

its public docket on <https://www.regulations.gov>.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are encouraged to be made electronically. If a public hearing is scheduled, a notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2023–16, 2023–20 I.R.B. 854 (May 15, 2023), provides that public hearings will be conducted in person, although the IRS will continue to provide a telephonic option for individuals who wish to attend or testify at a hearing by telephone. Any telephonic hearing will be made accessible to people with disabilities.

#### Statement of Availability of IRS Documents

Announcement 2023–16 is published in the Internal Revenue Bulletin and is available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at <http://www.irs.gov>.

#### Drafting Information

The principal author of these regulations is Julia Barlow of the Office of the Associate Chief Counsel (Energy, Credit, and Excise Tax). However, other personnel from the Treasury Department and the IRS participated in its development.

#### List of Subjects in 26 CFR Part 51

Drugs, Reporting and recordkeeping requirements.

#### Proposed Amendment to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 51 as follows:

#### PART 51—BRANDED PRESCRIPTION DRUG FEE

■ **Paragraph 1.** The authority citation for part 51 is amended by revising the general authority to read as follows:

**Authority:** 26 U.S.C. 7805(a); sec. 9008(i), Pub. L. 111–148, 124 Stat. 119.

\* \* \* \* \*

■ **Par. 2.** Section 51.4 is amended by:

- 1. Removing the word “and” at the end of paragraph (b)(2)(i)(A);
- 2. Removing the period at the end of paragraph (b)(2)(i)(B);
- 3. Adding the language “; and” at the end of paragraph (b)(2)(i)(B);
- 4. Adding paragraph (b)(2)(i)(C);
- 5. In paragraph (b)(2)(iv), by removing the word “manufactured-paid” and

adding the word “manufacturer-paid” in its place, and adding the language “or 70–percent (as applicable)” after the language “50–percent”; and

■ 6. Adding paragraph (b)(2)(v). The additions read as follows:

#### § 51.4 Information provided by the agencies.

\* \* \* \* \*

- (b) \* \* \*
- (2) \* \* \*
- (i) \* \* \*

(C) Any manufacturer discount program discount (within the meaning of paragraph (b)(2)(v) of this section).

\* \* \* \* \*

(v) *Manufacturer discount program discount.* For purposes of paragraph (b)(2)(i)(C) of this section, the term *manufacturer discount program discount* means a manufacturer-paid discount on certain drugs under the Manufacturer Discount Program described in section 1860D–14C of the Social Security Act.

\* \* \* \* \*

■ **Par. 3.** Section 51.11 is amended by revising the section heading and adding paragraph (c) to read as follows:

#### § 51.11 Applicability dates.

\* \* \* \* \*

(c) Section 51.4(b)(2)(i)(C) and (b)(2)(v) apply for fees calculated based on sales years beginning on and after January 1, 2025.

**Frank J. Bisignano,**

*Chief Executive Officer.*

[FR Doc. 2025–24153 Filed 12–31–25; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R08–OAR–2024–0550; FRL–13050–01–R8]

#### Air Plan Approval; CO; Revisions to Colorado Procedural Rules and Common Provisions Regulation

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve revisions to the Colorado State Implementation Plan (SIP) that were submitted by the Colorado Department of Public Health and Environment (CDPHE) on May 20, 2022. CDPHE requested EPA approval of revisions to the Colorado’s Procedural Rules and Common Provisions Regulation. The

revised rules include non-substantive updates to rule language that are administrative in nature and were intended to provide for general cleanup and improved readability. The EPA is proposing approval of these SIP revisions because we have determined that they are in accordance with the requirements for SIP provisions under the Clean Air Act (CAA). In the “Rules and Regulations” section of this **Federal Register**, we are approving these SIP revisions as a direct final rule without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

**DATES:** Written comments must be received on or before February 2, 2026.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R08–OAR–2024–0550, to the Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [www.regulations.gov](https://www.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, 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:** All documents in the docket are listed in the <https://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in <https://www.regulations.gov>. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

**FOR FURTHER INFORMATION CONTACT:** Liz Ulrich, Air and Radiation Division,

EPA, Region 8, Mailcode 8ARD-IO, 1595 Wynkoop Street, Denver, Colorado 80202-1129, telephone number: (406) 457-5008, email address: [ulrich.elizabeth@epa.gov](mailto:ulrich.elizabeth@epa.gov).

