Department of Health & Human Services Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop 00-00-00 Baltimore, Maryland 21244-1850



Prescription Drug Data Collection (RxDC) Reporting Instructions

Section 204 Data Submission Instructions for the 2023 Reference Year

Last Updated April 2024

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995 (PRA), no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. The valid OMB control number for this information collection is 0938-1407. This information collection is required under section 2799A-10 of the Public Health Service Act, section 725 of the Employee Retirement Income Security Act of 1974, and section 9825 of the Internal Revenue Code. The Departments of HHS, Labor, and the Treasury are collecting this information to improve transparency into health care costs and to prepare a public report on prescription drug cost trends. Any information will be protected to the extent provided by law (including the Privacy Act of 1974 (5 U.S.C. §552(a)), the Freedom of Information Act (5 U.S.C. §552(b)), and the Consolidated Appropriations Act, 2021 (Pub. L. No. 116–260 (2020))). The time required to complete this information collection is estimated to average 2,147 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Use of these instructions is mandatory under 45 CFR §149.720(b), which requires the information to be submitted in a form prescribed by the Secretary of the Treasury and the Secretary of Labor. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850, or jiyun.lim@cms.hhs.gov.

Primary Resources and Help Desk Information

RxDC Home Page

Download submission materials and user manuals at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

CMS Help Desk

If you still have questions after reading these instructions, contact our help desk at <u>CMS_FEPS@cms.hhs.gov</u>. Include "RxDC" in the body of the email to expedite processing. You can typically expect a response within the same day and a full resolution within 1-2 weeks. During periods of high volume, response times may be significantly longer.

REGTAP

Sign up for emails, register for training webinars, and access additional training materials at https://regtap.cms.gov/rxdc.php.

CMS Enterprise Portal

Submit your RxDC report in HIOS at https://portal.cms.gov/.

Changes from the Previous Version

The most significant changes to the RxDC reporting instructions from the previous version include the following:

- Clarified that medical devices, nutritional supplements, and over the counter (OTC) drugs are excluded from prescription drug lists (D3, D4, D5, D7, D8) unless the NDC for the product is on the CMS Drug and Therapeutic Class Crosswalk (Section 8.1)
- Simplified calculation of average monthly premium to use total annual premium divided by 12 instead of the average monthly premium on a per-member basis (Section 6.1)
- Simplified calculation of premium equivalents by removing restrictions on reporting on a cash basis and using paid claims rather than incurred claims (Section 6.1)
- Provided additional details about amounts that should be included or excluded from premium equivalents (Section 6.1)
- Updated instructions for populating the benefit carve-out field in P2 (Section 4.2)
- Provided additional detail on reporting information in the prior year columns in D5 and the restated rebate columns in D6, D7, and D8. Added corresponding instructions clarifying how to represent plans in P2 when the plan contributes to the prior year and restated fields but not to the current year fields (Sections 4.2, 8, and 9)
- Provided instructions to reporting entities on how to report information on retained rebates when exact amounts are unknown (Section 9.1)
- Provided instructions on how to submit data when plan list or data files exceed the maximum allowable size limit in the Health Insurance Oversight System (HIOS) (Section 3.6)
- Announced enforcement of the aggregation restriction (Section 5.6)
- Added a column to D6 to collect enrollment (Section 8.3)

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1 Overview

1.1 What is the RxDC report?

In these instructions, the term "RxDC report" refers to the data submission required under Section 204 of Division BB, Title II (Section 204) of the Consolidated Appropriations Act, 2021 (CAA).¹ The "Rx" stands for Prescription Drug and the "DC" stands for Data Collection.

Section 204 requires group health plans (plans) and health insurance issuers (issuers) offering group or individual health insurance coverage to submit information about prescription drugs and health care spending to the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (collectively, the Departments). In addition, the Director of the Office of Personnel Management (OPM) requires Federal Employees Health Benefits (FEHB) carriers (carriers) to submit Section 204 data to HHS. The Centers for Medicare & Medicaid Services (CMS) within HHS is collecting Section 204 data submissions on behalf of the Departments and OPM.

The implementing regulations for the Section 204 data collection are at <u>5 CFR part 890</u>, <u>26 CFR part 54</u>, <u>29 CFR part 2590</u>, and <u>45 CFR part 149</u>.

Is the RxDC report only for reporting information related to prescription drugs?

No. The RxDC report also collects information on total spending on health care services, including health care premium, enrollment, and spending broken down by hospital costs, provider and clinical service costs for primary and specialty care (separately), and other medical costs, including wellness services.

1.2 When is the deadline?

The deadline for the 2023 reference year report is June 1, 2024.

What is a Reference Year?

The reference year is the calendar year immediately preceding the calendar year in which the RxDC report is due. The RxDC report for the 2023 reference year, which is due in 2024, should contain information based on what happened in calendar year 2023.

1.3 Where can I get help?

CMS Website

You can find more information about RxDC reporting on the CMS website at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

REGTAP

Sign up for email announcements and register for training webinars at Registration for Technical Assistance Portal (REGTAP) at <u>https://regtap.cms.gov/rxdc.php</u>.

Help Desk

If you still have a question after reviewing the RxDC resources on the CMS website and in REGTAP, contact our help desk at <u>CMS_FEPS@cms.hhs.gov</u>. Include "RxDC" in the body of the email to expedite processing. You can typically expect a response within the same day and a full resolution within 1-2 weeks. During periods of high volume, response times may be significantly longer.

