Affordable Care Act: Despite Initial Challenges, the Internal Revenue Service Successfully Implemented the Branded Prescription Drug Fee

May 16, 2014

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1 = Tax Return/Return Information

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AFFORDABLE CARE ACT: DESPITE INITIAL CHALLENGES, THE INTERNAL REVENUE SERVICE SUCCESSFULLY IMPLEMENTED THE BRANDED PRESCRIPTION DRUG FEE

Highlights

Final Report issued on May 16, 2014

Highlights of Reference Number: 2014-33-032 to the Internal Revenue Service Commissioner for the Large Business and International Division.

IMPACT ON TAXPAYERS

Section 9008 of the Patient Protection and Affordable Care Act (ACA) imposes an annual fee on pharmaceutical manufacturers and importers (referred to as covered entities) based on branded prescription drug sales made to specified Government agencies. The fees collected under the branded prescription drug fee program are to be transferred to the Medicare Part B Trust Fund, which is used to subsidize a portion of the Medicare Part B program. By accurately assessing and promptly collecting the branded prescription drug fees, the IRS ensures timely availability of these funds to the Medicare Part B program.

WHY TIGTA DID THE AUDIT

This audit was initiated to assess the IRS's efforts to implement the branded prescription drug fee, which went into effect in Calendar Year 2011. The overall objective of this review was to determine the effectiveness of the IRS's efforts to implement Section 9008 of the ACA.

WHAT TIGTA FOUND

The IRS successfully implemented the branded prescription drug fee through collaborative efforts with the various third parties and an alternative approach to calculate and assess the fee. The alternative approach was needed after the IRS learned that the purchasing Government agencies' branded prescription drug sales data would not be available until after the legislative deadline for calculating the annual fee.

The IRS developed a new reporting form (Form 8947, *Report of Branded Prescription Drug Information*) and instructions. It also developed procedures and a database to process covered entities' sales data and to accurately calculate the annual fees. TIGTA reviewed a judgmental sample of 15 Forms 8947 (representing more than 80 percent of the sales volume used to calculate the fee) for Calendar Years 2011 and 2012 and independently calculated the fee assessments. TIGTA determined that the IRS's calculation, assessment, and collection of the fees were accurate for our sampled cases.

In addition, the IRS's efforts to identify noncompliant covered entities were effective. Data on branded prescription drug sales are reported to the IRS from both the covered entities and the Government agencies, creating a dual reporting process. The IRS merged and compared the data from each source to identify any inconsistencies and promptly followed up to resolve them.

TIGTA identified one area requiring management's attention. From TIGTA's sample of 15 cases, TIGTA determined that some covered entities incorrectly interpreted the temporary regulations. Changes to Form 8947 and its instructions should help clarify these issues and reduce the burden on taxpayers.

WHAT TIGTA RECOMMENDED

TIGTA recommended that the Commissioner, Large Business and International Division, revise sections of Form 8947 and its instructions to clarify certain issues. Covered entities should also be notified of these revisions.

IRS management agreed with TIGTA's recommendation and plans to revise sections of Form 8947 and its instructions to clarify taxpayer understanding and reduce taxpayer burden.

TREASURY INSPECTOR GENERAL
FOR TAX ADMINISTRATION

DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

May 16, 2014

MEMORANDUM FOR COMMISSIONER, LARGE BUSINESS AND INTERNATIONAL DIVISION

FROM: Michael E. McKenney
Acting Deputy Inspector General for Audit

SUBJECT: Final Audit Report – Affordable Care Act: Despite Initial Challenges, the Internal Revenue Service Successfully Implemented the Branded Prescription Drug Fee (Audit # 201330328)

This report presents the results of our review to determine the effectiveness of the Internal Revenue Service's (IRS) efforts to implement Section 9008 of the Patient Protection and Affordable Care Act (ACA).[1] This review is included in our Fiscal Year 2014 Annual Audit Plan and addresses the major management challenge of Implementing the Affordable Care Act and Other Tax Law Changes.

Management's complete response to the draft report is included as Appendix VI.

Copies of this report are also being sent to the IRS managers affected by the report recommendation. If you have any questions, please contact me or Bryce Kisler, Acting Assistant Inspector General for Audit (Compliance and Enforcement Operations).

[1] Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered section of the U.S. Code), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

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Abbreviations

ACA	Affordable Care Act
BPD	Branded Prescription Drugs
IRS	Internal Revenue Service

Background

Effective January 1, 2011, Section 9008 of the Patient Protection and Affordable Care Act (ACA)[1] imposed an annual fee on businesses engaged in manufacturing and/or importing branded prescription drugs (BPD) for sale to six specific types of Government programs.[2] The fees collected under the BPD fee program are to be transferred to the Medicare Part B Trust Fund, which is used to subsidize a portion of the Medicare Part B program.

The six types of Government programs are presented in Figure 1 in addition to the Federal departments and agencies having oversight of the programs.

Figure 1: The Six Government Programs Specified by the BPD Legislation

Federal Department	Agency	Government Program
Department of Health and Human Services	The Centers for Medicare and Medicaid Services	Medicare Part B
		Medicare Part D
		Medicaid
Department of Defense	Defense Health Agency (formerly the Military Health System)	Any program under which BPDs are procured.
		TRICARE Retail Pharmacy[3]
Department of Veteran's Affairs	Veteran's Health Administration	Any program under which BPDs are procured.

Source: Treasury Inspector General for Tax Administration's analysis of Section 9008(e)(4) of the ACA.

The ACA defines a prescription drug manufacturer or importer with any amount of gross receipts from BPD sales to one or more of the specified Government programs as a "covered entity." However, only a covered entity with net sales greater than $5 million in any given year is assessed a portion of the annual BPD fee. Each covered entity's fee is based on its percentage of total qualifying sales in relation to the population of all covered entities with net sales greater

[1] Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered section of the U.S. Code), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.
[2] The six Government programs are specified in Section 9008(e)(4) of the ACA and shown in Figure 1 of this report.
[3] TRICARE is a health care program for active duty and retired members of the uniformed services, their families, and survivors.

than $5 million during the same year.[4] As a result, all covered entity BPD fee assessments for a specific fee year[5] will total the BPD fee mandated by law for that year.

