



# MANUAL TRANSMITTAL

Department of the Treasury  
Internal Revenue Service

25.21.1

FEBRUARY 26, 2025

## EFFECTIVE DATE

(02-26-2025)

## 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, Program Scope and Objectives:
  - a. Paragraph (1) - Clarified purpose.
  - b. Paragraph (3) - Clarified policy owner.
  - c. Paragraph (4) - Clarified program owner.
  - d. Paragraph (6) - Added contact information.
- (2) IRM 25.21.1.1.1, Background - Removed definition of covered entity and moved to Terms and Acronyms table.
- (3) IRM 25.21.1.1.2(1), Authority - Added legal authority that governs the program.
- (4) IRM 25.21.1.1.3, Responsibilities:
  - a. Paragraph (1) to (4) - Expanded and clarified the roles and their responsibilities within the program.
  - b. Paragraph (5) - Updated dedicated BPD inquiry phone number.
- (5) IRM 25.21.1.1.4, Program Management and Review - Added new subsection and clarified information about review and oversight.
- (6) IRM 25.21.1.1.5, Program Controls - Added new subsection and clarified information about program controls.
- (7) IRM 25.21.1.1.6(1), Terms and Acronyms -
  - a. Controlled Group - Added definition.
  - b. Covered Entity - Moved from background subsection and updated definition.
  - c. Financial Institutions and Products - Added acronym.
  - d. Orphan Drug - Added definition.
- (8) IRM 25.21.1.2(3) - Referenced Pub. 509 for list of legal holidays instead of manual search and updated example
- (9) IRM 25.21.1.5(2) - Added new reference for definition of orphan drug.
- (10) IRM 25.21.1.10(1) - Referenced Pub. 509 for list of legal holidays instead of manual search.
- (11) IRM 25.21.1.13(2) - Removed effective date and updated instructions for manual refund process.
- (12) Throughout:
  - a. Updated hyperlinks.

- b. Changed Wage and Investment (W&I) to Taxpayer Services (TS).
- c. Stylistic editorial changes.

#### **EFFECT ON OTHER DOCUMENTS**

IRM 25.21.1 dated May 16, 2019 is superseded.

#### **AUDIENCE**

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

Ronald H. Hodge II  
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25.21.1

Branded Prescription Drug Fee

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25.21.1-1 BPD Fee Process Flowchart



25.21.1.1  
(02-26-2025)  
**Program Scope and Objectives**

- (1) **Purpose:** This IRM provides an awareness and understanding of the Branded Prescription Drug (BPD) Fee process for employees who may receive BPD inquiries. It also 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.
- (2) **Audience:** Frontline employees from all operating divisions and functions that may receive BPD inquiries.
- (3) **Policy Owner:** LB&I Policy under the Strategy, Policy and Governance office in the Assistant Deputy Commissioner Compliance Integration organization and LB&I Enterprise Activities Practice Area.
- (4) **Program Owner:** ACA Team, under Enterprise Activities Practice Area, Financial Institutions and Products, Actuaries and ACA.
- (5) **Primary Stakeholders:** The primary stakeholders are organizations with whom the BPD team collaborates.
- (6) **Contact Information:** To recommend changes or to make any other suggestions to this IRM section, contact the IRM author or see SPDER's IMD Contacts list by referencing guidelines provided in IRM 1.11.6.5, Providing Feedback About an IRM Section - Outside of Clearance. A request or inquiry can also be made using the *LB&I Policy Gateway*.

25.21.1.1.1  
(02-26-2025)  
**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) 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

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

25.21.1.1.2  
(02-26-2025)  
**Authority**

- (1) Section 9008 of the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), as amended by Section 1404 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)) (collectively the ACA) enacted the Branded Prescription Drug (BPD) fee.
- (2) 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  
(02-26-2025)  
**Responsibilities**

- (1) Director, Enterprise Activities, is responsible for the policies and procedures for this IRM section.
- (2) Director, Financial Institutions of Products (FIP), is responsible for the oversight of the Actuaries and ACA team.
- (3) Program Manager, Actuaries and ACA Team, is responsible for the oversight of the BPD Program Analysts.
- (4) BPD Program Analysts, ACA Team, are responsible for overseeing and administering the BPD fee.
- (5) 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, 1-681-260-3121 (not a toll-free number) or email at *it.bpd.fee@irs.gov*.

25.21.1.1.4  
(02-26-2025)  
**Program Management and Review**

- (1) The program generates BPD fee summary reports and provides to management for review after preliminary and final fee letters are mailed.
- (2) Director of FIP, Program Manager, and BPD Program Analysts hold bimonthly briefings on program review.

25.21.1.1.5  
(02-26-2025)  
**Program Controls**

- (1) The BPD Fee Process Flowchart in Exhibit 25.21.1-1 provides an overview of the program.

25.21.1.1.6  
(02-26-2025)  
**Terms and Acronyms**

- (1) The following are commonly used terms and acronyms:

***Defined Terms***

<b>Term</b>	<b>Definition</b>
Controlled Group	A group of two or more persons, including at least one person that is a covered entity, that is treated as a single employer. Refer to IRC 52(a), IRC 52(b), IRC 414(m), IRC 414(o).

Term	Definition
Covered Entity	Any manufacturer or importer with gross receipts from BPD sales, including a single-person covered entity or a controlled group.
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.
Orphan Drug	Any branded prescription drug for which any person claimed a credit under IRC 45C and that credit was allowed for any taxable year, but does not include: <ul style="list-style-type: none"> <li>a. Any drug for which there has been a final assessment or court order disallowing the full IRC 45C credit taken for the drug, or</li> <li>b. Any drug for any sales year after the calendar year in which the Federal Drug Administration (FDA) approved the drug for marketing for any indication other than the treatment of a rare disease or condition for which a IRC 45C credit was allowed, regardless of whether a IRC 45C credit was allowed for the drug either before, in the same year as, or after this FDA designation.</li> </ul>
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
FIP	Financial Institutions and Products
NDC	National Drug Code
TS AM	Taxpayer Services Accounts Management

25.21.1.1.7  
(05-16-2019)

#### Related Resources

- (1) Additional information can be found on the following website: *Annual Fee on Branded Prescription Drug Manufacturers and Importers*.

25.21.1.2  
(02-26-2025)

**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, refer to Pub 509. For example, for the 2025 fee year, a covered entity must submit its Form 8947 reporting information for the 2023 sales year by Friday, November 1, 2024 . 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  
(02-26-2025)  
**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. See IRM 25.21.1.1.6 (1) for definition of an orphan drug.
- (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 15 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 31 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 (02-26-2025) **Payment of Fee**

- (1) Each covered entity must pay its final fee by September 30 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, refer to Pub 509.
- (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  
(02-26-2025)  
**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(2)(e), any refund of \$100 million or more must be issued as a manual refund. Refunds under \$100 million are systemically generated on Integrated Data Retrieval System (IDRS) with a posted transaction code, TC 846, unless a manual refund is required for another reason.
- (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 TS 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. TS 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.

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

### High Level Overview of BPD Process



