

# Rules and Regulations

Federal Register

Vol. 76, No. 160

Thursday, August 18, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 51 and 602

[TD 9544]

RIN 1545-BK34

#### Branded Prescription Drug Fee

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations that provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs. This fee was enacted by section 9008 of the Patient Protection and Affordable Care Act, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010. The regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective on August 18, 2011.

*Applicability Date:* For dates of applicability, see §§ 51.11T and 51.6302-1T(b).

**FOR FURTHER INFORMATION CONTACT:** Celia Gabrysh, (202) 622-3130 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Paperwork Reduction Act

These temporary regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these

regulations has been reviewed and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545-2209.

An 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.

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-reference notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

Books or records relating to a collection of information must be retained as long as 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 26 U.S.C. 6103.

##### Background

This document adds the Branded Prescription Drug Fee Regulations to the Code of Federal Regulations (26 CFR Part 51) under section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111-152 (124 Stat. 1029 (2010)). All references in this preamble to section 9008 are references to section 9008 of ACA, as amended by section 1404 of HCERA. Section 9008 did not amend the Internal Revenue Code (Code) but cross-references to specified Code sections.

##### Statutory Provisions

Section 9008(a) imposes an annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs, to be paid not later than the annual date specified by the Secretary of the Treasury or his delegate (Secretary), but in no event later than September 30th of each calendar year in which a fee must be paid (fee year).

Section 9008(d)(1) defines a *covered entity* as any manufacturer or importer with gross receipts from branded

prescription drug sales. Section 9008(d)(2) provides a controlled group rule under which all persons treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code are treated as a single covered entity. For this purpose, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). Under section 9008(d)(3), all persons treated as a single employer under section 9008(d)(2) are jointly and severally liable for the fee.

Section 9008(e)(2) defines *branded prescription drug* as (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (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)). For this purpose, a *prescription drug* is any drug that is subject to section 503(b) of the FFDCA (21 U.S.C. 353(b)).

Section 9008(b) provides rules for determining the amount of the annual fee for each covered entity. Under section 9008(b)(4), the aggregate fee amount each year for all covered entities (referred to as the *applicable amount*) is \$2.5 billion for fee year 2011; \$2.8 billion for fee years 2012 and 2013; \$3 billion for fee years 2014 through 2016; \$4 billion for fee year 2017; \$4.1 billion for fee year 2018; and \$2.8 billion for fee year 2019 and thereafter. Section 9008(b)(1) requires the applicable amount for each year to be allocated, using a specified formula, among covered entities with aggregate branded prescription drug sales of over \$5 million to specified government programs or pursuant to coverage under such programs. Section 9008(e)(4) provides that the *specified government programs* are the Medicare Part B program, the Medicare Part D program, the Medicaid program, any program under which branded prescription drugs are procured by the Department of Veterans Affairs, any program under which branded prescription drugs are procured by the Department of Defense, and the TRICARE retail pharmacy program (collectively, the Programs).

Specifically, section 9008(b)(1) provides that the annual fee for each covered entity is calculated by determining the ratio of (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 taken into account for all covered entities during the same year, and applying this ratio to the applicable amount. *Sales taken into account* means branded prescription drug sales after the application of the percentage adjustment table in section 9008(b)(2). The sales data is generally to be provided by the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS), the Department of Veterans Affairs (VA), and the Department of Defense (DOD) (collectively, the Agencies) pursuant to section 9008(g).

Section 9008(b)(3) requires the Secretary to determine the amount of each covered entity's fee and permits the Secretary to rely on reports submitted by the Agencies and any other source of information available to the Secretary in determining that amount. Section 9008(i) also directs the Secretary to publish guidance necessary to carry out the purposes of the statute.

Section 9008(f) treats the fee as an excise tax with respect to which only civil actions for refunds under the provisions of subtitle F of the Code will apply. Thus, the fee may be assessed and collected using the procedures in subtitle F without regard to the restrictions on assessment in section 6213 (relating to petitions to the Tax Court). Section 9008(f) also characterizes the fee as a nondeductible tax under section 275 of the Code.

#### *IRS Guidance*

On November 29, 2010, the Internal Revenue Service (IRS) released Notice 2010-71 (2010-50 IRB 822), which proposed an approach to implementing the section 9008 fee and requested comments on the proposed approach. The proposed approach included an opportunity to report certain information to the IRS relevant to the fee calculation and provided that the IRS would provide each covered entity with notice of a preliminary fee calculation. This notice was modified and superseded by Notice 2011-9 (2011-6 IRB 459), which was released on January 14, 2011.

On April 29, 2011, the IRS released Rev. Proc. 2011-24 (2011-20 IRB 787), which established a process for covered entities to submit claimed errors in their preliminary fee calculations for consideration before final fee calculations for 2011. On May 27, 2011, the IRS released Notice 2011-46 (2011-25 IRB 887) to defer the due date for submission of error reports and the last

possible date for sending final fee calculations for 2011.

#### **Explanation of Provisions**

The temporary regulations describe the rules related to the fee and the actions to be taken before the September 30th due date of each year's fee. The temporary regulations first provide a general overview of the rules and then provide an explanation of terms used in implementing the fee. Next, the temporary regulations describe the information requested from covered entities and provided by the Agencies. The temporary regulations then describe how the fee is calculated and provide for a subsequent adjustment. The temporary regulations then provide for a notice of the preliminary fee calculation, a dispute resolution process to allow covered entities to submit error reports relating to the preliminary fee calculation, and a notice of the final fee calculation. The temporary regulations also explain how to pay the fee, how the fee is treated for tax purposes, and how to make refund claims.

These temporary regulations are generally consistent with the approach proposed in previous IRS guidance. Certain modifications and additions were made in response to public comments that were received in response to the solicitation in Notice 2011-9. The changes and the public comments are discussed in more detail in this preamble.

#### **I. Overview**

The temporary regulations provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008. Generally, each covered entity with aggregate branded prescription drug sales of over \$5 million to the Programs (or pursuant to the Programs) is liable for an annual fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the IRS under these temporary regulations.

#### **II. Explanation of Terms**

The temporary regulations define numerous key terms used in section 9008 and in these regulations, including *agencies*, *branded prescription drug*, *covered entity*, *fee year*, *government programs*, *sales taken into account*, and *sales year*. Explanations of several terms are discussed in more detail in this preamble.