The first year of the BPD fee program was Fee Year 2011. The total BPD fee started at $2.5 billion for Fee Year 2011 and continues in varying amounts for the subsequent years as detailed in Figure 2.

Figure 2: Annual Branded Prescription Drug Fees by Fee Year

Fee Year	Total Fee Amount
2011	$2.5 billion
2012	$2.8 billion
2013	$2.8 billion
2014	$3.0 billion
2015	$3.0 billion
2016	$3.0 billion
2017	$4.0 billion
2018	$4.1 billion
2019 and thereafter	$2.8 billion

Source: Health Care and Education Reconciliation Act of 2010.

The Internal Revenue Service (IRS) has a significant role in the administration of the ACA, with the responsibility to implement and oversee the numerous tax law changes—one of which includes calculating and assessing the annual BPD fee. To calculate this fee, the IRS must first obtain the BPD sales data from two sources: the covered entities and the Government agencies responsible for the specified Government programs. The covered entities file Form 8947, *Report of Branded Prescription Drug Information*, with the IRS to report the BPDs sold to the Government agencies. The Government agencies provide the sales data, including dollar value, for the BPDs purchased from the covered entities each year. The IRS matches the BPDs reported by the Government agencies as purchased to the BPDs reported as sold on the Forms 8947 filed by the covered entities. The IRS then uses this information to calculate and assess the BPD fee.

By April/May of each calendar year, the IRS notifies each covered entity of its preliminary fee calculation using Letter 4657, *Notice of Preliminary Calculation*. At this point, each covered

[4] See Appendix V for a detailed explanation of the fee calculation and adjustment process.
[5] The fee year is the calendar year in which the BPD fee must be paid to the Government.

entity has an opportunity to dispute the preliminary fee calculation by submitting specific information identifying the error with an explanation of why the IRS or Government agency should use the revised data from the covered entity.

After considering any dispute requests, the IRS sends out its final fee assessments to the covered entities by August 31 of each calendar year using Letter 4658, *Notification of Final Fee Calculation*. Each covered entity must then pay its final fee in full by September 30. Even if a covered entity does not agree with the final fee assessed after the dispute resolution process, the covered entity is still required to pay the full fee amount.

If, after paying the final fee, a covered entity still believes that the fee was incorrect, it can make a formal request for a refund from the IRS by submitting Form 843, *Claim for Refund and Request for Abatement*. If the IRS determines that it made an administrative error, it has the authority to correct the mistake and issue a refund. However, if the IRS does not approve the refund request, the ACA allows for the covered entity to file a lawsuit to attempt to recover any amount claimed.

This review was performed with information obtained from the ACA Project Management Office and the Large Business and International Division's Pre-Filing and Technical Guidance function in Washington, D.C., during the period October 2012 through November 2013. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. Detailed information on our audit objective, scope, and methodology is presented in Appendix I. Major contributors to the report are listed in Appendix II.

Results of Review

The Internal Revenue Service Successfully Implemented the Branded Prescription Drug Fee

Although the IRS faced significant challenges, it quickly developed guidance and new processes for implementing the new ACA provision and successfully implemented the BPD fee program through collaboration with the covered entities and specified Government agencies. The IRS developed an alternative approach to calculate and assess the fee. The alternative approach was needed after the IRS learned that Government BPD sales data would not be available until after the legislative deadline for calculating the annual BPD fee. In addition, the IRS needed to develop a new reporting form and implement a new process to accurately calculate the fee assessments and adjustments, as well as build a database application to effectively manage the new BPD business processes. The IRS also developed a process to identify and address any noncompliant pharmaceutical companies to ensure that they complied with the law.

Through collaborative efforts, the IRS obtained the necessary information to administer the BPD fee

To successfully implement the BPD fee, the IRS needed to obtain information from both the covered entities and the Government agencies that purchased the BPDs. Beginning in Fiscal Year 2010, the IRS issued a series of public notices providing details about critical program information and requirements for both parties. The IRS solicited comments from the covered entities to assist in the development of the regulations governing the BPD fee program. Temporary regulations for the program were published in August 2011 covering a variety of topics, including critical program definitions, information reporting requirements, explanations of fee assessment and fee adjustment calculations, and information on how to dispute an assessed fee and how to submit a refund claim. We reviewed the temporary regulations and determined that they contained adequate information to notify covered entities of the new process to collect the mandated BPD fee.

To address the public comments and revisions needed based on the first year of the program, the IRS updated program guidance and issued new notices. This guidance included a schedule of due dates for the mailing of the preliminary fee letters (Letter 4657), dispute filing, and the mailing of the final fee letters (Letter 4658). By the end of our fieldwork, the IRS was finalizing its guidance. It is required to issue the final regulations by August 2014.

The IRS also needed to develop new procedures and guidelines for the Government agencies to follow when submitting BPD sales data. Early in the planning for the BPD fee program, the IRS

collaborated with the Government agencies regarding the time frames the BPD sales data could be made available to the IRS. The ACA specifies that the allocation of the annual BPD fee be based on BPD sales from the calendar year immediately preceding the fee year. However, not all of the specified Government agencies were able to provide the BPD sales information early enough in the calendar year for the IRS to complete the BPD fee processing within the time frame set forth in the ACA.[6]

To overcome this obstacle, IRS analysts developed an innovative two-step approach to calculate the covered entities' BPD fees by the mandated deadline. The IRS used two-year-old prior BPD sales data as an estimate instead of the immediately preceding year's data. When the immediately preceding year's BPD sales data became available in the following year, the current year's BPD fee was adjusted for the difference between the actual BPD sales data and the two-year prior BPD sales data used in the estimate.[7]

The adjustment entered on the current fee year can be either a positive or a negative amount and corrects the discrepancy between the two-year-old BPD sales data used and the one-year-old BPD sales data. This "estimate and adjust" process enabled the IRS to meet the ACA's established schedule. Although this process helps to ensure that the BPD fee is accurately allocated among the various covered entities by the second year, the fee assessments on the covered entities' tax accounts are generally not correct for the fee year on which they appear because of the one-year lag before correction.

