HIGHLIGHTS OF THIS ISSUE

These synopses are intended only as aids to the reader in identifying the subject matter covered. They may not be relied upon as authoritative interpretations.

INCOME TAX

Fringe benefits aircraft valuation formula. The Standard Industry Fare Level (SIFL) cents-per-mile rates and terminal charge in effect for the second half of 2011 are set forth for purposes of determining the value of noncommercial flights on employer-provided aircraft under section 1.61–2(g) of the regulations.

This notice grants each executor of an estate of a decedent who died in 2010 an automatic 6-month extension of time to file Form 706, United States Estate (and Generation-Skipping Transfer) Tax Return, or Form 706-NA, United States Estate (and Generation-Skipping Transfer) Tax Return, Estate of non-resident not a citizen of the United States, and to pay the estate tax, if the executor files an extension request. The notice also changes the due date of Form 8939, Allocation of Increase in Basis for Property Acquired From a Decedent, to January 17, 2012. In addition, it provides limited penalty relief to recipients who sold property in 2010 that they acquired from a decedent whose executor elected for the provisions of section 1022 of the Code to apply to such property. Finally, it extends the date to affirmatively allocate the generation-skipping transfer (GST) exemption and provides guidance on the application of the automatic allocation of GST exemption for decedents who died in 2010.

Results of the 2010-11 allocation round of the qualifying advanced coal project program. This announcement discloses the results of the 2010-11 allocation round under the qualifying advanced coal project program of section 48A of the Code (the "section 48A program"). The Service did not allocate any credits under the 2010-11 allocation round under the section 48A program. The announcement also serves notice to applicants that the 2011-12 allocation round is currently open for the section 48A program pursuant to Notice 2009–24.

EMPLOYEE PLANS

Notice 2011–75, page 475.
Weighted average interest rate update; corporate bond indices; 30-year Treasury securities; segment rates. This notice contains updates for the corporate bond weighted average interest rate for plan years beginning in September 2011; the 24-month average segment rates; the funding transitional segment rates applicable for September 2011; and the minimum present value transitional rates for August 2011.

(Continued on the next page)
ESTATE TAX

This notice grants each executor of an estate of a decedent who died in 2010 an automatic 6-month extension of time to file Form 706, United States Estate (and Generation-Skipping Transfer) Tax Return, or Form 706-NA, United States Estate (and Generation-Skipping Transfer) Tax Return, Estate of non-resident not a citizen of the United States, and to pay the estate tax, if the executor files an extension request. The notice also changes the due date of Form 8939, Allocation of Increase in Basis for Property Acquired From a Decedent, to January 17, 2012. In addition, it provides limited penalty relief to recipients who sold property in 2010 that they acquired from a decedent whose executor elected for the provisions of section 1022 of the Code to apply to such property. Finally, it extends the date to affirmatively allocate the generation-skipping transfer (GST) exemption and provides guidance on the application of the automatic allocation of GST exemption for decedents who died in 2010.

EXCISE TAX

REG–112805–10, page 482.
Temporary and proposed regulations 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. The temporary regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The temporary regulations provide an explanation of terms, a description of the information requested from covered entities and agencies, the calculation and notification of a preliminary fee, a dispute resolution process, the final fee calculation and notification, the tax treatment of the fee, and instructions regarding how to claim a refund.

Notice 2011–73, page 474.
This notice requests comments on a proposed safe harbor for affordability under section 4980H(b) of the Code. Comments must be submitted by December 13, 2011.

ADMINISTRATIVE

T.D. 9543, page 470.
Final regulations amending regulations section 301.7502–1 to provide guidance as to the only ways to establish prima facie evidence of delivery of documents that have a filing deadline prescribed by the Internal Revenue laws, absent direct proof of actual delivery.
The IRS Mission

Provide America’s taxpayers top-quality service by helping them understand and meet their tax responsibilities and en-
force the law with integrity and fairness to all.

Introduction

The Internal Revenue Bulletin is the authoritative instrument of the Commissioner of Internal Revenue for announcing official rulings and procedures of the Internal Revenue Service and for publishing Treasury Decisions, Executive Orders, Tax Conven-
tions, legislation, court decisions, and other items of general interest. It is published weekly and may be obtained from the Superintendent of Documents on a subscription basis. Bulletin contents are compiled semiannually into Cumulative Bulletins, which are sold on a single-copy basis.

It is the policy of the Service to publish in the Bulletin all sub-
stantive rulings necessary to promote a uniform application of the tax laws, including all rulings that supersede, revoke, modify, or amend any of those previously published in the Bulletin. All published rulings apply retroactively unless otherwise indicated. Procedures relating solely to matters of internal management are not published; however, statements of internal practices and procedures that affect the rights and duties of taxpayers are published.

Revenue rulings represent the conclusions of the Service on the application of the law to the pivotal facts stated in the revenue ruling. In those based on positions taken in rulings to taxpayers or technical advice to Service field offices, identifying details and information of a confidential nature are deleted to prevent unwarranted invasions of privacy and to comply with statutory requirements.

Rulings and procedures reported in the Bulletin do not have the force and effect of Treasury Department Regulations, but they may be used as precedents. Unpublished rulings will not be relied on, used, or cited as precedents by Service personnel in the disposition of other cases. In applying published rulings and procedures, the effect of subsequent legislation, regulations, court decisions, rulings, and procedures must be considered, and Service personnel and others concerned are cautioned against reaching the same conclusions in other cases unless the facts and circumstances are substantially the same.

The Bulletin is divided into four parts as follows:

This part includes rulings and decisions based on provisions of the Internal Revenue Code of 1986.

Part II.—Treaties and Tax Legislation.
This part is divided into two subparts as follows: Subpart A, Tax Conventions and Other Related Items, and Subpart B, Leg-
islation and Related Committee Reports.

Part III.—Administrative, Procedural, and Miscellaneous.
To the extent practicable, pertinent cross references to these subjects are contained in the other Parts and Subparts. Also included in this part are Bank Secrecy Act Administrative Rul-
ings. Bank Secrecy Act Administrative Rulings are issued by the Department of the Treasury's Office of the Assistant Secre-
tary (Enforcement).

Part IV.—Items of General Interest.
This part includes notices of proposed rulemakings, disbar-
ment and suspension lists, and announcements.

The last Bulletin for each month includes a cumulative index for the matters published during the preceding months. These monthly indexes are cumulated on a semiannual basis, and are published in the last Bulletin of each semiannual period.

The contents of this publication are not copyrighted and may be reprinted freely. A citation of the Internal Revenue Bulletin as the source would be appropriate.

Part I. Rulings and Decisions Under the Internal Revenue Code of 1986

Section 61.—Gross Income Defined


Fringe benefits aircraft valuation formula. The Standard Industry Fare Level (SIFL) cents-per-mile rates and terminal charge in effect for the second half of 2011 are set forth for purposes of determining the value of noncommercial flights on employer-provided aircraft under section 1.61–2(g) of the regulations.

Rev. Rul. 2011–21

For purposes of the taxation of fringe benefits under section 61 of the Internal Revenue Code, section 1.61–21(g) of the Income Tax Regulations provides a rule for valuing noncommercial flights on employer-provided aircraft. Section 1.61–21(g)(5) provides an aircraft valuation formula to determine the value of such flights. The value of a flight is determined under the base aircraft valuation formula (also known as the Standard Industry Fare Level formula or SIFL) by multiplying the SIFL cents-per-mile rates applicable for the period during which the flight was taken by the appropriate aircraft multiple provided in section 1.61–21(g)(7) and then adding the applicable terminal charge. The SIFL cents-per-mile rates in the formula and the terminal charge are calculated by the Department of Transportation and are reviewed semi-annually.

The following chart sets forth the terminal charge and SIFL mileage rates:

<table>
<thead>
<tr>
<th>Period During Which the Flight Is Taken</th>
<th>Terminal Charge</th>
<th>SIFL Mileage Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/1/11 - 12/31/11</td>
<td>$43.79</td>
<td>Up to 500 miles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$0.2395 per mile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>501-1500 miles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$0.1826 per mile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Over 1500 miles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$0.1756 per mile</td>
</tr>
</tbody>
</table>

DRAFTING INFORMATION

The principal author of this revenue ruling is Kathleen Edmondson of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt/Government Entities). For further information regarding this revenue ruling, contact Ms. Edmondson at (202) 622–0047 (not a toll-free call).

Section 6161.—Extension of Time for Paying Tax

Notice 2011–76 grants each executor of an estate of a decedent who died in 2010 an automatic 6-month extension of time to pay the estate tax imposed under section 2031. See Notice 2011–76, page 479.

Section 6302.—Mode or Time of Collection

26 CFR 51.1T: Overview (temporary).

T.D. 9544

DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Parts 51 and 602
Branded Prescription Drug Fee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance on the annual fee imposed on covered entities engaged in the business of manufacturing or importing branded prescription drugs. This fee was enacted by section 9008 of the Patient Protection and Affordable Care Act, as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010. The regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations (REG–112805–10) set forth in the notice of proposed rulemaking on this subject in this issue of the Bulletin.

