



[4830-01-p]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 51 and 602

[TD 9684]

RIN 1545-BJ39

Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations, temporary regulations, and removal of temporary regulations.

SUMMARY: This document contains final 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. This document also withdraws the Branded Prescription Drug Fee temporary regulations and contains new temporary regulations regarding the definition of controlled group that apply beginning on January 1, 2015. The final regulations and the new temporary regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations in this document also serves as the text of

proposed regulations set forth in a notice of proposed rulemaking (REG-123286-14) on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: Effective Date: These regulations are effective on **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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

FOR FURTHER INFORMATION CONTACT: Celia Gabrysh at (202) 317-6855 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these regulations has been reviewed and approved by the Office of Management and Budget under control number 1545-2209. The collection of information in these final regulations is in §§51.2(f)(2) and 51.7. Section 51.2(f)(2) requires consents to be maintained, in the case of a controlled group that is not an affiliated group, by the designated entity and each member of the controlled group. Section §51.7 requires a covered entity that chooses to dispute its preliminary fee calculation to provide certain information.

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.

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 section 6103 of the Internal Revenue Code.

Background

This document contains final regulations that provide guidance under section 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively the ACA). All references in this preamble to section 9008 are references to section 9008 of the ACA. Section 9008 did not amend the Internal Revenue Code (Code) but cross-references specified Code sections.

On November 29, 2010, the 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 August 18, 2011, the **Federal Register** published temporary regulations relating to the fee on branded prescription drugs (TD 9544, 76 FR 51245). The **Federal Register** also published on the same day a notice of proposed rulemaking (REG-112805-10, 76 FR 51310) cross-referencing the temporary regulations (the proposed regulations).

In response to the proposed regulations, the Department of the Treasury (Treasury Department) and the IRS received a variety of comments from the public. All written comments are available at www.regulations.gov or upon request. The Treasury Department and the IRS held a public hearing on November 9, 2012. After considering the public comments and the hearing testimony, the final regulations adopted by this Treasury decision are generally consistent with the proposed regulations and also reflect certain minor changes as described in this preamble. The corresponding temporary regulations are removed. The final regulations and the new temporary regulations are discussed in this preamble.

All references to section 505 are references to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)). Unless otherwise indicated, all other references to subtitles, chapters, subchapters, and sections in this preamble are references to subtitles, chapters, subchapters, and sections in the Code and related regulations. All references to “fee” in the final regulations are references to the fee imposed by section 9008 of the ACA.

Effect on Other Documents

The following publications are obsolete as of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

Notice 2010-71, 2010-51 IRB 822, and Notice 2011-9, 2011-6 IRB 459.

Explanation of Provisions and Summary of Comments

Definitions

Manufacturer or importer

Section 9008(d)(1) defines covered entity as any manufacturer or importer with gross receipts from branded prescription drug sales. Section 9008(e) defines branded prescription drug sales to mean sales of branded prescription drugs to any specified government programs or pursuant to coverage under such programs. These 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).

The temporary regulations defined a manufacturer or importer of a branded prescription drug as the person identified in the Labeler Code of the National Drug Code (NDC). The NDC is a unique identifier that is assigned to all drug products approved by the Food and Drug Administration (FDA), including a branded 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.

Commenters asked the IRS to allocate drug sales to an entity other than the person identified in the Labeler Code of a drug's NDC when a covered entity transfers a drug to another covered entity during the sales year or engages in a transaction, such as a reorganization or a bankruptcy, that results in a different entity selling the drug. The final regulations do not adopt this request. A rule that uses the Labeler Code to identify the manufacturer or importer of a branded prescription drug provides certainty for both covered entities and the IRS. The FDA maintains a database that is available on the FDA website with information about each NDC, including its Labeler Code, which

is assigned by the FDA. The IRS refers to this database to identify the person in the NDC's Labeler Code. The IRS encourages covered entities to review and update their NDC data with the FDA to reflect changes in the manufacturer or importer of a branded prescription drug.

Covered Entity and Adjustment Amount

To be a covered entity, a manufacturer or importer must have gross receipts from branded prescription drug sales. Section 9008(b)(1) requires the IRS to calculate each covered entity's fee each fee year using sales data from the preceding calendar year. Pursuant to section 9008(g), 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) provide sales data to the IRS. For purposes of calculating the fee, the temporary regulations used the second calendar year preceding the fee year as the sales year. This rule is necessary because CMS cannot complete its data processing within the necessary time frame. The temporary regulations further provided that, 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 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. Because CMS cannot complete its data processing any earlier, the final regulations adopt this approach.

A commenter asserted that, under the temporary regulations, a former covered entity may not be eligible for an adjustment amount if the entity does not have any sales

in subsequent years and is, therefore, no longer a covered entity. According to the commenter, if a covered entity owes a fee in 2013 based on 2011 sales, but has no sales in 2012 or later years, then that entity would not qualify as a covered entity in 2014 because the temporary regulations do not provide a mechanism for the entity to receive an adjustment amount for 2013. The commenter suggested that if an adjustment amount results in a net credit to the covered entity's fee, the IRS should treat the adjustment amount as an overpayment. The final regulations do not adopt this suggestion. However, the final regulations clarify that an entity is treated as a covered entity for any year in which the entity has branded prescription drug sales and for any year for which those sales must be taken into account in calculating the fee and determining the adjustment amount. Therefore, an entity's status as a covered entity begins in the first year it has branded prescription drug sales to the Programs even though the fee does not take those sales immediately into account, and continues until all sales for that entity have been taken into account for both fee calculation and adjustment amount purposes.

For example, assume that an entity had sales in 2011 with no sales in earlier or later years. The entity is a covered entity beginning in 2011. The entity is not liable for a fee in 2011 or 2012 since those fee years are based on 2009 and 2010 sales, respectively. In 2013, the entity is liable for the fee based on its 2011 sales. Furthermore, the entity is liable for the adjustment amount for the difference between the 2012 fee for the entity computed using 2010 sales, which is \$0, and what the 2012 fee would have been using 2011 sales. Even though the entity does not have any sales in 2012 or later years, it will continue to be a covered entity in 2014 because its 2011

sales must be taken into account for purposes of determining the adjustment amount relating to the 2013 fee that applies to the 2014 fee year. The entity will not be a covered entity after 2014 because its 2011 sales will not be taken into account after 2014. The final regulations include this example.