The IRS developed procedures to process data and accurately calculate the BPD fees

The BPD project team sought advice from the IRS's Office of Chief Counsel in developing new policies and procedures for the BPD fee program. Counsel's advice confirmed the IRS's authority to request that covered entities furnish an information statement for fee administration purposes. As a result, the IRS developed Form 8947 for use by covered entities in reporting qualifying drugs sold to participating Government agencies. A Form 8947 should be filed the first year a covered entity participates in the program, but it does not need to be filed annually unless there is a change in the BPDs sold. A covered entity should file an updated Form 8947 when there are changes in the types of drugs it sells to the Government. The form includes a listing of BPD sales by the type of drug but does not require the reporting of the volume or dollar value of the sales. The instructions pertaining to Form 8947 are extensive and generally include sufficient information on how to complete the form.

[6] The fee process involves the initial calculation of the fees, a process to allow the covered entities to dispute the assessed fees, final calculation of the fees as a result of any disputes, and issuance of the final fee letters to the covered entities. The letters require covered entities to pay their portion of the fee by September 30 each year.
[7] See Appendix V for a detailed explanation of the fee calculation and adjustment process.

In addition, the IRS developed internal procedures to assign specific tasks to IRS employees within designated business units. For example, Forms 8947 are processed by employees in the Wage and Investment Division's Submission Processing function at the IRS campus[8] in Ogden, Utah. The procedures require IRS employees who initially receive the form to route it to the Office of Tax Shelter Analysis for scanning and retention. The IRS also provided Internal Revenue Manual update alerts to employees who assist covered entities, directing the employees to the appropriate IRS function for assistance with Form 8947 processing, fee assessment, dispute resolution, and refund claims. These new procedures helped the IRS successfully implement the new BPD fee.

Implementation of the BPD fee also required the IRS to develop a database to manage the BPD fee processes. After uploading and sorting sales data received from the Government agencies, the BPD database combines it with data manually input from the Forms 8947 received from the covered entities. The combined information is then validated, corrected, and updated before the fee assessment is calculated.

The BPD database calculates the fee assessments and adjustments necessary to determine each covered entity's portion of the mandated BPD fee. The BPD database also generates the preliminary and final fee notices to the covered entities and systemically posts the BPD assessments and related transactions to the Business Master File.[9]

The IRS processed BPD fee assessments for 143 covered entities for Fee Year 2011. The following year, the IRS processed an additional 17 fee assessments, increasing the total to 160 covered entities for Fee Year 2012. To evaluate the accuracy of the BPD fees assessed to the covered entities, we selected a judgmental sample[10] of 15 covered entities (out of 160) that ranked overall highest in sales volumes for Calendar Year 2010. We selected these 15 covered entities because they were responsible for 82.4 percent of all Sales Taken Into Account[11] used to calculate the fee assessments for Fee Year 2012.

We reconstructed the sales totals for each of the 15 covered entities in our judgmental sample and manually recomputed the unadjusted fee assessments, applicable adjustments, and final adjusted fee assessments to confirm the accuracy of the BPD database application programming. For our judgmental sample of 15 covered entities, our manual computations agreed 100 percent with the Fee Year 2012 final fee assessments issued by the IRS.

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[8] The data processing arm of the IRS. The campuses process paper and electronic submissions, correct errors, and forward data to the Computing Centers for analysis and posting to taxpayer accounts.
[9] The Business Master File is an IRS database that consists of Federal tax-related transactions and accounts for businesses. These include employment taxes, income taxes on businesses, and excise taxes.
[10] A judgmental sample is a nonstatistical sample, the results of which cannot be used to project to the population.
[11] Sales Taken Into Account is the BPD sales amount after the application of a percentage adjustment. See Appendix V for the calculation to determine Sales Taken Into Account.

We also evaluated the accuracy of the BPD database application's process for recording the fee assessment transactions to the covered entities' tax accounts. We reviewed these transactions for all 143 covered entities for Fee Year 2011 and all 160 covered entities for Fee Year 2012. For both fee years, we found that all transactions related to BPD processes were accurately and timely recorded to the covered entities' Business Master File tax accounts. However, for Fee Year 2012, **********1**********
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**********1**********. However, it was not part of our judgmental sample. **********1**********
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Because the ACA provides the IRS with the authority to fix an administrative error, ***1****
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Furthermore, the IRS has taken steps to reduce the probability of incorrectly routing BPD dispute claims in the future. The IRS issued additional guidance to its employees that clarify the process for handling and routing BPD documents. New information in the instructions for completing the dispute form states that if a covered entity files a dispute but is not contacted by the IRS within 10 days of submission, the covered entity should contact the IRS. Additionally, the instructions for filing the Form 8947, as well as the dispute and refund request forms, have been updated to include directions to the covered entities for them to include the words "BPD Fee" in the mailing address. These changes should help ensure that properly submitted BPD forms are routed to the appropriate function within the IRS to be worked.

Efforts to identify noncompliant covered entities are effective

To ensure that the information from the covered entities' Forms 8947 is complete and accurate, the BPD Database performs an automated match of the Form 8947 data to the BPD sales data provided by the Government agencies. Any mismatches (which might occur from issues such as omitted, invalid, or incorrectly transcribed drug codes, errors in rebate amounts, or errors in the classification of a drug) will generate an error notice that is manually reviewed by an IRS analyst. The analyst conducts research and corrects and updates the data in the BPD Database before the preliminary fee assessment is calculated. This process is known as "BPD due diligence."