#### *A. Manufacturer or Importer*

Section 9008(d)(1) provides that *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales. Consistent with the proposal in previous IRS guidance, the temporary regulations define a manufacturer or importer of a branded prescription drug as the person identified in the Labeler Code of the National Drug Code (NDC) for such a drug. The NDC is an identifier assigned by the FDA to a prescription drug. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

#### *B. Designated Entity*

Consistent with the proposal in previous IRS guidance, the temporary regulations provide that, in the case of a controlled group that is treated as a single covered entity under section 9008(d)(2), the controlled group may identify a person as the designated entity that acts for the controlled group concerning the section 9008 fee. However, the temporary regulations further provide that if the controlled group, without regard to foreign corporations included under section 9008(d), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group identified on the tax return filed for the sales year. If the controlled group is not an affiliated group that filed a consolidated return for Federal income tax purposes, it may select a person as the designated entity on Form 8947, "Report of Branded Prescription Drug Information." If the controlled group does not select a person as a designated entity on its Form 8947, the IRS will select a person as a designated entity for the controlled group and advise the filer accordingly.

#### *C. Orphan Drug Sales*

Section 9008(e)(3) excludes orphan drug sales from the definition of branded prescription drug sales. Consistent with the proposal in previous IRS guidance, the temporary regulations define *orphan drug*, subject to certain exceptions, as any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year. The temporary regulations further provide that an orphan drug does not include any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug. Additionally, an

orphan drug does not include any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, at the same time, or after this FDA approval.

Several commentators suggested that a drug should be considered an orphan drug if the section 45C credit was "allowable"; that is, the section 45C credit could have been claimed, rather than was claimed. Other commentators suggested that orphan drug status should be given to a drug for which a section 45C credit was allowed even though the drug had been approved by the FDA for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed.

The temporary regulations do not adopt these suggestions. The plain language of section 9008(e)(3) requires the section 45C credit to have actually been allowed rather than to have merely been allowable. In addition, the Treasury Department and the IRS interpret section 9008(e)(3) to mean that if a drug is ever approved for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, whether before, during, or after a section 45C credit was allowed for the drug, sales of that drug are not considered sales of an orphan drug. However, a drug will retain its orphan drug status if the drug receives approval for a subsequent indication for a rare disease or condition for which a subsequent section 45C credit was allowed.

### III. Information Requested From Covered Entities

Consistent with the proposal in previous IRS guidance, the temporary regulations give each covered entity the opportunity to provide information relevant to the determination of the section 9008 fee by annually submitting Form 8947, "Report of Branded Prescription Drug Information," and providing the information specified by the form and instructions, including the NDCs for branded prescription drugs that the covered entity sold to the Programs (or pursuant to coverage under the Programs), Medicare and Medicaid rebate information, section 45C orphan drug information, members of controlled groups, and designated entity information.

One commentator suggested that the Treasury Department and the IRS confirm that submission of Form 8947 is

voluntary. Section 51.3T(a) of the temporary regulations provides that a covered entity *may* file a completed Form 8947; thus, the submission of Form 8947 is voluntary.

Commentators expressed a preference for CMS to include all rebate data in their reports to the IRS rather than collecting rebate data from the covered entities on Form 8947. The IRS and CMS are continuing to work on this issue. Until CMS can report all the relevant rebate data, covered entities will continue to have the opportunity to submit rebate data as requested on Forms 8947 and in the format prescribed in the form instructions.

Several commentators suggested that the Treasury Department and the IRS provide guidance on how covered entities may amend their Form 8947 to correct errors or omissions in the information reported. A number of covered entities notified the IRS of corrections to their Forms 8947 in the error reports that they submitted as part of the dispute resolution process provided under Rev. Proc. 2011-24. That proved to be an efficient and effective way to relay corrections. Accordingly, under the temporary regulations, a covered entity may notify the IRS of any changes or additions to information it submitted on Form 8947 by submitting error reports in the dispute resolution process, discussed later in this preamble.

### IV. Information Provided by the Agencies

Consistent with the proposal in the previous IRS guidance, the temporary regulations provide that the IRS will (1) compile a list of branded prescription drugs by NDC using the data submitted on Forms 8947; (2) apply appropriate due diligence; and (3) provide the Agencies with the list. The temporary regulations describe the data the Agencies are to provide the IRS annually for each NDC on the list by Program. The temporary regulations further clarify that the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and that the data the IRS uses to produce the final fee determination includes any revisions provided by the Agencies at the completion of the dispute resolution process.

Commentators raised questions about the descriptions in previous IRS guidance of the methodology used by the Agencies to report branded prescription drug sales to the IRS and asked that these descriptions be clarified. In addition, some of the error reports submitted as part of the dispute

resolution process under Rev. Proc. 2011-24 identified the need for clarification in describing Agency data. In response to the comments and the issues illuminated by the error reports, the temporary regulations provide revised descriptions of the data and computations for some of the Programs.

Commentators raised questions about the methodology proposed for computing branded prescription drug sales for Medicare Part B. Specifically, they questioned the use of Medicare-allowed charges to establish the sales rather than a computation based on the per-unit average sales price (ASP) and the units paid for under Medicare Part B as specified in section 9008(g)(2). Commentators also asked whether CMS would use ASP (that is, ASP plus 0%) or ASP plus 6% (which reflects amounts actually paid) in computing the sales figures. After considering the comments, CMS refined its calculation process. Thus, the temporary regulations provide that branded prescription drug sales for Medicare Part B will be computed based on ASP and units paid for under Medicare Part B.

Commentators also requested clarification about how sales will be calculated for branded prescription drugs that are not separately payable or reported. In the unusual situation where CMS is unable to establish a reliable proportion of sales by NDC, for example due to unavailable, inaccurate, or incomplete manufacturer sales data, the temporary regulations clarify that CMS has a back-up method that will use Medicare Part D utilization percentages in lieu of manufacturer data. It should be noted, however, that for the 2011 fee calculations, this back-up method was not required.

Commentators also expressed concerns about whether Medicare Part B is capturing complete data with respect to non-separately payable drugs, that is, drugs that are not directly correlated with a specific HCPCS Code. CMS recognizes the commentators' concern and has made extensive efforts to gather as complete a data set as possible. CMS will continue to work with the data available to capture non-separately payable drugs.

Some commentators asked whether the sales data from Medicaid reflected sales where Medicaid was the secondary payer, resulting potentially in duplicate reporting where another one of the Programs (for example, Medicare Part B), was the primary payer. In response, CMS has revised the Medicaid methodology to exclude non-Medicaid payments, and the temporary regulations include a description of this aspect of the methodology.