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

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

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

Paperwork Reduction Act

These temporary regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–2209.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

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

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

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

Statutory provisions

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

Section 9008(d)(1) defines a covered entity as any manufacturer or importer with gross receipts from branded prescription drug sales. Section 9008(d)(2) provides a controlled group rule under which all persons treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Code are treated as a single covered entity. For this purpose, a foreign entity subject to tax under section 881 is included within a controlled group under section 52(a) or 52(b). Under section 9008(d)(3), all persons treated as a single employer under section 9008(d)(2) are jointly and severally liable for the fee.

Section 9008(e)(2) defines branded prescription drug as (i) any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 355(b)), or (ii) any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)). For this purpose, a prescription drug is any drug that is subject to section 503(b) of the FFDCA (21 U.S.C. 353(b)).

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

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

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

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

IRS guidance

On November 29, 2010, the Internal Revenue Service (IRS) released Notice 2010–71, 2010–50 I.R.B. 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 I.R.B. 459, which was released on January 14, 2011.


Explanation of Provisions

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

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

I. Overview

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

II. Explanation of terms

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

A. Manufacturer or importer

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

B. Designated entity

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

C. Orphan drug sales

Section 9008(e)(3) excludes orphan drug sales from the definition of branded prescription drug sales. Consistent with the proposal in previous IRS guidance, the temporary regulations define orphan drug, subject to certain exceptions, as any branded prescription drug for which any person claimed a section 45C credit and that credit was allowed for any taxable year. The temporary regulations further provide that an orphan drug does not include any drug for which there has been a final assessment or court order disallowing the full section 45C credit taken for the drug. Additionally, an orphan drug does not include any drug for any sales year after the calendar year in which the FDA approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed, regardless of whether a section 45C credit was allowed for the drug either before, at the same time, or after this FDA approval.

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

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

III. Information requested from covered entities

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

One commentator suggested that the Treasury Department and the IRS confirm that submission of Form 8947 is voluntary. Section 51.3T(a) of the temporary regulations provides that a covered entity may file a completed Form 8947; thus, the submission of Form 8947 is voluntary. Commentators expressed a preference for CMS to include all rebate data in their reports to the IRS rather than collecting rebate data from the covered entities on Form 8947. The IRS and CMS are continuing to work on this issue. Until CMS can report all the relevant rebate data, covered entities will continue to have the opportunity to submit rebate data as requested on Forms 8947 and in the format prescribed in the form instructions.

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

IV. Information provided by the Agencies

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

Commentators raised questions about the descriptions in previous IRS guidance of the methodology used by the Agencies to report branded prescription drug sales to the IRS and asked that these descriptions be clarified. In addition, some of the error reports submitted as part of the dispute resolution process under Rev. Proc. 2011–24 identified the need for clarification in describing Agency data. In response to the comments and the issues illuminated by the error reports, the temporary regulations provide revised descriptions of the data and computations for some of the Programs.

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

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

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

Some commentators asked whether the sales data from Medicaid reflected sales where Medicaid was the secondary payer, resulting potentially in duplicate reporting where another one of the Programs (for example, Medicare Part B), was the primary payer. In response, CMS has revised the Medicaid methodology to exclude non-Medicaid payments, and the temporary regulations include a description of this aspect of the methodology. Commentators asked whether TRICARE sales data would be net of refunds and rebates associated with specific NDCs. The temporary regulations make clear that DOD will report for TRICARE the sales data for each NDC based on retail pharmacy claims submitted during the sales year, net of any refunds or rebates. Commentators questioned whether the VA sales data excluded purchases made at individual treatment facilities. The VA includes most of its purchases made at the individual medical facilities. The VA includes most of its purchases made at individual treatment facilities.
treatment facility level in its data because most of these purchases are made via VA's Pharmaceutical Prime Vendor. The description of VA sales data contained in the temporary regulation is revised from the description contained in earlier guidance to eliminate language suggesting that sales at the individual medical treatment facility level are not included and to clarify that the sales data is net of refunds and rebates.

V. Fee calculation including adjustment

The temporary regulations clarify that the IRS will compute the fee for a covered entity based on the branded prescription drug sales data for each NDC reported by the Agencies and any rebate data for each NDC reported by the covered entities. For purposes of computing the fee, each NDC will be assigned to the covered entity that owns the NDC as of the end of the day on December 31st of the sales year. For a covered entity that is a controlled group, this includes all NDCs that a member of the covered entity owns as of the end of the day on December 31st of the sales year. The temporary regulations provide that two years are relevant to the calculation of the section 9008 fee: the fee year, and the calendar year of the branded prescription drug sales, which will be used to determine the amount of the fee (the sales year). As proposed in previous IRS guidance, the temporary regulations use the second calendar year preceding the fee year as the sales year for purposes of calculating the section 9008 fee. The Treasury Department and the IRS have determined that, although DOD and VA are expected to have complete data on branded prescription drug sales for the calendar year immediately preceding the fee year within the time frame necessary to administer the fee, CMS is not expected to have comparable data because it cannot complete its data processing within the necessary time frame. Accordingly, the IRS will calculate the fee based on the branded prescription drug sales data provided by the Agencies for the second calendar year preceding the fee year. Because the use of the second preceding year as the sales year, rather than the immediately preceding year, may affect the amount of the fee paid by a covered entity, the annual fee due in every year after 2011 will include an adjustment amount. This adjustment amount will be added (or subtracted), as appropriate, to (or from) the fee otherwise payable by the covered entity in the fee year in which the adjustment is calculated.

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

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

VI. Notice of preliminary fee calculation

Consistent with the proposal in the previous IRS guidance, the temporary regulations provide that the IRS will provide each covered entity with a notice of preliminary fee calculation each year that will include the covered entity’s preliminary fee calculation; the covered entity’s branded prescription drug sales, by NDC, for each Program; the covered entity’s branded prescription drug sales taken into account after application of section 9008(a)(2); the aggregate branded prescription drug sales taken into account for all covered entities; after the 2011 fee year, a preliminary adjustment amount; and a reference to the fee dispute resolution process set forth in guidance published in the Internal Revenue Bulletin. The date by which the IRS will send the preliminary fee calculation notice will be specified for future years in guidance published in the Internal Revenue Bulletin. For 2011, the IRS sent the notices by May 16, 2011. The Treasury Department and the IRS anticipate sending these notices earlier in future years.

VII. Dispute resolution process

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

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

VIII. Notification and payment of fee

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

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

IX. Tax treatment of fee

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

X. Refund claims

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

Availability of IRS documents

IRS notices and the revenue procedure cited in this preamble are published in the Internal Revenue Bulletin or Cumulative Bulletin and are available at IRS.gov.

Special Analyses

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

Section 553(b) of the APA does not apply to these regulations because they are interpretative rules. Alternatively, the Treasury Department and the IRS have determined that good cause exists under section 553(b)(B) of the APA. That section provides that an agency is not required to publish a notice of proposed rulemaking in the Federal Register when the agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Due to the novel and complex issues raised by the branded prescription drug fee provision and the required coordination with other governmental agencies, the Treasury Department and the IRS have concluded that it would take significantly longer than the time between enactment (March 23, 2010) and the date of collection of the first fee (no later than September 30, 2011) to draft and issue a proposed rule with a comment period, review comments thoroughly, and then draft and issue a final rule. Accordingly, the Treasury Department and the IRS have determined that the notice and comment procedures are impracticable.

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

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

Drafting Information

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

* * * *

Adoption of Amendments to the Regulations

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

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

PART 51—BRANDED PRESCRIPTION DRUG FEE

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

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

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

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

§51.2T Explanation of terms (temporary).

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

(b) Agencies. The term agencies means—

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

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

(3) The Department of Defense (DOD).

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

(i) Any prescription drug the application for which was submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)); or

(ii) Any biological product the license for which was submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

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

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

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

(i) A single-person covered entity; or

(ii) A controlled group.

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

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

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

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

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

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

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

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

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

(iv) Paying the fee to the IRS.

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

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

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

(g) Fee year. The term fee year means the calendar year in which the fee for a particular sales year must be paid to the government.

(h) Government programs. The term government programs (collectively “Programs”), means—

(1) The Medicare Part B program;

(2) The Medicare Part D program;

(3) The Medicaid program;

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

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

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

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

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

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

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

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

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

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

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

(ii) Analysis. In 2008 and 2009, Drug A is an orphan drug because: first, it was a branded prescription drug for which a person claimed a section 45C credit and for which that credit was allowed for a taxable year; second, there was no 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. Thus, Drug A is an orphan drug for the 2010 sales year.

