AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would provide guidance on how taxpayers will report liability for the excise tax imposed on manufacturers, producers, or importers of certain designated drugs. The proposed regulations affect manufacturers, producers, and importers of designated drugs that sell such drugs during certain statutory periods. The proposed regulations also would except such tax from semimonthly deposit requirements.

DATES: Written or electronic comments and requests for a public hearing must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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-115559-23) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Requests for a Public Hearing” section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn.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
SUPPLEMENTARY INFORMATION:

Background

This document contains proposed regulations that would amend the Excise Tax Procedural Regulations (26 CFR part 40) and add a new part 47 to 26 CFR chapter 1 to contain the “Designated Drugs Excise Tax Regulations” related to the excise tax imposed by section 5000D of the Internal Revenue Code (Code) on certain sales by manufacturers, producers, or importers of designated drugs (section 5000D tax).

Section 5000D, added to chapter 50A of the Code by section 11003 of Public Law 117-169, 136 Stat. 1818 (August 16, 2022), commonly known as the Inflation Reduction Act of 2022 (IRA), imposes an excise tax on the sale by the manufacturer, producer, or importer (taxpayer) of any designated drug during a day that falls within a period described in section 5000D(b). Because chapter 50A is a new chapter of the Code, the existing regulations that prescribe the procedural rules applicable to most excise taxes do not apply to chapter 50A.

Notice 2023-52 (2023-35 I.R.B. 650) announces that the Treasury Department and the IRS intend to propose regulations addressing substantive and procedural issues related to the section 5000D tax. These proposed regulations address return filing and other procedural requirements related to the section 5000D tax as set forth in
Notice 2023-52. The Treasury Department and the IRS will issue a separate notice of proposed rulemaking to address substantive issues related to the section 5000D tax.

Explanation of Provisions

I. Proposed Amendments to 26 CFR part 40

These proposed regulations would apply the Excise Tax Procedural Regulations in 26 CFR part 40 to excise taxes imposed by chapter 50A of the Code (and thus to the section 5000D tax), with some limited exceptions.

A. Proposed amendments to §40.0-1

Section 40.0-1(a) provides generally that the regulations in part 40 set forth administrative rules relating to the excise taxes imposed by chapters 31 through 34, 36, 38, 39, and 49 of the Code. Proposed §40.0-1(a) would amend that provision by adding chapter 50A of the Code to the list of Code chapters subject to the part 40 regulations.

B. Proposed amendments to §40.6011(a)-1

Section 40.6011(a)-1(a)(1) provides that the return of tax to which part 40 applies must be made on Form 720, Quarterly Federal Excise Tax Return, according to the instructions applicable to the form. Section 40.6011(a)-1(a)(2) provides, in part, that a return must be filed for the first calendar quarter in which liability for tax is incurred (or tax must be collected and paid over) and for each subsequent calendar quarter, whether or not liability is incurred (or tax must be collected and paid over) during that subsequent quarter, until a final return under §40.6011(a)-2 is filed.

Proposed §40.6011(a)-1(d) would provide that a return that reports liability imposed by section 5000D must be made for a period of one calendar quarter, and that a return must be filed for each calendar quarter in which liability for the section 5000D tax is incurred. Therefore, under these proposed regulations, taxpayers would be required to report any section 5000D tax liability on Form 720; however, taxpayers would not be required to file subsequent returns for quarters in which they incur no
section 5000D tax liability.

C. Proposed amendments to §40.6302(c)-1

Section 40.6302(c)-1(a) provides that except as provided by statute or by §40.6302(c)-1(e), each person required under §40.6011(a)-1(a)(2) to file a quarterly return must make a deposit of tax for each semimonthly period (as defined in §40.0-1(c)) in which tax liability is incurred. Section 40.6302(c)-1(e) provides a list of taxes that are excepted from the semimonthly deposit requirement.

Proposed §40.6302(c)-1(e)(1)(vi) would add the section 5000D tax to the list of taxes that are excepted from the semimonthly deposit requirement. Therefore, under these proposed regulations, taxpayers with section 5000D tax liability would not be required to make semimonthly deposits of the section 5000D tax.

II. Proposed Addition of 26 CFR part 47

In addition to proposing the addition of a new part 47 to 26 CFR chapter 1, proposed §47.5000D-1 would provide an introductory provision under part 47 that would designate 26 CFR part 47 as the “Designated Drugs Excise Tax Regulations.”

Proposed Applicability Dates

These proposed regulations, once adopted as final regulations in a Treasury Decision published in the Federal Register, are proposed to apply to calendar quarters beginning on or after October 1, 2023. Taxpayers may rely on these proposed regulations for such returns beginning on October 1, 2023, and before the date that a Treasury Decision published in the Federal Register adopts these regulations as final regulations.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Pursuant to the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the IRS
are not subject to the requirements of section 6 of Executive Order 12866, as amended. Therefore, a regulatory impact assessment is not required.