Commentators asked whether TRICARE sales data would be net of refunds and rebates associated with specific NDCs. The temporary regulations make clear that DOD will report for TRICARE the sales data for each NDC based on retail pharmacy claims submitted during the sales year, net of any refunds or rebates. Commentators questioned whether the VA sales data excluded purchases made at individual treatment facilities. The VA includes most of its purchases made at the individual medical treatment facility level in its data because most of these purchases are made via VA's Pharmaceutical Prime Vendor. The description of VA sales data contained in the temporary regulation is revised from the description contained in earlier guidance to eliminate language suggesting that sales at the individual medical treatment facility level are not included and to clarify that the sales data is net of refunds and rebates.

#### **V. Fee Calculation Including Adjustment**

The temporary regulations clarify that the IRS will compute the fee for a covered entity based on the branded prescription drug sales data for each NDC reported by the Agencies and any rebate data for each NDC reported by the covered entities. For purposes of computing the fee, each NDC will be assigned to the covered entity that owns the NDC as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year.

The temporary regulations provide that two years are relevant to the calculation of the section 9008 fee: The fee year, and the calendar year of the branded prescription drug sales, which will be used to determine the amount of the fee (the sales year). As proposed in previous IRS guidance, the temporary regulations use the second calendar year preceding the fee year as the sales year for purposes of calculating the section 9008 fee. The Treasury Department and the IRS have determined that, although DOD and VA are expected to have complete data on branded prescription drug sales for the calendar year immediately preceding the fee year within the time frame necessary to administer the fee, CMS is not expected to have comparable data because it cannot complete its data processing within the necessary time frame. Accordingly, the IRS will calculate the fee based on the branded prescription drug sales data provided by the Agencies for the second calendar year

preceding the fee year. Because the use of the second preceding year as the sales year, rather than the immediately preceding year, may affect the amount of the fee paid by a covered entity, the annual fee due in every year after 2011 will include an adjustment amount. This adjustment amount will be added (or subtracted), as appropriate, to (or from) the fee otherwise payable by the covered entity in the fee year in which the adjustment is calculated.

The proposal in previous guidance was to compute the adjustment separately for each NDC. Commentators raised questions about the effect of the adjustment where a drug is owned by different covered entities in the second preceding year and immediately preceding year and asked whether the adjustment could be computed at the covered entity level rather than the NDC level. The Treasury Department and the IRS have considered these questions, and have decided to calculate the adjustment at the covered entity level.

The adjustment will reflect the difference between the fee determined for a covered entity in the immediately preceding fee year, using data from the second calendar year preceding that fee year, and what the fee for the covered entity would have been for the immediately preceding fee year using data from the calendar year immediately preceding the prior fee year. For example, for 2012, the adjustment amount for a covered entity will be the difference between the 2011 fee computed using 2009 sales data, and what the 2011 fee would have been using 2010 sales data. Although the adjustment reflects a revision of the prior year's fee based on data from the sales year immediately preceding the prior fee year, the adjustment is only taken into account by adding it to or subtracting it from the fee computed for the current fee year.

#### **VI. Notice of Preliminary Fee Calculation**

Consistent with the proposal in the previous IRS guidance, the temporary regulations provide that the IRS will provide each covered entity with a notice of preliminary fee calculation each year that will include the covered entity's preliminary fee calculation; the covered entity's branded prescription drug sales, by NDC, for each Program; the covered entity's branded prescription drug sales taken into account after application of section 9008(a)(2); the aggregate branded prescription drug sales taken into account for all covered entities; after the 2011 fee year, a preliminary adjustment amount; and a reference to the fee

dispute resolution process set forth in guidance published in the Internal Revenue Bulletin. The date by which the IRS will send the preliminary fee calculation notice will be specified for future years in guidance published in the Internal Revenue Bulletin. For 2011, the IRS sent the notices by May 16, 2011. The Treasury Department and the IRS anticipate sending these notices earlier in future years.

#### **VII. Dispute Resolution Process**

Consistent with previous IRS guidance, the temporary regulations provide for a dispute resolution process that allows a covered entity to submit error reports in response to the preliminary fee calculation for the IRS to consider before performing a final fee calculation. The temporary regulations describe the information that covered entities must submit. The IRS will specify in guidance published in the Internal Revenue Bulletin the format for error report submissions and the date by which a covered entity must submit an error report(s). For 2011, a covered entity's error report was required to be submitted no later than June 10, 2011. The Treasury Department and the IRS anticipate that covered entities will have more time to prepare and send their error reports to the IRS in future years.

Several commentators requested the ability to submit additional error reports after the IRS sends notification of the final fee determination. In the interest of providing finality to the fee calculation process, the temporary regulations do not adopt this suggestion.

#### **VIII. Notification and Payment of Fee**

Section 9008(a) provides that the annual fee must be paid not later than the annual date specified by the Secretary, but in no event later than September 30th of each fee year. The temporary regulations provide that the IRS will send each covered entity its final fee calculation for that year no later than August 31st and that the covered entity must pay the fee by September 30th by electronic funds transfer. For 2011, the IRS will send covered entities notification of their 2011 final fee calculation by August 24th. This notification will include the covered entity's final fee; the covered entity's branded prescription drug sales by NDC for each Program; the covered entity's branded prescription drug sales taken into account after application of section 9008(a)(2); the aggregate branded prescription drug sales taken into account for all covered entities; after the 2011 fee year, an adjustment

amount; and the final determination with respect to error reports.

There is no tax return to be filed for the section 9008 fee.

#### IX. Tax Treatment of Fee

Section 9008(f)(1) provides that the branded prescription drug fee for purposes of subtitle F of the Internal Revenue Code shall be treated as an excise tax with respect to which only civil actions for refund under procedures of subtitle F shall apply. Thus, under the temporary regulations, the section 9008 fee is treated as an excise tax for purposes of subtitle F of the Code (sections 6001–7874) to which the deficiency procedures of sections 6211–6216 do not apply. The temporary regulations provide that the IRS must assess the amount of the section 9008 fee for any fee year within three years of September 30th of that fee year.

#### X. Refund Claims

The temporary regulations provide that any claim for refund must be filed on Form 843, “Claim for Refund and Request for Abatement.”

##### *Availability of IRS Documents*

IRS notices and the revenue procedure cited in this preamble are published in the Internal Revenue Bulletin or Cumulative Bulletin and are available at [IRS.gov](http://IRS.gov).

#### Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. chapter 5) does not apply to these regulations. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analysis section in the preamble to the cross-referenced notice of proposed rulemaking in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

Section 553(b) of the APA does not apply to these regulations because they are interpretative rules. Alternatively, the Treasury Department and the IRS have determined that good cause exists under section 553(b)(B) of the APA. That section provides that an agency is not required to publish a notice of

proposed rulemaking in the **Federal Register** when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Due to the novel and complex issues raised by the branded prescription drug fee provision and the required coordination with other governmental agencies, the Treasury Department and the IRS have concluded that it would take significantly longer than the time between enactment (March 23, 2010) and the date of collection of the first fee (no later than September 30, 2011) to draft and issue a proposed rule with a comment period, review comments thoroughly, and then draft and issue a final rule. Accordingly, the Treasury Department and the IRS have determined that the notice and comment procedures are impracticable.