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

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

Example 3: Allowance of section 45C credit and subsequent allowance of section 45C credit with no intervening FDA marketing approval of drug for an indication other than the treatment of a rare disease or condition for which a section 45C credit was allowed. (i) Facts. Drug C is a branded prescription drug that was not on the market before 2007. In 2007, a covered entity claimed a section 45C credit for its qualified clinical testing expenses related to Drug C. In 2009, a covered entity claimed an additional section 45C credit for its qualified clinical testing expenses related to Drug C for marketing for the treatment of a rare disease or condition different than the one for which the section 45C credit was claimed in 2007. There was no final IRS assessment or court order that disallowed the full credit for Drug C in 2007 or 2009. The FDA has not approved Drug C for an indication other than the treatment of a rare disease or condition for which a section 45C was allowed.

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

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

(m) Sales year. The term sales year means the second calendar year preceding the fee year. Thus, for example, for the fee year of 2011, the sales year is 2009.
review of error reports submitted as part of the dispute resolution process. The calculation methodology for calculating the sales amounts for each Program, including any reasonable estimation techniques and assumptions that the Agencies expect to use, is described in this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 reported to the IRS (that is, percentage x (annual weighted ASP x allowed units) = total sales reported to IRS for the NDC). The sales for each manufacturer’s NDCs assigned to a HCPCS code are summed and the total sales for each manufacturer’s NDCs in a HCPCS code will be reported to the IRS.

(5) HCPCS code; unable to establish a reliable proportion of sales. If CMS is unable to establish a reliable proportion of sales attributable to each NDC assigned to the HCPCS code using the method described in paragraph (c)(4)(ii)(A) of this section, CMS will use Medicare Part D utilization percentages in lieu of the proportion of sales determined under paragraph (c)(4)(ii)(A) of this section to perform the calculation described in paragraph (c)(4)(ii)(B) of this section.

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

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

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

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

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

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

(f) Department of Defense. The DOD will provide, by Labeler Code, the manufacturer’s name, the NDC, brand name, and the amount paid (net of rebates and rebates and

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

§51.5T Fee calculation (temporary).

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

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

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

<table>
<thead>
<tr>
<th>Fee year</th>
<th>Applicable amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>$2,500,000,000</td>
</tr>
<tr>
<td>2012</td>
<td>$2,800,000,000</td>
</tr>
<tr>
<td>2013</td>
<td>$2,800,000,000</td>
</tr>
<tr>
<td>2014</td>
<td>$3,000,000,000</td>
</tr>
<tr>
<td>2015</td>
<td>$3,000,000,000</td>
</tr>
<tr>
<td>2016</td>
<td>$3,000,000,000</td>
</tr>
<tr>
<td>2017</td>
<td>$4,000,000,000</td>
</tr>
<tr>
<td>2018</td>
<td>$4,100,000,000</td>
</tr>
<tr>
<td>2019 and thereafter</td>
<td>$2,800,000,000</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Covered entity’s branded prescription drug sales during the calendar year that are:</th>
<th>Percentage of branded prescription drug sales taken into account is</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not more than $5,000,000</td>
<td>0 percent</td>
</tr>
<tr>
<td>More than $5,000,000 but not more than $125,000,000</td>
<td>10 percent</td>
</tr>
<tr>
<td>More than $125,000,000 but not more than $225,000,000</td>
<td>40 percent</td>
</tr>
<tr>
<td>More than $225,000,000 but not more than $400,000,000</td>
<td>75 percent</td>
</tr>
<tr>
<td>More than $400,000,000</td>
<td>100 percent</td>
</tr>
</tbody>
</table>

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

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

(2) For each sales year, the IRS will calculate the aggregate branded prescription drug sales taken into account for all covered entities. The resulting number is the denominator of the ratio described in paragraph (d)(2) of this section.
(d) Allocated fee calculation. For each covered entity for each fee year, the IRS will calculate the entity’s allocated fee by multiplying the applicable amount from paragraph (a)(2) of this section by a fraction—

(1) The numerator of which is the covered entity’s branded prescription drug sales taken into account during the sales year (described in paragraph (c)(1) of this section); and

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

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

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

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

(1) The covered entity’s allocated fee;

(2) The covered entity’s branded prescription drug sales, by NDC, by Program;

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

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

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


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

§51.7T Dispute resolution process (temporary).

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The covered entity’s allocated fee;
(2) After the 2011 fee year, an adjustment amount calculated as described in §51.5T;
(3) The covered entity’s branded prescription drug sales, by NDC, by Program;
(4) The covered entity’s branded prescription drug sales taken into account after application of §51.5T(a)(3);
(5) The aggregate branded prescription drug sales taken into account for all covered entities; and
(6) The final determination with respect to error reports.

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

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

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

§51.9T Tax treatment of fee (temporary).

(a) Treatment as an excise tax. The fee imposed by section 9008 is treated as an excise tax for purposes of subtitle F of the Code (sections 6001–7874). Thus, references in subtitle F to “taxes imposed by this title,” “internal revenue tax,” and similar references, are also references to the fee imposed by section 9008. For example, the fee imposed by section 9008 is assessed at the conclusion of the dispute resolution process.

(b) Deficiency procedures. The deficiency procedures of sections 6211–6216 of 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 at the conclusion of the dispute resolution process.

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

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

§51.10T Refund claims (temporary).

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

§51.11T Effective/applicability date (temporary).

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

§51.12T Expiration date (temporary).

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

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

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

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

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

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

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

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

§602.101 OMB Control numbers.

(a) * * *

(b) * * *
SUMMARY: This document contains regulations amending a Treasury Regulation to provide guidance as to the only ways to establish \textit{prima facie} evidence of delivery of documents that have a filing deadline prescribed by the internal revenue laws, absent direct proof of actual delivery. The regulations provide that the proper use of registered or certified mail, or a service of a private delivery service (PDS) designated under criteria established by the IRS, will constitute \textit{prima facie} evidence of delivery. The regulations are necessary to provide greater certainty on this issue and to provide specific guidance. The regulations affect taxpayers who mail Federal tax documents to the Internal Revenue Service or the United States Tax Court.

DATES: Effective Date: These regulations are effective on August 23, 2011.

Applicability Date: These regulations apply to any payment or document mailed and delivered in accordance with the requirements of this section in an envelope bearing a postmark dated after September 21, 2004.

FOR FURTHER INFORMATION CONTACT: Steven Karon, (202) 622–4570 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1899. The collection of information in these final regulations is in §301.7502–1. This information is required in order for taxpayers to be able to establish the postmark date and \textit{prima facie} evidence of delivery when using certified or registered mail.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number.

Books or records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains regulations amending 26 CFR part 301 under section 7502 of the Internal Revenue Code (Code). Section 7502(a) first appeared as part of the recodification of the Code in 1954. Section 7502(a) is commonly known as the timely mailing/timely filing rule. Section 301.7502–1 of the Procedure and Administration Regulations provides rules for taxpayers to follow to qualify for favorable treatment under section 7502. There is a conflict among the Federal circuit courts of appeal as to whether the provisions in section 7502 provide the exclusive means to establish \textit{prima facie} evidence of delivery of a document to the IRS or the United States Tax Court. Specifically, courts have reached differing conclusions regarding whether a taxpayer may raise a presumption of delivery of Federal tax documents to the IRS and the United States Tax Court only in situations in which the taxpayer uses registered or certified mail.

A notice of proposed rulemaking (REG–138176–02, 2004–2 C.B. 710) was published in the Federal Register (69 FR 56377) on September 21, 2004. The proposed regulations clarified that, other than direct proof of actual delivery, the exclusive means to establish \textit{prima facie} evidence of delivery of Federal tax documents to the IRS and the United States Tax Court is to prove the use of registered or certified mail. Under section 7502(f)(3), the IRS may extend to a service provided by a PDS a rule similar to the \textit{prima facie} evidence of delivery rule applicable to certified and registered...
mail. Prior to the publication of the notice of proposed rulemaking, the IRS had not received any comments or suggestions for extending this rule, even though the IRS and the Treasury Department previously requested comments in a prior notice of proposed rulemaking under section 7502. See Federal Register, 64 FR 2606 (January 15, 1999). Because the IRS was clarifying what documentation it will accept as proof of delivery, additional comments were sought on this issue. Accordingly, the notice of proposed rulemaking, the IRS and the Treasury Department encouraged the public to make comments regarding whether the prima facie evidence of delivery rule should be extended to a service provided by a PDS.

Eighteen written comments were received in response to the notice of proposed rulemaking. Three commenters requested a public hearing. A notice of public hearing on proposed rulemaking was published in the Federal Register (69 FR 68282) on November 24, 2004. A public hearing was held on January 11, 2005. Three commenters appeared at the public hearing and commented on the notice of proposed rulemaking.

All comments were considered and are available for public inspection upon request. After consideration of the written comments and the comments provided at the public hearing, the proposed regulations under section 7502 are adopted as revised by this Treasury Decision. The public comments, public hearing, and the revisions are discussed in this preamble.

Summary of Comments and Explanation of Provisions

Four commenters expressed concern that the proposed regulations limited the proof to satisfy the timely mailing/timely filing rule of section 7502(a) rather than the prima facie evidence of delivery rule of section 7502(c). These final regulations do not limit the use of U.S. Mail, other delivery options offered by the United States Postal Service (USPS), or a PDS for purposes of satisfying the timely mailing/timely filing rule of section 7502(a). Instead, these final regulations clarify the prima facie evidence of delivery rule of section 7502(c).