¹ The CAA is available at <u>https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf</u>. Section 204 starts on page 1737.

You can also reach the help desk by phone at 1-855-267-1515. The help desk phone line is for general questions about CMS programs. If you have a question that is specific to RxDC, the help desk will ask for your email address and create a ticket so that an RxDC specialist can respond by email.

Help Desk Tips

You can help us respond to help desk tickets faster if you:

- Contact us by email rather than phone.
- Include "RxDC" in the body of the email.
- Do not email or call for status updates on an existing ticket.
- Do not create multiple tickets on the same topic.
- If you figure out the answer to your question before you hear back from the help desk, respond to your ticket confirmation email and say: "I no longer need help on this topic. Please close this ticket."
- If you have a follow-up question after we respond to your inquiry, reply to our latest email to ask the follow-up question. However, if we have answered your question, please do not reply only to thank us (while we appreciate it, if you reply to the email, it re-opens the ticket).

1.4 Who must submit the RxDC report?

Required to Submit	Not Required to Submit
 Health insurance issuers offering group market coverage Health insurance issuers offering individual market coverage, including: Student health plans Plans sold through the Exchanges Plans sold outside of the Exchanges Individual coverage issued through an association Fully-insured and self-funded group health plans, including: Group health plans subject to Employee Retirement Income Security Act of 1974 (ERISA) Non-federal governmental plans, such as plans sponsored by state and local government Church plans that are subject to the Internal Revenue Code FEHB plans 	 Account-based plans, such as health reimbursement arrangements (HRAs) Excepted benefits² including but not limited to: Limited-scope standalone dental and vision plans Short-term, limited-duration insurance Hospital or other fixed indemnity insurance Disease-specific insurance Medicare Advantage and Part D plans Medicaid plans State children's health insurance program plans Basic Health Program plans Retiree-only plans³ Plans maintained outside of the U.S. primarily for the benefit of persons substantially all of whom are nonresident aliens⁴

These requirements apply regardless of whether a plan is considered a grandfathered or grandmothered health plan.⁵

² Public Health Service Act section 2722(b) and (c), Employee Retirement Income Security Act section 732, and Internal Revenue Code section 9831.

³ A retiree-only plan is a plan that covers retirees with fewer than two participants who are active employees.

⁴ An alien is any individual who is not a U.S. citizen or U.S. national. A nonresident alien is an alien who has not passed the green card test or the substantial presence test.

⁵ Grandmothered plans, sometimes referred to as transitional plans, are non-grandfathered plans in the individual and small group market that were issued prior to January 1, 2014, and for which CMS announced it will not take enforcement

Plans, issuers, and carriers may have vendors submit the RxDC report on their behalf. See Section 3 for more information about vendor submissions.

1.5 Applicability FAQs

Below are common questions about who must submit the RxDC report.

My plan has only medical benefits and does not have pharmacy benefits. Do I have to submit the RxDC report?

Yes. Unless your plan is exempt from the Section 204 reporting requirements (see Section 1.4 above), you (or your reporting entity, as defined in Section 3.2) must submit a plan list (P1, P2, or P3), data files D1 and D2, and a narrative response to report the required information about the plan's medical benefit. You do not need to submit data files D3 – D8 if your plan does not have pharmacy benefits.

Does RxDC apply to U.S. territories?

Yes. Plans, issuers, and carriers must report RxDC data for all 50 states, the District of Columbia (D.C.), and the U.S. territories. In these instructions, the term "State" includes all 50 states, D.C., and the territories.

What if my company went out of business? Do I still need to report?

For self-funded terminated plans, reporting entities may choose to include or exclude the business associated with the terminated plan. For fully-insured terminated plans, reporting entities should include the business associated with the terminated plan.

Issuers that go into liquidation during or after the reference year are still subject to the RxDC reporting requirements and must submit data for the portion of the reference year before the liquidation was completed. If a reporting entity, such as a Pharmacy Benefit Manager (PBM), submits on behalf of an issuer, the issuer should ensure that the vendor includes data for the portion of the reference year before the issuer went into liquidation.

2 Required Files

Plans, issuers, and carriers must submit (or have submitted on their behalf) a **plan list** (P1, P2, and/or P3), **eight data files** (D1-D8), and **a narrative response**. A submission can include more than one plan list file type but cannot contain more than one file of the same type. For example, you can upload P1 and P2 in the same submission, but not two versions of P2. Similarly, you cannot upload two versions of the same data file type or two versions of the narrative response in the same submission.

Subject Plan Lists **Data Files File Names** P stands for Plan D stands for Data P1 Individual and student market plan list D1 Premium and Life-Years P2 Group health plan list D2 Spending by Category P3 FEHB plan list D3 Top 50 Most Frequent Brand Drugs • D4 Top 50 Most Costly Drugs . D5 Top 50 Drugs by Spending Increase • D6 Rx Totals D7 Rx Rebates by Therapeutic Class D8 Rx Rebates for the Top 25 Drugs

2.1 Plan Lists and Data Files

action with respect to certain market requirements. See Bulletin: Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies, available at <u>https://www.cms.gov/files/document/extension-limited-non-</u> enforcement-policy-through-calendar-year-2023-and-later-benefit-years.pdf.

