing sources. CAA section 129 directs the EPA to establish standards of

performance for new sources (NSPS) and emissions guidelines (EG) for existing sources for each category of solid waste incinerator specified in CAA section 129. Under CAA section 129, NSPS and EG must contain numerical emissions limitations for particulate matter, opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans. While NSPS are directly applicable to new sources (affected facilities), EG for existing sources (designated facilities) are intended for states to use to develop a state plan to submit to the EPA. Once approved by the EPA, the state plan becomes federally enforceable. If a state does not submit an approvable state plan to the EPA, the EPA is responsible for developing, implementing, and enforcing a federal plan.

The regulations at 40 CFR part 60, subpart B, contain general provisions applicable to the adoption and submittal of state plans for controlling designated pollutants from designated facilities. Additionally, 40 CFR part 62, subpart A, provides the procedural framework by which the EPA will approve or disapprove such plans submitted by a state. When designated facilities are located in a state, the state must then develop and submit a plan for the control of the designated pollutant(s). However, 40 CFR 60.23(b) and 40 CFR 62.06 provide that if there are no designated facilities of the designated pollutant(s) in the state, the state may submit a letter of certification to that effect (*i.e.*, negative declaration) in lieu of a plan. The negative declaration exempts the state from the requirements of subpart B that require the submittal of a CAA section 111(d)/129 plan.

### C. Other Solid Waste Incineration Emission Guidelines

EPA promulgated OSWI NSPS and EG on December 16, 2005, codified at 40 CFR part 60, subparts EEEE and FFFF, respectively (70 FR 74870). Thus, states were required to submit plans for incinerators subject to the OSWI EG pursuant to sections 111(d) and 129 of the Act and 40 CFR part 60, subpart B. The designated facilities to which the current OSWI EG apply are OSWI and certain ACI<sup>1</sup> that commenced construction on or before December 9, 2004, and were not modified or reconstructed on or after June 16, 2006, as specified in 40 CFR 60.2991 and

60.2992, with limited exceptions as provided under 40 CFR 60.2993. The EPA proposed revisions to the OSWI EG and NSPS on August 31, 2020 (85 FR 54178). When the EPA finalizes the revisions to the OSWI EG,<sup>2</sup> each state (and air quality control jurisdiction) will need to submit a negative declaration or plan, as applicable, for those sources subject to the requirements of the final revised OSWI EG.

### D. Negative Declarations From New Mexico and Albuquerque-Bernalillo County

In order to fulfill obligations under CAA sections 111(d) and 129, the New Mexico Environment Department (NMED) and the City of Albuquerque Environmental Health Department (AEHD) submitted negative declarations for incinerators subject to the OSWI EG for their individual air pollution control jurisdictions.<sup>3</sup> The submittal of these negative declarations exempts New Mexico (including Albuquerque-Bernalillo County) from the requirement to submit a state plan under 40 CFR part 60, subpart FFFF.

NMED and AEHD each determined that there are no existing incinerators subject to the OSWI EG in accordance with the CAA sections 111(d) and 129 requirements in their individual air pollution control jurisdictions. In order to fulfill obligations under CAA sections 111(d) and 129, NMED and AEHD submitted negative declaration letters to the EPA on June 15, 2020, and December 13, 2006, respectively. As stated earlier in this notice, the information provided in the negative declaration letter previously submitted by NMED on October 11, 2007, was clarified and reaffirmed in NMED's June 15, 2020, negative declaration letter. A copy of each negative declaration letter is included in the docket for this rulemaking (Docket No. EPA-R06-OAR-2011-0513).

## II. Supplemental Proposed Action

In this SNPRM, the EPA is supplementing our previous proposal and proposing to amend 40 CFR part 62 to reflect receipt of the negative declaration letters from NMED and AEHD, received on June 15, 2020, and December 13, 2006, respectively, certifying that there are no existing incinerators subject to 40 CFR part 60, subpart FFFF, in their respective jurisdictions in accordance with 40 CFR

60.23(b), 40 CFR 62.06, 40 CFR 60.2982, and sections 111(d) and 129 of the CAA.

## III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a CAA section 111(d)/129 submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7411(d); 42 U.S.C. 7429; 40 CFR part 60, subparts B and FFFF; and 40 CFR part 62, subpart A. With regard to negative declarations for designated facilities received by the EPA from states, the EPA's role is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. For the reasons stated above, 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because this action is not significant under Executive Order 12866;
- 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);
- 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 the 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).

