

Date of Approval: 04/25/2025
Questionnaire Number: 2243

Basic Information/Executive Summary

What is the name of your project (system, database, pilot, product, survey, social media site, etc.)?

Branded Prescription Drug

Acronym:
BPD

Business Unit
Large Business and International

Preparer
For Official Use Only

Subject Matter Expert
For Official Use Only

Program Manager
For Official Use Only

Designated Executive Representative
For Official Use Only

Executive Sponsor
For Official Use Only

Executive Summary: Provide a clear and concise description of your project and how it will allow the IRS to achieve its mission.

The Branded Prescription Drugs (BPD) application collects, stores, manages, and validates data from pharmaceutical companies and federal agencies. It implements the tools necessary to carry out Provision 9008 of the Affordable Care Act. The IRS collects sales data from government agencies and corporate information from the pharmaceutical companies to assess fees and collect payment from these companies. Once collected, the funds are transferred to the Medicare Part B Trust Fund.

Personally Identifiable Information (PII)

Will this project use, collect, receive, display, store, maintain, or disseminate any type of Sensitive but Unclassified (SBU), Personally Identifiable Information (PII), or Federal Tax Information (FTI)?

Yes

Please explain in detail how this project uses sensitive data from inception to destruction (data lifecycle).

BPD will only collect the minimum information (EIN, Company Name, company address, name of person who filled out the form, phone number and signature of the filer of the information report) required to assess fees and transmit data to generate letters to the pharmaceutical companies.

Please select all types of Sensitive but Unclassified data (SBU)/Personally Identifiable Information (PII)/Federal Tax Information (FTI) that this project uses.

Address

Employer Identification Number

Internet Protocol Address (IP Address)

Name

Standard Employee Identifier (SEID)

Telephone Numbers

Cite the authority for collecting SBU/PII/FTI (including SSN if relevant).

PII for federal tax administration - generally IRC Sections 6001 6011 or 6012

Product Information (Questions)

1 Is this PCLIA a result of a specific initiative or a process improvement?

No

2 What type of project is this (system, project, application, database, pilot/proof of concept/prototype, power platform/visualization tool)?

System

3 What Tier designation has been applied to your system? (Number)

2

4 Is this a new system?

No

4.1 Is there a previous Privacy and Civil Liberties Impact Assessment (PCLIA) for this project?

Yes

4.11 What is the previous PCLIA number?

1174

4.12 What is the previous PCLIA title (system name)?

Branded Prescription Drug

4.2 You have indicated this is not a new system; explain what has or will change and why. (Expiring PCLIA, changes to the PII or use of the PII, etc.)

Update to the PII is needed because of a privacy risk (POA&M ID 22129).

5 Is this system considered a child system/application to another (parent) system?

No

6 Indicate what OneSDLC State is the system in (Allocation, Readiness, Execution) or indicate if you go through Information Technology's (IT) Technical Insertion Process and what stage you have progressed to.

Execution

7 Is this a change resulting from the OneSDLC process?

No

8 Please provide the full name and acronym of the governance board or Executive Steering Committee (ESC) this system reports to.

Application Development (AD) Compliance Governance Board

9 If the system is on the As-Built-Architecture (ABA), what is the ABA ID number of the system? If this PCLIA covers multiple applications shown on the ABA, please indicate the ABA ID number(s) for each application covered separated by a comma. If the system is not in the ABA, then contact the ABA (<https://ea.web.irs.gov/aba/index.html>) for assistance.

210117

10 If this system discloses any PII to any third party outside the IRS, does the system have a process in place to account for such disclosures in compliance with IRC

6103(p)(3)(A) or Subsection c of the Privacy Act?

No

10.1 You have indicated that you do not have an "accounting of disclosures" process in place; please indicate a projected completion date or explain the steps taken to develop your accounting of disclosures process. Note: The Office of Disclosure should be contacted to develop this system's accounting of disclosures process.

Disclosures are made to the BPD analysts on a need-to-know basis, thus should be excluded from the accounting requirement.

11 Does your project/system involve any use of artificial intelligence (AI), including virtual assistant, chat bot, and robotic process automation, as defined in Executive Order 13960 and 14110?

No

12 Does this system use cloud computing?

No

13 Does this system/application interact with the public?

No

14 Describe the business process allowing an individual to access or correct their information. (Due Process)

After the preliminary fee letters are mailed to pharmaceutical companies, they have opportunities to dispute the preliminary fee. After disputes are reviewed, the BPD analysts update the BPD application as needed and compute the final fee. Notice, consent and due process are provided via tax form 8947 instructions, and pursuant to 5 USC.

15 Is this system owned and/or operated by a contractor?

IRS Owned and Operated

16 Identify what role(s) the IRS and/or the contractor(s) performs; indicate what access level (to this system's PII data) each role is entitled to. (Include details about completion status and level of access of the contractor's background investigation was approved for.)

LB&I BPD Analysts have read/write/administrator access level to the PII data.