Subject	Plan Lists	Data Files
Purpose	The plan list identifies the plans in a submission. The plan list also collects plan- level information required by statute, such as the beginning and end dates of the plan year, the number of members, and the states in which the plan or coverage is offered.	The data files collect premium and spending information at an aggregate level.
Requirement	 P1 is required for plans in the individual or student market P2 is required for employer-based group health plans that are not FEHB plans P3 is required for FEHB plans 	 D1 – D8 are required for plans with medical and pharmacy benefits D1 and D2 are required for plans with only medical benefits D1 and D3 – D8 are required for plans with pharmacy benefits only
File Format	Comma Separated Values (CSV)	Comma Separated Values (CSV)

The file layouts for the plan lists and data files are in Appendix A of these instructions. The plan list and data file templates and the data dictionary are on the CMS website at https://www.cms.gov/CCIIO/Programs-and-initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

2.2 Narrative Response

A narrative response is required. The narrative response file format must be Portable Document Format (.pdf) or Microsoft Word (.doc or .docx). See Section 10 for more information on the narrative response.

2.3 Optional Supplemental Documents

If you want to provide additional information about your submission, the system will allow you to upload up to 30 supplemental documents. The supplemental files must be in PDF, Word, Excel, or CSV format.

3 Submission Process

3.1 Where do I submit my data?

Submit your data through the RxDC module in the Health Insurance Oversight System (HIOS). To log in to HIOS, go to the CMS Enterprise Portal at <u>https://portal.cms.gov/portal/</u>.

Do I need to create a CMS Enterprise Portal or HIOS Account?

You do **NOT** need to create a CMS Enterprise Portal or HIOS account if:

- You already have a HIOS account, or
- You are not uploading any files (because an issuer, third-party administrator (TPA), PBM, or other reporting entity is uploading files on your behalf).

NOTE: It can take up to two weeks to create your accounts. Don't wait until the last minute!

The instructions for how to create your CMS Enterprise Portal account and access HIOS are in the <u>RxDC HIOS</u> <u>Access Guide</u>.

The instructions for using the RxDC module are in the <u>RxDC HIOS Module User Manual</u>.

3.2 Can a vendor submit information on my behalf?

Yes. Plans, issuers, and carriers can contract with issuers, TPAs, Administrative Services Only providers (ASOs), PBMs, or other third-party vendors to submit data on their behalf. An entity that submits some or all required information is called a **reporting entity**. In these instructions, "you" generally refers to the reporting entity.

What is a reporting entity?

An entity that submits some or all required information with respect to a plan, issuer, or carrier is called a **reporting entity**. In these instructions, "you" generally refers to the reporting entity.

3.3 Can multiple vendors submit my data?

Yes. A plan, issuer, or carrier can allow multiple reporting entities to submit on its behalf. For example, a selffunded group health plan may contract with a TPA to submit the Spending by Category data file (D2) and separately contract with a PBM to submit the Top 50 Most Costly Drugs file (D4). The submission for a plan, issuer, or carrier is considered complete if CMS receives all required files, regardless of who submits the files.

Can multiple reporting entities upload files into the same HIOS submission?

No. Each reporting entity must create its own submission in HIOS. For example, if an issuer is submitting D1 and D2 and a PBM is submitting D3 – D8 on behalf of the same plan, the issuer and the PBM must create separate submissions with different submission IDs. In this example, the issuer's submission would contain P2, D1, and D2. The PBM's submission would contain P2 and D3 – D8. The issuer and the PBM both have the opportunity to upload a narrative response and/or supplemental files.

Can multiple vendors submit the same data file type?

Plans, issuers, carriers, and their reporting entities are encouraged to work together to submit only one data file of each data file type for the same plan, issuer, or carrier. For example, if one reporting entity is responsible for only some of the fields in a data file, it might fill out those fields and then give the data file to the other reporting entity to complete the remaining information before submitting the data file in HIOS.

However, if entities are unwilling or unable to work together, more than one reporting entity may submit the same type of data file on behalf of the same plan, issuer, or carrier. For example, if a plan has two issuers, one for behavioral health benefits and another for other medical benefits, then both issuers can submit D2 on behalf of the plan. The first issuer's D2 would include the plan's data related to behavioral health benefits. The second issuer's D2 would include the plan's data related to other medical benefits.

Similarly, if a plan, issuer, or carrier changes vendors during the reference year (such as changing a TPA or PBM), it's acceptable for the previous vendor to report the data from the period prior to the change, and the new vendor to report the data from the period beginning on the date the change was effective. Alternatively, the previous vendor may provide the data to the new vendor and the new vendor would report the entire year of data.

3.4 Does every reporting entity need to submit a plan list?

Yes. Each reporting entity must submit a plan list file (P1, P2, and/or P3) so that CMS will know which plan's data are included in the submission and when multiple entities are reporting for the same plan. If you know which reporting entity will be reporting on behalf of a plan, enter that reporting entity's company name and Employer Identification Number (EIN) in the appropriate columns in the plan list file. (See Plan List Definitions in Section 4.) CMS will use this information to streamline the reconciliation process when there are multiple reporting entities.

Note: Multiple reporting entities may upload different narrative responses on behalf of the same plan, issuer, or carrier. Also, a reporting entity may submit a data file without a narrative response, or a narrative response without a data file. However, each reporting entity must submit a plan list.

