



MANUAL TRANSMITTAL

Department of the Treasury
Internal Revenue Service

25.21.1

MAY 16, 2019

EFFECTIVE DATE

(05-16-2019)

PURPOSE

- (1) This transmits revised IRM 25.21.1, Affordable Care Act, Branded Prescription Drug Fee. This IRM section provides an awareness and understanding of the Branded Prescription Drug (BPD) Fee process.

MATERIAL CHANGES

- (1) IRM 25.21.1.1 was retitled Program Scope and Objectives to conform to IRM 1.11.2.2.5, Address Management and Internal Controls. Rearranged existing IRM content to place information involving internal controls in this first subsection. Subsections added under Program Scope and Objectives include:
 - a. IRM 25.21.1.1.1 - Background
 - b. IRM 25.21.1.1.2 - Authority
 - c. IRM 25.21.1.1.3 - Responsibilities
 - d. IRM 25.21.1.1.4 - Terms and Acronyms
 - e. IRM 25.21.1.1.5 - Related ResourcesSubsequent subsections were renumbered.
- (2) Updated dates in IRM 25.21.1.2, Information Requested from Covered Entities.
- (3) IRM 25.21.1.13 was retitled Manual Refund Procedures for Overpayment over \$100 Million and content was updated to address refunds over \$100 million.
- (4) Editorial corrections made.
- (5) Addresses and citations updated throughout.

EFFECT ON OTHER DOCUMENTS

IRM 25.21.1 dated August 24, 2015 is superseded.

AUDIENCE

Frontline employees from all operating divisions and functions that may receive BPD inquiries.

Peter M. Puzakulics
Director, Financial Institutions and Products
Enterprise Activities Practice Area
Large Business and International Division

25.21.1

Branded Prescription Drug Fee

Table of Contents

25.21.1.1 Program Scope and Objectives

25.21.1.1.1 Background

25.21.1.1.2 Authority

25.21.1.1.3 Responsibilities

25.21.1.1.4 Terms and Acronyms

25.21.1.1.5 Related Resources

25.21.1.2 Information Requested from Covered Entities

25.21.1.3 Data Transcription and Due Diligence

25.21.1.4 Information Requested from the Agencies

25.21.1.5 Fee Calculation

25.21.1.6 Adjustment Methodology

25.21.1.7 Notice of Preliminary Calculation (Letter 4657)

25.21.1.8 Dispute Resolution Process

25.21.1.8.1 Program Drug Sales Data Errors

25.21.1.8.2 Errors Other than Program Drug Sales Errors

25.21.1.8.3 Receipt and Disposition of Error Reports

25.21.1.9 Notification of Final Fee Calculation (Letter 4658)

25.21.1.10 Payment of Fee

25.21.1.11 Fee is Not Deductible

25.21.1.12 Refund Claims

25.21.1.13 Manual Refund Procedures for Overpayment Over \$100 Million

Exhibits

25.21.1-1 BPD Fee Process Flowchart

25.21.1.1
(05-16-2019)
Program Scope and Objectives

- (1) This IRM provides an awareness and understanding of the Branded Prescription Drug (BPD) Fee process for employees who may receive BPD inquiries.
- (2) **Purpose:** This IRM section provides information to employees about the BPD Fee imposed by section 9008 of the Affordable Care Act (ACA). This provision of the ACA did not amend the Internal Revenue Code.
- (3) **Audience:** Frontline employees from all operating divisions and functions that may receive BPD inquiries.
- (4) **Policy Owner:** LB&I Enterprise Activities Practice Area
- (5) **Program Owner:** ACA Team within Enterprise Activities Practice Area, Financial Institutions and Products
- (6) **Primary Stakeholders:** The primary stakeholders are organizations with whom the BPD team collaborates.