Controlled Group

In accordance with the statute, the temporary regulations provided that a covered entity includes a controlled group. The temporary regulations defined the term controlled group to mean 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). Under the final regulations, this definition applies through December 31, 2014. Therefore, this definition applies for purposes of determining who is in the controlled group through the 2016 fee year because the fee for the 2016 fee year is based upon data from the 2014 sales year. In this Treasury decision, the Treasury Department and the IRS are also issuing new temporary regulations (the 2014 temporary regulations), that define the term controlled group to mean a group of two or more persons, including at least one person that is a covered entity, that are treated as a single employer under section 52(a), 52(b), 414(m) or 414(o). This new definition applies beginning on January 1, 2015. Therefore, this definition applies for purposes of determining who is in the controlled group beginning with the 2017 fee year because the fee for the 2017 fee year is based upon data from the 2015 sales year. The broader definition of controlled group in the 2014 temporary regulations is supported by the statutory language and is consistent with how controlled group rules with similar statutory language are applied, including how controlled group is defined in §57.2(c)(1) for purposes of the health

insurance providers fee under ACA section 9010. The Treasury Department and the IRS expect that the broader definition in the 2014 temporary regulations will primarily impact joint and several liability for the fee and will not otherwise affect the administration of the fee. The final regulations include conforming changes to the provision for joint and several liability to clarify that joint and several liability applies to all members of the controlled group under either definition of controlled group, whichever applies.

Designated Entity

The temporary regulations required each controlled group that files a Form 8947, "Report of Branded Prescription Drug Information," to have a designated entity. A designated entity is the person within the controlled group that acts on behalf of the controlled group with regard to the fee. The temporary regulations further provided that if the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group that files 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 files a consolidated return, the temporary regulations allowed the controlled group to select its designated entity. However, if the controlled group did not select a designated entity, the IRS would select a member of the controlled group as the designated entity.

The final regulations modify the temporary regulations to better coordinate with the consolidated return regulations. Specifically, the final regulations provide that the designated entity of a controlled group, without regard to foreign corporations included

under section 9008(d)(2)(B), that is a consolidated group (within the meaning of §1.1502-1(h)) is the agent for the group (within the meaning of §1.1502-77).

The temporary regulations required the designated entity to state under penalties of perjury that all the covered entities that are members of the controlled group have consented to the selection of the designated entity. The final regulations adopt this requirement and further require each member of the controlled group to maintain a record of its consent. The final regulations also require the designated entity to maintain a record of all of the members' consents. Under the final regulations, this consent requirement does not apply to a controlled group that is a consolidated group (within the meaning of §1.1502-1(h)). If a controlled group that is not a consolidated group does not select a designated entity, the final regulations provide that the IRS will select a designated entity and all covered entities in the controlled group will be deemed to have consented to the IRS's selection of a designated entity.

Orphan Drug Sales

Section 9008(e)(3) provides that the term branded prescription drug sales does not include sales of any drug or biological product with respect to which a credit was allowed for any taxable year under section 45C. Section 9008(e)(3) also provides that this exclusion does not apply with respect to any such drug or biological product after the date on which such drug or biological product is approved by the FDA for marketing for any indication other than the treatment of the rare disease or condition with respect to which such credit was allowed. In accordance with the statute, the temporary regulations generally defined the term orphan drug to mean 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 provided 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, in accordance with the statute, the temporary regulations provided that 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 before, in the same year as, or after this FDA approval.

Commenters requested that the final regulations treat a drug as an orphan drug if the section 45C credit was “allowable”; that is, the section 45C credit could have been claimed, but was not actually claimed. Another commenter requested that the final regulations extend orphan drug treatment to any drug for which the section 45C credit was allowable but for which a research tax credit under section 41 was claimed with respect to a taxable year ending on or before December 31, 2010. Several commenters also reasoned that the statutory exception for orphan drugs should be extended to any drug that has been designated by the FDA as an orphan drug. Commenters also requested that the final regulations extend the orphan drug exclusion to drug sales for therapies that have only been approved to treat orphan diseases, and to all products that are FDA-approved for marketing solely for rare diseases and conditions. The final regulations do not adopt these suggestions because the plain language of section 9008(e)(3) requires that the drug be an orphan drug for which the section 45C credit was actually allowed rather than merely allowable. The terms

"allowed" and "allowable" have separate and distinct meanings throughout the Code. For example, under section 1016(a)(2), a taxpayer may adjust basis to the extent the amount was "allowed" as a deduction in computing taxable income but not less than the amount "allowable."¹ In addition, the overwhelming weight of authority under the case law interprets the term "allowed" in the Code to require the taxpayer to have actually taken the amount into account for tax purposes.² The FDA's mere classification of a drug as an orphan drug is not a determining factor because the plain language of section 9008(e)(3) applies the exclusion only to sales of drugs for which a section 45C credit was in fact allowed.

Commenters also requested that orphan drug status be given to a drug for which a section 45C credit was allowed, even though the drug had been subsequently 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 final regulations do not adopt this suggestion because the plain language of section 9008(e)(3) indicates 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, in the same year as, or after a section 45C credit was allowed for the drug, sales of that drug are not considered sales of an orphan drug beginning in the following sales year. However, a drug will retain its orphan drug status if the drug subsequently receives

¹ Likewise, under section 1250(b)(3), if a taxpayer can establish that the amount "allowed" as a deduction was less than the amount "allowable," then the amount taken into account for purposes of a depreciation adjustment is the amount "allowed." See also section 36B(c)(1)(D) and section 42(j)(5)(A)(i).

² See *Virginian Hotel Corporation of Lynchburg v. Helvering*, 319 U.S. 523, 526 (1943); *Flood v. United States*, 33 F.3d 1174, 1178 n.5 (9th Cir. 1994); *Lenz v. Commissioner*, 101 T.C. 260, 265 (1993); *Hightower v. Commissioner*, T.C. Memo 1982-559.

approval only for another indication for a rare disease or condition for which a section 45C credit was allowed.

Pre-1984 Generic Drugs

Section 9008(e)(2)(A) defines the term branded prescription drug to include any prescription drug the application for which was submitted to the FDA under section 505(b). The final regulations track the statutory language in defining the term branded prescription drug. Neither the statute nor the final regulations specifically refer to or address the treatment of generic drugs.