3.5 Can a reporting entity create multiple submissions in HIOS?

A reporting entity may make multiple submissions in HIOS if the content of the submissions is mutually exclusive. That is, if a reporting entity creates multiple submissions, each plan in the plan lists and data files

must be included in only one of the submissions. If you accidentally create multiple submissions with overlapping content, please refer to the <u>RxDC HIOS Manual User Guide</u> for instructions on editing and deleting submissions.

3.6 What if my file exceeds the file size limit in HIOS?

The HIOS file size limit is 200 megabytes per file. If your file exceeds the file size limit, use one or both of the following methods to reduce the size of your file.

Option 1: Break up your files by market segment and aggregation state

If your files are too large, you may break them up into multiple smaller files by market segment (or groupings of market segments) and submit them separately in HIOS. If the files are still too large after breaking them up by market segment, you may break them up by aggregation state (or groupings of aggregation states). If you choose this method, every file in your submission should be broken up in the same way. (See Sections 5.3 and 5.4 for more information on market segment and aggregation state.)

Option 2 – Leave drug name and therapeutic class name blank

If data file D7 is too large, you may leave therapeutic class name blank as long as therapeutic class code is populated with a class code from the CMS crosswalk. (See Section 8.1 for more information on the CMS crosswalk.) If data files D3, D4, D5 and/or D7 are too large, you may leave drug name blank as long as the drug code field is populated with a drug code from the CMS crosswalk.

File	Text field that may be blank to reduce file size	Corresponding fields that must NOT be blank
D3 Top 50 Most Frequent Brand Drugs	Drug Name	Drug Code
D4 Top 50 Most Costly Drugs	Drug Name	Drug Code
D5 Top 50 Drugs by Spending Increase	Drug Name	Drug Code
D7 Rx Rebates by Therapeutic Class	Therapeutic Class Name	Therapeutic Class Code
D8 Rx Rebates for the Top 25 Drugs	Drug Name	Drug Code

3.7 Can other reporting entities see my data?

No. To preserve confidentiality, a reporting entity can view only the files that it uploads. It cannot view files uploaded by a different reporting entity even if the information is related to the same plan, issuer, or carrier. Further, a reporting entity cannot see whether another reporting entity submitted a file.

Note: If a reporting entity has more than one employee with an RxDC Submitter role in HIOS, those employees will be able to view and edit each other's RxDC submissions.

3.8 How do I know if a reporting entity submitted my data?

CMS does not have a mechanism to notify plans, issuers, or carriers when data has been submitted on their behalf. To confirm submission, plans, issuers, and carriers should contact their reporting entities directly.

What should I do if my insurance company or TPA sent me an RxDC survey?

Some insurance companies (issuers) and vendors (such as TPAs, ASOs, PBMs, or brokers) may send surveys or otherwise request information from their clients so that the issuer or vendor can complete plan list P2 and data file D1 on behalf of their clients. The survey is not from CMS and is generally a different document than what issuers or vendors submit to CMS as the federal RxDC report. If your issuer or vendor does not submit P2 and D1 (or other required files) to CMS on your behalf, then you (or another reporting entity) must submit P2 and D1 directly to CMS.

If you have a question about the logistics of a survey that you receive from an issuer or vendor, such as how to submit or edit your response or the survey deadline, you must contact your issuer or vendor. CMS is not involved in any outside survey.

4 Plan List Definitions

Use the following definitions when you fill out your plan lists.

Punctuation

Note 1: Do not uses slashes ("/") in alphanumeric fields. HIOS won't accept text with slashes because data with slashes requires additional security screening that would slow down processing time. The exception is that you can use slashes in the column headers and in date fields.

Note 2: You may use commas in alphanumeric fields if the string is enclosed by double-quotation marks as text qualifiers. (Example: "Mary's Hardware Store, Inc."). The double-quotation marks are necessary so that HIOS can differentiate from commas used as delimiters and commas used in a text string.

4.1 P1 Individual and Student Market Plan List

Note: Plan list P1 is only applicable to insurance companies that file the Medical Loss Ratio report, and to reporting entities, such as PBMs, that submit data on behalf of insurance companies. Do not fill out P1 if you are a group health plan.

HIOS Plan Name

Location: P1 Column A | Max length: 20 characters | Must not be blank

Enter the HIOS Plan Name. If a plan isn't registered in HIOS, enter the plan marketing name. Do not use slashes.

HIOS Plan ID

Location: P1 Column B | Max length: 25 characters | Must not be blank

Enter the 14-character Plan ID from HIOS. Do not enter multiple HIOS Plan IDs in the same cell in P1. Do not leave this cell blank.

Some grandfathered, grandmothered, and student health plans may not have HIOS Plan IDs. If an individual or student market plan does not have a HIOS Plan ID, create a unique 14-character plan ID as follows:

Plan Type	Characters 1-5	Characters 6-7	Characters 8-14	Example
Grandfathered Plans (excluding student plans)	5-digit HIOS Issuer ID	GF	Generate a unique 7-digit number.	52986GF0000147
Grandmothered Plans (excluding student plans)	5-digit HIOS Issuer ID	GM	Generate a unique 7-digit number.	52986GM0000148
Student Health Plans	5-digit HIOS Issuer ID	SH	Generate a unique 7-digit number.	52986SH0000149

All insurance companies should already have a HIOS Issuer ID, even if they only offer plans that don't have a HIOS Plan ID. Contact the help desk if you are an insurance company and you do not know your HIOS Issuer ID. (Do not contact the help desk for a HIOS Issuer ID or HIOS Plan ID if you are not an insurance company.)

