PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1619 by revising paragraph (c) to read as follows:

§ 91.1619 Special Federal Aviation Regulation No. 119—Prohibition Against Certain Flights in the Kabul Flight Information Region (FIR) (OAKX).

* * * * *

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in the Kabul Flight Information Region (FIR) (OAKX) under the following circumstances:

(1) *Permitted operations that do not require an approval or exemption from the FAA.* (i) Overflights of the Kabul Flight Information Region (FIR) (OAKX) may be conducted at altitudes at and above Flight Level (FL) 320, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

(ii) Transiting overflights of the Kabul Flight Information Region (FIR) (OAKX) may be conducted on jet routes P500–G500 at altitudes at and above FL300, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Afghanistan.

(2) *Operations permitted under an approval or exemption issued by the FAA.* Flight operations may be conducted in the Kabul Flight Information Region (FIR) (OAKX) at altitudes below FL320, provided that such flight operations occur under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the U.S. Government department, agency, or instrumentality and the person described in paragraph (a) of this section) with the approval of the FAA or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: first, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

* * * * *

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5).

Michael Gordon Whitaker,

Administrator.

[FR Doc. 2024–14708 Filed 7–3–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40 and 47

[TD 10003]

RIN 1545–BQ93

Excise Tax on Designated Drugs; Procedural Requirements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule.

SUMMARY: This document contains final regulations relating to the excise tax imposed on certain sales by manufacturers, producers, or importers of designated drugs. Specifically, the final regulations set forth procedural provisions relating to how taxpayers must report liability for such tax. The final regulations also except such tax from semimonthly deposit requirements. The final regulations affect manufacturers, producers, or importers of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare during certain statutory periods.

DATES:

Effective date: These regulations are effective on August 5, 2024.

Applicability dates: For dates of applicability, see §§ 40.0–1(e), 40.6011(a)–1(e), 40.6302(c)–1(f), and 47.5000D–1(b).

FOR FURTHER INFORMATION CONTACT: Jacob W. Peeples or James S. Williford at (202) 317–6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Excise Tax Procedural Regulations (26 CFR part 40) and adds new part 47 to 26 CFR chapter I 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).

Sections 1191 through 1198 of the Social Security Act (SSA), added by sections 11001 and 11002 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022 (IRA), require the Secretary of Health and Human Services to establish a Medicare prescription drug price negotiation program (Medicare Drug Price Negotiation Program) to negotiate maximum fair prices for certain high expenditure, single-source drugs covered under Medicare.

Section 5000D, added to new chapter 50A of the Code by section 11003 of the IRA, imposes an excise tax on certain sales by manufacturers, producers, or importers of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare during a day that falls within a period described in section 5000D(b). The periods described in section 5000D(b) relate to certain statutorily prescribed milestones in the Medicare Drug Price Negotiation Program. Because chapter 50A is a new chapter of the Code, the existing regulations that prescribe procedural rules applicable to most Federal excise taxes do not apply to chapter 50A.

Notice 2023–52 (2023–35 I.R.B. 650; August 28, 2023) announced that the Department of the Treasury (Treasury Department) and the IRS intended to propose regulations addressing substantive and procedural issues related to the section 5000D tax.

On October 2, 2023, a notice of proposed rulemaking (REG–115559–23) was published in the **Federal Register** (88 FR 67690) (proposed regulations). No public hearing was requested or held. The Treasury Department and the IRS received several comments in response to the proposed regulations. The comments addressing the proposed regulations are summarized in the Summary of Comments and Explanation of Revisions section of this preamble.

Summary of Comments and Explanation of Revisions

I. Overview

As noted in the Background section of this preamble, the Treasury Department and the IRS received several public comment submissions in response to the proposed regulations. The public comments fall into six general categories: timing of the publication of the proposed regulations; the quarterly filing requirement in the proposed regulations; the proposed regulations'

retroactive applicability dates; the constitutionality of the section 5000D tax; technical issues and questions relating to the implementation of the section 5000D tax itself; and comments on the Special Analyses provided in the proposed regulations. Each of these categories of comments is addressed in turn in parts II through VII of this Summary of Comments and Explanation of Revisions.