In the months following enactment of section 9008, the Treasury Department and the IRS, in coordination with other governmental agencies, developed the proposed methodologies and processes to compute, verify, assess and collect the annual fee amounts, and published notices and a revenue procedure in the Internal Revenue Bulletin describing the proposed approach and soliciting public comments. The Treasury Department and the IRS provided an extended comment period to give the covered entities an opportunity to review their preliminary fee calculations before submitting comments on the proposed approach. In addition, the Treasury Department and the IRS engaged in discussions with affected external stakeholders and extensively coordinated with other governmental agencies. Consequently, the Treasury Department and the IRS also have determined that additional notice and comment before implementation of the process set forth in these regulations is unnecessary.

Since Congress mandated that the IRS collect the applicable fee amount for the first fee year no later than September 30, 2011, it is necessary that these regulations be issued immediately in order to provide covered entities with the rules governing the fee and payment prior to issuance of final fee determinations. However, comments are being solicited in the cross-referenced notice of proposed rulemaking that is in the Proposed Rules section in this issue of the **Federal Register** and will be considered before final regulations are issued regarding the branded prescription drug fee.

#### Drafting Information

The principal author of these regulations is Celia Gabrysh, Office of

the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

#### List of Subjects

##### *26 CFR Part 51*

Drugs, Reporting and recordkeeping requirements.

##### *26 CFR Part 602*

Reporting and recordkeeping requirements.

#### Adoption of Amendments to the Regulations

Accordingly, 26 CFR chapter 1 is amended by adding part 51 to subchapter D and amending part 602 as follows:

■ **Paragraph 1.** Part 51 is added to read as follows:

#### **PART 51—BRANDED PRESCRIPTION DRUG FEE**

##### Sec.

- 51.1T Overview (temporary).
- 51.2T Explanations of terms (temporary).
- 51.3T Information requested from covered entities (temporary).
- 51.4T Information provided by the agencies (temporary).
- 51.5T Fee calculation (temporary).
- 51.6T Notice of preliminary fee calculation (temporary).
- 51.7T Dispute resolution process (temporary).
- 51.8T Notification and payment of fee (temporary).
- 51.9T Tax treatment of fee (temporary).
- 51.10T Refund claims (temporary).
- 51.11T Effective/applicability date (temporary).
- 51.12T Expiration date (temporary).
- 51.6302–1T Method of paying the branded prescription drug fee (temporary).

**Authority:** 26 U.S.C. 7805; sec. 9008, Public Law 111–347 (124 Stat. 119).

Section 51.8 also issued under 26 U.S.C. 6302(a).

Section 51.6302–1 also issued under 26 U.S.C. 6302(a).

##### **§ 51.1T Overview (temporary).**

(a) The regulations in this part 51 are designated “Branded Prescription Drug Fee Regulations.”

(b) The regulations in this part 51 provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs by section 9008 of the Patient Protection and Affordable Care Act (ACA), Public Law 111–148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA), Public Law 111–152 (124 Stat. 1029 (2010)). All references in

these regulations to section 9008 are references to section 9008 of the ACA, as amended by section 1404 of HCERA. Unless otherwise indicated, all other section references are to sections in the Internal Revenue Code. All references to "fee" in these regulations are references to the fee imposed by section 9008.

(c) Section 9008(b)(4) sets an applicable fee amount for each year, beginning with 2011, that will be apportioned among covered entities with aggregate branded prescription drug sales of over \$5 million to government programs or pursuant to coverage under such programs. Generally, each covered entity is liable for a fee in each fee year that is based on its sales of branded prescription drugs in the sales year that corresponds to the fee year in an amount determined by the Internal Revenue Service (IRS) under the rules of this part.

#### § 51.2T Explanation of terms (temporary).

(a) *In general.* This section explains the terms used in this part for purposes of the fee imposed by section 9008 on branded prescription drugs.

(b) *Agencies.* The term *agencies* means—

(1) The Centers for Medicare and Medicaid Services of the Department of Health and Human Services (CMS);

(2) The Department of Veterans Affairs (VA); and

(3) The Department of Defense (DOD).

(c) *Branded prescription drug*—(1) *In general.* The term *branded prescription drug* means—

(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)).

(2) *Prescription drug.* The term *prescription drug* means any drug that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(d) *Branded prescription drug sales.* The term *branded prescription drug sales* means sales of branded prescription drugs to any government program or pursuant to coverage under any such government program. However, the term does not include sales of orphan drugs.

(e) *Covered entity*—(1) *In general.* The term *covered entity* means any manufacturer or importer with gross receipts from branded prescription drug sales including—

- (i) A single-person covered entity; or
- (ii) A controlled group.

(2) *Single-person covered entity.* The term *single-person covered entity* means a covered entity that is not affiliated with any other covered entity.

(3) *Controlled group.* The term *controlled group* means a group of at least two covered entities that are treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(4) *Special rules for controlled groups.* For purposes of paragraph (e)(3) of this section (related to controlled groups)—

(i) A foreign entity subject to tax under section 881 is included within a group under section 52(a) or 52(b); and

(ii) A covered entity is treated as being a member of a controlled group if it is a member of the group on the end of the day on December 31st of the sales year.

(f) *Designated entity*—(1) *In general.* The term *designated entity* means the person that acts for a controlled group regarding the fee by—

(i) Filing Form 8947, "Report of Branded Prescription Drug Information";

(ii) Receiving IRS communications about the fee for the group;

(iii) Filing an error report for the group, if applicable, as described in § 51.7T; and

(iv) Paying the fee to the IRS.

(2) *Selection of designated entity*—(i) *Choice of controlled group.* Unless the controlled group is an affiliated group that filed a consolidated return for Federal income tax purposes, the controlled group may select a person as the designated entity by filing Form 8947 in accordance with the form instructions. Among other requirements, the designated entity must state that all the manufacturers or importers of branded prescription drugs that are members of the group have consented to the selection of the designated entity.

(ii) *Requirement for affiliated groups; common parent.* If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that filed a consolidated return for Federal income tax purposes, the designated entity is the common parent of the affiliated group as identified on the tax return filed for the sales year. The covered entities in an affiliated group must name the common parent as the designated entity on Form 8947.

