Authority: 26 U.S.C. 7805

* * * * *

■ **Par. 5.** Section 301.6011–2 is amended by revising paragraph (b)(1) to read as follows:

§ 301.6011–2 Required use of electronic form.

* * * * *

(b) * * *

(1) If the use of Form 1042–S, Form 1094 series, Form 1095–B, Form 1095–C, Form 1097–BTC, Form 1098, Form 1098–C, Form 1098–E, Form 1098–Q, Form 1098–T, a Form to report information required under section 6050AA, Form 1099 series, Form 3921, Form 3922, Form 5498 series, Form 8027, or Form W–2G is required by the applicable regulations or revenue procedures for the purpose of making an information return, the information required by the form must be submitted electronically, except as otherwise provided in paragraph (c) of this section. Returns filed electronically must be made in accordance with applicable revenue procedures, publications, forms, or instructions.

* * * * *

■ **Par. 6.** Section 301.6721–1 is amended by:

■ 1. Revising paragraphs (h)(3)(xxvi) and (xxvii);

■ 2. Adding paragraph (h)(3)(xxviii); and

■ 3. Revising paragraph (j)(2).

The additions and revision read as follows:

§ 301.6721–1 Failure to file correct information returns.

* * * * *

(h) * * *

(3) * * *

(xxvi) Section 6050Y (relating to returns relating to certain life insurance contract transactions);

(xxvii) Section 6050Z (relating to reports relating to long-term care premium statements); or

(xxviii) Section 6050AA (relating to returns relating to QPVLI received in trade or business from individuals).

* * * * *

(j) * * *

(2) *Exceptions.*

(i) Paragraph (h)(2)(xii) of this section applies with respect to information returns required to be filed after September 17, 2024.

(ii) Paragraph (h)(2)(xxviii) of this section applies with respect to information returns required to be filed for taxable years beginning after December 31, 2024, and before January 1, 2029.

■ **Par. 7.** Section 301.6722–1 is amended by:

■ 1. Revising paragraphs (e)(2)(xxxvii) and (xxxviii);

■ 2. Adding paragraph (e)(2)(xxxix); and

■ 3. Revising paragraph (g)(2).

The additions and revision read as follows:

§ 301.6722–1 Failure to furnish correct payee statements.

* * * * *

(e) * * *

(2) * * *

(xxxvii) Section 6226(a)(2) (regarding statements relating to alternative to payment of imputed underpayment by a partnership) or under any other provision of this title 26 that provides for the application of rules similar to section 6226(a)(2);

(xxxviii) Section 6050Z (relating to reports relating to long-term care premium statements); or

(xxxix) Section 6050AA (relating to returns relating to QPVLI received in trade or business from individuals).

* * * * *

(g) * * *

(2) *Exceptions.*

(i) Paragraph (e)(2)(xxxv) of this section applies with respect to payee statements required to be furnished after September 17, 2024.

(ii) Paragraph (e)(2)(xxxix) of this section applies with respect to payee statements required to be furnished for taxable years beginning after December 31, 2024, and before January 1, 2029.

Frank J. Bisignano,

Chief Executive Officer.

[FR Doc. 2025–24154 Filed 12–31–25; 8:45 am]

BILLING CODE 4831–GV–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 51

[REG–103430–24]

RIN 1545–BR16

Statutory Updates to Branded Prescription Drug Fee Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes amendments to regulations regarding the annual fee imposed on covered entities engaged in the business of manufacturing or importing certain branded prescription drugs. In response to the replacement of the Coverage Gap Discount Program with the new Manufacturer Discount Program by the Inflation Reduction Act of 2022, the proposed regulations would make updates regarding the discounts, rebates, and other price concessions used to determine branded prescription drug sales under Medicare Part D and would update for prior statutory changes. These proposed regulations would affect persons engaged in the business of manufacturing or importing certain branded prescription drugs.