Seven commenters suggested that the proposed regulations provide that evidence of proper use of a service offered by a PDS should establish prima facie evidence of delivery of Federal tax documents to the IRS and the United States Tax Court. Seven commenters observed that PDSs offered services similar to certified and registered mail, and that the services offered by the PDSs were as reliable as registered mail and certified mail. Two commenters noted that PDSs generally provide a greater level of detail with respect to tracking and delivery information than certified and registered mail for purposes of establishing proof of delivery. Three commenters expressed concern that it is inconsistent to permit individuals to rely upon PDSs to satisfy the timely mailing/timely filing rule of section 7502(a), but not for section 7502(c). One commentator observed that section 7502(f)(3) requires that the Treasury Secretary and the IRS consider PDS alternatives as substitutes for certified and registered mail.

After considering comments received on the proposed regulations, these final regulations provide that the Treasury Department and IRS will issue guidance that will establish the criteria to be used to designate PDSs for purposes of the prima facie evidence of delivery rule. Cf. Notice 2004–83, 2004–2 C.B. 1030 (listing PDSs that the Secretary has designated pursuant to section 7502(f)(2)) (see §601.601(d)(2)(ii)(b) of this chapter); Rev. Proc. 97–19, 1997–1 C.B. 644 (providing the criteria to determine whether a PDS qualifies as a designated private delivery service under section 7502(f) and the procedures under which a PDS can apply to become a designated PDS) (see §601.601(d)(2)(ii)(b) of this chapter). Thus, these final regulations provide that, other than direct proof of actual delivery, proof of proper use of registered or certified mail (registered or certified mail sender’s receipt), and proof of proper use of a PDS duly designated under criteria established by the IRS, are the sole means to establish prima facie evidence of delivery of documents that have a filing deadline prescribed by the internal revenue laws.

The existing regulations under section 7502 are being reorganized. Section 301.7502–1(e) will still be entitled “Delivery,” but will now focus on the requirement for actual delivery or the use of one of the means discussed above to establish a presumption of delivery. Former paragraph (e)(2) and the example in paragraph (e)(3) are moved to paragraph (b)(2) to consolidate the discussion of the effect of section 7502 on certain claims for refund.

Section 7502 does not authorize the Treasury Department or the IRS to adopt a rule that would permit USPS services in addition to certified and registered mail to establish prima facie evidence of delivery. Congress has been clear when it intended to change section 7502 to allow proof of delivery by other means. In 1958, Congress amended section 7502 to provide the IRS with the authority to treat certified mail the same as registered mail. See Technical Amendments Act of 1958, Public Law No. 85–866 (72 Stat. 1606 (1958)). Congress also amended section 7502 to authorize the IRS to publish rules providing the extent to which a PDS is the equivalent of certified mail. See Taxpayer Bill of Rights 2, Public Law No. 104–168 (110 Stat. 1452 (1996)); Internal Revenue Service Restructuring and Reform Act of 1998, Public Law No. 105–206 (112 Stat. 685 (1998)). Similar legislation would be necessary to authorize the IRS to treat additional USPS services as prima facie evidence of delivery.

Two commenters expressed concern that certified and registered mail services are expensive and inconvenient in comparison to first class mail. These commenters suggested that regular first class mail should suffice to establish prima facie evidence of delivery. As described above, the prima facie evidence of delivery rule provides an exception to the actual delivery rule. Absent actual delivery, however, first class mail without additional services provides nothing, such as certified or registered mail receipt, to establish proof of delivery. Moreover, without legislative action, the Treasury Department and the
Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 is amended by removing the entry for §301.7502–1T to read in part as follows:

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

Par. 2. Section 301.7502–1 is amended by:

1. Revising paragraphs (b)(2) and (e).

2. Adding paragraphs (c)(3) and (g)(4).

The additions and revisions read as follows:

§301.7502–1 Timely mailing of documents and payments treated as timely filing and paying.

* * * * *

(b) * * *

(2) Claims for refund—(i) In general.

In the case of certain taxes, a return may constitute a claim for credit or refund. Section 7502 is applicable to the determination of whether a claim for credit or refund is timely filed for purposes of section 6511(a) if the conditions of section 7502 are met, irrespective of whether the claim is also a return. For rules regarding claims for refund on late filed tax returns, see paragraph (f) of this section. Section 7502 is also applicable when a claim for credit or refund is delivered after the last day of the period specified in section 6511(b)(2)(A) or in any other corresponding provision of law relating to the limit on the amount of credit or refund that is allowable.

(ii) Example. The rules of paragraph (b)(2)(i) of this section are illustrated by the following example:

Example. (A) Taxpayer A, an individual, mailed his 2004 Form 1040, “U.S. Individual Income Tax Return,” on May 10, 2005, but no tax was paid at that time because the tax liability disclosed by the return had been completely satisfied by the income tax that had been withheld on A’s wages. On April 15, 2008, A mails, in accordance with the requirements of this section, a Form 1040X, “Amended U.S. Individual Income Tax Return,” claiming a refund of a portion of the tax that had been paid through withholding during 2004. The date of the postmark on the envelope containing the claim for refund is April 15, 2008. The claim is received by the IRS on April 18, 2008.

(B) Under section 6511(a), A’s claim for refund is timely if filed within three years from May 10, 2005, the date on which A’s 2004 return was filed. As a result of the limitations of section 6511(b)(2)(A), if A’s claim is not filed within three years after April 15, 2005, the date on which A is deemed under section 6513 to have paid his 2004 tax, A is not entitled to any refund. Because A’s claim for refund is postmarked and mailed in accordance with the requirements of this section and is delivered after the last day of the period specified in section 6511(b)(2)(A), section 7502 is applicable and the claim is deemed to have been filed on April 15, 2008. * * * * *

(c) * * *

(3) Private delivery services. Under section 7502(f)(1), a service of a private delivery service (PDS) may be treated as an equivalent to United States mail for purposes of the postmark rule if the Commissioner determines that the service satisfies the conditions of section 7502(f)(2). Thus, the Commissioner may, in guidance published in the Internal Revenue Bulletin (see §601.601(d)(2)(ii)(b) of this chapter), prescribe procedures and additional rules to designate a service of a PDS for purposes of the postmark rule of section 7502(a).

* * * * *

(e) Delivery—(1) General rule. Except as provided in section 7502(f) and paragraphs (c)(3) and (d) of this section, section 7502 is not applicable unless the document or payment is delivered by U.S. mail to the agency, officer, or office with which the document is required to be filed or to which payment is required to be made.

(2) Exceptions to actual delivery—(i) Registered and certified mail. In the case of a document (but not a payment) sent by registered or certified mail, proof that the document was properly registered or that a postmarked certified mail sender’s receipt was properly issued and that the envelope was properly addressed to the agency, officer, or office constitutes _prima facie_ evidence that the document was delivered to the agency, officer, or office. Other than direct proof of actual delivery, proof of proper use of registered or certified mail, and proof of proper use of a duly designated PDS as provided for by paragraph (e)(2)(ii) of this section, are the exclusive means to establish _prima facie_ evidence of delivery of a document to the agency, officer, or office with which the document is required to be filed. No other evidence of a postmark or of mailing will be _prima facie_ evidence of delivery.
evidence of delivery or raise a presumption that the document was delivered.

(ii) **Equivalents of registered and certified mail.** Under section 7502(f)(3), the Secretary may extend the *prima facie* evidence of delivery rule of section 7502(c)(1)(A) to a service of a designated PDS, which is substantially equivalent to United States registered or certified mail. Thus, the Commissioner may, in guidance published in the Internal Revenue Bulletin (see §601.601(d)(2)(ii)(b) of this chapter), prescribe procedures and additional rules to designate a service of a PDS for purposes of demonstrating *prima facie* evidence of delivery of a document pursuant to section 7502(c).

* * * * *

(g) * * *

(4) Registered or certified mail as the means to prove delivery of a document. Section 301.7502–1(e)(2) will apply to all documents mailed after September 21, 2004.

* * * * *

Steven T. Miller,
Deputy Commissioner for Services and Enforcement.

Approved August 10, 2011.

Emily S. McMahon,
Acting Assistant Secretary (Tax Policy).

(*Filed by the Office of the Federal Register on August 22, 2011, 8:45 a.m., and published in the issue of the Federal Register for August 23, 2011, 76 F.R. 52561*)
Part III. Administrative, Procedural, and Miscellaneous

Request for Comments on Health Coverage Affordability Safe Harbor for Employers (Section 4980H)

Notice 2011–73

I. PURPOSE AND BACKGROUND

This request for comments is intended to continue the process of developing regulatory guidance on the shared employer responsibility provisions of § 4980H of the Internal Revenue Code (Code). The process was initiated with the release of Notice 2011–36, 2011–21 I.R.B. 792, which described potential approaches to interpreting and applying certain provisions of § 4980H and invited comments on those approaches. Section 4980H was added to the Code by § 1513 of the Patient Protection and Affordable Care Act (Affordable Care Act) enacted March 23, 2010, Pub. L. No. 111–148, and amended by § 1003 of the Health Care and Education Reconciliation Act of 2010, enacted March 30, 2010, Pub. L. No. 111–152. Section 4980H is effective for months beginning after December 31, 2013.