17 The Privacy Act of 1974 (5 USC § 552a(e)(3)) requires each agency that maintains a system of records, to inform each individual requested to supply information about himself or herself. Please provide the Privacy Act Statement presented by your system or indicate a Privacy Act Statement is not used and individuals are not given the opportunity to consent to the collection of their PII.

The Privacy act is included under Paperwork Reduction Act Notice at the end of the instructions of Form 8947, Report of Branded Prescription Drug Information. Paperwork Reduction Act Notice should have been labeled Privacy Act and Paperwork Reduction Act Notice, but Privacy Act was inadvertently omitted.

18 How many records in the system are attributable to IRS Employees? Enter "Under 50,000", "50,000 to 100,000", "More than 100,000" or "Not Applicable".

Not Applicable

19 How many records in the system are attributable to contractors? Enter "Under 5,000", "5,000 to 10,000", "More than 10,000" or "Not Applicable".

Not Applicable

20 How many records in the system are attributable to members of the public? Enter "Under 100,000", "100,000 to 1,000,000", "More than 1,000,000" or "Not applicable".

Not Applicable

21 Identify any "other" records categories not attributable to the categories listed above; identify the category and the number of corresponding records, to the nearest 10,000; if no other categories exist, enter "Not Applicable".

Pharmaceutical company points of contact approximately 600 records.

22 How is access to SBU/PII determined and by whom?

Access to the PII data in BPD application is limited to BPD analysts and, when required, assigned system maintenance personnel. Access to the data is determined by the manager based on a user's position and need-to-know. Access is granted via Business Entitlement Access Request System (BEARS) system as determined by manager approval.

23 Is there a data dictionary on file for this system? Note: Selecting "Yes" indicates an upload to the Attachment Section is required.

Yes

24 Explain any privacy and civil liberties risks related to privacy controls.

Risk-BPD captures PII (IP addresses) that are not approved in the PCLIA; Planned remediation-Update PCLIA to capture IP addresses. Actual remediation-BPD application is a stand-alone system. Access to the BPD application is limited to BPD analysts and a data transcriber and, when required, assigned system maintenance personnel. Taxpayer data from Form 8947 is manually transcribed to the BPD system. PCLIA PII is updated to state BPD application does not capture e-mail addresses, but IP addresses is captured as it is the part of the audit log.

25 Please upload all privacy risk finding documents identified for the system (Audit trail, RAFT, POA&M, Breach Plan, etc.); click "yes" to confirm upload(s) are complete.

Yes

26 Describe this system's audit trail in detail. Provide supporting documents.

The BPD application must meet the auditing requirements set forth in Internal Revenue Manual (IRM) 10.8.1.4.3, National Institute of Standards and Technology (NIST) Special Publications (SP) 800-92 and SP 800-53 Rev. 5 (09/23/2020), Federal Information Processing Standards (FIPS) Publication 199, and Office of Management and Budget (OMB) M-21-31 (08/27/21) pages 33, 39, and 40. The BPD system is configured to monitor auditable events and log those events and capture an audit trail of relevant data.

27 Does this system use or plan to use SBU data in a non-production environment?

Yes

27.1 Please upload the Approved Email and one of the following SBU Data Use Forms, Questionnaire (F14664) or Request (F14665) or the approved Recertification (F14659). Select Yes to indicate that you will upload the Approval email and one of the SBU Data Use forms.

Yes

Interfaces

Interface Type

IRS Systems, file, or database

Agency Name

Splunk (f/k/a SAAS)

Incoming/Outgoing

Outgoing (Sending)

Transfer Method

Electronic File Transfer Utility (EFTU)

Interface Type

IRS Systems, file, or database

Agency Name

IDRS

Incoming/Outgoing

Outgoing (Sending)

Transfer Method

Application to Application (A2A)

Interface Type

Forms

Agency Name

Form 8947, Report of Branded Prescription Drug Information

Incoming/Outgoing

Incoming (Receiving)

Transfer Method
Other
Other Transfer Method
Manual transcription

Systems of Records Notices (SORNs)

SORN Number & Name

IRS 24.046 - Customer Account Data Engine Business Master File

Describe the IRS use and relevance of this SORN.

BPD sends calculated fee amounts through IDRS to the Business Master File where they are posted for collection.

SORN Number & Name

IRS 34.037 - Audit Trail and Security Records

Describe the IRS use and relevance of this SORN.

BPD captures auditable user activity and sends details to Splunk for Security Review.

Records Retention

What is the Record Schedule System?

Record Control Schedule (RCS)

What is the retention series title?

RCS 26 for Tax Administration, International

What is the GRS/RCS Item Number?

49

What type of Records is this for?

Electronic

Please provide a brief description of the chosen GRS or RCS item.

The Branded Prescription Drug System is used to support the Affordable Care Act and will receive data elements from pharmaceutical companies related to the drugs they sell as well as sales data from specified government agency programs. The system will be used to facilitate the allocation, billing and collection of fees from the pharmaceutical companies to transfer to the Medicare Part B Trust Fund.

What is the disposition schedule?

Cut off at the end of the FY. Delete/Destroy 10 years after cutoff.