(iii) *IRS selection of a designated entity.* If a controlled group does not select a designated entity, the IRS will select a member of the controlled group as the designated entity for the controlled group.

(g) *Fee year.* The term *fee year* means the calendar year in which the fee for a

particular sales year must be paid to the government.

(h) *Government programs.* The term *government programs* (collectively "Programs"), means—

(1) The Medicare Part B program;

(2) The Medicare Part D program;

(3) The Medicaid program;

(4) Any program under which branded prescription drugs are procured by the Department of Veterans Affairs;

(5) Any program under which branded prescription drugs are procured by the Department of Defense; and

(6) The TRICARE retail pharmacy program.

(i) *Manufacturer or importer.* The term *manufacturer or importer* means the person identified in the Labeler Code of the National Drug Code (NDC) for a branded prescription drug.

(j) *NDC.* The term *NDC* means the National Drug Code. The NDC is an identifier assigned by the Food and Drug Administration (FDA) to a branded prescription drug, as well as other drugs. The Labeler Code is the first five numeric characters of the NDC or the first six numeric characters when the available five-character code combinations are exhausted.

(k) *Orphan drugs*—(1) *In general.* Except as provided in paragraph (j)(2) of this section, the term *orphan drug* means any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year.

(2) *Exclusions.* The term *orphan drug* does not include—

(i) Any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug; or

(ii) Any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, in the same year as, or after this FDA designation.

(3) *FDA marketing approval for treatment of another rare disease or condition.* If a drug has prior FDA marketing approval for the treatment of a rare disease or condition for which a section 45C credit was allowed, and the FDA subsequently gives the drug marketing approval for the treatment of another rare disease or condition for which another section 45C credit was also allowed, the drug retains its status as an orphan drug provided the FDA has never approved the drug for marketing for any indication other than the treatment of a rare disease or condition

for which a section 45C credit was allowed.

(4) *Examples.* The following examples illustrate the rules of this paragraph (k):

*Example 1: Allowance of section 45C credit and later FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition.* (i) *Facts.* Drug A is a branded prescription drug that was not on the market before 2008. In 2008, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug A. There was no final IRS assessment or court order that disallowed the full credit for Drug A. In 2009, the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for another rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2008 and 2009, Drug A is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, before 2009, the FDA did not approve the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. However, Drug A is not an orphan drug for the 2010 sales year or later sales years because in 2009 the FDA approved Drug A for marketing for an indication other than the treatment of the rare disease or condition for which the section 45C credit was allowed and this indication was not for treatment of another rare disease or condition for which a section 45C credit was allowed.

*Example 2: FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition and later allowance of section 45C credit.* (i) *Facts.* Drug B is a branded prescription drug that was not on the market before 2008. In 2008, FDA approved Drug B for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug B. There was no final IRS assessment or court order that disallowed the full credit for Drug B.

(ii) *Analysis.* In 2008, Drug B is not an orphan drug because no section 45C credit was allowed. In 2009, although the covered entity was allowed a section 45C credit for its qualified clinical testing expenses related to Drug B and there was no final IRS assessment or court order that disallowed the full credit, Drug B still is not an orphan drug because the FDA had approved the drug in 2008 for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed in 2009. Thus, Drug B is not an orphan drug for the 2009 sales year or later sales years.

*Example 3: Allowance of section 45C credit and subsequent allowance of section 45C*

*credit with no intervening FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed.*

(i) *Facts.* Drug C is a branded prescription drug that was not on the market before 2007. In 2007, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2009, a covered entity claimed an additional section 45C credit for its qualified clinical testing expenses related to Drug C for marketing for the treatment of a rare disease or condition different than the one for which the section 45C credit was claimed in 2007. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2007 or 2009. The FDA has not approved Drug C for an indication other than the treatment of a rare disease or condition for which a section 45C was allowed.

(ii) *Analysis.* In 2007 and 2008, Drug C is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was not a final assessment or court order disallowing the full credit taken for the drug; and third, FDA had not approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. In 2009, Drug C retains its orphan drug status because another section 45C credit was allowed and the FDA did not approve Drug C for marketing for any indication other than the treatment of another rare disease or condition for which a section 45C credit was allowed. Thus, Drug C is an orphan drug for the 2010 sales year.

(l) *Sales taken into account.* The term *sales taken into account* means branded prescription drug sales after application of the percentage adjustment table in section 9008(b)(2) (relating to annual sales less than \$400,000,001). See § 51.5T(a)(3).

(m) *Sales year.* The term *sales year* means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2011, the sales year is 2009.

#### **§ 51.3T Information requested from covered entities (temporary).**

(a) *In general.* Annually, each covered entity may submit a completed Form 8947, "Report of Branded Prescription Drug Information," in accordance with the instructions for the form. Generally, the form solicits information from covered entities on NDCs, orphan drugs, designated entities, rebates, and other information specified by the form or its instructions.

(b) *Due date.* Form 8947 must be filed by the date prescribed in guidance in the Internal Revenue Bulletin.

#### **§ 51.4T Information provided by the agencies (temporary).**

(a) *In general.* For each sales year, the IRS will compile a list of branded

prescription drugs by NDC using the data submitted on Forms 8947 and in error reports submitted as part of the dispute resolution process (described in § 51.7T) and, after applying appropriate due diligence, will provide this list to the Agencies. The Agencies will provide data to the IRS on branded prescription drug sales during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§ 51.5T and 51.6T) and may revise or supplement that data following review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

(b) *Medicare Part D.* CMS will aggregate the ingredient cost reported in the "Ingredient Cost Paid" field and the units reported in the "Quantity Dispensed" field of the Prescription Drug Event (PDE) records at the NDC level for each sales year. Only PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and have been approved for inclusion in the Part D payment reconciliation will be included.

(c) *Medicare Part B—(1) In general.* CMS will determine branded prescription drug sales under Medicare Part B using the following two data sources:

(i) CMS will use data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System (HCPCS) code for the sales year.

(ii) CMS will use the Medicare Part B National Summary Data File located at [http://www.cms.gov/NonIdentifiableDataFiles/03\\_PartBNationalSummaryDataFile.asp](http://www.cms.gov/NonIdentifiableDataFiles/03_PartBNationalSummaryDataFile.asp) to obtain the number of allowed billing units per HCPCS code for claims incurred during the sales year.

(2) *Calculation.* Using the data described in paragraph (c)(1) of this section, CMS will determine branded prescription drugs sales under Medicare Part B as described in paragraphs (c)(3), (4), and (5) of this section.