Generally, § 4980H provides that an applicable large employer (as defined in § 4980H(c)(2)) is subject to an assessable payment if any full-time employee (and their dependents) is offered an applicable premium tax credit or cost-sharing reduction and either (1) the employer does not offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (§ 4980H(a))1; or (2) the employer offers its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan, and (2) the employer portion of the self-only premium for the employer’s lowest cost coverage that provides minimum value (the employee contribution) must not exceed 9.5 percent of the employee’s household income for the taxable year.2

II. PROPOSED AFFORDABILITY SAFE HARBOR FOR EMPLOYERS

Whether an applicable large employer’s health coverage is affordable to its full-time employees is essential in determining whether an employee can receive a premium tax credit and, in turn, whether the employer is subject to an assessable payment under § 4980H(b). Coverage under an employer-sponsored plan is affordable to a particular employee if the employee’s required contribution (within the meaning of § 5000A(e)(1)(B)) to the plan does not exceed 9.5 percent of the employer’s household income for the taxable year.2 Section 36B(c)(2)(C)(i). Household income for this purpose is defined as the modified adjusted gross income of the employee and any members of the employee’s family (which would include any spouse and dependents) who are required to file an income tax return. Section 36B(d)(2)(A).

Modified adjusted gross income means adjusted gross income (within the meaning of § 62) increased by amounts excluded from gross income under § 911 and by the amount of any tax-exempt interest a taxpayer receives or accrues during the taxable year. Section 36B(d)(2)(B).

Because affordability is determined by reference to household income and because household income is determined by reference to variables that are generally unknown to an employer (i.e., the modified adjusted gross income of the employee and the employee’s spouse and dependents), employers may encounter practical difficulties in assessing whether the coverage they are offering is affordable to certain employees. To address this concern and provide employers a more workable option for determining the affordability of their health coverage, Treasury and the IRS expect to propose an affordability safe harbor whereby, for purposes of § 4980H(b), affordability of an employer’s coverage would be measured by reference to an employee’s wages from that employer. Wages for this purpose would be the total amount of wages as defined in § 3401(a), which is the amount required to be reported in Box 1 of Form W–2, Wage and Tax Statement (W–2 wages).

It is contemplated that under this proposed safe harbor, an employer would need to meet certain requirements, including: (1) that the employer must offer its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan, and (2) that the employer portion of the self-only premium for the employer’s lowest cost coverage that provides minimum value (the employee contribution) must not exceed 9.5 percent of the employee’s W–2 wages. If the employer satisfies both of these requirements for a particular employee (as well as any other conditions for the safe harbor), the employer would not be subject to an assessable payment under § 4980H(b) with respect to that particular employee, even if that employee receives a premium tax credit or cost sharing reduction. Application of this safe harbor would be determined after the end of the calendar year and on an employee-by-employee basis, taking into account the W–2 wages and the employee contribution. So, for example, the employer would determine whether it met the proposed affordability safe harbor for 2014 for an employee by looking at that employee’s W–2 wages for 2014 and comparing 9.5 percent of that amount to the employee’s 2014 employee contribution.

1 Minimum essential coverage is defined in § 5000A(f) of the Code. The definition of “eligible employer-sponsored plan” in § 5000A(f)(2) applies for purposes of § 4980H.

2 The 9.5 percent may be adjusted after 2014 to reflect rates of premium growth relative to growth in income and after 2018 to reflect rates of premium growth relative to growth in the consumer price index. See Prop. Treas. Reg. §§ 1.36B–0 through 1.36B–5.
Although the determination of whether an employer actually satisfied the safe harbor would be made after the end of the calendar year, an employer could also use the safe harbor prospectively, at the beginning of the year, by structuring its plan and operations to set the employee contribution at a level so that the employee contribution for each employee would not exceed 9.5 percent of that employee’s W–2 wages for that year. It is contemplated that employers, on a consistent basis, would be permitted to make reasonable and necessary adjustments for pay periods so that the employee contribution does not exceed 9.5 percent of the employee’s W–2 wages.

By allowing employers to base their affordability calculations on each employee’s W–2 wages (which employers know) instead of each employee’s household income (which employers generally would not know), the safe harbor could provide a more workable and practical method for measuring the affordability of an employer’s coverage for § 4980H(b) purposes. In most instances, if employer-sponsored coverage were affordable based on the employee’s W–2 wages, it would also be affordable based on the employee’s household income because an employee’s household income is likely to be greater than the employee’s W–2 wages. In that case, a premium tax credit would not be available to that employee and, in turn, the employer would not be subject to an assessable payment under § 4980H(b) with respect to that employee. In some circumstances, an employee’s household income may be less than the employee’s W–2 wages. In that case, a premium tax credit could be treated as unaffordable (based on household income) for purposes of determining whether the employee is eligible for a premium tax credit under § 36B.

III. REQUEST FOR COMMENTS

As noted, Treasury and the IRS intend to issue guidance, including proposed regulations, on the employer shared responsibility provisions under § 4980H. To help inform that guidance, comments are invited on the affordability safe harbor for employers for purposes of § 4980H(b). In particular, comments are invited on the following issues:

- Whether or how wages and employee contribution amounts would need to be determined for employees who are employed by an employer for less than a full year, employees who move between full-time and part-time status, situations in which the plan year is not a calendar year, and other similar special circumstances.
- Whether there are other possible safe harbor methods for determining the affordability of coverage under an employer-sponsored plan for purposes of calculating an employer’s potential assessable payment under § 4980H(b).
- How to coordinate any affordability safe harbor with the full-time employee look-back/stability safe harbor described in Notice 2011–36.

Comments must be submitted by December 13, 2011. Comments should include a reference to Notice 2011–73. Send submissions to CC:PA:LPD:PR (Notice 2011–73), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2011–73), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC 20044, or sent electronically, via the following e-mail address: Notice.comments@irs.counsel.treas.gov. Please include “Notice 2011–73” in the subject line of any electronic communication. All material submitted will be available for public inspection and copying.

NO INFERENCE

No inference should be drawn from any provision of this notice concerning any other provision of § 4980H or any other section of the Affordable Care Act.

DRAFTING INFORMATION

The principal author of this notice is Mireille Khoury of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). For further information regarding this notice, contact Mireille Khoury at (202) 622–6080 (not a toll-free call).

Update for Weighted Average Interest Rates, Yield Curves, and Segment Rates

Notice 2011–75

This notice provides guidance as to the corporate bond weighted average interest rate and the permissible range of interest rates specified under § 412(b)(5)(B)(ii)(II) of the Internal Revenue Code as in effect for plan years beginning before 2008. It also provides guidance on the corporate bond monthly yield curve (and the corresponding spot segment rates), and the 24-month average segment rates under § 430(h)(2). In addition, this notice provides guidance as to the interest rate on 30-year Treasury securities under § 417(e)(3)(A)(ii)(II) as in effect for plan years beginning before 2008, the 30-year Treasury weighted average rate under § 431(c)(6)(E)(ii)(I), and the minimum present value segment rates under § 417(e)(3)(D) as in effect for plan years beginning after 2007.
CORPORATE BOND WEIGHTED AVERAGE INTEREST RATE

Sections 412(b)(5)(B)(ii) and 412(l)(7)(C)(i), as amended by the Pension Funding Equity Act of 2004 and by the Pension Protection Act of 2006 (PPA), provide that the interest rates used to calculate current liability and to determine the required contribution under § 412(l) for plan years beginning in 2004 through 2007 must be within a permissible range based on the weighted average of the rates of interest on amounts invested conservatively in long term investment grade corporate bonds during the 4-year period ending on the last day before the beginning of the plan year.

Notice 2004–34, 2004–1 C.B. 848, provides guidelines for determining the corporate bond weighted average interest rate and the resulting permissible range of interest rates used to calculate current liability. That notice establishes that the corporate bond weighted average is based on the monthly composite corporate bond rate derived from designated corporate bond indices. The methodology for determining the monthly composite corporate bond rate as set forth in Notice 2004–34 continues to apply in determining that rate. See Notice 2006–75, 2006–2 C.B. 366.

The composite corporate bond rate for August 2011 is 4.99 percent. Pursuant to Notice 2004–34, the Service has determined this rate as the average of the monthly yields for the included corporate bond indices for that month.

The following corporate bond weighted average interest rate was determined for plan years beginning in the month shown below.