Plan Year Beginning and End Dates

Location: P1 Columns C and D | Format: MM/DD/YYYY

Enter the plan year beginning and end dates. If an individual or student market plan doesn't have a designated plan year, you may enter the first and last day of the reference year.

Note: If a plan is included on the plan list solely because it contributed to prior year columns (D5) or the restated rebate column (D6, D7, D8) but didn't contribute to fields for the current reference year, you have the option of including the plan in the plan list. If you choose to include the prior year plan in the plan list, report 01/01/2023 and 01/02/2023 as the plan year beginning and end dates, respectively, or leave both values blank. (HIOS will reject submissions if a plan year end date is in the year prior to the reference year.)

See Sections 4.2 and 4.3 for the instructions for group health plans and FEHB plans, respectively.

Market Segment

Location: P1 Column E | Max length: 100 characters | Must not be blank

In P1, enter "Individual market" for individual market plans that are not student market plans. Enter "student market" for plans in the student market. Do not enter more than one market segment in the same cell. This field is not case sensitive, but you must use exact spelling.

See Sections 4.2 and 4.3 for the instructions for group health plans and FEHB plans, respectively.

Members as of 12/31

Location: P1 Column F| Max decimal places: 0

Enter the number of members as of 12/31 of the reference year. You must enter a whole number without decimal places. If a plan year ended before 12/31 of the reference year, enter 0.

In the individual and student market, the term "member" means a person who has health coverage through an individual market or student market plan. The term includes policyholders and dependents.

See Sections 4.2 and 4.3 for the instructions for group health plans and FEHB plans, respectively.

PBM Name

Location: P1 Column G | Max Length 2,048 characters

Enter the PBM name. Do not use slashes. If there is more than one PBM, separate the names with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

See Section 4.2 for the definition of a PBM.

PBM EIN

Location: P1 Column H | Format: 9 digits

Enter the PBM 9-digit EIN without dashes. (Example: 012345678.) If there is more than one PBM, separate the PBMs with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

Included in D1 – D8

Location: P1 Columns I – P | Valid Values: 0 or 1

Enter 1 if a plan's data is included in the respective data file <u>in your submission</u>. Enter 0 if the plan's data is not included in the respective data file in your submission. Do NOT enter 1 if a different entity is submitting a data file. For example, if an issuer is submitting D1 and D2 on behalf of a plan and a PBM is submitting D3 – D8, the issuer should enter 1 in "Included in D1" and "Included in D2" and enter 0 for "Included in D3" through "Included in D8." The PBM should enter 0 in "Included in D1" and "Included in D1" and "Included in D2" and enter 1 for "Included in D3" through "Included in D8."

CMS will use this information to reconcile submissions when more than one reporting entity is submitting on behalf of a plan.

Example:

An issuer is submitting on behalf of three plans. For two of those plans, the issuer is submitting D1 and D2 only and the PBM is submitting D3 - D8. For the third plan, the issuer is submitting all 8 data files D1 - D8.

P1 Submitted by the Issuer

HIOS Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 1	1	0	0	0	0	0	0
Plan B	 1	1	0	0	0	0	0	0
Plan C	 1	1	1	1	1	1	1	1

P1 Submitted by the PBM

HIOS Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 0	0	1	1	1	1	1	1
Plan B	 0	0	1	1	1	1	1	1

4.2 P2 Group Health Plan List

If a group health plan offers multiple benefit options, you may combine them into one row in the plan list or use multiple rows. It's up to you.

Group Health Plan Name

Location: P2 Column A | **Max length:** 512 characters | **Must not be blank** Enter the group health plan name. Do not use slashes.

Group Health Plan Number

Location: P2 Column B | Max length: 25 characters | Must not be blank

Enter a unique plan number. You may use numbers, letters, or punctuation marks (except for slashes). You may use the plan number from your accounting system, the Form 5500 Plan Number⁶ (if a Form 5500 is filed for the plan), the plan sponsor EIN (if the plan sponsor only has one plan), or create a new identification number to enumerate the plans in the plan list.

If you use a Form 5500 Plan Number as the Group Health Plan Number, you must also enter the Form 5500 Plan Number in the Form 5500 Plan Number column. That is, the Form 5500 Plan Number would be in the Group Health Plan Number column *and* the Form 5500 Plan Number column.

If you use the plan sponsor EIN as the Group Health Plan Number, you must also enter the plan sponsor EIN in the Plan Sponsor EIN column. That is, the plan sponsor EIN would be in the Group Health Plan Number column *and* the Plan Sponsor EIN column.

⁶ For more information on the Form 5500 Plan Number, see the Form 5500 Instructions at <u>https://www.dol.gov/sites/dolgov/files/EBSA/employers-and-advisers/plan-administration-and-compliance/reporting-and-filing/form-5500/2023-sf-instructions.pdf</u>.

When multiple entities submit information about the same plan, do they need to use the same plan number?

Multiple entities submitting information about the same plan are encouraged to use the same plan name and plan number to help CMS reconcile submissions.

Note: Entities must use the same plan sponsor EIN in the Plan Sponsor EIN column when reporting on behalf of the same plan, regardless of whether they use the same plan name and number.