On September 24, 1984, Congress enacted the Drug Price Competition and Patent Restoration Act of 1984, Public Law 98-417 (1984) (the 1984 Act). The 1984 Act added section 505(j) to provide an expedited approval process for generic drugs. Because an applicant submits an application for approval of a generic drug after the 1984 Act under section 505(j) rather than section 505(b), such a drug is not a branded prescription drug for purposes of the branded prescription drug fee.

It has come to our attention that, before the 1984 Act, an applicant submitted an application for approval of any prescription drug under section 505(b), and no separate statutory process existed for approval of a generic drug. The Treasury Department and the IRS request comments on whether a special rule is appropriate regarding the treatment of generic drugs for which applications were submitted under section 505(b) prior to the 1984 Act, including comments on how to distinguish generic drugs for which applications were submitted under section 505(b) prior to the 1984 Act from other prescription drugs for which applications were submitted under section 505(b) prior to the 1984 Act in a manner that is both administrable and consistent with section

9008. Any special rule regarding the treatment of these generic drugs would be prospective only.

Comments with regard to this issue should be submitted in writing and can be mailed to the Office of Associate Chief Counsel (Passthroughs and Special Industries), Re: REG-112805-10, CC;PSI:B7, Room 5314, 1111 Constitution Avenue, NW, Washington, DC 20224. All comments received will be available for public inspection at <http://www.regulations.gov> (IRS REG-112805-10).

Information Requested From Covered Entities

The temporary regulations gave each covered entity the opportunity to provide information relevant to the determination of the fee by annually submitting Form 8947, including information regarding rebates. Commenters asked that CMS include all rebate data in its reports to the IRS, rather than have the IRS collect rebate data from the covered entities on Form 8947. CMS now includes rebate data for Medicare and federal Medicaid in its reports. Therefore, the final regulations eliminate the provision for separate reporting of Medicare and federal Medicaid rebates by covered entities and Form 8947 no longer requests information on these rebates. However, CMS does not include Medicaid state supplemental rebate data. Until CMS can include Medicaid state supplemental rebate data in its reports to the IRS, covered entities will continue to have the opportunity to submit this rebate data on Form 8947. Therefore, the final regulations retain the provision that permits separate reporting of Medicaid state supplemental rebate data by covered entities.

A commenter asked whether to include state-only pharmaceutical program rebates on Form 8947 as Medicaid Drug Rebates. According to CMS, state-only

pharmaceutical programs are not part of the Medicaid Drug Rebate Program or the federal Medicaid program. Therefore, the final regulations specify that the Medicaid Drug Rebate Program's calculated branded prescription drug fee does not include state-only pharmaceutical sales or rebates. Accordingly, a covered entity may not report on its Form 8947 or error report a rebate paid by the covered entity in connection with a state-only pharmaceutical program.

A commenter asked that the final regulations provide that a covered entity may submit an incomplete Form 8947. The final regulations do not adopt this suggestion. Submission of Form 8947 is voluntary. A covered entity that chooses to file Form 8947, however, must state, under penalties of perjury, that to the best of the filer's knowledge and belief, the information provided on Form 8947 is true, correct, and complete. As in the past, a covered entity may correct and supplement information it submitted on Form 8947, if necessary, by submitting one or more error reports as part of the dispute resolution process.

Information Provided by the Agencies

Section 9008(g) requires each Program to calculate and provide sales data based on the methodologies described in section 9008(g). Section 9008(b)(3) requires the IRS to use the data provided by the Programs to calculate the fee. In accordance with the statute, the temporary regulations required the Agencies to provide data to the IRS on branded prescription drug sales that occurred during the sales year by Program and NDC. The temporary regulations also set forth the methodologies used by the Agencies for calculating the sales amounts for each Program.

Commenters raised questions about the descriptions in the temporary regulations of the methodologies used by the Agencies, asked that these descriptions be clarified, suggested alternative methods of calculating Program sales data, and requested additional data. In response to these comments, the final regulations adopt certain suggestions to include revised descriptions of the data and computations the Agencies use to calculate branded prescription drug sales as described in the following sections for each Program. In addition, this preamble provides further background on the methodologies used by the Agencies as described in the following sections for each Program. Because the Agencies have the responsibility to compute and report the data described in the statute, the Treasury Department and the IRS coordinated extensively with the Agencies in preparing the additional background information in the preamble and the revised descriptions in the final regulations.

Medicare Part D

The temporary regulations provided that, to determine branded prescription drug sales amounts for 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. Section 9008(g)(1)(A) requires Medicare Part D sales amounts to be reduced by “any per-unit rebate, discount, or other price concession provided by the covered entity.”

Commenters asked that the final regulations clarify how CMS determines these net sales amounts. The final regulations adopt this suggestion. The final regulations clarify that CMS will aggregate the “Ingredient Cost Paid” field on the PDE records at the NDC level, reduced by discounts, rebates, and other price concessions provided by

the covered entity. To obtain this information, CMS uses two main data sources to determine net sales amounts: the PDE records and the Detailed Direct and Indirect Remuneration (DIR) Report. CMS obtains information for these two data sources from Medicare Part D sponsors.

The final regulations specifically define “discounts, rebates, and other price concessions provided by the covered entity” to include, in part, DIR. DIR is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Medicare Part D sponsor (whether directly or indirectly) for the Medicare Part D drug. See 42 CFR 423.308. Thus, DIR includes discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. However, DIR does not include price concessions that CMS does not consider to directly or indirectly impact drug costs incurred by the Medicare Part D sponsor.

The final regulations further provide that DIR includes both DIR reported on the PDE records at the point of sale and DIR reported on the Detailed DIR Report. The temporary regulations provided that, if CMS does not have Medicare Part D rebate information for a sales year, then the IRS will reduce the branded prescription drug sales reported for Medicare Part D by rebates reported by covered entities on Form 8947. This procedure was necessary for fee year 2011 because CMS did not have the information necessary to report Medicare Part D sales data net of DIR. To provide this

data to the IRS at the individual drug level as the statute requires, CMS began to collect DIR at the NDC level from Medicare Part D sponsors for use in the 2012 fee year, which Medicare Part D sponsors report to CMS on the Detailed DIR Report. Medicare Part D sponsors also report DIR on the PDE records at the point of sale, though these amounts tend to be nominal. Therefore, since fee year 2012, CMS has been reporting its Medicare Part D sales data to the IRS net of all DIR by deducting from the Ingredient Cost both DIR reported on the PDE records at the point of sale and DIR reported on the Detailed DIR Report. The final regulations reflect this approach. As stated earlier in this preamble, the final regulations also eliminate the provision for separate reporting of Medicare Part D rebates by covered entities on Form 8947.