DATES: Written or electronic comments and requests for a public hearing must be received by March 3, 2026. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov* (indicate IRS and REG–103430–24) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS's public docket. Send paper submissions to: CC:PA:01:PR (REG–103430–24), Room 5503, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. A plain language summary of the proposed regulations will be made available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact Julia Barlow at (202) 317–6855 (not a toll-free number); concerning the submission of comments and requests to participate in the public hearing, contact the Publications and Regulations Section by phone at (202) 317–6901 (not a toll-free number) or by email at *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Authority

This document contains proposed amendments to the Branded Prescription Drug Fee Regulations (26 CFR part 51).

The proposed regulations are issued under the express delegation of authority under section 9008(i) of the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029 (2010). These acts are collectively referred to in this preamble as the ''ACA.'' All references in this preamble to ''section 9008'' are

references to section 9008 of the ACA. Section 9008(i) provides that the Secretary of the Treasury or the Secretary's delegate (Secretary) ''shall publish guidance necessary to carry out the purposes of [section 9008].''

The proposed regulations are also issued under the express delegation of authority under section 7805(a) of the Internal Revenue Code (Code), which provides that the Secretary ''shall prescribe all needful rules and regulations for the enforcement of [the Code], including all rules and regulations as may be necessary by reason of any alteration of law in relation to internal revenue.''

Background

I. Overview

The branded prescription drug fee was enacted by section 9008. Section 9008 did not amend the Code but cross-references specific Code sections.

Under section 9008(a)(1), each covered entity engaged in the business of manufacturing or importing branded prescription drugs must pay an annual fee to the Secretary.

Section 9008(b) provides rules for determining the amount of the annual fee for each covered entity. Specifically, section 9008(b)(1) provides that the annual fee for each covered entity for calendar years 2019 and thereafter shall bear the same ratio to $2.8 billion as (i) the covered entity's branded prescription drug sales taken into account during the preceding calendar year to (ii) the aggregate branded prescription drug sales of all covered entities taken into account during the same year.

Section 9008(d)(1) generally defines the term ''covered entity'' to mean any manufacturer or importer with gross receipts from branded prescription drug sales. Section 9008(e)(1) defines the term ''branded prescription drug sales'' to mean sales of branded prescription drugs to any specified government program or pursuant to coverage under such program. Section 9008(e)(2)(A) generally defines the term ''branded prescription drug'' to mean (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or (ii) any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). Section 9008(e)(2)(B) defines the term ''prescription drug'' for purposes of section 9008(e)(2)(A)(i) to mean any drug which is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

Section 9008(e)(4) defines the term ''specified government programs'' as the Medicare Part D program, the Medicare Part B program, the Medicaid program, any program under which branded prescription drugs are procured by the Department of Veterans Affairs (VA), any program under which branded prescription drugs are procured by the Department of Defense (DOD), and the TRICARE retail pharmacy program, which are collectively referred to in this preamble as the ''Programs.''

Section 9008(g) requires the Secretary of Health and Human Services (Secretary of HHS), the Secretary of Veterans Affairs, and the Secretary of Defense to report to the Secretary the total branded prescription drug sales for each covered entity with respect to each specified government program. Section 9008(g)(1) specifies the information that the Secretary of HHS shall report for the Medicare Part D program. Section 9008(g)(1)(A) specifies that the costs of prescription drug plans and Medicare Advantage prescription drug plans reported by the Secretary of HHS is reduced by ''any per-unit rebate, discount, or other price concession provided by the covered entity.'' Section 9008(b)(3) requires the Secretary to use the data provided by the Programs to calculate the fee.

The Branded Prescription Drug Fee Regulations (TD 9684, 79 FR 43631 (July 28, 2014), as amended by TD 9823, 82 FR 34611 (July 26, 2017)), provide the method by which each covered entity's annual fee is calculated. The regulations also define terms and provide rules for the administration of the fee. *See* 26 CFR 51.1 through 51.11 and 51.6302.