Carve-Out Description

Location: P2 Column C | Max length: 2,048 characters

This field is required when a reporting entity is submitting data for a carved-out benefit. An example of a carveout benefit is a benefit administered, offered, or insured by an entity that is different than the entity that administers, offers, or insures the majority of the plan's other benefits.

Enter one of the following:

- Pharmacy only
- Behavioral health only
- Fertility only
- Specialty drugs only
- Hospital only
- Other

Plans without pharmacy benefits

If you are submitting on behalf of a plan that, to the best of your knowledge, does not cover pharmacy benefits (and therefore a PBM or other reporting entity will not be submitting D3 – D8 for that plan), enter "This plan does not include pharmacy benefits." (*Do not include the quotation marks*.) This will let CMS know that we shouldn't expect D3 – D8 for that plan.

If you are submitting data regarding a plan's medical benefit and, to the best of your knowledge, a different reporting entity will submit data regarding the plan's pharmacy benefit, enter "Medical only." (*Do not include the quotation marks*.) This will let CMS know that we should expect another reporting entity to submit D3 – D8 for that plan.

If you don't know whether a plan has a pharmacy benefit or whether another reporting entity is expected to report on a plan's pharmacy benefit, you may leave this field blank.

Note: You may leave this field blank if you are reporting information about the carve-out benefit and information about the majority of the plan's other benefits, and you are using one row in the plan list that represents the main plan and the carve-out (or two rows for non-calendar year plans).

Form 5500 Plan Number

Location: P2 Column D | Max length: 1,024 characters

If a group health plan submits a Form 5500 to the Department of Labor, enter the 3-digit Form 5500 plan number (self-assigned by the filer in accordance with Form 5500 Instructions). If there is more than one value, separate them with a semicolon.

If you don't have a Form 5500 Plan Number, leave this field blank. If you're not sure if you have a Form 5500 Plan Number, you can look it up using the Form 5500 search tool on the Department of Labor website at https://www.efast.dol.gov/5500search. If the reporting entity does not obtain this information from the plan, the reporting entity may leave this field blank.

States in which the plan is offered

Location: P2 Column E | Max length: 200 characters

Enter the states and territories in which the plan or coverage is offered using two-character state postal code. If there is more than one state or territory, separate them with a semicolon. (Example: AL; AK; MA.) If a plan is offered in every state and in DC, enter "National". If a plan is offered nationally and also in one or more territories, enter "National" as well as the two-character postal code for the applicable territories, separated by a semicolon. (Example: National; PR; GU.)

For purposes of RxDC reporting, a plan is considered "offered" in a state if a person living or working in that state would be eligible to obtain coverage under the plan. Self-funded plans may enter "National" if a person living or working in any state would be eligible to obtain coverage under the plan.

Note 1: "States in which the plan is offered" in the plan lists (P2, P3) is not the same thing as "Aggregation State" in the aggregate data files (D1 - D8). See Section 5.4 for more information on state aggregation.

Note 2: If multiple vendors submit on behalf of the same plan, issuer, or carrier, only one of them is required to report the states in which the plan is offered.

Market Segment

Location: P2 Column F | Max length: 512 characters | Must not be blank

Enter small group market, large group market, SF small employer plans, or SF large employer plans. If a plan is partially insured and partially self-funded, enter both market segments in the same cell, separated by a semicolon. (Example: Large group market; SF large employer plans.)

See Section 5.3 for more information on market segments and how to determine whether an employer is a small employer or a large employer.

Note: P2 is the only place where you can put more than one market segment in a single cell. Do not enter more than one value for market segment in data files D1 - D8.

Plan Year Beginning and End Dates

Location: P2 Columns G and H | **Format:** MM/DD/YYYY Enter the actual beginning and end dates of the plan year, even if they fell outside of the reference year.

The plan year may be the year in the plan document of a group health plan, the deductible or limit year used under the plan, or the policy year.

Note 1: If a plan is included on the plan list solely because it contributed to prior year columns (D5) or the restated rebate column (D6, D7, D8) but didn't contribute to fields for the current reference year, you have the option of including the plan in the plan list. If you choose to include the prior year plan in the plan list, report 01/01/2023 and 01/02/2023 as the plan year beginning and end dates, respectively, or leave both values blank. (HIOS will reject submissions if a plan year end date is in the year prior to the reference year.)

Note 2: When multiple vendors submit on behalf of the same plan, at least one vendor must enter the beginning and end dates of the plan year. The other vendors may enter the beginning and end dates of the plan year, or the first and last day of the portion of the reference year for which they are submitting data.

How do I fill out the plan list for plans with non-calendar plan years?

Suppose for example that the plan year is July 1, 2022 through June 30, 2023. Enter 07/01/2022 for the beginning date and 06/30/2023 for the end date in the 2023 RxDC report. Because the plan year ended before the end of the reference year, enter 0 for the number of members as of 12/31/2023 in the 2023 RxDC report.

Similarly, if the plan year is July 1, 2023 through June 30, 2024, enter 07/01/2023 for the beginning date and 06/30/2024 for the end date in the 2023 RxDC report. Enter the actual number of members as of 12/31/2023 in the 2023 RxDC report.

If a plan renews in the middle of the reference year, use two rows in the plan list file: one row for the plan year that ended on 6/30/2023 and another for the plan year that began on 7/1/2023.

Group Health Plan Name	Group Health Plan Number	Market Segment	Plan Year Beginning Date	Plan Year End Date	Members as of 12/31 of the reference year
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2022	06/30/2023	0
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2023	06/30/2024	27

Example: Non-calendar year plan in the 2023 RxDC report.