A commenter requested that the final regulations clarify the treatment of coverage gap discount amounts. The final regulations adopt this suggestion effective for fee years beginning in 2014. The Medicare Part D coverage gap, also known as the “donut hole,” is a gap in prescription drug coverage that is being closed due to the Affordable Care Act. Part of closing the coverage gap is the Coverage Gap Discount Program described in section 1860D-14A of the Social Security Act, which requires a 50-percent manufacturer-paid discount on covered brand-name drugs in certain instances. For fee years 2012 and 2013, CMS did not deduct coverage gap discount amounts from the Ingredient Cost. This comment, however, prompted CMS to recharacterize coverage gap discount amounts as a type of rebate, discount, or other price concession for purposes of the fee calculation. Therefore, beginning with the final fee calculation for fee year 2014, CMS will report Medicare Part D sales data to the IRS that is net of coverage gap discount amounts. The final regulations reflect this change.

The final regulations also remove the reference to the “Quantity Dispensed” field of the PDE records. This field has no impact on sales because CMS totals the ingredient cost at the NDC level and determines DIR reported on the PDE records at the point of sale and DIR reported on the Detailed DIR Report at the NDC level. Thus, the unit of reference used by CMS is consistently at the NDC level.

Commenters suggested that the final regulations require CMS to exclude sales in Puerto Rico in determining sales amounts for Medicare Part D. The final regulations do not adopt this suggestion. Section 9008(g) requires each Agency to report to the IRS the total branded prescription drug sales for each covered entity for each Program. Section 9008 does not provide any exclusion for sales in Puerto Rico or any other territory. When calculating its branded prescription drug sales data for Medicare Part D, CMS includes sales, DIR reported on the PDE records at the point of sale, and DIR reported on the Detailed DIR Report for all sales in the United States and its territories, including the Commonwealth of Puerto Rico.

Medicare Part B

The temporary regulations provided that CMS will determine branded prescription drug sales under Medicare Part B using two data sources. First, CMS will use the data reported by manufacturers pursuant to section 1847A(c) of the Social Security Act (42 U.S.C. 1395w-3a(c)) to calculate the annual weighted average sales price (ASP) for each Healthcare Common Procedure Coding System code (HCPCS code) for the sales year. Second, CMS will use the Medicare Part B National Summary Data File located at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html> to obtain the

number of allowed billing units per HCPCS code for claims incurred during the sales year. The temporary regulations further provided separate detailed methods for CMS to use this data to determine Medicare Part B sales amounts depending on whether (1) the HCPCS code consists solely and exclusively of branded prescription drugs manufactured by a single entity, (2) the HCPCS code consists of a mixture of branded prescription drugs made by different manufacturers and/or a mixture of branded prescription and generic drugs, or (3) CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code.

Under the third method in the temporary regulations, if CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code, CMS will calculate Medicare Part B sales by using Medicare Part D utilization percentages. A commenter requested that CMS develop a more accurate backup method. The final regulations do not adopt this suggestion. In CMS's view, the existing backup method is sufficiently reliable. Additionally, CMS did not anticipate frequent use of this approach and has not needed to use the backup method for any fee calculation to date. The final regulations do, however, include a more detailed explanation of how CMS uses HCPCS codes as well as an example.

Commenters also expressed concern about whether Medicare Part B is capturing complete data on what are sometimes referred to as non-separately payable drugs. Non-separately payable drugs may not be directly correlated with a single specific HCPCS code. Some non-separately payable drugs are associated with more than one HCPCS code or are bundled with services, such as dialysis. CMS recognizes this concern and makes extensive effort to gather as complete a data set as possible.

CMS will continue to work with the data available to capture non-separately payable drugs.

Medicaid

The temporary regulations provided that CMS will determine branded prescription drug sales as the per-unit Average Manufacturer Price (AMP) less the Unit Rebate Amount (URA) that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported billed by the states to manufacturers. Specifically, the temporary regulations provided that 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 uses the following methodology to derive the branded prescription sales amounts that account for third-party payers:

Step 1. Report total dollars per NDC for AMP minus URA, multiplied by the units reported by a state or states;

Step 2. Determine the percentage of the total amount reimbursed that is the Medicaid amount of that reimbursement; and

Step 3. Multiply the percentage of the Medicaid amount of that reimbursement by the dollar figure from step 1 (AMP minus URA, multiplied by units) to get the new adjusted sales dollar totals.

The final regulations clarify that CMS will determine branded prescription drug sales as the per-unit AMP less the URA that CMS calculates based on manufacturer-reported pricing data multiplied by the number of units reported as paid by the states rather than as billed by the states.

Commenters requested that the final regulations require Medicaid to use the per-unit ingredient cost paid to pharmacies by the states as provided in section 9008(g)(3) instead of AMP in computing total branded prescription drug sales. The final regulations do not adopt this suggestion. Medicaid does not have the ability to use the per-unit ingredient cost paid to pharmacies by the states because Medicaid systems are not designed to track drug sales data in this manner or obtain this type of detailed information from the states. Instead, Medicaid systems track drug sales data using AMP. AMP is the best alternative that Medicaid systems permit and serves as a reasonable proxy for the per-unit ingredient cost paid to pharmacies by the states.

The temporary regulations provided that Medicaid branded prescription drug sales 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. The final regulations clarify that the sales data is based on the data that covered entities report for the sales year rather than the data that covered entities report during the sales year because some reporting for a sales year may occur after that year ends.

Commenters requested that the final regulations clarify the meaning of the phrase “drugs paid for by the states in the Medicaid Drug Rebate Program” and whether it includes units paid for under managed care organization plans. In response to this request, the final regulations specify that “drugs paid for by the states in the Medicaid Drug Rebate Program” includes all branded prescription drug units for which the states bill rebates to covered entities under the Medicaid Drug Rebate Program. This program includes, but is not limited to, units paid for under various health care plans such as fee

for service, managed care organizations, and drugs administered in a non-retail setting such as drugs administered in a physician's office, clinic, hospital or other setting.

Under the Medicaid Drug Rebate Program, states provide the required utilization data. States report separate totals for each NDC for both fee-for-service and managed care organization utilization data. Also, as stated earlier in this preamble, the final regulations specify that the Medicaid Drug Rebate Program's calculated branded prescription drug fee does not include state-only pharmaceutical program sales or rebates.