25.21.1.1.1
(05-16-2019)
Background

- (1) Section 9008 of the Patient Protection and Affordable Care Act imposes an annual fee on the sales of BPDs to certain government programs by covered entities engaged in the business of manufacturing or importing BPDs. The government programs are Medicare Part B, Medicare Part D, Medicaid, any program under which BPDs are procured by the Department of Veterans Affairs, any program under which BPDs are procured by the Department of Defense, and the TRICARE retail pharmacy program.
- (2) A covered entity is any manufacturer or importer with gross receipts from BPD sales.
- (3) Section 9008 (b)(4) sets an applicable fee amount for each year that will be apportioned among covered entities with aggregate BPD sales of over \$5 million to government programs or pursuant to coverage under such programs. The applicable fee amounts for fee years are:

Fee Year	Applicable 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

- (4) BPD fees collected under the provision are credited to the Medicare Part B trust fund.
- (5) Exhibit 25.21.1-1 provides a high level overview of the BPD fee process.

25.21.1.1.2
(05-16-2019)
Authority

- (1) The IRS has issued guidance on the BPD fee as follows:
- Branded Prescription Drug Fee Regulations 26 CFR 51, 26 CFR 602 TD 9823 2017-33 IRB 206 July 24, 2017
 - Notice 2014-42, 2014-34 IRB 387

25.21.1.1.3
(05-16-2019)
Responsibilities

- (1) The BPD program analysts are responsible for overseeing and administering the BPD fee.
- (2) A Section 9008 team is designated to administer the BPD fee. BPD inquiries or questions may be directed to the team at their dedicated phone number, 1-908-301-2118 (not a toll-free number) or email at *it.bpd.fee@irs.gov*.

25.21.1.1.4
(05-16-2019)
Terms and Acronyms

Defined Terms

Term	Definition
Fee Year	The fee year means the calendar year in which the fee for a particular sales year must be paid to the government. For example, for the fee year of 2019, the sales year is 2017.
Sales Year	The sales year is the second calendar year preceding the fee year.

Acronyms

Acronym	Definition
ACA	Affordable Care Act
ACH	Automated Clearing House
BPD	Branded Prescription Drug
CFR	Code of Federal Regulations
NDC	National Drug Code
W&I AM	Wage and Investment Accounts Management

25.21.1.1.5
(05-16-2019)
Related Resources

- (1) Additional information can be found on the following website: *www.irs.gov/ACA9008BPD*.

25.21.1.2
(05-16-2019)
Information Requested from Covered Entities

- (1) Covered entities may provide information relevant to the determination of the BPD fee by submitting Form 8947, Report of Branded Prescription Drug Information, and providing the information specified by the form and instruction.
- (2) Information requested on Form 8947 includes:
- National Drug Codes (NDCs)
 - Medicaid state rebate information

- Section 45C orphan drug information,
- Designated entity and members of controlled groups, if applicable

- (3) For each fee year, a covered entity that chooses to submit Form 8947 reporting information for the sales year must file the form by November 1 of the preceding year. If the due date falls on a Saturday, Sunday, or legal holiday, Form 8947 is due on the next business day. The term “legal holiday” means any legal holiday in the District of Columbia. For a list of legal holidays, go to IRS.gov and enter the words “legal holidays” in the search box. For example, for the 2019 fee year, a covered entity must submit its Form 8947 reporting information for the 2017 sales year by Thursday, November 1, 2018 (after applying IRC 7503). A covered entity must submit its Form 8947 to:

Dept. of Treasury
Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4916 BPDF
Ogden, UT 84201-0051

25.21.1.3
(08-24-2015)
Data Transcription and Due Diligence

- (1) All Form 8947 data received is transcribed onto the BPD application system.
- (2) Data perfection is performed as necessary to perfect data in the system.
- (3) Due diligence is performed to determine proper NDC, orphan drugs, and rebate information reported.
- (4) A list of BPDs by NDC will be compiled from all transcribed Forms 8947.

25.21.1.4
(08-24-2015)
Information Requested from the Agencies

- (1) The list of BPDs by NDC (described in IRM 25.21.1.3 (4) above) and a request for sales data by NDC and by program will be forwarded to the contact person for each of these agencies:
 - The Centers for Medicaid and Medicare Services of the Department of Health and Human Services will provide BPD sales data for the relevant sales year by NDC for the Medicare Part D, Medicare Part B, and Medicaid programs.
 - The Department of Veteran Affairs will provide BPD sales data for the relevant sales year by NDC and program.
 - The Department of Defense will provide BPD sales data for the relevant sales year by NDC and program.
 - The Department of Defense will provide BPD sales data for the relevant sales year by NDC for the TRICARE retail pharmacy program.
- (2) All sales data from agencies are input into the BPD application system by NDC and by covered entities.