Note: In the <u>data files</u> (as opposed to the plan lists), the reporting entity would include only the data related to the 2023 <u>calendar year</u> (e.g., the last six months of the "old" plan and the first six months of the "new" plan).

Members as of 12/31

Location: P2 Column I | Max decimal places: 0

Enter the number of members as of 12/31 of the reference year. You must enter a whole number without decimal places. If a plan year ended before 12/31 of the reference year, enter 0.

What is a Member?

For the purposes of these instructions, the term "member" means a person who has health coverage, regardless of whether the coverage is associated with an insurance policy, a group health plan, or an FEHB plan. For example, enrollees, dependents, participants, beneficiaries, and FEHB annuitants are all considered members. Retirees and COBRA participants, including their dependents, also are considered members if they are covered by a plan that is not a retiree-only plan.

Note: In the plan lists, report members as of 12/31 of the reference year. In data file D1, report the average number of members during the reference year, which is called life-years.

Plan Sponsor Name

Location: P2 Column J | **Max length:** 2,048 characters The term plan sponsor means:

- The employer, for an employee benefit plan that a single employer established or maintains. **Note:** A plan of a controlled group of corporations that is treated as a single employer generally is a single-employer plan and should enter the name of the parent corporation or other member of the controlled group considered the sponsor;⁷
- The employee organization (such as a labor union) in the case of a plan of an employee organization; or

⁷ If companies are in the same controlled group but have different EINs and file separate Form 5500s, the companies may, but do not have to, submit separate RxDC reports.

• The association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, if the plan is established or maintained jointly by one or more employers and one or more employee organizations, or by two or more employers.⁸

Do not enter more than one plan sponsor name in the same cell unless plan sponsorship changed during the reference year. In that case, separate the names with a semicolon. (Alternatively, you may use a separate row in the plan list for each plan sponsor.)

Note: Sometimes the Plan Sponsor Name is the same as the Group Health Plan Name.

Multiple-Employer Plans

If an association or other entity is not the plan sponsor, you may enter the name of a participating employer. Use the same name in future RxDC reports unless there is a change in sponsorship.

In HIOS, you may upload a supplemental document with the names and EINs of the participating employers and/or sponsoring members of the multi-employer plan. This is optional.

Plan Sponsor EIN

Location: P2 Column K | Max length: 2,048 characters | Must not be blank

Enter the 9-digit employer EIN assigned to the plan sponsor. (Example: 012345678.) Do not use dashes. A multiple-employer plan or plan of a controlled group of corporations should use the EIN of the entity identified in the Plan Sponsor Name field.

What if I don't know the plan sponsor EIN?

You must report the plan sponsor EIN. If you don't know the EIN, you must obtain the information from the plan sponsor.⁹ CMS uses the plan sponsor EIN to reconcile submissions made by multiple reporting entities on behalf of the same plan.

Note: HIOS has been updated to accept EINs with more than one leading zero.

Issuer Name

Location: P2 Column L | Max Length: 2,048 characters

Only required if an insurance company or stop-loss carrier is one of the plan's reporting entities.

Enter the issuer name. Do not use slashes. If there is more than one issuer, enter both in the same cell separated by a semicolon.

An issuer refers to the insurance company, service, or organization (including an HMO) with which a fullyinsured group health plan has a contract or policy for insurance coverage. If the plan is not insured, leave the cell blank.

Self-funded plans:

- For self-funded plans with stop-loss coverage, enter the name of the stop-loss carrier.
- For self-funded plans that use an issuer as a TPA or ASO provider, do NOT enter the name of the issuer here. Instead, enter the name of the issuer providing the TPA/ASO services in the "TPA Name" column.

⁸ Public Health Service Act section 2791(d)(13), referencing Employee Retirement Income Security Act section 3(16)(B). ⁹ If a plan sponsor files the Form 5500 report with the Department of Labor, you may use the public Form 5500 data sets or search tool to obtain a plan sponsor's EIN in lieu of collecting the EIN from the plan sponsor. The Form 5500 datasets are available at <u>https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/public-disclosure/foia/form-5500-datasets</u>. The search tool is available <u>https://www.efast.dol.gov/5500search/</u>. If you are unable to obtain the EIN using the publicly available Form 5500 data, you must obtain the EIN from the plan sponsor directly.

- If an issuer provides stop-loss and also provides TPA/ASO services to a self-funded plan, enter the name of the issuer in the "Issuer Name" column and in the "TPA Name" column.
- Otherwise, leave the "Issuer Name" column blank.

Issuer EIN

Location: P2 Column M | Format: 9 digits

Only required if an issuer or stop-loss carrier is one of the plan's reporting entities.

Enter the 9-digit EIN of the company you entered in the Issuer Name field. Do not use dashes. (Example: 012345678.) If there is more than one EIN, enter both EINs in the same cell separated by a semicolon. If the plan is not insured, leave the cell blank.

TPA Name

Location: P2 Column N | **Max Length:** 2,048 characters Only required if TPA or ASO provider is one of the plan's reporting entities.

Enter the name of the TPA and/or ASO. Do not use slashes. If there is more than one TPA or ASO, separate their names with a semicolon. If a plan doesn't have a TPA or an ASO provider, leave the cell blank.