Because of the dual reporting by both the covered entities and the Government agencies, any reporting noncompliance is identified through the BPD due diligence process. Using this process, the IRS identified and corrected 861 omitted BPDs for the 15 covered entities in our judgmental sample, representing an additional $932 million in applicable drug sales that were then included in the BPD fee calculation and assessment for Fee Year 2012.

In addition, payment compliance has generally been very high. For Fee Year 2011, 92 of the 143 covered entities received fee assessments, and all entities paid their assessed fees timely.[12] In Fee Year 2012, 114 of the 160 covered entities received BPD fee adjustments or assessments, resulting in 102 entities with balances due and 12 entities with overpaid accounts once the actual Calendar Year 2010 sales adjustments were factored into the calculation. Of the 102 entities with balances due, 95 complied with timely payments by the due date of September 30, 2012. Of the seven remaining balance due accounts, four were paid within 30 days of the due date and the other three were resolved shortly thereafter with minimal compliance contact to the covered entities from the IRS. In addition, for the 12 covered entities with overpaid accounts as a result of the adjustment, the IRS timely issued refunds. Figure 3 presents BPD fee program compliance statistics for Fee Years 2011 and 2012.

Figure 3: BPD Fee Program Compliance Statistics

Program Category	Fee Year 2011 (Sales Year 2009)	Fee Year 2012 (Sales Year 2010)
BPD Fee to Be Allocated	**$2.5 Billion**	**$2.8 Billion**
Total Covered Entities	**143**	**160**
Covered Entities That Did Not Meet BPD Fee Criteria	**51**	**46**
Covered Entities That Met BPD Fee Criteria	**92**	**102**
Covered Entities That Fully Paid Timely	92	95
Covered Entities That Fully Paid Late	0	7
Covered Entities With an Overpayment	**0**	**12**
Refunds Issued Timely	0	12

Source: Treasury Inspector General for Tax Administration's analysis of IRS BPD fee program data and covered entities' IRS tax account records.

[12] Some covered entities had BPD sales of less than $5 million and therefore were not assessed any BPD fee in Fee Years 2011 or 2012.

Revisions to Form 8947 and Its Instructions Could Reduce the Number of Covered Entity Fee Assessment Disputes and Refund Claims

We noted one area requiring management's attention that would help reduce taxpayer burden and improve the efficiency of the BPD process. Fee assessment disputes related to BPD sales may arise from a variety of reasons, such as errors in the Government agency sales data, mathematical calculations, or Medicaid State rebate[13] data. Errors related to Government agency data are forwarded to the responsible agency to review. Any discrepancies should be resolved together with the related covered entity. Because the dispute resolution process has only a limited window of opportunity, if a covered entity is nonresponsive or not timely responsive to a Government agency's attempt to resolve a dispute, the Government agency will reject the error assertion. If a covered entity and the Government agency cannot reach agreement on the disputed matter, the IRS will rely on the Government agency's BPD sales data. The IRS does not mediate between the Government agency and the covered entity for this type of discrepancy.

For all other types of errors unrelated to sales, the IRS makes the final dispute decisions. These errors include classification of non-BPDs, ownership of drugs, *etc*. In Calendar Year 2011, the IRS issued Revenue Procedures[14] that established the BPD fee dispute resolution process. For subsequent years, updated guidance for the dispute process has been issued in notices.[15]

In our judgmental sample of 15 covered entities, 10 filed fee assessment dispute claims for Fee Year 2012. We reviewed each dispute claim to identify the issues involved, whether the IRS or a Government agency resolved the dispute, whether an assessment change resulted, and whether the change was for the full disputed amount or a lesser portion. Of the 10 covered entities filing disputes, the IRS adjusted seven of the fee assessments. For the remaining three dispute claims, no changes to the fee assessments were made. In all 10 cases, we determined that the fee assessment disputes were appropriately handled.

However, we identified that four covered entities filed fee assessment dispute claims resulting, in part, from their incorrect interpretation of the temporary regulations. These included the following.

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[13] The Medicaid Drug Rebate Program is a partnership between the Centers for Medicaid and Medicare Services of the Department of Health and Human Services, State Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients. It is authorized by Section 1927 of the Social Security Act.

[14] Revenue procedures are official published statements of the IRS about procedural and administration matters of the tax laws, first published in the *Internal Revenue Bulletin* and later transferred to the *Cumulative Bulletin*.

[15] A notice is an official IRS public pronouncement that may contain guidance that involves interpretations of the Code or other provisions of the law.

- Expired Drugs:[16] The covered entities stated that expired drugs should be omitted from the calculation. According to Temporary Regulation 51.2T(c), expired drugs are BPDs and are to be included in the BPD fee filings. The expired condition does not change the applicability to the program requirements.[17]

- BPD Ownership: The covered entities stated that ownership of the drug had changed and should be omitted from the calculation. According to Temporary Regulations 51.2T(i) and (m), drug ownership is determined by the Labeler Code[18] as of December 31 of the sales year. If a covered entity transfers ownership rights to manufacture or import a BPD but does not change the Labeler Code, the IRS will assess all post-transfer sales to the former owner until the Labeler Code reflects the new ownership. Under the BPD fee program, the Labeler Code must be changed before the change of ownership is recognized.

In addition, during Calendar Years 2011 and 2012, the IRS received four refund claims from three covered entities. We reviewed all four refund claims ****1********** ********************************1********************************** *****1*******.

- Orphan Drugs:[19] **********1********** ****1****According to Temporary Regulations 51.2T(d) and (k), orphan drugs are subject to the rules established for claiming a tax credit under Internal Revenue Code Section 45C, the Orphan Drug Credit. Drugs claimed for the Orphan Drug Credit are generally not considered BPDs and are not subject to the BPD fee assessment. However, if the Orphan Drug Credit is not claimed or is disallowed as a drug for that particular orphan disease or if the orphan drug is subsequently approved by the Food and Drug Administration for any treatment of diseases or conditions that are not rare, the drug loses the "orphan" status and becomes a BPD. If a covered entity mistakenly lists orphan drugs on its Form 8947 as BPDs, the IRS would interpret this as the covered entity providing notice of a change to the drugs' "orphan" status.