II. Paperwork Reduction Act

The collections of information contained within these proposed regulations will be submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3507(d)). See 5 CFR 1320.11. The Treasury Department and the IRS request comments on the information collection burdens related to the proposed regulations. Commenters are strongly encouraged to submit public comments electronically. Written comments and recommendations for the proposed information collection should be sent to https://www.reginfo.gov/public/do/PRAMain, with copies to the IRS. To find this particular information collection, select “Currently under Review - Open for Public Comments” and then use the search function. Submit electronic submissions for the proposed information collection to the IRS via email at pra.comments@irs.gov (indicate REG-115595-23 in the subject line). Comments on the collection of information must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collections of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other
forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collections of information in these proposed regulations relate to reporting and recordkeeping requirements that will allow section 5000D taxpayers to meet their tax reporting obligations. The collections of information would generally be used by the IRS for tax compliance purposes and by taxpayers to facilitate proper tax reporting and compliance. The reporting and recordkeeping requirements are covered within the form and instructions for Form 720. IRS is seeking OMB approval on the statutorily required revisions to the form. Therefore, collection requirements will be submitted to OMB under control number 1545-0023.

Because the section 5000D tax is a new tax that has never been reported to the IRS, the Treasury Department and the IRS do not have historical data on the number of affected taxpayers. The Centers for Medicare and Medicaid Services (CMS) has selected 10 drugs for price negotiation for initial price applicability year 2026. CMS will select for negotiation a limited number of drugs for each initial price applicability year after that, as outlined in the IRA. Further, manufacturers, producers, and importers of such drugs may or may not become subject to section 5000D tax liability. Based on the foregoing, the IRS estimates that there will be between 0 and 50 taxpayers during the next 3 years.

If a taxpayer has a section 5000D tax liability, it would be required to file Form 720 to report such liability. Form 720 is a quarterly return. A taxpayer would only be required to file Form 720 during calendar quarters in which the taxpayer has a section 5000D tax liability. Therefore, a taxpayer that has a section 5000D tax liability in one calendar quarter but not in subsequent calendar quarters would only be required to file one Form 720.
The respondents with regard to the section 5000D tax are manufacturers, producers, and importers of certain drugs. The Treasury Department and the IRS estimate the annual burden of the collections of information as follows (these estimates, which are for PRA purposes only, are based on the high end of the range of possible taxpayers and the high end of the range of the frequency of responses, in which a taxpayer would have tax liability in all four calendar quarters):

Estimated frequency of responses: Quarterly.
Estimated number of responses: 50.
Estimated burden time per respondent: 6.9 hours.
Estimated total annual reporting burden: 1,380 hours.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the section 5000D tax is imposed only when certain drug manufacturers, producers, and importers sell certain drugs during periods described in section 5000D(b). The periods described in section 5000D(b) relate to benchmarks in the Medicare Drug Price Negotiation Program, which involves only certain drugs with high Medicare expenditures. If any section 5000D tax liability arises, the taxpayers will primarily not be small entities. As noted earlier, data is not readily available about the number of
taxpayers affected, but the number is likely to be limited, in part due to the limited number of drugs selected for the Drug Price Negotiation Program in any particular year. In addition, these proposed regulations will assist taxpayers in meeting their tax reporting obligations by providing clarity on how to report section 5000D tax liability, which will make it easier for taxpayers to comply with section 5000D. Therefore, these proposed regulations will not create additional obligations for, or impose a significant economic impact on, small entities, and a regulatory flexibility analysis under the Regulatory Flexibility Act is not required. Notwithstanding this certification, the Treasury Department and the IRS welcome comments on the impact of these proposed regulations on small entities.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, these proposed regulations have been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 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. These proposed 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.

V. 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, do not impose substantial direct compliance costs on State and local governments, and do not preempt State law within the meaning of the Executive order.

**Statement of Availability of IRS Documents**


**Comments and Requests for a Public Hearing**

Before these 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** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. Any comments submitted will be made available at [https://www.regulations.gov](https://www.regulations.gov) or upon request.

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 also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

**Drafting Information**

The principal author of these regulations is Jacob W. Peeples of the Office of the Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

**List of Subjects**

26 CFR Part 40
Excise taxes, Reporting and recordkeeping requirements.

26 CFR Part 47

Excise taxes.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR chapter I, subchapter D, as follows:

PART 40—EXCISE TAX PROCEDURAL REGULATIONS

Paragraph 1. The authority citation for part 40 continues to read in part as follows:


* * * * *

Par. 2. Section 40.0-1 is amended by revising paragraphs (a) and (e) to read as follows:

§40.0-1 Introduction.