(3) *HCPCS code; single entity.* For each HCPCS code consisting solely and exclusively of branded prescription drugs (as identified by their respective NDCs) manufactured by a single entity, CMS will multiply the annual weighted ASP by the total number of allowed billing units paid during the sales year

to determine the total sales for all NDCs associated with the HCPCS code attributed to Medicare Part B.

(4) *HCPCS code; multiple manufacturers and/or multiple drugs—*

(i) *Step one.* For each HCPCS code consisting of a mixture of branded prescription drugs made by different manufacturers and/or a mixture of branded prescription and generic drugs, CMS will determine—

(A) The annual weighted ASP for the HCPCS code;

(B) The total number of allowed billing units paid by Medicare Part B for each HCPCS code during the sales year;

(C) The names of the entities engaged in manufacturing each NDC assigned to the HCPCS code; and

(D) Those entities (if any) identified in paragraph (c)(4)(C) of this section that are manufacturing branded prescription drugs assigned to the HCPCS code.

(ii) *Step two.* Using the information from paragraph (c)(4)(i) of this section, CMS will then do the following:

(A) Calculate the proportion of sales, expressed as a percentage, attributed to each NDC assigned to the HCPCS code by determining the percentage of total sales reported to CMS by each manufacturer of NDC(s) that are assigned to the HCPCS code. For example, if HCPCS code JXXXX contains three drugs with a total of \$310,000 sales reported by manufacturers to CMS for the sales year, and \$100,000 was reported for Drug A, \$200,000 was reported for Drug B, and \$10,000 was reported for Drug C, the proportion of sales attributed to each NDC will be 32.26 percent for Drug A, 64.52 percent for Drug B, and 3.22 percent for Drug C; and

(B) For each NDC, multiply the product of the annual weighted ASP and the total allowed billing units paid by Medicare Part B for the HCPCS code by the proportion of sales calculated in paragraph (c)(4)(ii)(A) of this section to determine the sales reportable to the IRS (that is, percentage × (annual weighted ASP × allowed units) = total sales reported to IRS for the NDC). The sales for each manufacturer's NDCs assigned to a HCPCS code are summed and the total sales for each manufacturer's NDCs in a HCPCS code will be reported to the IRS.

(5) *HCPCS code; unable to establish a reliable proportion of sales.* If CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code using the method described in paragraph (c)(4)(ii)(A) of this section, CMS will use

Medicare Part D utilization percentages in lieu of the proportion of sales determined under paragraph (c)(4)(ii)(A) of this section to perform the calculation described in paragraph (c)(4)(ii)(B) of this section.

(d) *Medicaid.* (1) CMS will determine the branded prescription drug sales for Medicaid as the per-unit Average Manufacturer Price (AMP) less the Unit Rebate Amounts (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by states to manufacturers. This data will be based on the data reported to CMS during the sales year by covered entities and the states for drugs paid for by the states in the Medicaid drug rebate program during the sales year.

(2) For any covered entity identified in the first five (or six) digits of an NDC during any of the four quarters of a sales year, CMS will use the following methodology to derive the sales figures that account for third-party payers, such as Medicare Part B:

(i) Report total dollars per NDC for AMP-URA multiplied by the units reported by a state or states.

(ii) Determine the percentage of the total amount reimbursed that is the Medicaid amount of that reimbursement. For example, if the total amount reimbursed is \$100,000, and the Medicaid amount reimbursed is \$20,000, then the percentage is 20 percent.

(iii) Multiply the percentage of the Medicaid amount of that reimbursement (in the example in paragraph (d)(2)(ii) of this section, 20 percent) by the dollar figure derived from paragraph (d)(2)(i) of this section (AMP minus URA multiplied by units) to get the new adjusted sales dollar totals.

(e) *Department of Veterans Affairs.* VA will provide, by NDC, the total amount paid (net of refunds and rebates, when they are associated with a specific NDC) for each branded prescription drug procured by the VA for its beneficiaries during the sales year. For this purpose, a drug is procured on the invoice (billing) date. The basis of this information will be national procurement data reported during the sales year by VA's Pharmaceutical Prime Vendor to the VA Pharmacy Benefits Management Service and National Acquisition Center.

(f) *Department of Defense.* The DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates and or refunds) for each branded

prescription drug procured by DOD (for DOD programs other than the TRICARE retail pharmacy program) during the sales year. For DOD programs other than the TRICARE retail pharmacy program, a drug is procured based upon the date it was ordered. DOD will provide, by Labeler Code, the manufacturer's name, the NDC, brand name, and the amount paid (net of rebates or refunds) for each branded prescription drug procured by DOD through the TRICARE Retail Pharmacy Program during the sales year. For the TRICARE retail pharmacy program, a drug is procured based upon the date it was dispensed. The amount paid is based on the submitted ingredient cost paid, aggregated by NDC, for eligible TRICARE retail pharmacy claims submitted during the program year, minus any refunds or rebates for the corresponding claims.

**§ 51.5T Fee calculation (temporary).**

(a) *Fee components—(1) In general.* For every fee year, the IRS will calculate a covered entity's total fee as described in this section. For each fee year after 2011, the IRS will determine a covered entity's total fee by applying, if applicable, the adjustment amount described in paragraph (e) of this section to the entity's allocated fee described in paragraph (d) of this section.

(2) *Calculation of branded prescription drug sales.* Each covered entity's allocated fee for any fee year is equal to an amount that bears the same ratio to the applicable amount as the covered entity's branded prescription drug sales taken into account during the sales year bears to the aggregate branded prescription drug sales of all covered entities taken into account during the sales year.

(3) *Applicable amount.* The applicable amounts for fee years are—

Fee year	Applicable amount
2011 .....	\$2,500,000,000
2012 .....	2,800,000,000
2013 .....	2,800,000,000
2014 .....	3,000,000,000
2015 .....	3,000,000,000
2016 .....	3,000,000,000
2017 .....	4,000,000,000
2018 .....	4,100,000,000
2019 and thereafter .....	2,800,000,000

(3) *Sales taken into account.* A covered entity's branded prescription drug sales taken into account during any calendar year are as follows:



Covered entity's branded prescription drug sales during the calendar year that are:	Percentage of branded prescription drug sales taken into account is
Not more than \$5,000,000 .....	0
More than \$5,000,000 but not more than \$125,000,000 .....	10
More than \$125,000,000 but not more than \$225,000,000 .....	40
More than \$225,000,000 but not more than \$400,000,000 .....	75
More than \$400,000,000 .....	100

(b) *Determination of branded prescription drug sales.* The IRS will compile each covered entity's branded prescription drug sales for each Program by NDC. Each NDC will be attributed to the covered entity that owns the NDC as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year. For this purpose, the IRS may revise the list of NDCs as a result of information received in the dispute resolution process, and the data the IRS uses to produce the final fee calculation will include any revisions provided by the Agencies at the completion of the dispute resolution process. Each covered entity's branded prescription drug sales will be reduced by its Medicare Part D rebates and Medicaid state supplemental rebate amounts in the following manner. If CMS has the rebate information for these Programs for a sales year, CMS will report to the IRS branded prescription drug sales net of rebates. If CMS does not have the rebate information for these programs for a sales year, the IRS will reduce the branded prescription drug sales reported for these Programs by rebates reported by the covered entities on Forms 8947.