We reviewed Form 8947 and accompanying instructions and found that they do not provide specific guidance regarding these three issues. Revision of Form 8947 and its instructions to

[16] If the drug expiration date was reached by the end of the sales year, the drug was considered to be expired.
[17] Covered entities do not sell drugs that are past their expiration date to Government agencies; however, electronic management of Government agency data records may result in reporting a BPD as expired that was not expired at the time of purchase.
[18] The Labeler Code is the leading five digits of a unique number assigned to each drug through a national coding system.
[19] An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease. The assignment of orphan status to a disease and to any drugs developed to treat it is a matter of public policy in many countries and has resulted in medical breakthroughs that may not have otherwise been achieved due to the economics of drug research and development.

clarify common issues that may be misunderstood by covered entities should prevent or reduce future fee assessment disputes and refund claims. Furthermore, addressing these errors with the covered entities through planned outreach would elevate the issues to wider attention and ensure continued compliance.

Recommendation

Recommendation 1: The Commissioner, Large Business and International Division, should revise the following sections of Form 8947 and its instructions as well as notify the covered entities of these revisions:

- "General Instructions/Definitions/Branded prescription drug sales" should address expired drugs per Temporary Regulation 51.2T(c).
- "Specific Instructions/Item B. Covered Entity Information/Covered entity" should clarify ownership of a BPD Labeler Code per Temporary Regulations 51.2T(i) and (m).
- Schedule D and "Specific Instructions/Schedule D. Branded Prescription Drug Medicaid State Supplemental Rebates – Previously Reported National Drug Codes" should alert filers that unless the status of an orphan drug is being changed, it should not be listed on Schedule D per Temporary Regulations 51.2T(d) and (k).

Management's Response: IRS management agreed with this recommendation. The Large Business and International Division's Pre-Filing and Technical Guidance Function will revise the instructions for the three sections of Form 8947 by March 31, 2015, and will notify the covered entities of these revisions by the same date.

Appendix I

Detailed Objective, Scope, and Methodology

The overall objective of this review was to determine the effectiveness of the IRS's efforts to implement Section 9008 of the Patient Protection and Affordable Care Act.[1] To accomplish our objective, we:

I. Determined whether the IRS obtained the information needed to properly carry out its duties with respect to the law.

   A. Reviewed Internal Revenue Manual 25.21.1 and alerts issued for BPD Fee Years[2] 2011 and 2012 to identify IRS guidance issued for BPD fee assessments and determined whether the guidance was adequate.

   B. Interviewed BPD management and participated in a walk-through of the BPD fee calculation process to understand how the BPD assessment and adjustment calculations were performed.

   C. Conducted interviews with officials at the six specified Government agencies that participate in the BPD fee program to determine whether the IRS developed procedures and guidelines for Government agency sales report submissions. We also determined the earliest date BPD sales data could be provided to the IRS.

   D. Interviewed BPD management and reviewed Form 8947, *Report of Branded Prescription Drug Information*, and its instructions as well as the IRS's Form 8947 processing procedures to determine whether the IRS's procedures for processing Forms 8947 and posting the fee assessment to covered entities'[3] tax accounts were adequately documented.

II. Determined whether the IRS developed and issued the proper guidance to the pharmaceutical manufacturers/importers and Government agencies by reviewing IRS issued public notices and temporary regulations for the BPD fee program. We also determined whether the guidance provided to the pharmaceutical manufacturers and importers for filing requirements, fee explanation, dispute process, and remittance of payment was sufficient.

[1] Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered section of the U.S. Code), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.
[2] The fee year is the calendar year in which the BPD fee must be paid to the Government.
[3] The ACA defines a prescription drug manufacturer or importer with any amount of gross receipts from BPD sales to one or more of the six Government programs specified in the ACA as a "covered entity."

III. Determined whether the IRS correctly calculated and allocated the proper portion of the fees to the pharmaceutical manufacturers/importers.

A. Obtained a copy of the BPD database application and electronically analyzed it to determine whether the BPD database contained records for all covered entities subject to fee assessments for Fee Years 2011 and 2012. We electronically matched independently obtained Government agency BPD sales reports to the BPD database records of sales used to assess the BPD fee for Fee Year 2012 to determine whether database records for Government agency sales were accurate.

B. Electronically analyzed all Fee Years 2011 and 2012 covered entities' Business Master File[4] tax accounts for transaction codes[5] related to the BPD fee program.

C. Obtained a copy of the IRS's BPD fee calculation formula and verified whether the computation produced accurate results.

D. Selected a judgmental sample[6] of 15 covered entities with the largest sales volumes for Calendar Year 2010 from a population of 160 covered entities. We electronically analyzed the BPD database records to determine whether the Forms 8947 for the sampled covered entities accurately reported all BPDs sold to the Government agencies.

E. Reviewed the IRS's due diligence process to determine whether it was effective in identifying any omitted drugs on the 15 sampled covered entities' Forms 8947.

F. Electronically recreated the Fee Year 2012 fee assessment process for the 15 sampled covered entities to determine whether the totals matched the IRS fee assessments. We manually recalculated the preliminary fees, adjustments, and the final fees for all 15 sampled covered entities for Fee Year 2012.

G. Electronically analyzed all Fee Years 2011 and 2012 covered entities' tax accounts to determine whether they were documented on the Business Master File with the required fee assessment transaction codes and if the fee assessment amounts were accurately recorded in the tax account.

H. Reviewed the dispute claims for the 10 covered entities in our judgmental sample that filed dispute claims to determine whether there were any errors common to multiple disputes.