All public comments were considered and are available at *https://www.regulations.gov* or upon request. After full consideration of the public comments received in response to the proposed regulations, this Treasury decision adopts the proposed regulations with three non-substantive modifications. Specifically, the final regulations modify proposed §§ 40.0–1, 40.6011–1(d), and 40.6302(c)–1 by clarifying that the section 5000D tax is imposed on ''the sale of'' designated drugs. The language, as modified, more closely tracks the language of section 5000D(a).

II. Timing of the Publication of the Proposed Regulations

A commenter stated that the Treasury Department and the IRS acted prematurely when publishing proposed regulations related to procedural rules prior to publishing substantive rules for the section 5000D tax and requested that the Treasury Department and the IRS withdraw the proposed regulations until substantive rules are published.

The section 5000D tax is a self-executing tax—that is, the section 5000D tax is effective and applicable regardless of whether implementing regulations are published by the Treasury Department and the IRS. *See Sundance Helicopters, Inc.* v. *United States,* 104 Fed. Cl. 1, 11 (2012) (in determining whether the issuance of regulations is a precondition to the application of a statute, the court followed Tax Court precedent in *Estate of Neumann* v. *Comm'r,* 106 T.C. 216 (1996) (setting out the rule that ''a tax statute is self-executing if the regulation referred to in the statute deals only with how, not whether, the tax is to be applied.'')). Further, under section 5000D(b)(1), the first date that a manufacturer, producer, or importer could be liable for the section 5000D tax is October 2, 2023. As a result, publication of the proposed regulations was not premature because liability can arise under section 5000D in the absence of substantive regulatory guidance, and taxpayers needed this procedural guidance on how to meet their tax reporting and payment obligations for section 5000D tax liability incurred on and after October 2, 2023. Accordingly, the Treasury Department and the IRS are finalizing the proposed regulations without adopting this comment.

III. Quarterly Filing Requirement

A commenter expressed concern regarding the proposed regulations' quarterly filing and payment requirement. Specifically, the commenter stated that—in the absence of substantive guidance such as clarification of what sales are subject to the section 5000D tax—it is ''impossible'' for the IRS to determine that a ''quarterly cadence'' for filing returns and paying the section 5000D tax is rational. Further, the commenter stated that the quarterly filing requirement will be overly burdensome on taxpayers.

Generally, § 40.6011(a)–1(a)(2)(i) requires that taxpayers subject to Federal excise tax must file a Form 720, *Quarterly Federal Excise Tax Return,* beginning with the first calendar quarter during which their Federal excise tax liability arises. Once the first Form 720 is filed, a taxpayer is generally required to continue filing Forms 720 for every calendar quarter thereafter—regardless of whether additional Federal excise tax liabilities are incurred during a particular subsequent calendar quarter—until the taxpayer permanently ceases all operations with respect to which the Federal excise tax liability was incurred. *See* §§ 40.6011(a)–1(a)(2)(i) and 40.6011(a)–2(a)(1). Failure to file subsequent quarterly returns after filing the first Form 720 may result in the assessment of penalties under section 6651(a) of the Code.

In developing the proposed regulations, the Treasury Department and the IRS recognized that in the context of the section 5000D tax (under which a taxpayer may incur liability in a particular calendar quarter and then never incur liability again in subsequent calendar quarters), to require a taxpayer to continue to file Form 720 for every calendar quarter following the filing of its first Form 720 even if no tax liability is incurred in subsequent calendar quarters would be both unnecessary for tax administration and unduly burdensome on the taxpayer. As a result, the proposed regulations exempted taxpayers that incur a section 5000D tax liability (section 5000D taxpayers) and report that tax liability on a timely filed Form 720 from the general requirement to file subsequent Forms 720 if no section 5000D tax liability is incurred during a subsequent calendar quarter. Specifically, proposed § 40.6011(a)–1(d) required a taxpayer to file a subsequent Form 720 only if a new section 5000D tax liability arises during a particular calendar quarter.

Regarding the requirement to pay a section 5000D tax liability quarterly with the taxpayer's Form 720, generally, §§ 40.6071(a)–1(a) and 40.6151(a)–1 require that Form 720 filers must pay the tax shown on the return at the same time the return is filed. Providing a different rule for section 5000D taxpayers would introduce unnecessary complexity into the excise tax filing and payment regime. An increase in complexity could lead to taxpayer confusion and likely result in a greater burden on both taxpayers and the IRS with little to no benefit accruing to stakeholders. The Treasury Department and the IRS also note that proposed § 40.6302(c)–1 exempted the section 5000D tax from the semimonthly deposit requirements that apply to most other Federal excise taxpayers. By finalizing this proposed rule without this modification to the requirement to pay with the quarterly filing, the compliance burden on section 5000D taxpayers will be further reduced.