Commenters asked how a covered entity can ensure that a state has updated its Medicaid data files to accurately reflect state rebates. This issue is beyond the scope of these regulations. However, since 2011, in the context of the dispute resolution process, CMS, IRS, and covered entities have devoted extensive resources to resolving discrepancies between a state's reported rebate data that CMS uses to compute Medicaid's branded prescription drug sales data for the IRS and the rebate data that covered entities receive from that state. To resolve these discrepancies on a timely basis, CMS has established a reconciliation process. To maximize the effectiveness of this reconciliation process, however, a covered entity must use the CMS reconciliation process in a timeframe that allows discrepancies to be resolved before CMS computes the branded prescription sales data that it sends the IRS for purposes of computing a covered entity's preliminary fee calculation. A covered entity's timely use of the CMS reconciliation process will help minimize, if not eliminate, the errors related to CMS's Medicaid data that a covered entity would otherwise include in its error report. The web address for this resource is <http://medicaid.gov/Medicaid-CHIP-Program-Information/By->

[Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html](#). This CMS Medicaid Branded Prescription Drug Fee program webpage also has additional information regarding Medicaid sales data. Covered entities may e-mail questions to CMS Medicaid regarding the data used in this program at MedicaidBPD@cms.hhs.gov with “BPD” in the e-mail subject line.

Department of Veterans Affairs

The temporary regulations provided that 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 VA for its beneficiaries during the sales year. For this purpose, a drug is procured on the invoice (billing) date. The temporary regulations further provided that 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.

A commenter requested that the final regulations require that the amount of the IFF and CRF be excluded from VA sales either by requiring VA to exclude these amounts from its sales data or by allowing a covered entity to report these amounts on its Form 8947. The final regulations do not adopt this suggestion. According to VA, these amounts are part of the total price VA pays to its Pharmaceutical Prime Vendor and are properly included in the sales amount.

A commenter requested that the final regulations confirm that VA sales data does not include DOD, Coast Guard, Indian Health, or other purchases made under the Federal Supply Schedule. VA does not include in its sales data purchases made by

other agencies. Because the methodology in the regulations is already limited to purchases made by VA, the final regulations do not need further clarification.

Department of Defense

The temporary regulations provided that, for DOD programs other than TRICARE, 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 during the sales year. For this purpose, a drug is procured based upon the date it was ordered.

A commenter requested that the final regulations require that the amount of the Industrial Funding Fee (IFF) and the Cost Recovery Fee (CRF) be excluded from DOD sales, either by requiring DOD to exclude these fees from its sales data or by allowing a covered entity to report these fees on its Form 8947. The IFF and CRF are administrative fees that are added to the cost of purchasing under the Federal Supply Schedule and National Contract Service. The final regulations do not adopt this suggestion. According to DOD, these fee amounts are part of the total price DOD pays to procure a drug and are properly included in the sales amount.

TRICARE

The temporary regulations provided that 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 (TRICARE) during the sales year. For TRICARE, 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 claims

submitted during the program year, minus any refunds or rebates for the corresponding claims.

Commenters expressed concern that TRICARE's drug sales overlap with DOD and VA and asked that the final regulations address this perceived overlap. The final regulations do not adopt this suggestion. No overlap exists because TRICARE only reports sales from its retail pharmacy network, which is distinct from sales reported by DOD and VA. TRICARE, DOD, and VA separately maintain and report their own drug sales data.

Section 51.4T(f) described the TRICARE and DOD methodologies for calculating sales data. Section 51.4(f) continues to describe the DOD methodology. A new subsection, §51.4(g), describes the TRICARE methodology.

Fee Calculation Including Adjustment

As stated earlier in this preamble, 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 temporary regulations provided that 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.

A commenter asked that the final regulations provide for a separate dispute resolution process for the adjustment amount after the final fee calculation because errors reported in the dispute resolution process may not be resolved in time to be reflected in the final fee calculation. The final regulations do not adopt this suggestion. The adjustment amount is part of the preliminary fee calculation. Therefore, each

covered entity has an opportunity to raise disputes regarding the adjustment amount during the existing dispute resolution process. Moreover, an adjustment to one covered entity's final fee calculation would necessitate a recalculation of each covered entity's prior final fee calculation because the fee is an allocated fee. The final regulations clarify that the IRS will not make adjustments to a final fee calculation.

Because the amount of the fee under the temporary regulations was based on sales from the second preceding year, commenters suggested that the final regulations allow a covered entity to reduce its fee liability in the same year that the covered entity experiences an event that would significantly reduce its sales to the Programs and make corresponding adjustments in future years. Such events may include a drug recall, a loss of patent exclusivity, or bankruptcy. The final regulations do not adopt this suggestion. The statute requires the IRS to determine each covered entity's branded prescription drug sales on the basis of reports submitted by the Agencies and to uniformly apply the fee determination rules to each covered entity's sales data. The methodology adopted in the final regulations ensures that the applicable fee amount is appropriately apportioned among the covered entities.

In accordance with section 9008(f)(1), the temporary regulations treated the fee as an excise tax for purposes of subtitle F. A commenter suggested that the final regulations provide for interest payments for adjustment amounts that are credited to a covered entity. The final regulations do not adopt this suggestion. Instead, the final regulations clarify that an adjustment amount itself is neither an overpayment nor an underpayment, but rather a component of the current year's fee. Thus, for purposes of section 6601, any increase in the current year's fee resulting from any adjustment

amount, along with the remainder of the fee, is treated as due on the due date for the current year's fee. Conversely, for purposes of section 6611, any adjustment amount that decreases the current year's fee is treated as a payment towards the current fee amount made on the due date of the current fee year.

Commenters asked that the final regulations clarify whether a covered entity must file Form 843, "Claim for Refund and Request for Abatement," to request that the IRS calculate an adjustment amount when a covered entity anticipates that it is entitled to a positive adjustment amount. As stated earlier in this preamble, a positive adjustment amount is not an overpayment. Accordingly, in response to this comment, the final regulations clarify that a covered entity does not file Form 843 to obtain an adjustment amount. The IRS automatically calculates adjustment amounts. Additionally, the final regulations clarify that if a covered entity's adjustment amount reduces the fee below zero and results in an amount due to the covered entity for the fee year, the IRS will automatically pay this amount due to the covered entity.