[4] The Business Master File is an IRS database that consists of Federal tax-related transactions and accounts for businesses. These include employment taxes, income taxes on businesses, and excise taxes.
[5] A three-digit code used to identify a processed transaction and to maintain a history of actions posted to a taxpayer's account on the Master File.
[6] A judgmental sample is a nonstatistical sample, the results of which cannot be used to project to the population. Judgmental samples were used throughout because we did not intend to project the results to the entire population.

I. Electronically analyzed all Fee Years 2011 and 2012 covered entities' tax accounts to determine whether they were documented on the Business Master File with the required fee payment transaction codes and whether the payment amounts were accurately recorded in the tax account.

J. Reviewed the guidance and procedures for processing BPD refund requests as well as all refund claims filed.

IV. Determined whether the IRS's efforts to identify covered entity noncompliance and enforce compliance with the provisions of the law were effective.

A. Interviewed Small Business/Self-Employed Division management regarding procedures for identifying covered entities not timely remitting BPD fee payments.

B. Interviewed Small Business/Self-Employed Division management regarding procedures for satisfying a balance due BPD fee if a covered entity did not pay.

C. Reviewed guidance for enforcement procedures used to collect delinquent BPD fees.

D. Interviewed Small Business/Self-Employed Division management regarding enforcement actions taken on noncompliant covered entities for Fee Year 2012.

Data validation methodology

During this review, we relied on data extracts from the BPD Database and the Business Master File, as well as Government agency BPD sales reports. Before relying on this data, we conducted validation tests. As a result, we determined that the data used in our review were sufficiently reliable to perform our audit analyses.

Internal controls methodology

Internal controls relate to management's plans, methods, and procedures used to meet their mission, goals, and objectives. Internal controls include the processes and procedures for planning, organizing, directing, and controlling program operations. They include the systems for measuring, reporting, and monitoring program performance. We determined the following internal controls were relevant to our audit objective: the processes for planning, organizing, directing, and controlling program operations for the implementation and operation of the BPD fee program for Fee Years 2011 and 2012. We accomplished this by reviewing IRS published guidance, reviewing IRS procedures, and interviewing IRS management. We also evaluated the controls that are incorporated directly into computer applications to help ensure the validity, completeness, and accuracy of transactions and data during application processing of BPD fee assessments for Fee Years 2011 and 2012.

Appendix II

Major Contributors to This Report

Carl Aley, Acting Assistant Inspector General for Audit (Compliance and Enforcement Operations)
Augusta R. Cook, Acting Assistant Inspector General for Audit (Compliance and Enforcement Operations)
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Appendix III

Report Distribution List

Commissioner C
Office of the Commissioner – Attn: Chief of Staff C
Deputy Commissioner for Services and Enforcement SE
Deputy Commissioner, Large Business and International Division SE:LB
Director, Affordable Care Act Office SE:ACA
Chief Financial Officer OS:CFO
Associate Chief Financial Officer for Financial Management OS:CFO:FM
Director, Pre-Filing and Technical Guidance, Large Business and International Division SE:LB:PFTG
Chief Counsel CC
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Director, Office of Legislative Affairs CL:LA
Director, Office of Program Evaluation and Risk Analysis RAS:O
Office of Internal Control OS:CFO:CPIC:IC
Audit Liaison: Large Business and International Division SE:LB

Appendix IV

Outcome Measure

This appendix presents detailed information on the measurable impact that our recommended corrective action will have on tax administration. This benefit will be incorporated into our Semiannual Report to Congress.

Type and Value of Outcome Measure:

- Reduction of Taxpayer Burden – Potential; five business taxpayers (*i.e.*, covered entities)[1] affected (see pages 9-10).

Methodology Used to Measure the Reported Benefit:

The outcome measure is based on the five covered entities that filed *******1********* **********1*****resulting, in part, from their incorrect interpretation of the temporary regulations.

[1] The ACA defines a prescription drug manufacturer or importer with any amount of gross receipts from BPD sales to one or more of the six Government programs specified in the ACA as a "covered entity."

Appendix V

Branded Prescription Drug Fee Calculation

Each year, the amount of the total legislated BPD fee is allocated to each covered entity[1] based on a formula. The formula considers the ratio between an individual covered entity's BPD Sales Taken Into Account[2] and the total BPD Sales Taken Into Account during the sales year for all covered entities. BPD Sales Taken Into Account for each covered entity is determined based on the BPD sales amounts and applicable percentages mandated by the ACA. The percentage application of the sales amounts ensures that the covered entities benefitting the most from selling BPDs to Government agencies are those that will be responsible for paying the greatest percentage of the BPD fee. The first $5 million in net sales for all covered entities is exempt from the BPD fee assessment calculation. Each successive sales amount is subject to a greater percentage of the fee in the calculation process. Figure 1 provides the sales amounts used to calculate each covered entity's Sales Taken Into Account.

Figure 1: BPD Sales Amounts Used to Calculate a Covered Entity's Applicable BPD Fee

Covered Entity's Yearly BPD Sales to Specified Government Program by Sales Amount	Percentage of the Covered Entity's Sales Used to Calculate Its Fee
Not more than $5 million	0%
More than $5 million but not more than $125 million	10%
More than $125 million but not more than $225 million	40%
More than $225 million but not more than $400 million	75%
More than $400 million	100%

Source: Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119.

The ACA specifies that the allocation of the annual BPD fee should be based on BPD sales from the calendar year immediately preceding the fee year.[3] However, not all Government agencies are able to provide the BPD sales data to the IRS in time for the IRS to calculate and assess the

[1] The ACA defines a prescription drug manufacturer or importer with any amount of gross receipts from BPD sales to one or more of the six Government programs specified in the ACA as a "covered entity."
[2] Sales Taken Into Account is the BPD sales amount after the application of a percentage adjustment.
[3] The fee year is the calendar year in which the BPD fee must be paid to the Government.

fee. As a result, the allocation of the annual BPD fee is based on drug sales from the second calendar year preceding the fee year; it is then adjusted in the subsequent year based on actual sales data.