Section 51.2 explains the terms used in 26 CFR part 51 for purposes of the fee imposed by section 9008 on branded prescription drugs. Section 51.2(b) defines the term ''Agencies'' to mean the Centers for Medicare & Medicaid Services of the Department of Health and Human Services (CMS), the VA, and the DOD. Section 51.2(i) defines ''manufacturer or importer'' as the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

Section 51.4 sets forth the methodologies that the Agencies are required to use to calculate the drug sales amount for each specified government program. Section 51.4(b)(1) requires CMS to determine branded prescription drug sales under Medicare Part D by aggregating the ingredient cost reported in the ''Ingredient Cost Paid'' field on the Prescription Drug Event (PDE) records at the NDC level, reduced by discounts, rebates, and other price concessions provided by the covered entity, for each sales year. Under § 51.2(m), the term ''sales year'' means the second calendar year preceding the fee year.

Section 51.4(b)(2) provides that for purposes of § 51.4(b)(1), ''discounts, rebates, and other price concessions'' means (A) any direct and indirect remuneration (DIR) (within the meaning of § 51.4(b)(2)(ii)), which includes any DIR reported on the PDE records at the point of sale and any DIR reported on a Detailed DIR Report (within the meaning of § 51.4(b)(2)(iii)); and (B) any coverage gap discount amount (within the meaning of § 51.4(b)(2)(iv)).

Section 51.4(b)(2)(iv) provides that for purposes of § 51.4(b)(2)(i)(B), the term ''coverage gap discount amount'' means a 50-percent manufactured-paid (sic) discount on certain drugs under the Coverage Gap Discount Program described in section 1860D–14A of the Social Security Act (SSA) (42 U.S.C. 1395w–114a). The Coverage Gap Discount Program described in section 1860D–14A of the SSA initially required a 50-percent manufacturer-paid discount on applicable drugs in certain instances. In section 53116(b) of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, 132 Stat 64 (February 9, 2018), Congress expanded the discount to 70 percent for plan years after plan year 2018. See 42 U.S.C. 1395w–114a(g)(4)(A).

II. Inflation Reduction Act of 2022 Changes to Medicare Part D Discounts

Section 11201 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly known as the Inflation Reduction Act of 2022 (IRA), redesigned the Medicare Part D benefit, including sunsetting the Coverage Gap Discount Program described in section 1860D–14A of the SSA as of January 1, 2025. Section 11201(c)(1) of the IRA amended the SSA by adding section 1860D–14C (42 U.S.C. 1395w–114c) to establish the new Manufacturer Discount Program beginning January 1, 2025, which requires participating manufacturers to provide discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries who are in the initial and catastrophic coverage phases of the Part D benefit. Under section 1860D–43(a) of the SSA, in order for coverage to be available under Part D for covered Part D drugs of a manufacturer beginning January 1, 2025, the manufacturer must participate in the Manufacturer Discount Program by entering into and having in effect a Manufacturer Discount Program agreement under which the

manufacturer agrees to provide discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries.

Section 11201(c)(2) of the IRA amended section 1860D–14A of the SSA to sunset the Coverage Gap Discount Program for applicable drugs dispensed on or after January 1, 2025, but the provisions (including all responsibilities and duties) of the Coverage Gap Discount Program continue to apply with respect to applicable drugs dispensed before January 1, 2025.

Explanation of Provisions

To reflect statutory changes made by the BBA, the proposed regulations would update the percentage discount amount for the Coverage Gap Discount Program to reflect the statutory change from a 50 percent manufacturer-paid discount to a 70 percent manufacturer-paid discount (for plan years after plan year 2018). The proposed regulations would also correct ''manufactured-paid'' in the current § 51.4(b)(2)(i)(B) to ''manufacturer-paid.'' To reflect statutory changes made by the IRA, the proposed regulations would add references to the Manufacturer Discount Program to the rules regarding the discounts, rebates, and other price concessions that CMS uses to determine branded prescription drug sales under Medicare Part D, for purposes of the Branded Prescription Drug Fee.