<table>
<thead>
<tr>
<th>For Plan Years Beginning in</th>
<th>Corporate Bond Weighted Average</th>
<th>Permissible Range</th>
</tr>
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<tbody>
<tr>
<td>Month</td>
<td>Year</td>
<td></td>
</tr>
<tr>
<td>September</td>
<td>2011</td>
<td>5.91</td>
</tr>
</tbody>
</table>

YIELD CURVE AND SEGMENT RATES

Generally for plan years beginning after 2007 (except for delayed effective dates for certain plans under sections 104, 105, and 106 of PPA), § 430 of the Code specifies the minimum funding requirements that apply to single employer plans pursuant to § 412. Section 430(h)(2) specifies the interest rates that must be used to determine a plan’s target normal cost and funding target. Under this provision, present value is generally determined using three 24-month average interest rates (“segment rates”), each of which applies to cash flows during specified periods. However, an election may be made under § 430(h)(2)(D)(ii) to use the monthly yield curve in place of the segment rates. Section 430(h)(2)G) set forth a transitional rule applicable to plan years beginning in 2008 and 2009 under which the segment rates were blended with the corporate bond weighted average described above, including an election under § 430(h)(2)(G)(iv) for an employer to use the segment rates without the transitional rule.

Notice 2007–81, 2007–2 C.B. 899, provides guidelines for determining the monthly corporate bond yield curve, the 24-month average corporate bond segment rates, and the funding transitional segment rates used to compute the target normal cost and the funding target. Pursuant to Notice 2007–81, the monthly corporate bond yield curve derived from August 2011 data is in Table I at the end of this notice. The spot first, second, and third segment rates for the month of August 2011 are, respectively, 1.85, 4.62, and 6.02. The three 24-month average corporate bond segment rates applicable for September 2011 under the election of § 430(h)(2)(G)(iv) are as follows:

<table>
<thead>
<tr>
<th>Segment</th>
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<tbody>
<tr>
<td>First Segment</td>
<td>2.06</td>
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<tr>
<td>Second Segment</td>
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<td></td>
</tr>
<tr>
<td>Third Segment</td>
<td>6.32</td>
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</tr>
</tbody>
</table>

The transitional rule of § 430(h)(2)(G) does not apply to plan years beginning after December 31, 2009. Therefore, for a plan year beginning after 2009 with a lookback month to September 2011, the funding segment rates are the three 24-month average corporate bond segment rates applicable for September 2011, listed above without blending for any transitional period.

30-YEAR TREASURY SECURITIES INTEREST RATES

Section 417(e)(3)(A)(ii)(II) (prior to amendment by PPA) defines the applicable interest rate, which must be used for purposes of determining the minimum present value of a participant’s benefit under § 417(e)(1) and (2), as the annual rate of interest on 30-year Treasury securities for the month before the date of distribution or such other time as the Secretary may by regulations prescribe. Section 1.417(e)–1(d)(3) of the Income Tax Regulations provides that the applicable interest rate for a month is the annual rate of interest on 30-year Treasury securities as specified by the Commissioner for that month in revenue rulings, notices or other guidance published in the Internal Revenue Bulletin.

The rate of interest on 30-year Treasury securities for August 2011 is 3.65 percent. The Service has determined this rate as the average of the yield on the 30-year Treasury bond maturing in May 2041 determined each day through August 10, 2011, and the yield on the 30-year Treasury bond maturing in August 2041 determined each day for the balance of the month.
Generally for plan years beginning after 2007, § 431 specifies the minimum funding requirements that apply to multiemployer plans pursuant to § 412. Section 431(c)(6)(B) specifies a minimum amount for the full-funding limitation described in section 431(c)(6)(A), based on the plan’s current liability. Section 431(c)(6)(E)(ii)(I) provides that the interest rate used to calculate current liability for this purpose must be no more than 5 percent above and no more than 10 percent below the weighted average of the rates of interest on 30-year Treasury securities during the four-year period ending on the last day before the beginning of the plan year. Notice 88–73, 1988–2 C.B. 383, provides guidelines for determining the weighted average interest rate. The following rates were determined for plan years beginning in the month shown below.

<table>
<thead>
<tr>
<th>For Plan Years Beginning in</th>
<th>30-Year Treasury Weighted Average</th>
<th>Permissible Range</th>
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<tr>
<td>30-Year Treasury Weighted Average</td>
<td>4.23</td>
<td>3.81 to 4.44</td>
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**MINIMUM PRESENT VALUE SEGMENT RATES**

Generally for plan years beginning after December 31, 2007, the applicable interest rates under § 417(e)(3)(D) are segment rates computed without regard to a 24-month average. For plan years beginning in 2008 through 2011, the applicable interest rates are the monthly spot segment rates blended with the applicable rate under § 417(e)(3)(A)(ii)(II) as in effect for plan years beginning in 2007. Notice 2007–81 provides guidelines for determining the minimum present value segment rates. Pursuant to that notice, the minimum present value transitional segment rates determined for August 2011, taking into account the August 2011 30-year Treasury rate of 3.65 stated above for plan years beginning in 2010 and 2011, are as follows:

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<th>For Plan YearsBeginning in</th>
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<th>Third Segment</th>
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<td>2012</td>
<td>1.85</td>
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</table>

**DRAFTING INFORMATION**

The principal author of this notice is Tony Montanaro of the Employee Plans, Tax Exempt and Government Entities Division. Mr. Montanaro may be e-mailed at RetirementPlanQuestions@irs.gov.
### Table 1

Monthly Yield Curve for August 2011

Derived from August 2011 Data

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<th>Yield</th>
<th>Maturity</th>
<th>Yield</th>
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Due Dates for Filing Form 706, Form 706-NA, or Form 8939, Extension of Time to Pay Estate Tax, and Penalty Relief for Recipients of Property Acquired from Decedents who Died in 2010

Notice 2011–76

Purspose

This notice provides the executor of an estate of a decedent who died in 2010 (Executor of a 2010 Estate) who timely files a Form 4768, Application for Extension of Time To File a Return and/or Pay U.S. Estate (and Generation-Skipping Transfer) Taxes, an automatic extension of time to file an estate tax return and to pay the estate tax due. Furthermore, this notice revises the due date of Form 8939, Allocation of Increase in Basis for Property Acquired From a Decedent. It also provides penalty relief to certain persons who acquired property, the basis of which is determined under section 1022, and disposed of such property during 2010. This notice applies to each Executor of a 2010 Estate and to recipients of property acquired from decedents who died in 2010.

Background

In General

Section 501 of the Economic Growth and Tax Relief Reconciliation Act of 2001, P.L. 107–16 (115 Stat. 69) (EGTRRA), repealed the estate tax for the estates of decedents who died in 2010 (2010 Decedents). EGTRRA also repealed section 1014 and replaced it with section 1022. Section 1014 generally provides that the recipient’s basis in property passing from a decedent is the fair market value (FMV) of the property on the decedent’s date of death. Section 1022 generally provides that the recipient’s basis in property acquired from a decedent is the lesser of the decedent’s adjusted basis in the property and the FMV of the property on the decedent’s date of death.

Section 301(a) of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, P.L. 111–312 (124 Stat. 3296) (TRUIRJCA), repealed section 501 of EGTRRA and section 1022. The repeal of EGTRRA retroactively reinstated the estate tax for 2010 Decedents and also reinstated section 1014. TRUIRJCA also increased the applicable exclusion amount to $5,000,000 for 2010 Decedents. Section 301(c) of TRUIRJCA, however, allows the Executor of a 2010 Estate to elect not to have the estate tax provisions and section 1014 apply, but rather, to have the provisions of section 1022 apply (Section 1022 Election). With the election, the estate will pay no estate tax and in most cases the basis of the property acquired from the decedent will be determined under section 1022. In addition, the executor may allocate additional basis to certain property. See Rev. Proc. 2011–41, 2011–35 I.R.B. 188.

Filing and Payment Dates

Under section 301(d) of TRUIRJCA, the due date for filing an estate tax return and for paying the estate tax for an estate of a decedent who died after December 31, 2009, and before December 17, 2010, is no earlier than September 17, 2011. The due date, therefore, for estates of decedents who died on or after January 1, 2010, and on or before December 16, 2010, is September 19, 2011, because September 17, 2011, falls on a Saturday. Under section 6075(a), the due date for filing an estate tax return for a decedent who died after December 16, 2010, is nine months after the date of the decedent’s death. Section 6151 provides that, when a tax return is required, the person required to make such return shall pay such tax at the time and place fixed for filing the return (determined without regard to any extension of time for filing the return).

Section 542 of EGTRRA provides that the return required under former section 6018 (Form 8939, which is filed to make a Section 1022 Election, to report the information required under section 6018, and to allocate additional basis under section 1022) shall be filed with the decedent’s final income tax return (for example: Form 1040, United States Individual Income Tax Return, or Form 1040-NR, United States Nonresident Alien Income Tax Return) or by such later date specified in regulations prescribed by the Secretary. Notice 2011–66, 2011–35 I.R.B. 184, which the Treasury Department and IRS intend to confirm in regulations, provides that Form 8939 is due on or before November 15, 2011.