Another commenter suggested that the final regulations clarify whether the period of limitations on filing a claim set forth in section 6511 applies to the adjustment amount. Under the final regulations, section 6511 applies to the fee, but not separately to the adjustment amount, because the adjustment amount is merely a component of the fee. For purposes of section 6511, any adjustment amount that decreases the current year's fee is treated as a payment towards the current fee amount made on the due date of the current fee year.

Notification and Payment of Fee

The temporary regulations provided that, no later than August 31st of each fee year, the IRS will send each covered entity its final fee calculation for that fee year. Several commenters suggested that the IRS send the final fee notice in an electronic format. The final regulations do not adopt this suggestion because it is outside the scope of these regulations. However, the final regulations do not prohibit the IRS from using an electronic format for the final fee notice. Moreover, at the time these comments were submitted, the IRS was already sending a covered entity's sales data with its preliminary fee notice on a separate CD-ROM in Microsoft Excel format to each covered entity that timely requested it. After receiving these comments, the IRS began also sending a covered entity's sales data with its final notice on a separate CD-ROM in Microsoft Excel format if the entity had made a timely request for the CD-ROM to be sent with its preliminary fee notice. More information about the manner for notifying covered entities of their preliminary and final fee calculations is contained in Notice 2014-42.

In accordance with section 9008(a)(2), the temporary regulations provided that each covered entity must pay its final fee by September 30th of the fee year. A commenter suggested that the final regulations clarify whether section 7503 applies to the deadline for fee payment. Section 7503 provides that if the last day for performing an act required under the authority of the internal revenue laws falls on a Saturday, Sunday, or a legal holiday, the performance of the act is timely if the act is performed on the next succeeding day that is not a Saturday, Sunday, or a legal holiday. The final regulations do not provide a special rule because section 9008(f)(1) and the final

regulations treat the fee as an excise tax for purposes of subtitle F. Therefore, section 7503 applies to the deadline for fee payment.

Dispute Resolution Process

The temporary regulations provided 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 the final fee calculation. The temporary regulations described the information that covered entities must submit. The final regulations adopt these provisions with the following minor changes that will allow the IRS to more accurately process a covered entity's disputes.

The temporary regulations required that a Form 2848, "Power of Attorney and Declaration of Representative" must be filed with an error report. The final regulations clarify that a Form 2848 is required only when the representative is not an employee of the covered entity who is authorized under section 6103 or designated on Form 8947 to discuss the information reported on Form 8947.

The temporary regulations required the name, telephone number, and e-mail address (if available) of one or more employees or representatives with whom errors may be discussed. The final regulations also require a fax number.

For Program errors, the temporary regulations required a covered entity to submit a separate error report for each Program with the asserted errors. For non-Program errors, the temporary regulations required a covered entity to submit one error report with all of the non-Program errors. To streamline the error reporting process, the final regulations require a covered entity to combine both Program and non-Program errors on a single error report, with each asserted error on a separate line.

Availability of IRS Documents.

The IRS notices, the revenue procedure, and the temporary regulations cited in this preamble are published in the Internal Revenue Bulletin and are available at www.irs.gov. The temporary regulations are also available in the Code of Federal Regulations.

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 (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in 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 only collection burden imposed by these regulations is the requirement to maintain a record of consent to the selection of a designated entity, and this collection burden applies only to designated entities of controlled groups, which tend to be large corporations, and their members. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f), the notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

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 parts 51 and 602 are amended as follows:

PART 51--BRANDED PRESCRIPTION DRUG FEE

Paragraph 1. The authority citation for part 51 continues to read as follows:

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).

Par. 2. Section 51.1 is added to read as follows:

§51.1 Overview.

(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.

§51.1T [Removed]

Par. 3. Section 51.1T is removed.

Par. 4. Section 51.2T is revised to read as follows:

§51.2T Explanation of terms (temporary).

(a) through (e)(2) [Reserved]. For further guidance see §51.2(a) through (e)(2).

(3) Controlled Group. The term controlled group means a group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer under section 52(a), 52(b), 414(m), or 414(o).

(e)(4) through (m) [Reserved]. For further guidance see §51.2(e)(4) through (m).

Par. 5. Section 51.2 is added to read as follows:

§51.2 Explanation of terms.

(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)) (FFDCA); 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 FFDCA.

(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 a controlled group.

(3) Controlled group-- (i) On or before December 31, 2014. 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).

(ii) After December 31, 2014. For guidance regarding the definition of controlled group after December 31, 2014, see §51.2T(e)(3).

(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 person 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.

(5) Covered entity status--(i) Rule. An entity's status as a covered entity begins in the first fee year in which the entity has branded prescription drug sales and continues each subsequent fee year until there are no remaining branded prescription drug sales for that entity to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e).

(ii) Example. The following example illustrates the rule of paragraph (e)(5)(i) of this section:

(A) Facts. Entity A is a manufacturer with gross receipts of more than \$5 million from branded prescription drugs sales in 2011. Entity A does not have any gross receipts from branded prescription drug sales before or after 2011.

(B) Analysis. Entity A is a covered entity beginning in 2011 because it had gross receipts from branded prescription drug sales in 2011. For the 2011 fee year, Entity A does not owe a fee because the 2011 fee is based on sales data from the 2009 sales year. For the 2012 fee year, Entity A does not owe a fee because the 2012 fee is based on sales data from the 2010 sales year. Entity A continues to be a covered entity for the 2012 fee year because its branded prescription drug sales from the 2011 sales year have not yet been taken into account as described in §51.5(c) and used to calculate the adjustment amount described in §51.5(e). For the 2013 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales from the 2011 sales year are taken into account as described in §51.5(c) for purposes of computing the 2013 fee. For the 2013 fee year, Entity A is also liable for the adjustment amount described in §51.5(e) for the difference between its 2012 fee computed using sales data from the 2010 sales year, which is \$0, and what the 2012 fee would have been using sales data from the 2011 sales year. For the 2014 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales for the 2011 sales year are used to calculate the adjustment amount described in §51.5(e). Therefore, for the 2014 fee year, Entity A will receive an adjustment amount for the difference between its 2013 fee computed using sales data from the 2011 sales year, and what the 2013 fee would have been using sales data from the 2012 sales year, which is \$0. After the 2014 fee year, there are no remaining branded prescription drug sales to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e) for Entity A. Accordingly, Entity A is not a covered entity after the 2014 fee year.

(f) Designated entity--(1) In general. The term designated entity means the person within a controlled group that is designated to act for the 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 §51.7; and
- (iv) Paying the fee to the government.