The proposed regulations would not remove the Coverage Gap Discount Program from the rules regarding the discounts, rebates, and other price concessions because, due to the manner in which the fee is calculated, the discounts that the Coverage Gap Discount Program provides through December 31, 2024, may still be used to calculate the fee for sales that occurred while the Coverage Gap Discount Program was effective. Beginning in the 2027 fee year, it is expected that there will be no Coverage Gap Discount Program discounts to take into account.

The Treasury Department and the IRS are considering whether to include a sunset for using the Coverage Gap Discount Program in the final regulations. The Treasury Department and the IRS request comments about whether the final regulations should include a sunset for using the Coverage Gap Discount Program for applicable drugs dispensed on or after January 1, 2025.

Proposed Applicability Date

Because these regulations reflect statutory changes that took effect at the beginning of 2025, these regulations are proposed to apply to fees calculated based on sales years beginning with calendar year 2025, which will also be sales years ending on or after the date these proposed regulations are filed in the **Federal Register**.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The proposed regulations have been designated by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) as subject to review under Executive Order 12866 pursuant to the Memorandum of Agreement (MOA, July 4, 2025) between the Treasury Department and the OMB regarding review of tax regulations. OIRA has determined that the proposed rulemaking is significant and subject to review under Executive Order 12866 and section 1(b) of the Memorandum of Agreement. Accordingly, the proposed regulations have been reviewed by OMB.

A. Need for Regulation

Section 9008 of the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (2010), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029 (2010) (ACA) imposes an annual fee on covered entities engaged in the business of manufacturing or importing branded prescription drugs. The amount of the annual fee is set by statute. For calendar years 2019 and thereafter, the amount of the annual fee is $2.8 billion. *See* section 9008(b)(4). Each covered entity's share of the annual fee is calculated by determining the ratio of the covered entity's branded prescription drug sales taken into account during the preceding calendar year to the aggregate branded prescription drug sales of all covered entities taken into account during the same year. Under section 9008(e)(1), branded prescription drug sales are sales of branded prescription drugs to any specified government program or pursuant to coverage under such program. Section 9008(g) requires the Secretary of Health and Human Services (Secretary of HHS), the Secretary of Veterans Affairs, and the Secretary of Defense to report to the Secretary the total branded prescription drug sales for each covered entity with respect to each specified government program.

Existing regulations in 26 CFR part 51 specify the method by which each covered entity's share of the annual fee is calculated. Section 51.4(b)(1) specifies the method by which the Centers for Medicare & Medicaid Services of the Department of Health and Human Services (CMS) is required to determine branded prescription drug sales under Medicare Part D. Two subsequent statutes altered inputs that CMS uses to determine Medicare Part D sales for this purpose. First, the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, 132, Stat. 64 (February 9, 2018), increased the Coverage Gap Discount Program manufacturer discount rate from 50 percent to 70 percent for plan years after 2018. Second, the Inflation Reduction Act of 2022 (IRA), Public Law 117–169, 136 Stat. 1818 (August 16, 2022), sunsets the Coverage Gap Discount Program effective January 1, 2025, and establishes the Manufacturer Discount Program.

The proposed regulations update existing regulations so that they are consistent with the statute and with how the covered entities have been calculating their share of the annual fee since enactment of the BBA and the IRA. The proposed regulations reflect the BBA's increase to a 70-percent manufacturer discount (as applicable) and add the IRA's Manufacturer Discount Program discounts to the list of reductions CMS uses when computing branded prescription drug sales under Medicare Part D. Because fees are calculated using sales from prior years, Coverage Gap Discount Program discounts provided through December 31, 2024, may still enter fee computations for several sales years. Beginning in the 2027 fee year, no Coverage Gap Discount Program discounts are expected to be taken into account. The updates are necessary to align the regulations with statutory changes so that CMS-reported Medicare Part D sales accurately incorporate the discount programs in effect for the relevant sales years.