(c) *Determination of sales taken into account.* (1) For each sales year and for each covered entity, the IRS will calculate sales taken into account. The resulting number is the numerator of the ratio described in paragraph (d)(1) of this section.

(2) For each sales year, the IRS will calculate the aggregate branded prescription drug sales taken into account for all covered entities. The resulting number is the denominator of the ratio described in paragraph (d)(2) of this section.

(d) *Allocated fee calculation.* For each covered entity for each fee year, the IRS will calculate the entity's allocated fee by multiplying the applicable amount from paragraph (a)(2) of this section by a fraction—

(1) The numerator of which is the covered entity's branded prescription

drug sales taken into account during the sales year (described in paragraph (c)(1) of this section); and

(2) The denominator of which is the aggregate branded prescription drug sales taken into account for all covered entities during the same year (described in paragraph (c)(2) of this section).

(e) *Adjustment amount.* For each fee year after 2011, in addition to the allocated fee computed under paragraph (d) of this section, the IRS will also calculate an adjustment amount that reflects the difference between the allocated fee determined for the covered entity in the immediately preceding fee year, using data from the second calendar year preceding that fee year, and what the allocated fee would have been for that entity for the immediately preceding fee year using data from the calendar year immediately preceding that fee year. For example, for 2012, the adjustment amount for a covered entity will be the difference between the entity's 2011 allocated fee, using 2009 data, and what the 2011 allocated fee would have been using 2010 data. Although the adjustment reflects a revision of the prior year's fee based on data from the year immediately preceding the prior fee year, the adjustment is only taken into account by adding it to or subtracting it from the allocated fee computed under paragraph (d) of this section for the current fee year to arrive at the total fee for the current fee year.

#### § 51.6T Notice of preliminary fee calculation (temporary).

(a) *Content of notice.* For each sales year, the IRS will make a preliminary calculation of the fee for each covered entity as described in § 51.5T. The IRS will notify each covered entity of its preliminary fee calculation for that sales year. The notification to a covered entity of its preliminary fee calculation will include—

- (1) The covered entity's allocated fee;
- (2) The covered entity's branded prescription drug sales, by NDC, by Program;
- (3) The covered entity's branded prescription drug sales taken into

account after application of § 51.5T(a)(3);

(4) The aggregate branded prescription drug sales taken into account for all covered entities;

(5) After the 2011 fee year, the covered entity's adjustment amount calculated as described in § 51.5T(e); and

(6) A reference to the fee dispute resolution procedures set forth in guidance published in the Internal Revenue Bulletin.

(b) *Time of notice.* The IRS will send each covered entity notice of its preliminary fee calculation by the date prescribed in guidance published in the Internal Revenue Bulletin.

#### § 51.7T Dispute resolution process (temporary).

(a) *In general.* Upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the IRS an error report as described in this section. The IRS will provide its final determination with respect to error reports no later than the time the IRS provides a covered entity with a final fee calculation.

(b) *Program errors.* To assert that there has been one or more errors in drug sales data, a covered entity must submit a separate error report for each Program with the asserted errors. Each report must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and Employer Identification Number (EIN) as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the Agencies may discuss the claimed errors. A Form 2848, "Power of Attorney and Declaration of Representative," must be filed with the error report; and

(3) The name of the Program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation of why the Agency should use the proposed corrected data instead,

and documentation of any Program drug sales data or other information used to establish the existence of any errors.

(c) *Errors other than Program drug sales errors.* To assert that there has been one or more errors in the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error (other than Program drug sales data errors), a covered entity must submit one error report, separated into sections by type of error, and must include the following information—

(1) Entity name, entity number (if applicable, from Part I (a) of the Form 8947), address, and EIN as previously reported on the Form 8947;

(2) The name, telephone number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the IRS and/or the Agencies may discuss the claimed errors. If the representative is not an employee of the entity, a Form 2848 must be filed with the error report;

(3) For a mathematical calculation error, the specific calculation element(s) that the entity disputes and its proposed corrected calculation;

(4) For a rebate data error, the NDC for the drug to which it relates; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on rebates; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(5) For the listing of an NDC for an orphan drug, the name and NDC of the orphan drug; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(6) For any other asserted error, an explanation of the nature of the error, how the error affects the fee calculation, an explanation of how the entity established that an error occurred, the proposed correction to the error, and an explanation of why the IRS or Agency should use the proposed corrected data instead;

(7) If an entity is using data to establish the existence of an error and that data was not reported on Form 8947 or contained in the notification of the preliminary fee calculation, a description of what the data is, how the

entity acquired the data, and who maintains it; and

(8) Documentation of any rebate and orphan drug data, or other information used to establish the existence of any errors.

(d) *Form, manner, and timing of submission.* Each covered entity must submit its error report(s) in the form and manner that is prescribed in guidance published in the Internal Revenue Bulletin. This guidance will also prescribe the date by which each covered entity must submit its report(s).

#### **§ 51.8T Notification and payment of fee (temporary).**

(a) *Notification of final fee calculation.* No later than August 31st of each fee year, the IRS will send each covered entity its final fee calculation for that year. In any fee year, the IRS will base its final fee calculation on data provided to it by the Agencies as adjusted pursuant to the dispute resolution process. The notification to a covered entity of its final fee calculation will include—

(1) The covered entity's allocated fee;

(2) After the 2011 fee year, an adjustment amount calculated as described in § 51.5T;

(3) The covered entity's branded prescription drug sales, by NDC, by Program;

(4) The covered entity's branded prescription drug sales taken into account after application of § 51.5T(a)(3);

(5) The aggregate branded prescription drug sales taken into account for all covered entities; and

(6) The final determination with respect to error reports.