(2) Selection of designated entity--(i) Controlled group selection of a designated entity. Except as provided in paragraph (f)(2)(ii) of this section, the controlled group may select a person as the designated entity by filing Form 8947 in accordance with the form instructions. The designated entity must state under penalties of perjury that all

members of the controlled group have consented to the selection of the designated entity. The designated entity must maintain a record of all member consents. Each member of a controlled group must maintain a record of its consent to the controlled group's selection of the designated entity.

(ii) Requirement for affiliated groups; agent for the group. If the controlled group, without regard to foreign corporations included under section 9008(d)(2)(B), is also an affiliated group whose common parent files a consolidated return for federal income tax purposes, the designated entity is the agent for the group (within the meaning of §1.1502-77 of this title).

(iii) IRS selection of a designated entity. Except as provided in paragraph (f)(2)(ii) of this section, if a controlled group does not select a designated entity as provided in paragraph (f)(2)(i) of this section, the IRS will select a member of the controlled group as the designated entity for the controlled group. If the IRS selects the designated entity, then all members of that controlled group will be deemed to have consented to the IRS's selection of the designated entity.

(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 a unique identifier that is assigned to all drug products approved by the Food and Drug Administration (FDA), including a branded 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.

(k) Orphan drugs--(1) In general. Except as provided in paragraph (k)(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 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 2011. In 2011, 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 2012, 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 2011 and 2012, 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 2012, 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 2013 sales year or later sales years because in 2012 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 2011. In 2011, FDA approved Drug B for marketing for the treatment of a rare disease or

condition and also approved Drug B for marketing for an indication other than the treatment of a rare disease or condition. In 2012, 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 2011, Drug B is not an orphan drug because no section 45C credit was allowed and because the FDA approved Drug B for an indication other than the treatment of a rare disease or condition. In 2012, 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 2011 for marketing for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed in 2012. Thus, Drug B is not an orphan drug for the 2012 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 2010. In 2010, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2012, 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 2010. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2010 or 2012. 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 2010 and 2011, 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 2012, 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 2013 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 §51.5(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 2014, the sales year is 2012.

Par. 6. Section 51.3 is added to read as follows:

§51.3 Information requested from covered entities.

(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.

§51.3T [Removed]

Par. 7. Section 51.3T is removed.

Par. 8. Section 51.4 is added to read as follows:

§51.4 Information provided by the Agencies.

(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 §51.7) 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 that occurred during the sales year by Program and NDC. The Agencies will provide data for use in preparing the preliminary fee calculation (described in §§51.5 and 51.6) 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--(1) In general. CMS will determine branded prescription drug sales under Medicare Part D by aggregating the ingredient cost reported in the “Ingredient Cost Paid” field on the Prescription Drug Event (PDE) records at the NDC level, reduced by discounts, rebates, and other price concessions provided by the covered entity, for each sales year. CMS will only include PDE data that Part D sponsors have submitted by the PDE submission deadline (within 6 months after the end of the sales year) and that CMS has approved for inclusion in the Part D payment reconciliation.

(2) Discounts, rebates, and other price concessions--(i) In general. For purposes of paragraph (b)(1) of this section, the term discounts, rebates, and other price concessions means:

(A) Any direct and indirect remuneration (DIR) (within the meaning of paragraph (b)(2)(B) of this section), which includes any DIR reported on the PDE records at the point of sale and any DIR reported on a Detailed DIR Report (within the meaning of paragraph (b)(2)(C) of this section); and

(B) Any coverage gap discount amount (within the meaning of paragraph (b)(2)(D) of this section).

(ii) Direct and indirect remuneration. For purposes of paragraph (b)(2)(A)(i) of this section, the term direct and indirect remuneration (DIR) has the same meaning as found in the definition of actually paid in 42 CFR 423.308.

(iii) Detailed DIR Report. For purposes of paragraph (b)(2)(A)(i) of this section, the term Detailed DIR Report means the report containing any DIR (within the meaning of paragraph (b)(2)(B) of this section) that is collected yearly from Part D sponsors at the NDC level.

(iv) Coverage gap discount amount. For purposes of paragraph (b)(2)(A)(ii) of this section, the term coverage gap discount amount means a 50-percent manufacturer-paid discount on certain drugs under the Coverage Gap Discount Program described in section 1860D-14A of the Social Security Act.

(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 to obtain the number of allowed billing units per HCPCS code for claims incurred during the sales year.

(2) Calculation--(i) In general. 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. CMS reports sales amounts per HCPCS billing code, not per NDC. Therefore, a covered entity's total Part B sales amounts for all NDCs in a given HCPCS billing code appears under only one

NDC in each HCPCS billing code and the covered entity's remaining NDCs in the HCPCS billing code are listed with a sales amount of zero.

(ii) Example of a Part B sales report:

HCPCS	NDC	Part B amount
J9876	12345-6789-01	\$789,000
	12345-6789-02	0
	12345-6789-03	0
	12345-6800-80	0
	12345-6800-90	0

(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, $\text{percentage} \times (\text{annual weighted ASP} \times \text{allowed units}) = \text{total sales reported to IRS for the NDC}$). 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 for the sales year by covered entities and the states for drugs paid for by the states in the Medicaid Drug Rebate Program for the sales year. The data will include all branded prescription drug units for which the states bill rebates to covered entities under the Medicaid Drug Rebate Program. This program includes, but is not limited to, units paid for under various health care plans such as fee for service, managed care organizations, and drugs administered in a non-retail setting such as drugs administered in a physician's office, clinic, hospital or other setting. The Medicaid Drug Rebate Program's calculated branded prescription drug fee does not include state-only pharmaceutical program sales or rebates.

(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 minus 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 determine branded prescription drug sales to VA by providing, 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 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. VA sales data includes the Industrial Funding Fee and the Cost Recovery Fee because these amounts are part of the price VA pays to its Pharmaceutical Prime Vendor to procure a drug.

(f) Department of Defense. DOD will determine branded prescription drug sales to DOD (for DOD programs other than the TRICARE retail pharmacy program) by providing, 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 includes the Industrial Funding Fee and the Cost Recovery Fee in its drug sales data because these amounts are part of the price DOD pays to procure a drug.

(g) TRICARE. DOD will determine branded prescription drug sales to DOD for the TRICARE retail pharmacy program by providing, 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.