B. The Statute and the Proposed Regulations

The proposed regulations update the existing regulations regarding the discounts, rebates, and other price

concessions that CMS uses to determine branded prescription drug sales, to reflect changes made by the BBA and IRA and to reflect how covered entities are currently calculating their share of the fee. The proposed regulations add the Manufacturer Discount Program, which was established by the IRA, to the list of reductions that CMS uses to calculate branded prescription drug sales. The proposed regulations also update the percentage discount amount used for the Coverage Gap Discount Program to reflect the statutory change made by the BBA for plan years after plan year 2018.

C. Baseline

The Treasury Department and the IRS have assessed the benefits and costs of the proposed regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these proposed regulations.

D. Affected Entities and Taxpayers

The Branded Prescription Drug Fee affects manufacturers and importers of branded prescription drugs with sales to specified government programs (Medicare Part D, Medicare Part B, Medicaid, Department of Veterans Affairs programs that procure branded prescription drugs, Department of Defense programs that procure branded prescription drugs, and TRICARE). Based on records from tax year 2024, the Treasury Department and the IRS estimate the fee impacts roughly 300 affected entities. The proposed regulations apply to how other Federal agencies compile and transmit data, not to new reporting requirements for these affected entities.

E. Economic Effects of the Proposed Regulations

The primary effect of the proposed regulations would be improved administrative alignment and clarity. Under the baseline, existing regulations would continue to reference only the Coverage Gap Discount Program and a 50-percent discount, which would not reflect post-2018 discount levels or the post-2024 Medicare Part D discount program. That mismatch would increase uncertainty about how agency data should be compiled after changes made by the IRA and BBA. The proposal clarifies which Medicare Part D discounts reduce branded prescription drug sales for fee computations—ensuring the regulations mirror the BBA and IRA changes. Because the rule clarifies information-collection procedures that already occur at other Federal agencies, Treasury and IRS expect minimal impact on affected entity compliance costs since the covered entities are calculating fees according to the statute. Affected entities are expected to benefit from clearer rules that reduce policy uncertainty and the risk of disputes about discount treatment, but, in aggregate, Treasury and IRS expect these benefits to be small. The regulations will also improve administrative efficiency for CMS and the IRS through consistent data definitions across years. Minor one-time administrative costs incurred by CMS to reflect the updated Manufacturer Discount Program are already part of CMS's program implementation under the IRA and are not imposed by this regulation.

F. Alternatives Considered

The Treasury Department and the IRS considered the alternative option of taking no action to update the existing regulations in 26 CFR part 51 to reflect the changes made by the IRA and BBA. This alternative would leave uncertainty as to how CMS data will be reported to the IRS for purposes of calculating each covered entity's share of the Branded Prescription Drug Fee. Therefore, the approach to issue proposed regulations to update the existing regulations to align with changes made by the IRA and BBA was selected over the alternative option of taking no action.

II. Paperwork Reduction Act

This rulemaking does not contain a collection of information from the public, and therefore it is not required to be reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number.

III. Regulatory Flexibility Act

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. These regulations do not affect small entities because they merely clarify procedures that already occur at another Federal agency. Affected entities exclude the first $5 million in sales and exclude 90 percent of sales that are over $5 million and not more than $125 million, which minimizes or completely eliminates any additional burden these proposed regulations might impose on small businesses. Entities engaged in pharmaceutical manufacturing or drug wholesaling with aggregate branded drug sales more than $5 million may benefit from clearer rules, but these impacts are not substantial. Entities with aggregate branded drug sales not more than $5 million will not be impacted.

IV. Section 7805(f) of the Code

Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small businesses.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. The final regulations do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

VI. Executive Order 13132: Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. These proposed regulations do not have federalism implications and do not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive order.

Comments and Requests for a Public Hearing

Before the proposed amendments to the regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in the preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. All commenters are strongly encouraged to submit comments electronically. The Treasury Department and the IRS will publish for public availability any comment submitted electronically or on paper to

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]

BILLING CODE 4831–GV–P

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.* 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,