25.21.1.5
(05-16-2019)
Fee Calculation

- (1) The annual applicable fee amount is apportioned among the covered entities based on the ratio between a covered entity's BPD sales taken into account during the sales year and the aggregate BPD sales taken into account during the sales year for all covered entities.
- (2) BPD sales are sales of BPDs to the government programs identified in IRM 25.21.1.1.1 (1). BPD sales do not include orphan drug sales.

- (3) A covered entity's BPD sales taken into account during the calendar year are as follows:

BPD Sales	Percentage
Not more than \$5M	0%
More than \$5M but not more than \$125M	10%
More than \$125M but not more than \$225M	40%
More than \$225M but not more than \$400M	75%
More than \$400M	100%

25.21.1.6
(05-16-2019)
**Adjustment
Methodology**

- (1) In addition to the allocated fee for the fee year, there will also be an adjustment calculation starting for each fee year after 2011.
- (2) The adjustment calculation 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 the 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 the fee year.

25.21.1.7
(08-24-2015)
**Notice of Preliminary
Calculation (Letter 4657)**

- (1) For each sales year, the IRS will notify a covered entity of its preliminary fee calculation.
- (2) The notification will include the following:
- The covered entity's allocated fee
 - The covered entity's BPD sales, by NDC and by program
 - The covered entity's BPD sales taken into account
 - The aggregate BPD sales taken into account for all covered entities
 - The adjustment amount
 - A reference to the fee dispute resolution process. See 26 CFR 51.7 (BPD regs.) and Notice 2014-42, 2014-34 IRB 387.

25.21.1.8
(05-16-2019)
**Dispute Resolution
Process**

- (1) Upon receipt of the preliminary fee calculation, each covered entity will have an opportunity to dispute the calculation by submitting an error report to the IRS by May 15th of each fee year. There are two types of errors:
- Program drug sales data errors
 - Errors other than program drug sales data errors

25.21.1.8.1
(08-24-2015)
**Program Drug Sales
Data Errors**

- (1) The covered entity must submit an error report with each asserted error reported on a separate line. Each error report for program errors must include:
- Entity name, address, and Employer Identification Number (EIN) as previously reported on the Form 8947

- The name, telephone number, fax number, and email address (if available) of one or more employees or representatives of the entity with whom the IRS may discuss the claimed errors

Note: If the contact is not an employee of the entity, Form 2848, Power of Attorney and Declaration of Representative, must be filed with the error report. See also 26 CFR 51.7(b)(2).

- Name of the program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation, and documentation to establish the existence of an error.

25.21.1.8.2
(08-24-2015)
**Errors Other than
Program Drug Sales
Errors**

- (1) All error reports for errors other than program drug sales errors must include:
 - Entity name, address, and Employer Identification Number (EIN) as previously reported on the Form 8947
 - The name, telephone number, fax number, and email address (if available) of one or more employees or representatives of the entity with whom the IRS may discuss the claimed errors

Note: If the contact is not an employee of the entity, Form 2848, Power of Attorney and Declaration of Representative, must be filed with the error report. See also 26 CFR 51.7(b)(2).
- (2) For a mathematical calculation error, the error report must identify the specific calculation element(s) the entity disputes and its proposed corrected calculation.
- (3) For a rebate data error, the error report must include:
 - The NDC for the drug to which it relates
 - A discussion on whether data used in the preliminary fee calculation matches previously reported Form 8947 data on rebates
 - If data used in the preliminary fee calculation matches previously reported Form 8947, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead
- (4) For an error in the listing of an NDC for an orphan drug, the error report must include:
 - The name and NDC of the orphan drug
 - A discussion of whether data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs
 - If data used in the preliminary fee calculation matches the Form 8947 data, an explanation of why the Form 8947 was erroneous and why the IRS should use the proposed corrected data instead
- (5) For any other asserted errors not previously described, the report must contain:
 - 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
 - An explanation of why the IRS or agency should use the proposed corrected data instead

See IRM 25.21.1.4 for a list of the agencies.