§51.4T [Removed]

Par. 9. Section 51.4T is removed.

Par. 10. Section 51.5 is added to read as follows:

§51.5 Fee calculation.

(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. 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--

<u>Fee year</u>	<u>Applicable amount</u>
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

(4) 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 percent
More than \$5,000,000 but not more than \$125,000,000	10 percent
More than \$125,000,000 but not more than \$225,000,000	40 percent
More than \$225,000,000 but not more than \$400,000,000	75 percent
More than \$400,000,000	100 percent

(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 identified in the Labeler Code 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 in which a member of the covered entity is identified. 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 Medicaid state supplemental rebate amounts in the following manner. If CMS has Medicaid state supplemental rebate information for a sales year, CMS will report to the IRS branded prescription drug sales for Medicaid net of Medicaid state supplemental rebates. If CMS does not have complete Medicaid state supplemental rebate information for a sales year, the IRS will reduce the branded prescription drug sales that CMS reported for Medicaid by Medicaid state supplemental rebates reported by the covered entities on Form 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--(1) In general. In addition to the allocated fee computed under paragraph (d) of this section, the IRS will also automatically calculate for each covered entity an adjustment amount. An adjustment amount 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 2014, the adjustment amount for a covered entity will be the difference between the entity's 2013 allocated fee, using 2011 data, and what the 2013 allocated fee would have been using 2012 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. An adjustment amount is treated as a component of the current year's fee. For purposes of section 6601, any increase in the allocated fee computed under paragraph (d) of this section for the current fee year resulting from any adjustment amount, along with the remainder of the fee, is treated as

a fee liability due on the due date for the current year's fee. For purposes of sections 6511 and 6611, any adjustment amount that decreases the allocated fee computed under paragraph (d) of this section for the current fee year is treated as a payment towards the current fee liability made on the due date of the current fee year.

(2) Amounts paid to a covered entity because of an adjustment amount. If a covered entity's adjustment amount reduces the fee computed under paragraph (d) of this section below zero and results in an amount due to the covered entity for the fee year, the IRS will pay this amount due to the covered entity. A covered entity does not file Form 843, Claim for Refund and Request for Abatement, to receive this amount owed to a covered entity.

§51.5T [Removed]

Par. 11. Section 51.5T is removed.

Par. 12 Section 51.6 is added to read as follows:

§51.6 Notice of preliminary fee calculation.

(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 §51.5. 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 §51.5(a)(4);

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

(5) The covered entity's adjustment amount calculated as described in §51.5(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.

§51.6T [Removed]

Par. 13. Section 51.6T is removed.

Par. 14 Section 51.7 is added to read as follows:

§51.7 Dispute resolution process.

(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) Error report information. To assert that there have been one or more errors in the drug sales data reported by a Program, the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error, a covered entity must submit an error report with each asserted error reported on a separate line. The report must include the following information--

(1) Entity name, address, and Employer Identification Number (EIN) as previously reported on the Form 8947;

(2) The name, telephone number, fax number, and e-mail address (if available) of one or more employees or representatives of the entity with whom the IRS may discuss the claimed errors. If the representative is not an employee of the covered entity who is authorized under section 6103 or designated on Form 8947 to discuss the information reported on Form 8947 with the IRS, a Form 2848, "Power of Attorney and Declaration of Representative," must be filed with the error report;

(3) For an error in the drug sales data reported by a Program, 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.

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

(5) 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 not 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 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;

(7) 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;

(8) 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

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

(c) 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).

(d) Finality. A covered entity must assert any basis for contesting its preliminary fee calculation during the dispute resolution period. In the interest of providing finality to the fee calculation process, the IRS will not accept an error report after the end of the dispute resolution period or alter the final fee calculation on the basis of information provided after the end of the dispute resolution period.

§51.7T [Removed]

Par. 15. Section 51.7T is removed.

Par. 16. Section 51.8 is added to read as follows:

§51.8 Notification and payment of fee.

(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) The covered entity's adjustment amount calculated as described in §51.5;
- (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 §51.5(a)(4);
- (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 §51.7. Even if a covered entity did not file an error report described in §51.7, 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 §51.6302-1. 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 members of the controlled group are jointly and severally liable for the fee. Accordingly, if a controlled group's fee is not paid, the IRS will separately assess each member of the group for the full amount of the controlled group's fee.

§51.8T [Removed]

Par. 17. Section 51.8T is removed.

Par. 18. Section 51.9 is added to read as follows:

§51.9 Tax treatment of fee.

(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 Internal Revenue Code (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 7402 and 7403), 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).

§51.9T [Removed]

Par. 19. Section 51.9T is removed.

Par. 20. Section 51.10 is added to read as follows:

§51.10 Refund claims.

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.

§51.10T [Removed]

Par. 21. Section 51.10T is removed.

Par. 22. Section 51.11T is revised to read as follows:

§51.11T Effective/applicability date.

(a) through (b) [Reserved]. For further guidance see §51.11(a) through (b).

(c) Section 51.2T(e)(3) applies to any fee on branded prescription drug sales that is due on or after January 1, 2015.

(d) The applicability of §51.2T(e)(3) expires on July 24, 2017.

Par. 23. Section 51.11 is added to read as follows:

§51.11 Effective/applicability date.

(a) Except as otherwise provided in this section, §§51.1 through 51.10 apply on and after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

(b) Section 51.2(e)(3) applies on **[INSERT DATE OF PUBLICATION OF IN THE FEDERAL REGISTER]** through December 31, 2014.

(c) [Reserved]. For further guidance see §51.11T(c).

§51.12T [Removed]

Par. 24. Section 51.12T is removed.

Par. 25. Section 51.6302-1 is added to read as follows:

§51.6302-1 Method of paying the branded prescription drug fee.

(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 §51.5 must be paid by electronic funds transfer as defined in §31.6302-1(h)(4)(i) of this title, as if the fee were a depository tax. For the time for paying the fee, see §51.8.

(b) Effective/applicability date. This section applies on and after **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

§51.6302-1T [Removed]

Par. 26. Section 51.6302-1T is removed.

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

Par. 27. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 28. In §602.101, paragraph (b) is amended by:

1. Removing the entry for 51.8T from the table; and
2. Adding entries, in numerical order, for 51.2(f)(2)(ii) and 51.7 to the table to

read as follows:

§602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
51.2(f)(2)(ii).....	1545-2209
51.7.....	1545-2209
* * * * *	

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: July 22, 2014.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).