<sup>1</sup> The air curtain incinerators (ACI) subject to the OSWI EG at 40 CFR part 60, subpart FFFF do not fit the definition of a "OSWI," as defined in the OSWI EG. See 40 CFR 60.2994(b) and 40 CFR 60.3078.

<sup>2</sup> The court ordered deadline to promulgate the final OSWI review is May 31, 2021. *Sierra Club v. Wheeler*, 330 F. Supp. 3d 407. (D.D.C. 2018).

<sup>3</sup> The OSWI negative declarations from NMED and AEHD do not cover sources located in Indian country.

This rule also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

#### List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Waste treatment and disposal.

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

Dated: September 15, 2020.

**Kenley McQueen,**

*Regional Administrator, Region 6.*

[FR Doc. 2020-20678 Filed 9-25-20; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 51c

**RIN 0906-AB25**

#### Implementation 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:** Notice of proposed rulemaking.

**SUMMARY:** The Department of Health and Human Services (HHS) proposes to implement the Executive Order 13937 (Executive Order) of July 24, 2020. The Executive Order requires that entities funded under section 330(e) of the Public Health Service Act (PHS Act or the Act), whether by receiving a federal award or a subaward, and who also participate in the 340B Drug Pricing Program, must establish practices to provide access to insulin and injectable epinephrine to low-income patients at the price the health center purchased these two drugs through the 340B Drug Pricing Program. The Executive Order supports the improved access to these life-saving medications by low-income individuals who do not have access to affordable insulin and injectable epinephrine due to either lack of insurance or high cost sharing requirements. HHS is seeking public comment on this notice of proposed rulemaking (NPRM).

**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 October 28, 2020.

**ADDRESSES:** Comments must be identified by HHS Docket No. HRSA-2020-0004 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 comment will be made public, you are solely responsible for ensuring that your comment does 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 as well.

#### 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](mailto:jjoseph@hrsa.gov); telephone: 301-594-4300; fax: 301-594-4997.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On March 13, 2020, President Trump declared the ongoing Coronavirus Disease COVID-19 pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, territories, and the District of Columbia. With the COVID-19 emergency, many low-income individuals are experiencing significant economic hardship. These low-income individuals who are dependent upon the life-saving medications of insulin and/or injectable epinephrine are now less able to access these drugs at an affordable price. On July 24, 2020, President Trump issued Executive Order 13937 (Executive Order), "Executive Order on Access to Affordable Life-saving Medications," was issued to direct health centers that receive grants under section 330(e) of the PHS Act to support the improved access to certain life-saving medications by low income individuals. As provided in the Executive Order, it is the policy of the United States to enable Americans without access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs, such as Medicare and Medicaid, to purchase these

pharmaceuticals from a health center at the same price at which the health center acquired the medication through the 340B Drug Pricing Program.

Through the Executive Order, the President directed the Secretary of Health and Human Services (the Secretary) to take action, to the extent permitted by law, to ensure all future grants available under section 330(e) of the PHS Act, as amended, 42 U.S.C. 254b(e), are conditioned upon health centers having established practices to make insulin and injectable epinephrine available at the discounted price paid by the health center grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who:

- (a) Have a high cost sharing requirement for either insulin or injectable epinephrine;
- (b) have a high unmet deductible; or
- (c) have no health care insurance.

Under section 330(k)(3) of the Act, the Secretary may not approve an application for a grant under subparagraph (A) or (B) of subsection (e)(1) unless the Secretary determines that the entity for which the application is submitted meets the requirements enumerated in section 330(k)(3)(A)-(N). Section 330(k)(3)(N) requires that "the center has written policies and procedures in place to ensure the appropriate use of Federal funds in compliance with applicable Federal statutes, regulations, and the terms and conditions of the Federal award." Consistent with the Act, the HRSA would include in the Terms section of applicable Notices of Award (NOAs) issued under section 330(e) grant awards, the requirement that health center awardees comply with the discounted price provisions described herein.

This proposed regulation would apply to new grants and new project periods for service area, new access point, supplemental, and expanded services awards issued under section 330(e) of the PHS Act.

##### II. Statutory Authority

The statement of authority for 42 CFR part 51c continues to read section 330 of the PHS Act (42 U.S.C. 254b) and section 215 of the PHS Act, (42 U.S.C. 216).

##### III. Discussion of Proposed Rule

###### Overview

The Executive Order was issued to support the improved access to certain life-saving medications for low-income individuals. HRSA is proposing to