25.21.1.8.3
(08-24-2015)

**Receipt and Disposition
of Error Reports**

- (1) Covered entities must submit error reports to the following designated address:
Dept. of Treasury
Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4916 BPDF
Ogden, UT 84201-0051
- (2) Upon receipt of error reports:
 - Disputes for program errors are forwarded to the agencies for review and consideration.
 - The IRS will review and consider disputes for all other errors.
- (3) Any changes made pursuant to the dispute resolution process will be reflected in the final fee calculation.

25.21.1.9
(08-24-2015)

**Notification of Final Fee
Calculation (Letter 4658)**

- (1) The final fee calculation for a fee year will be sent to each covered entity no later than August 31st of each fee year.
- (2) The final fee calculation will be based on the preliminary fee calculation as adjusted pursuant to the dispute resolution process.
- (3) A covered entity's final fee may differ from the covered entity's preliminary fee calculation because of changes made pursuant to the dispute resolution process. There may be a difference in a covered entity's fee even if the covered entity did not submit an error report because the fee is an allocated fee.

25.21.1.10
(07-27-2012)

Payment of Fee

- (1) Each covered entity must pay its final fee by September 30th of the fee year. If the due date for payment falls on a Saturday, Sunday, or legal holiday, the fee may be paid on the next business day. The term "legal holiday" means any legal holiday in the District of Columbia. For a list of legal holidays, go to IRS.gov and enter the words "legal holidays" in the search box.
- (2) The fee must be paid by electronic funds transfer.
- (3) For a controlled group, the payment must be made using the designated entity's EIN as reported on Form 8947. All covered entities within a controlled group are jointly and severally liable for the fee.

25.21.1.11
(03-28-2012)

Fee is Not Deductible

- (1) Section 9008(f)(2) of the ACA provides that for purposes of IRC 275, the BPD fee shall be considered to be a tax described in IRC 275(a)(6).

25.21.1.12
(08-24-2015)

Refund Claims

- (1) A claim for refund of the fee must be made by the entity that paid the fee.
- (2) The claim must be made on Form 843, Claim for Refund and Request for Abatement.
- (3) A claim for refund of the fee cannot be processed in the usual way and must be routed to the following address for special handling:

Dept. of Treasury
Internal Revenue Service
1973 Rulon White Boulevard
Mail Stop 4921 BPDF
Ogden, UT 84201-0051

25.21.1.13
(05-16-2019)

**Manual Refund
Procedures for
Overpayment Over \$100
Million**

- (1) The final fee calculation, after application of the adjustment amount, may result in an amount owed to a covered entity.
- (2) A systems-generated check will be mailed to a covered entity in 4-6 weeks from the date of the final fee letter unless the payment is offset because a covered entity owes other federal debts. According to IRM 3.17.79.3.6 paragraph (2)(e), effective January 1, 2016, overpayments that exceed \$9,999,999.99 and under \$100,000,000.00 may be processed systemically or by preparing Form 3753, Manual Refund Posting Voucher, and forward the complete case file to Accounting.
- (3) For an overpayment over \$100 million, a BPD analyst will mail a letter to a covered entity. The letter should outline the options to receive overpayment via Automated Clearing House (ACH) Direct Deposit or paper check. For ACH Direct Deposit, a covered entity must provide the following: (Refer to IRM 3.17.79.3.10.1 for additional information on electronic deposit of overpayment.)
 - A covered entity's name on the Form 8947
 - EIN
 - Phone Number
 - Name and location (City, State) of bank
 - Routing number
 - Account number
 - Type of account
 - Signature of official denoting consent
- (4) When the BPD analyst receives the covered entity's response to the letter of options to receive overpayment via ACH Direct Deposit or paper check, the BPD analyst will send a manual refund request to W&I AM. A manual refund request should include: a copy of Letter 4658, name of covered entity, EIN, Tax Period, MFT, amount of overpayment, Line number=99 and method of deposit letter from a covered entity. W&I AM will prepare Form 3753 and process the request to Accounting function.
- (5) In accordance with the Accounting IRM 3.17.79.3.7 procedural guidelines, the Manual Refund team will notify the Treasury in advance whenever a single overpayment or several overpayments with an aggregate total of \$50 million or more has been received for processing.

This Page Intentionally Left Blank

Exhibit 25.21.1-1 (03-28-2012) BPD Fee Process Flowchart

High Level Overview of BPD Process