(b) *Differences in preliminary fee calculation and final fee calculation.* A covered entity's final fee calculation may differ from the covered entity's preliminary fee calculation because of changes made pursuant to the dispute resolution process described in § 51.7T. Even if a covered entity did not file an error report described in § 51.7T, a covered entity's final fee may differ from a covered entity's preliminary fee because of a change in data reported by the Agencies after resolution of error reports, including a change in the aggregate prescription drug sales figure. A change in aggregate prescription drug sales data can affect each covered entity's fee because each covered entity's fee is a fraction of the aggregate fee collected from all covered entities. A covered entity's final fee may also differ from its preliminary fee calculation because the data used in the preliminary fee calculation may have contained inaccurate branded prescription drug

sales information that was corrected or updated at the conclusion of the dispute resolution process.

(c) *Payment of final fee.* Each covered entity must pay its final fee by September 30th of the fee year. For a controlled group, the payment must be made using the designated entity's EIN as reported on Form 8947. The fee must be paid by electronic funds transfer as required by § 51.6302-1T. There is no tax return to be filed for the fee.

(d) *Joint and several liability.* In the case of a controlled group that is liable for the fee, all covered entities within the controlled group are jointly and severally liable for the fee. Accordingly, if a covered entity's fee is not paid, the IRS will separately assess each covered entity in the group for the full amount of the controlled group's fee.

#### **§ 51.9T Tax treatment of fee (temporary).**

(a) *Treatment as an excise tax.* The fee imposed by section 9008 is treated as an excise tax for purposes of subtitle F of the Code (sections 6001-7874). Thus, references in subtitle F to "taxes imposed by this title," "internal revenue tax," and similar references, are also references to the fee imposed by section 9008. For example, the fee imposed by section 9008 is assessed (section 6201), collected (sections 6301, 6321, and 6331), enforced (section 7602), subject to examination and summons (section 7602), and subject to confidentiality rules (section 6103), in the same manner as taxes imposed by the Code.

(b) *Deficiency procedures.* The deficiency procedures of sections 6211-6216 do not apply to the fee imposed by section 9008.

(c) *Limitation on assessment.* The IRS must assess the amount of the fee for any fee year within three years of September 30th of that fee year.

(d) *Application of section 275.* The fee is treated as a tax described in section 275(a)(6) (relating to taxes for which no deduction is allowed).

#### **§ 51.10T Refund claims (temporary).**

Any claim for a refund of the fee must be made by the person that paid the fee to the government and must be made on Form 843, "Claim for Refund and Request for Abatement," in accordance with the instructions for that form.

#### **§ 51.11T Effective/applicability date (temporary).**

Sections 51.1T through 51.10T apply to any fee on branded prescription drug sales that is due on or after September 30, 2011.

#### **§ 51.12T Expiration date (temporary).**

The applicability of §§ 51.1T through 51.10T expires August 15, 2014.

**§ 51.6302–1T Method of paying the branded prescription drug fee (temporary).**

(a) *Fee to be paid by electronic funds transfer.* Under the authority of section 6302(a), the fee imposed on branded prescription drug sales by section 9008 and § 51.5T must be paid by electronic funds transfer as defined in § 31.6302–1(h)(4)(i), as if the fee were a depository tax. For the time for paying the fee, see § 51.8T.

(b) *Effective/applicability date.* This section applies on and after August 18, 2011.

(c) *Expiration date.* The applicability of this section expires August 15, 2014.

**PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT**

■ **Par. 2.** The authority citation for part 602 continues to read as follows:

*Authority:* 26 U.S.C. 7805.

■ **Par. 3.** In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

**§ 602.101 OMB Control numbers.**

CFR part or section where identified and described	Current OMB Control No.
(b) * * *	
51.8T .....	1545–2209
* * *	* * *

**Sarah Hall Ingram,**  
*Deputy Commissioner for Services and Enforcement.*

Approved: August 12, 2011.

**Emily S. McMahon,**  
*Acting Assistant Secretary of the Treasury (Tax Policy).*

[FR Doc. 2011–21011 Filed 8–15–11; 11:15 am]

BILLING CODE 4830–01–P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[Docket No. USCG–2011–0760]

RIN 1625–AA87

**Security Zone; Potomac River, Georgetown Channel, Washington, DC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary security zone encompassing certain waters of the Potomac River, Georgetown Channel, in Washington, DC, in order to safeguard high-ranking public officials from terrorist acts and incidents. This action is necessary to ensure the safety of persons and property, and prevent terrorist acts or incidents. This rule prohibits vessels and people from entering the security zone and requires vessels and persons in the security zone to depart the security zone, unless specifically exempt under the provisions in this rule or granted specific permission from the Coast Guard Captain of the Port Baltimore.

**DATES:** This rule is effective from 6 a.m. until 6 p.m. on August 28, 2011.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0760 and are available online by going to <http://www.regulations.gov>, inserting USCG–2011–0760 in the “Keyword” box, and then clicking “Search.” They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or e-mail Mr. Ronald L. Houck, at Sector Baltimore Waterways Management Division, Coast Guard; telephone 410–576–2674, e-mail [Ronald.L.Houck@uscg.mil](mailto:Ronald.L.Houck@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is contrary to public interest to delay the effective date of this rule. The Coast Guard is establishing the security zone

to protect high-ranking government officials, mitigate potential terrorist acts, and enhance public and maritime safety and security. The Coast Guard was unable to publish a NPRM due to the short time period between event planners notifying the Coast Guard of the event and publication of the security zone. Furthermore, delaying the effective date would be contrary to the security zone’s intended objectives of protecting high-ranking government officials, mitigating potential terrorist acts and enhancing public and maritime safety security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment, therefore, a 30-day notice period is impracticable. Delaying the effective date would be contrary to the security zone’s intended objectives of protecting high-ranking government officials, mitigating potential terrorist acts and enhancing public and maritime safety and security.

**Background and Purpose**

The President of the United States will be attending the Martin Luther King, Jr. National Memorial in Washington, DC dedication ceremony on August 28, 2011. The ceremony is located along the waterfront in Washington, DC, in close proximity to navigable waterways within the Captain of the Port’s Area of Responsibility.

The Coast Guard has given each Coast Guard Captain of the Port the ability to implement comprehensive port security regimes designed to safeguard human life, vessels, and waterfront facilities while still sustaining the flow of commerce. The Captain of the Port Baltimore is establishing this security zone to protect high-ranking government officials, mitigate potential terrorist acts, and enhance public and maritime safety and security in order to safeguard life, property, and the environment on or near the navigable waters.

**Discussion of Rule**

Through this regulation, the Coast Guard will establish a security zone. The security zone will be in effect from 6 a.m. until 6 p.m. on August 28, 2011. The security zone will include all navigable waters of the Potomac River, Georgetown Channel, within 75 yards from eastern shore measured perpendicularly to the shore between the Theodore Roosevelt Memorial Bridge and the Arlington Memorial