For these reasons, as well as for reasons similar to those discussed in part II of this Summary of Comments and Explanation of Revisions (related to the necessity to timely provide section 5000D taxpayers with procedural guidance on how to meet their tax reporting and payment obligations), the Treasury Department and the IRS are finalizing the proposed regulations without adopting this comment.

IV. Applicability Dates

The proposed regulations provided that the Treasury decision finalizing the proposed regulations will apply to calendar quarters beginning on or after October 1, 2023; in other words, the proposed regulations provided that this Treasury decision will not apply beginning on the date that it is published in the **Federal Register**, but rather it will retroactively apply as of the first day of the fourth calendar quarter of 2023. A commenter requested that the Treasury Department and the IRS reconsider the retroactive applicability dates provided in the proposed regulations because the section 5000D tax is new.

As discussed in part II of this Summary of Comments and Explanation of Revisions, the Treasury Department and the IRS prioritized providing section 5000D taxpayers with procedural guidance on how to meet their tax reporting and payment obligations by October 2, 2023, the first date when a taxpayer could incur a section 5000D tax liability. Because the

first date when a taxpayer could incur liability for the section 5000D tax is October 2, 2023, which falls within the fourth calendar quarter of 2023, it is appropriate for the final regulations that provide rules relating to filing and payment of the section 5000D tax to relate back to the beginning of the fourth calendar quarter of 2023 (that is, October 1, 2023), which in accordance with section 7805(b)(1)(B), would be the first taxable period ending after October 2, 2023 (that is, the date the proposed regulations were published in the **Federal Register**). As a result, the Treasury Department and IRS are finalizing the proposed applicability dates without adopting this comment.

V. Constitutionality

Some commenters stated that the Medicare Drug Price Negotiation Program generally, and the section 5000D tax specifically, may be unconstitutional. These comments are outside the scope of the proposed regulations, which set forth proposed rules for administering a duly enacted tax law. Therefore, it is not appropriate for the Treasury Department and the IRS to address these comments in the context of this rulemaking.

VI. Technical Comments

A commenter requested that the Treasury Department and the IRS consider providing sales-reporting and calculation ''safe harbors'' in these final regulations. Another commenter stated their belief that Notice 2023–52 requested clarification on how the Treasury Department and the IRS should define ''sales'' for purposes of the section 5000D tax. These comments are outside the scope of the proposed regulations, which related only to the procedures for reporting and paying the section 5000D tax.

VII. Comments on the Special Analyses

A. Paperwork Reduction Act

A commenter requested that the Treasury Department and the IRS reconsider the paperwork burden estimate in the Paperwork Reduction Act (44 U.S.C. 3507(d)) (PRA) section of the proposed regulations because the commenter believes that the number of estimated hours is too low. In this request, the commenter suggested that it is possible that no taxpayers will ever incur a section 5000D tax liability. The commenter accepted that the Treasury Department and the IRS do not have historical data on the number of compliance hours affected taxpayers may experience if a section 5000D tax liability is incurred and did not offer a specific estimated number of hours it views as more accurate than the estimate provided in the proposed regulations. Similarly, the commenter did not offer an alternative calculation methodology that the Treasury Department and the IRS could use to provide a better burden estimate.

The Treasury Department and the IRS calculated the estimated number of paperwork burden hours using the long-standing and established methodology outlined in Publication 5743, *Taxpayer Compliance Burden,* to arrive at the estimated total annual reporting burden of 1,380 hours stated in the proposed regulations. For these reasons, the Treasury Department and the IRS estimate that this Treasury decision will impose a total annual reporting burden of 1,380 hours, as discussed in part II of the Special Analyses section of this preamble. However, the Treasury Department and the IRS will regularly examine and, as necessary, update the estimated total annual reporting burden of this Treasury decision as required by the PRA.