Section 6081 provides that the Secretary may grant a reasonable extension of time for filing any return and that, except in the case of taxpayers who are abroad, no such extension may be for more than six months. In addition, section 6161(a) provides that the Secretary may extend the time for payment of the amount of the tax shown, or required to be shown, on any return for a reasonable period from the date fixed for payment thereof.

Guidance

Forms 706 and 706-NA

Because of the date Congress enacted TRUIRJCA and the length of time required to implement the legislative changes and to issue the Form 8939 with related instructions, the Executor of a 2010 Estate may not have sufficient time to make an informed decision as to whether or not to make a Section 1022 Election and to complete the required filings. Therefore, the Treasury Department and IRS believe it is reasonable to grant the estates of 2010 Decedents an automatic extension of time to file the estate tax return and an extension of time to pay the estate tax. Accordingly, the Treasury Department and IRS grant the Executor of a 2010 Estate who files a Form 4768 by the due date for filing Form 706, United States Estate (and Generation-Skipping Transfer) Tax Return, or Form 706-NA, United States Estate (and Generation-Skipping Transfer) Tax Return Estate of Nonresident not a Citizen of the United States, both an automatic six-month extension of time to file Form 706 or Form 706-NA pursuant to section 6081, and a six-month extension of time to pay the estate tax. The Executor of a 2010 Estate is not required to substantiate on the Form 4768 the reason for requesting an extension of time for payment of the estate tax to receive the six-month extension of time to pay the estate tax due. However, interest will accrue on the estate tax liability from the due date of the return, excluding extensions. See I.R.C. § 6601.

Except in the case of an executor abroad, under section 6081, the Treasury...
Department and IRS cannot grant additional extensions of time to file Form 706 or Form 706-NA to such estates, regardless of whether an executor files a Form 4768 requesting an additional extension of time to file. An executor, however, may apply for an additional extension of time to pay the estate tax under section 6161 if the executor files a Form 4768 on or before the extended due date of the payment of tax and provides the documentation required with such form. See I.R.C. § 6161.

The IRS will not impose late filing and late payment penalties under section 6651(a)(1) or (2) on estates of decedents who died after December 31, 2009, and before December 17, 2010, if the estate timely files Form 4768 and then files Form 706 or Form 706-NA and pays the estate tax by March 19, 2012. The IRS also will not impose late filing or late payment penalties under section 6651(a)(1) or (2) on estates of decedents who died after December 16, 2010, and before January 1, 2011, if the estate timely files Form 4768 and then files Form 706 or Form 706-NA and pays the estate tax within 15 months after the decedent’s date of death.

Form 8939

The due date for filing Form 8939 is changed from November 15, 2011, to January 17, 2012. Thus, a Section 1022 Election is timely if made on a Form 8939 filed by (and may be amended or revoked on or before) January 17, 2012. The Treasury Department and IRS will not grant any further extension of time to file Form 8939, to make the Section 1022 Election, or to amend or revoke the Section 1022 Election, except as provided in sections I.A, B, or D.1 or 2 of Notice 2011–66. Accordingly, as contemplated in section I.D.2 of Notice 2011–66, an executor may file an amended Form 8939 if the provisions of § 301.9100–2(b) are satisfied, by July 17, 2012.

Moreover, the penalty under section 6716 does not apply to the Executor of a 2010 Estate solely because the Form 8939 is filed after November 15, 2011, but on or before January 17, 2012. Similarly, a penalty under section 6716 does not apply to the Executor of a 2010 Estate solely because a statement required to be furnished to beneficiaries is provided after December 15, 2011, but on or before February 17, 2012.

Generation-Skipping Transfer (GST) Tax

If an executor makes a Section 1022 Election on a Form 8939 filed on or before January 17, 2012, and allocates the decedent’s available GST exemption (or makes an election under the GST tax) on an attached Schedule R or R–1, the allocation or election will be considered timely and effective as of the decedent’s date of death pursuant to section 2632. Alternatively, the automatic allocation rules under section 2632 will apply if the executor timely files the Form 8939 without attaching a Schedule R or R–1. If the executor does not make the Section 1022 Election or if the executor timely revokes a Section 1022 Election, then the automatic allocation rules under section 2632 will apply unless the executor timely files Form 706 or Form 706-NA with the Schedule R or R–1 attached.

Federal Income Tax Return for any Individual, Estate, or Trust, Form 709, and State Estate or Inheritance Tax

This notice does not extend the due date for paying any income tax or for filing any income tax return for any individual, estate, or trust (for example, Form 1040, Form 1040-NR, or Form 1041, United States Income Tax Return for Estates & Trusts). In addition, this notice does not extend the due date for paying any gift tax or for filing any Form 709, United States Gift (and Generation-Skipping-Transfer) Tax Return. Finally, this notice does not extend the time to file an estate or inheritance tax return required by any state of the United States or to pay any estate or inheritance tax due to such state.

Penalty Relief

Section 6651(a)(2) generally provides that, in the case of any failure to pay the tax shown on any return required to be filed under subchapter A of chapter 61 on its due date, unless it is shown that the failure is due to reasonable cause and not willful neglect, an addition to tax shall apply. In addition, section 6662(a) imposes a 20 percent penalty on any portion of an underpayment of tax due to negligence, disregard of rules or regulations, or a substantial understatement of income tax. Section 6664(c) provides that no penalty under section 6662(a) shall be imposed on any portion of an underpayment if it is shown that there is a reasonable cause for such portion and that the taxpayer acted in good faith with respect to such portion.

Revenue Procedure 2011–41 provides a safe harbor for determining a recipient’s basis and other pertinent information such as the tax character and holding period of property acquired from a 2010 Decedent and whose executor makes a Section 1022 Election. However, when the recipient of property acquired from a decedent who disposed of such property during 2010 files the recipient’s income tax return, the recipient may not know whether the decedent’s executor will make the Section 1022 Election and, if so, the amount (if any) of Basis Increase (as defined in Rev. Proc. 2011–41) the executor will allocate to that property. Therefore, the recipient may not know the property’s basis or other pertinent information such as tax character and holding period. When filing the recipient’s income tax return and computing the income tax liability, the recipient will have to make a good faith estimate, based on the facts and circumstances, regarding such information with respect to the property acquired from the 2010 Decedent. Accordingly, to the extent that the recipient’s tax liability is increased, as shown on an amended return or otherwise, by reason of the application of section 1022 to the estate of a 2010 Decedent, the recipient’s reasonable cause and good faith will be presumed and the Treasury Department and IRS will not impose either the section 6651(a)(2) addition to tax for failure to pay, or the section 6662(a) penalty. The recipient should write across the top of the amended return “IR Notice 2011–76” to alert the IRS that the recipient meets these requirements for reasonable cause.

EFFECTIVE DATE

This notice is effective on September 13, 2011. This notice applies to each Executor of a 2010 Estate and to persons acquiring property from a 2010 Decedent.

DRAFTING INFORMATION

The principal authors of this notice are Laura Daly, Theresa Melchiorre, and...
Mayer Samuels of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this notice, contact Laura Daly, Theresa Melchiorre, or Mayer Samuels at (202) 622–3090 (not a toll-free call).
Notice of Proposed Rulemaking by Cross-Reference to Temporary Regulations

Branded Prescription Drug Fee

REG–112805–10

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In this issue of the Bulletin, the IRS is issuing temporary regulations (T.D. 9544) relating to the branded prescription drug fee imposed by the Affordable Care Act (ACA). The regulations affect persons engaged in the business of manufacturing or importing certain branded prescription drugs. The text of the temporary regulations also serves as the text of the proposed regulations.

DATES: Written and electronic comments and requests for a public hearing must be received by November 16, 2011.


FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Celia Gabrysh at (202) 622–3130; concerning submissions of comments and request for a hearing Richard.A.Hurst@irsounsel.treas.gov, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking has been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d) and assigned control number 1545–2209.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by October 17, 2011. Comments are specifically requested concerning:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;
- The accuracy of the estimated burden associated with the proposed collection of information;
- How the quality, utility, and clarity of the information to be collected may be enhanced;
- How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and
- Estimates of capital or start-up costs of operation, maintenance, and purchase of service to provide information.

The collection of information in this proposed regulation is in §51.7. This information is necessary to evaluate whether an error report regarding a preliminary fee calculation is valid and justifies an adjustment to the preliminary fee calculation. The likely respondents are manufacturers and importers of branded prescription drugs.

Estimated total annual reporting and/or recordkeeping burden: 1800 hours.

Estimated annual burden per respondent/recordkeeper: 40 hours.

Estimated number of respondents and/or record keepers: 45

Estimated frequency of responses: Annually.

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 26 U.S.C. 6103.

Background

Temporary regulations in this issue of the Bulletin add a new part, Part 51, to subchapter D, Miscellaneous Excise Taxes. Part 51 provides 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 ACA. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the new part.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory flexibility 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 regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations primarily affect large corporations. Thus, Treasury Department and the IRS do not expect a substantial number of small entities to be effected. Therefore, a Regulatory Flexibility Analysis under the Regulatory
Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

**Comments and Requests for a Public Hearing**

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are requested on all aspects of the proposed regulations. In addition, the IRS and the Treasury Department specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the Federal Register.