**SUPPLEMENTARY INFORMATION:** This document proposes to approve revisions to the Colorado SIP that incorporate certain provisions of Colorado's Procedural Rules and Common Provisions Regulation. We have published a direct final rule approving those revisions in the Rules and Regulations section of this **Federal Register** because we view this as a noncontroversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule, and it will not take effect. We will address all public comments in any subsequent final rule based on this proposed rule.

We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information, please see the information provided in the **ADDRESSES** section of this document.

Dated: December 16, 2025.

**Cyrus M. Western,**

*Regional Administrator, Region 8.*

[FR Doc. 2025-24140 Filed 12-31-25; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 52 and Part 81

[EPA-R03-OAR-2025-1872; FRL-12994-01-R3]

### Proposed Revisions of the Nonattainment Designation for the 2008 and 2015 Ozone Standards and Clean Data Determinations for the 2008 and 2015 Ozone Standards: Cecil County, MD and New Castle County, DE

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve two separate requests from Maryland and Delaware to revise the designation for the Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE nonattainment area (hereafter referred to as the Philadelphia nonattainment area)

for the 2008 primary and secondary ozone national ambient air quality standards (NAAQS) and the 2015 primary and secondary ozone NAAQS. Due to the concurrent requests from Maryland and Delaware, the EPA is proposing to revise the existing Philadelphia nonattainment area boundary into three distinct nonattainment areas that together cover the identical geographic area of the existing area. The EPA is also proposing to issue clean data determinations (CDDs) for the revised Maryland and Delaware nonattainment areas for both the 2008 and 2015 ozone NAAQS. The EPA is taking this action pursuant to Clean Air Act (CAA) sections 107, 110, 172, and 182.

**DATES:** Written comments must be received on or before February 2, 2026.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R03-OAR-2025-1872 at [www.regulations.gov](http://www.regulations.gov), or via email to [gordon.mike@epa.gov](mailto:gordon.mike@epa.gov). For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, 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 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 [www.epa.gov/dockets/commenting-epa-dockets](http://www.epa.gov/dockets/commenting-epa-dockets).

### FOR FURTHER INFORMATION CONTACT:

Sarah McCabe, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F. Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-5786. Ms. McCabe can also be reached via electronic mail at [mccabe.sarah@epa.gov](mailto:mccabe.sarah@epa.gov).

**SUPPLEMENTARY INFORMATION:** On February 13, 2025, Maryland submitted a request to revise the Philadelphia nonattainment area into two separate nonattainment areas, covering the identical geographic area of the existing Philadelphia nonattainment area, and creating a smaller stand-alone nonattainment area for Cecil County, MD and a larger nonattainment area consisting of the remainder of the counties in the existing Philadelphia nonattainment area. On August 15, 2025, Delaware also submitted a request to revise the boundaries for the existing Philadelphia nonattainment area and create a stand-alone nonattainment area for New Castle County, DE. However, considering both requests, the EPA is proposing to act on these separate requests in the same notice to streamline the changes to the Philadelphia nonattainment area boundaries. Thus, the EPA is proposing to split the identical geographic area of the existing Philadelphia nonattainment area into three nonattainment areas: the Cecil County, MD nonattainment area, the New Castle County, DE nonattainment area, and the revised Philadelphia-Atlantic City, PA-NJ nonattainment area. These proposed revised designations are supported by an analysis of air quality data, emissions and emissions-related data, meteorology, geography/topography, and jurisdictional boundaries. If finalized, all areas would retain their current designation statuses and classifications for each respective ozone NAAQS. Additionally, if the revised designations and CDDs are finalized, the proposed CDDs would suspend the obligations of Maryland and Delaware to submit certain attainment planning requirements for their respective nonattainment areas for as long as each area continues to attain the 2008 and 2015 ozone NAAQS. Nonetheless, the EPA views each state's request as separable redesignation requests and may take separate final action on each request and adjust the area boundaries accordingly.

### I. Background

Under section 109 of the CAA, the EPA has established primary and secondary NAAQS for certain air pollutants (referred to as "criteria pollutants") and conducts periodic reviews of the NAAQS to determine whether they should be revised or whether new NAAQS should be established. The primary NAAQS represent ambient air quality standards which the EPA has determined are necessary to protect the public health with an adequate margin of safety. The