B. Regulatory Flexibility Act

A commenter requested that the Treasury Department and the IRS conduct a Regulatory Flexibility Act (5 U.S.C. chapter 6) (RFA) analysis because the commenter is concerned that this Treasury decision may have an indirect effect on small entities. An agency may properly certify that no RFA analysis is needed when it determines that a rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the proposed rule. See *Mid-Tex Elec. Co-op., Inc.* v. *FERC,* 773 F.2d 327, 342 (D.C. Cir. 1985) (holding that Congress did not intend to require consideration of every indirect effect that any regulation might have on small businesses). Accordingly, as discussed in part III of the Special Analyses section of this preamble, the Treasury Department and the IRS continue to certify that this Treasury decision will not create additional obligations for, or impose a significant economic impact on, small entities, and as a result, a regulatory flexibility analysis under the RFA is not required.

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 collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the PRA under control number 1545–0023.

The collections of information in these regulations relate to reporting and recordkeeping requirements that will allow 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.

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, or importers of such drugs may or may not become subject to a 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, or 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.

The Treasury Department and the IRS received a comment suggesting that the paperwork burden estimate provided in the proposed regulations was too low. However, for the reasons discussed in detail in the Summary of Comments and Explanation of Revisions section of this preamble and in this Special Analyses section, the Treasury Department and the IRS have not changed the estimates provided herein.

III. Regulatory Flexibility Act

For the reasons discussed in detail in the Summary of Comments and Explanation of Revisions section of this preamble and in this Special Analyses section, pursuant to the RFA, it is hereby certified that these final 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 on certain sales by manufacturers, producers, or importers of designated drugs during periods described in section 5000D(b). The periods described in section 5000D(b) relate to milestones in the Medicare Drug Price Negotiation Program, which involve only certain drugs with high Medicare expenditures. Drugs with high Medicare expenditures that are not already excluded from the Medicare Drug Price Negotiation Program under an exception such as the SSA's small biotech exception (sections 1192(b) and (d)(2) of the SSA) are likely to be manufactured, produced, or imported by large entities, so if any section 5000D tax liability arises, an insubstantial number of taxpayers will be small entities. As noted earlier, data is not 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 Medicare Drug Price Negotiation Program in any particular year. In addition, these final 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 final regulations will not create additional obligations for, or impose a significant economic impact on, small entities, and a regulatory flexibility analysis under the RFA is not required.

IV. Section 7805(f)

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these final regulations was submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business. No comments were received from the Chief Counsel for the Office of Advocacy of the Small Business Administration.

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 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 final 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

The IRS Notice cited in this preamble 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 *https://www.irs.gov.*

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.

Adoption of Amendments to the Regulations

Accordingly, the Treasury Department and the IRS 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:

Authority: 26 U.S.C. 7805.

* * * * *

■ **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 the sale of 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, 2024.

(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 the sale of designated drugs.* A return that reports liability imposed by section 5000D of the Internal Revenue Code 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, 2024.

(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).

■ 3. 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 the sale of 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, 2013.

(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, 2024.

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

PART 47—DESIGNATED DRUGS EXCISE TAX REGULATIONS

Sec.

Authority: 26 U.S.C. 7805.

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–4.

§§ 47.5000D–2—47.5000D–4 [Reserved]

§ 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–4 [Reserved]

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: June 24, 2024.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–14706 Filed 7–3–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 15

[Docket No. CIV 150; AG Order No. 5968–2024]

RIN 1105–AB37

Process for Determining That an Individual Shall Not Be Deemed an Employee of the Public Health Service

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule sets forth a process by which the Attorney General or a designee may determine that an individual shall not be deemed an employee of the Public Health Service for purposes of medical malpractice coverage under the Public Health Service Act. The process described in this rule applies to individuals who are deemed to be Public Health Service employees, as well as any other individuals deemed to be Public Health Service employees under different statutory provisions to which the procedures set out in the Public Health Service Act have been made applicable.

DATES: This rule is effective on August 5, 2024.

FOR FURTHER INFORMATION CONTACT: James G. Touhey, Jr., Director, Torts Branch, Civil Division, Department of Justice, Washington, DC 20530, (202) 616–4400.

SUPPLEMENTARY INFORMATION: This rule finalizes, with some changes, a proposed rule that the Department of Justice (''Department'') published on this subject on March 6, 2015, at 80 FR 12104. In brief, the following changes were made to the text of the proposed rule:

In § 15.11, a sentence was added to clarify that an individual who is no longer ''deemed'' to be an employee of the Public Health Service pursuant to section 224(i) of the Public Health Service Act, 42 U.S.C. 233(i), is excluded from medical malpractice protections otherwise available to individuals ''deemed'' to be Public Health Service employees under the