To illustrate the fee calculation for Fee Year 2011, a hypothetical example is presented in Figure 2. Assume that "Company ABC" had total BPD sales to the Government agencies of $133 million in Calendar Year 2009. Based on the formula contained in the law, the Calendar Year 2009 BPD Sales Taken Into Account to calculate the Fee Year 2011 fee for Company ABC would be $15.2 million. This amount is calculated as follows:

- None of the first $5 million of sales would be included ($5,000,000 x 0 percent).
- $12 million of next $120 million of sales would be included (sales between $5,000,000 and $125,000,000: $120,000,000 x 10 percent = $12,000,000).
- $3.2 million of the remaining $8 million of sales would be included (sales between $125,000,000 and 225,000,000: $8,000,000 x 40 percent = $3,200,000).

Figure 2: Hypothetical Calculation Example of Company ABC's Calendar Year 2009 Sales Taken Into Account for Fee Year 2011

Amount of BPD Sales Amounts Used to Calculate Applicable BPD Fee	Total Calendar Year 2009 BPD Sales for Company ABC	Percentage of Sales Used to Calculate Fee	Calendar Year 2009 BPD Sales of Company ABC Taken Into Account
Not more than $5 million	$5,000,000	0%	$0
More than $5 million but not more than $125 million	$120,000,000	10%	$12,000,000
More than $125 million but not more than $225 million	$8,000,000	40%	$3,200,000
More than $225 million but not more than $400 million		75%	$0
More than $400 million		100%	$0
Total for Covered Entity ABC	$133,000,000		$15,200,000

Source: Treasury Inspector General for Tax Administration analysis of the ACA and a hypothetical example of a pharmaceutical company's applicable BPD sales.

This same calculation is performed for each covered entity. The calculated fees are then summed to determine the Total BPD Sales Taken Into Account for Calendar Year 2009. The Total BPD Sales Taken Into Account would then be used to apportion the $2.5 billion BPD fee for Fee Year 2011. If the Total BPD Sales Taken Into Account for all covered entities selling

BPDs to the Government agencies were $60 billion in Calendar Year 2009, the fee assessed to Company ABC would be $633,333. This is based on its $15,200,000 BPD Sales Taken Into Account divided by the $60 billion Total BPD Sales Taken Into Account for all covered entities multiplied by the $2.5 billion total fee mandated for Fee Year 2011.

$$\frac{\$15,200,000}{\$60,000,000,000} \times \$2,500,000,000 = \$633,333$$

To calculate the Fee Year 2012 BPD fee for Company ABC, the same formula used in the first part of this example is applied using Calendar Year 2010 sales data. Continuing with the example, Company ABC had total BPD sales to the Government agencies of $150 million in Calendar Year 2010. Based on the formula contained in the law, the Calendar Year 2010 BPD Sales Taken Into Account would be $22 million. This amount is calculated as follows:

- None of the first $5 million of sales would be included ($5,000,000 x 0 percent).
- $12 million of next $120 million of sales would be included (sales between $5,000,000 and $125,000,000: $120,000,000 x 10 percent = $12,000,000).
- $10 million of the remaining $25 million of sales would be included (sales between $125,000,000 and 225,000,000: $25,000,000 x 40 percent = $10,000,000).

Figure 3: Hypothetical Calculation Example of Company ABC's Calendar Year 2010 Sales Taken Into Account for Fee Year 2012

Amount of BPD Sales Amounts Used to Calculate Applicable BPD Fee	Total Calendar Year 2010 BPD Sales for Company ABC	Percentage of Sales Used to Calculate Fee	Calendar Year 2010 BPD Sales of Company ABC Taken Into Account
Not more than $5 million	$5,000,000	0%	$0
More than $5 million but not more than $125 million	$120,000,000	10%	$12,000,000
More than $125 million but not more than $225 million	$25,000,000	40%	$10,000,000
More than $225 million but not more than $400 million		75%	$0
More than $400 million		100%	$0
Total for Covered Entity ABC	$150,000,000		$22,000,000

Source: Treasury Inspector General for Tax Administration analysis of the ACA and a hypothetical example of a pharmaceutical company's applicable BPD sales.

If the Calendar Year 2010 Total BPD Sales Taken Into Account for all covered entities were $63 billion, the fee for Company ABC would be $977,778 without factoring in the Fee Year 2011 fee adjustment. This is based on its $22,000,000 BPD Sales Taken Into Account divided by the $63 billion Total BPD Sales Taken Into Account for all covered entities multiplied by the $2.8 billion total fee mandated for Fee Year 2012.

$$\frac{\$22,000,000}{\$63,000,000,000} \times \$2,800,000,000 = \$977,778$$

However, Company ABC's portion of the Fee Year 2012 BPD fee needs to be adjusted based on the actual amount of Calendar Year 2010 sales data for the Fee Year 2011 BPD fee. This recalculated Fee Year 2011 fee will factor into the total fee assessed in Fee Year 2012.

The adjustment calculation (*e.g.*, for Fee Year 2011) reflects the difference between:

- The allocated fee for the preceding fee year as originally determined using sales data from the second preceding calendar year (*e.g.*, Calendar Year 2009), and
- The allocated fee for the preceding fee year as determined using sales data from the calendar year immediately preceding the fee year (*e.g.*, Calendar Year 2010).

For example, for Calendar Year 2012, the adjustment amount for a covered entity will be the difference between the Fee Year 2011 fee computed using Calendar Year 2009 sales data and what the Fee Year 2011 fee would have been using Calendar Year 2010 sales data. For Fee Year 2011, Company ABC was allocated and paid $633,333 of the BPD fee, which was based on the $15,200,000 in BPD Sales Taken Into Account in Calendar Year 2009.