(a) In general. The regulations in this part are designated the Excise Tax Procedural Regulations. The regulations in this part set forth administrative provisions relating to the excise taxes imposed by chapters 31 through 34, 36, 38, 39, 49, and 50A of the Internal Revenue Code (Code) (except for the chapter 32 tax imposed by section 4181 (firearms tax) and the chapter 36 taxes imposed by sections 4461 (harbor maintenance tax) and 4481 (heavy vehicle use tax)), and to floor stocks taxes imposed on articles subject to any of these taxes. Chapter 31 relates to retail excise taxes; chapter 32 to manufacturers’ excise taxes; chapter 33 to taxes imposed on communications services and air transportation services; chapter 34 to taxes imposed on certain insurance policies; chapter 36 to taxes imposed on transportation by water; chapter 38 to environmental taxes; chapter 39 to taxes imposed on registration-required obligations; chapter 49 to taxes imposed on indoor tanning services; and chapter 50A to
taxes imposed on designated drugs. References in this part to taxes also include references to the fees imposed by sections 4375 and 4376 of the Code. See parts 43, 46 through 49, and 52 of this chapter for regulations related to the imposition of tax.

* * * * *

(e) Applicability dates--(1) Paragraph (a). Paragraph (a) of this section applies to returns required to be filed under §40.6011(a)-1 for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2023.

(2) Paragraphs (b) and (c). Paragraphs (b) and (c) of this section apply to returns for calendar quarters beginning after March 31, 2013. For rules that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2012.

(3) Paragraph (d). Paragraph (d) of this section applies to returns for calendar quarters beginning on or after January 19, 2021. For rules that apply before January 19, 2021, see 26 CFR part 40, revised as of April 1, 2020.

Par. 3. Section 40.6011(a)-1 is amended by:

1. Revising the first sentence of paragraph (a)(2)(i).

2. Adding paragraphs (d) and (e).

The revision and additions read as follows:

§40.6011(a)-1 Returns.

(a) * * *

(2) * * *

(i) * * * Except as provided in paragraphs (b) through (d) of this section, the return must be made for a period of one calendar quarter. * * *

* * * * *

(d) Tax on designated drugs. A return that reports liability imposed by section 5000D must be made for a period of one calendar quarter. A return must be filed for
Each calendar quarter in which liability for the tax imposed by section 5000D is incurred. There is no requirement that a return be filed for a calendar quarter in which there is no liability imposed by section 5000D.

(e) Applicability dates—(1) Paragraph (a)(2)(i). Paragraph (a)(2)(i) of this section applies to returns filed for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2023.

(2) Paragraph (c). See paragraph (c)(2) of this section.

(3) Paragraph (d). Paragraph (d) of this section applies to returns filed for calendar quarters beginning on and after October 1, 2023.

Par. 4. Section 40.6302(c)-1 is amended by:

1. Revising paragraphs (e)(1)(iv) and (v).

2. Adding paragraph (e)(1)(vi).

2. Revising paragraph (f).

The revisions and addition read as follows:

§40.6302(c)-1 Deposits.

* * * * *

(e) * * *

(1) * * *

(iv) Sections 4375 and 4376 (relating to fees on health insurance policies and self-insured insurance plans);

(v) Section 5000B (relating to indoor tanning services); and

(vi) Section 5000D (relating to designated drugs).

* * * * *

(f) Applicability dates—(1) Paragraphs (a) through (d). Paragraphs (a) through (d) of this section apply to deposits and payments made after March 31, 2013. For rules
that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2012.

(2) Paragraph (e). Paragraph (e) of this section applies to calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2023.

Par. 5. Add part 47 to read as follows:

PART 47—DESIGNATED DRUGS EXCISE TAX REGULATIONS

Sec.
47.5000D-0 Table of contents.
47.5000D-1 Introduction.
47.5000D-2 - 47.5000D-3 [Reserved]


Section 47.5000D-1 also issued under 26 U.S.C. 5000D.

§47.5000D-0 Table of contents.
This section lists the table of contents for §§47.5000D-1 through 47.5000D-3.

§47.5000D-1 Introduction.

(a) In general. The regulations in this part are designated the Designated Drugs Excise Tax Regulations. The regulations in this part relate to the tax imposed by section 5000D of the Internal Revenue Code. See part 40 of this chapter for regulations relating to returns, payments, and other procedural rules applicable to this part.

(b) Applicability date. This section applies to returns filed for calendar quarters beginning on or after October 1, 2023.

§§47.5000D-2 - 47.5000D-3 [Reserved]
Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2023-21586 Filed: 9/27/2023 11:15 am; Publication Date: 10/2/2023]