**Drafting Information**

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

* * * *

**Proposed Amendments to the Regulations**

Accordingly, and under the authority of 26 U.S.C. 7805 (sec. 9008, Public Law 111–347 (124 Stat. 119)), 26 CFR part 51 is proposed to be added to read as follows:

**PART 51—BRANDED PRESCRIPTION DRUGS**

[The text of proposed §§51.1 through 51.11 is the same as the text of §§51.1T through 51.11T published elsewhere in this issue of the Bulletin.]  
[The text of proposed §51.6302–1 is the same as the text of paragraphs (a) and (b) of §51.6302–1T published elsewhere in this issue of the Bulletin.]

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

(Filed by the Office of the Federal Register on August 15, 2011, 11:15 a.m., and published in the issue of the Federal Register for August 18, 2011, 76 F.R. 51310)

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**Announcement of the Results of the 2010–2011 Allocation Round of the Qualifying Advanced Coal Project Program**

**Announcement 2011–62**

This announcement discloses the results of the 2010–11 allocation round under the qualifying advanced coal project program of § 48A of the Internal Revenue Code. This announcement also serves as notice to applicants that a 2011–12 allocation round under the qualifying advanced coal project program is currently open pursuant to Notice 2009–24, 2009–16 I.R.B. 817.

**QUALIFYING ADVANCED COAL PROJECT PROGRAM**

Section 48A provides a qualifying advanced coal project credit in an amount equal to (1) 20 percent of the qualified investment (as defined in § 48A(b)) for that taxable year in qualifying advanced coal projects (as defined in § 48A(c)(1) and (e)) described in § 48A(d)(3)(B)(i), (2) 15 percent of the qualified investment for that taxable year in qualifying advanced coal projects described in § 48A(d)(3)(B)(ii), and (3) 30 percent of the qualified investment for that taxable year in qualifying advanced coal projects described in § 48A(d)(3)(B)(iii).

Section 48A(d)(5) provides that the Secretary shall, upon making a certification under § 48A(d) or § 48B(d), publicly disclose the identity of the applicant and the amount of the credit certified with respect to such applicant.

On April 20, 2009, the Internal Revenue Service (“Service”) issued Notice 2009–24 to announce an initial allocation round for the qualifying advanced coal projects described in § 48A(d)(3)(B)(iii) (“the Phase II advanced coal program”). The Service will certify $1.25 billion of credits to qualifying projects under the Phase II advanced coal program.

Section 10.01 of Notice 2009–24 provides that the Service intends to publish the results of the allocation process, and disclose the following information in the event a qualifying advanced coal project credit under § 48A is allocated to the taxpayer’s project: (a) the name of the taxpayer and (b) the amount of the qualifying advanced coal project credit allocated to the project.


The allocation round in 2010–11 closed on March 1, 2011, and did not result in any allocation of the qualifying advanced coal project credit. Therefore, the Service will conduct an allocation round for 2011–12 in the manner and under the procedures as provided under Notice 2009–24, as modified by Notice 2011–24, 2011–14 I.R.B. 603.

The available credit amount for 2011–12 allocation round under Phase II of the qualifying advanced coal project program is $240,564,000, out of which $103,564,000 is available for qualifying advanced coal projects that use sub-bituminous coal as a primary feedstock, and $137,000,000 is available for qualifying advanced coal projects that use lignite as a primary feedstock. No credit amount is available for advanced coal projects that use bituminous coal as a primary feedstock. As provided under Notice 2009–24, the application period for the 2011–12 allocation round began on March 2, 2011, and ends on March 1, 2012, and taxpayers must submit applications.

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1 Notice 2011–24 updated the rules relating to the annual measurement of separated and sequestered carbon dioxide and applies the recapture rules of § 50(a) in the event that a taxpayer fails to attain or maintain the carbon dioxide separation and sequestration requirements of § 48A or § 48B.
to the Department of Energy (DOE) on or before November 1, 2011, and to the Service on or before March 1, 2012.

DRAFTING INFORMATION

The principal author of this announcement is Jennifer Bernardini of the Office of Associate Chief Counsel (Passthroughs & Special Industries). For further information regarding this announcement, contact Jennifer Bernardini at (202) 622–3110 (not a toll-free call).
Definition of Terms

Revenue rulings and revenue procedures (hereinafter referred to as “rulings”) that have an effect on previous rulings use the following defined terms to describe the effect:

Amplified describes a situation where no change is being made in a prior published position, but the prior position is being extended to apply to a variation of the fact situation set forth therein. Thus, if an earlier ruling held that a principle applied to A, and the new ruling holds that the same principle also applies to B, the earlier ruling is amplified. (Compare with modified, below.)

Clarified is used in those instances where the language in a prior ruling is being made clear because the language has caused, or may cause, some confusion. It is not used where a position in a prior ruling is being changed.

Distinguished describes a situation where a ruling mentions a previously published ruling and points out an essential difference between them.

Modified is used where the substance of a previously published position is being changed. Thus, if a prior ruling held that a principle applied to A but not to B, and the new ruling holds that it applies to both A and B, the prior ruling is modified because it corrects a published position. (Compare with amplified and clarified, above).

Obsoleted describes a previously published ruling that is not considered determinative with respect to future transactions. This term is most commonly used in a ruling that lists previously published rulings that are obsoleted because of changes in laws or regulations. A ruling may also be obsoleted because the substance has been included in regulations subsequently adopted.

Revoked describes situations where the position in the previously published ruling is not correct and the correct position is being stated in a new ruling.

Superseded describes a situation where the new ruling does nothing more than restate the substance and situation of a previously published ruling (or rulings). Thus, the term is used to republish under the 1986 Code and regulations the same position published under the 1939 Code and regulations. The term is also used when it is desired to republish in a single ruling a series of situations, names, etc., that were previously published over a period of time in separate rulings. If the new ruling does more than restate the substance of a prior ruling, a combination of terms is used. For example, modified and superseded describes a situation where the substance of a previously published ruling is being changed in part and is continued without change in part and it is desired to restate the valid portion of the previously published ruling in a new ruling that is self contained. In this case, the previously published ruling is first modified and then, as modified, is superseded.

Supplemented is used in situations in which a list, such as a list of the names of countries, is published in a ruling and that list is expanded by adding further names in subsequent rulings. After the original ruling has been supplemented several times, a new ruling may be published that includes the list in the original ruling and the additions, and supersedes all prior rulings in the series.

Suspended is used in rare situations to show that the previous published rulings will not be applied pending some future action such as the issuance of new or amended regulations, the outcome of cases in litigation, or the outcome of a Service study.

Abbreviations

The following abbreviations in current use and formerly used will appear in material published in the Bulletin.

A—Individual.
Acq.—Acquiescence.
B—Individual.
BE—Beneficiary.
BK—Bank.
B.T.A.—Board of Tax Appeals.
C—Individual.
CI—City.
COOP—Cooperative.
Ct.D.—Court Decision.
CY—County.
D—Decedent.
DC—Dummy Corporation.
DE—Donee.
Del. Order—Delegation Order.
DISC—Domestic International Sales Corporation.
DR—Donor.
E—Estate.
EE—Employee.
E.O.—Executive Order.
ER—Employer.
EX—Executor.
F—Fiduciary.
FC—Foreign Country.
FISC—Foreign International Sales Company.
FPH—Foreign Personal Holding Company.
FR—Federal Register.
FX—Foreign corporation.
G.C.M.—Chief Counsel’s Memorandum.
GE—Grantee.
GP—General Partner.
GR—Grantor.
IC—Insurance Company.
LE—Lessee.
LP—Limited Partner.
LR—Lessor.
M—Minor.
Nonacq.—Nonacquiescence.
O—Organization.
P—Parent Corporation.
PHC—Personal Holding Company.
PO—Possession of the U.S.
PR—Partner.
PRS—Partnership.
PTE—Prohibited Transaction Exemption.
Pub. L.—Public Law.
REIT—Real Estate Investment Trust.
Rev. Proc.—Revenue Procedure.
Rev. Rul.—Revenue Ruling.
S—Subsidiary.
Stat.—Statutes at Large.
T—Target Corporation.
T.C.—Tax Court.
T.D.—Treasury Decision.
TFE—Transferee.
TFR—Transferor.
TP—Taxpayer.
TR—Trust.
TT—Trustee.
X—Corporation.
Y—Corporation.
Z—Corporation.

October 3, 2011

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¹ A cumulative list of all revenue rulings, revenue procedures, Treasury decisions, etc., published in Internal Revenue Bulletins 2011–1 through 2011–26 is in Internal Revenue Bulletin 2011–26, dated June 27, 2011.
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1 A cumulative list of current actions on previously published items in Internal Revenue Bulletins 2011–1 through 2011–26 is in Internal Revenue Bulletin 2011–26, dated June 27, 2011.
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