Company ABC's BPD Sales Taken Into Account for Calendar Year 2010 was actually $22,000,000, which is the amount that should have been the basis for the Fee Year 2011 fee as mandated by the ACA. Therefore, the Fee Year 2011 BPD fee must be recalculated using the Calendar Year 2010 BPD sales data ($873,016). The difference between what was allocated and paid in Fee Year 2011 based on Calendar Year 2009 BPD sales data ($633,333) and what should have been allocated and paid based on Calendar Year 2010 BPD sales data ($873,016) becomes an adjustment amount (+$239,683). However, rather than assessing the covered entities a second time for the Fee Year 2011 fee, this adjustment is added to the Fee Year 2012 BPD fee. In this way, covered entities will only be assessed one fee each year. However, that fee amount will eventually be recalculated and corrected the following year. The fee assessments on covered entities' tax accounts are generally never correct for the fee year on which they appear because of the one-year lag before correction.

The Fee Year 2012 BPD fee for Company ABC is allocated based on Calendar Year 2010 BPD sales data.

$\frac{\$22,000,000}{\$63,000,000,000}$	X $2,800,000,000	=	$ 977,778
Fee Year 2011 BPD fee adjustment amount			$ 239,683
Total fee allocated for Company ABC for Fee Year 2012			$1,217,461

Appendix VI

Management's Response to the Draft Report

COMMISSIONER
LARGE BUSINESS AND
INTERNATIONAL DIVISION

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, DC 20224

May 1, 2014

MEMORANDUM FOR ACTING DEPUTY INSPECTOR GENERAL FOR AUDIT

FROM: Heather C. Maloy
Commissioner, Large Business and International Division

SUBJECT: Response to Draft Audit Report, *Affordable Care Act: Despite Initial Challenges, the IRS Effectively Implemented the Branded Prescription Drug Fee* (audit # 201330328)

Thank you for sharing your subject draft report for our review. Section 9008, Branded Prescription Drug (BPD) Fee Program, became effective January 1, 2011. This Affordable Care Act section requires an annual fee on pharmaceutical manufacturers and importers (referred to as covered entities) based on their branded prescription drug sales to six specific Government programs. The fees, which the IRS collects, are transferred to the Medicare Part B Trust Fund to subsidize a portion of the Medicare Part B Program.

Your overall objective for the Section 9008 review was to assess the effectiveness of IRS efforts to implement the BPD Fee Program, including whether the IRS:

1. obtained the information it needed to properly carry out its duties with respect to the law;
2. developed and issued the proper guidance to the pharmaceutical manufacturers/importers and Government agencies;
3. correctly calculated and allocated the proper portion of the fees to the covered entities; and
4. determined the effectiveness of the IRS's efforts to identify covered entities that do not comply with the provisions of the law and the effectiveness of any associated enforcement efforts.

The IRS is very pleased with the positive outcome of your review based on the stated objectives. In particular, we are pleased with the following audit findings, which indicate that in spite of the significant challenges we encountered, the IRS implemented Section 9008 successfully.

1. Implemented the BPD Fee Program through collaboration with the covered entities and other Government agencies.

2. Obtained the necessary information to administer the BPD Fee Program, issued Public Notices, and Temporary Regulations to share information on the program, and developed procedures and guidelines for the Government agencies to follow when submitting BPD sales data.
3. Developed policies and innovative procedures to process data and calculate accurately the BPD fees with assistance from the Office of the Chief Counsel.
4. Developed a new Tax Form 8947, Report of Branded Prescription Drug Information, for use by covered entities in reporting qualifying drugs sold to the participating Government agencies.
5. Developed and implemented a database to manage the BPD fee processes, including a due diligence process to update data in the BPD database before the preliminary assessment is calculated.
6. Identified noncompliant covered entities effectively by comparing data from the covered entities and the pertinent Government agencies to detect inconsistencies and promptly followed up to resolve issues.

We agree with your recommendation to revise sections of the Form 8947 and its instructions to clarify certain issues and provide specific guidance regarding expired drugs, BPD ownership, and orphan drugs. The revisions may reduce the number of the covered entities' fee assessment disputes and refund claims. We also agree with the Outcome Measures in Appendix IV of the draft report.

Attached is a detailed response outlining the corrective actions the IRS will take to address your recommendation. If you have any questions, please contact Tina D. Meaux, Acting Director, Pre-Filing and Technical Guidance, at 713-209-4074.

Attachment

Attachment

RECOMMENDATION 1:

The Commissioner, Large Business and International Division, should revise the following sections of Form 8947, Report of Branded Prescription Drug Information, and its related instructions, as well as notify the covered entities of these revisions:

1. "General Instructions/Definitions/Branded prescription drug sales" should address expired drugs per Temporary Regulation 51.2T(c).

2. "Specific Instructions/Item B. Covered Entity Information/Covered entity" should clarify ownership of a BPD Labeler Code per Temporary Regulations 51.2T(i) and (m).

3. Schedule D and "Specific Instructions/Schedule D Branded Prescription Drug Medicaid State Supplemental Rebates – Previously Reported National Drug Codes" should alert filers that unless the status of an orphan drug is being changed, it should not be listed on Schedule D per Temporary Regulations 51.2T(d) and (k).

CORRECTIVE ACTIONS:

We will revise the instructions for the three sections of Form 8947 indicated above and notify the covered entities of these revisions.

IMPLEMENTATION DATE:

Show proposed completion dates for revisions of Form 8947 and notification to covered entities of these revisions:

Estimated date for revisions: March 31, 2015
Estimated date for notifications: March 31, 2015

RESPONSIBLE OFFICIAL(S):

Director, Pre-Filing and Technical Guidance, SE:LB&I:PFTG

CORRECTIVE ACTION(S) MONITORING PLAN:

The LB&I Internal Control Coordinator will track the progress of the implementation of the corrective actions and update the Joint Audit Management Enterprise System based on progress updates from management.

OUTCOME MEASURE

Reduction of burden for five business taxpayers (i.e., covered entities) that filed *******1******** **********1********** resulting, in part, from their incorrect interpretation of the temporary regulations.

We agree with this Outcome Measure.