If you are a third-party vendor that does not otherwise act as a TPA and your only relationship with a plan is to submit data on their behalf, you may (but are not required to) include your company name in the TPA Name field. (If the plan also has a TPA, separate your company name from the TPA name using a semicolon.)

If you are reporting for a self-administered self-funded plan that doesn't have a TPA or ASO, you may enter your company name or you may leave this field blank.

TPA EIN

Location: P2 Column O | Format: 9 digits

Only required if TPA or ASO provider is one of the plan's reporting entities.

Enter the 9-digit EIN of the company you entered in the TPA Name field. Do not use dashes. (Example: 012345678.) If there is more than one EIN, separate the EINs with a semicolon. If a plan does not have a TPA, leave the cell blank.

PBM Name

Location: P2 Column P | **Max Length:** 2,048 characters Only required if a PBM is one of the plan's reporting entities.

Enter the PBM name. Do not use slashes. If there is more than one PBM, separate the names with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

Pharmacy benefit manager (PBM) generally means an entity that, either directly or through an intermediary, acts as a price negotiator, manages the prescription drug benefits, or provides other pharmacy benefit management services to the plan, issuer, or carrier. Pharmacy benefit management services include processing and paying of prescription drug claims, performing drug utilization review, processing prior authorization requests, adjudicating appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, designing formularies, and controlling the cost of covered prescription drugs.

PBM EIN

Location: P2 Column Q | **Format:** 9 digits Only required if a PBM is one of the plan's reporting entities. Enter the PBM 9-digit EIN without dashes. (Example: 012345678.) If there is more than one PBM, separate the EINs with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

Included in D1 – D8

Location: P2 Columns R – Y | Valid Values: 0 or 1 | Must not be blank

Enter 1 if a plan's data is included in the respective data file in your submission. Enter 0 if the plan's data is not included in the respective data file in your submission. For example, if an issuer is submitting only D1 and D2 on behalf of a plan, the issuer should enter 1 in "Included in D1" and "Included in D2" and enter 0 for "Included in D3" through "Included in D8." CMS will use this information to reconcile submissions when more than one reporting entity is submitting on behalf of a plan.

Example 1: A self-funded group health plan is submitting D1 on its own behalf, a TPA is submitting D2 for that plan, and a PBM is submitting D3 – D8 for that plan.

P2 submitted by the group health plan

Group Health Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 1	0	0	0	0	0	0	0

P2 submitted by the TPA (The TPA's P2 plan list would also have rows for the other plans the TPA is submitting on behalf of.)

Group Health Plan Name		Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan	Α …	0	1	0	0	0	0	0	0

P2 submitted by the PBM

(The PBM's P2 plan list would also have rows for the other plans the PBM is submitting on behalf of.)

Group Health Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 0	0	1	1	1	1	1	1

Example 2: A TPA is submitting D2 for Plan A and D1 and D2 for Plan B. The "included in" columns for that TPA's P2 file would look like this:

Group Health Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 0	1	0	0	0	0	0	0
Plan B	 1	1	0	0	0	0	0	0

4.3 P3 FEHB Plan List

FEHB Plan Name

Location: P3 Column A | **Max Length:** 2,048 characters | **Must not be blank** Enter the FEHB Plan Name. Do not use slashes.

FEHB Contract Number

Location: P3 Column B | **Max Length:** 2,048 characters | **Must not be blank** Enter the FEHB Contract Number in this format: XXXX.

FEHB Plan Code

Location: P3 Column C | **Max Length:** 2,048 characters | **Must not be blank** Enter the three-digit FEHB plan code as it appears in the FEHB plan brochure. If there are multiple plan codes, separate them with a semicolon. (Example: S11; S12.)

States in which the plan is offered

Location: P3 Column D | Max length: 200 characters

Enter the states and territories in which the plan or coverage is offered using two-character state postal code. If there is more than one state or territory, separate them with a semicolon. (Example: AL; AK; MA.) If a plan is offered in every state and in DC, enter "National". If a plan is offered nationally and also in the territories, enter "National" as well as the two-character postal code for the territories, separated by a semicolon. (Example: National; PR; GU.)

For purposes of RxDC reporting, a plan is considered "offered" in a state if a person living or working in that state would be eligible to have coverage under the plan.

Note 1: "States in which the plan is offered" in the plan lists (P2, P3) is not the same thing as "Aggregation State" in the aggregate data files (D1 - D8). See Section 5.4 for more information on state aggregation.

Note 2: If multiple vendors submit on behalf of the same plan, issuer, or carrier, only one of them is required to report the states in which the plan is offered.

Plan Year Beginning and End Dates

Location: P3 Columns E and F | **Format:** MM/DD/YYYY Enter the plan year beginning and end dates. For FEHB plans, the plan year is the calendar year.

Note: If a plan is included on the plan list solely because it contributed to prior year columns (D5) or restated rebates (D6, D7, D8) but didn't contribute to fields for the current reference year, you have the option of including the plan in the plan list. If you choose to include the prior year plan in the plan list, report 01/01/2023 and 01/02/2023 as the plan year beginning and end dates, respectively, or leave both values blank. (HIOS will reject submissions if a plan year end date is in the year prior to the reference year.)

Members as of 12/31 of the Reference Year

Location: P3 Column G | Max decimal places: 0

Enter the number of members as of 12/31 of the reference year. Include FEHB covered individuals including enrollees, annuitants, family members, and Temporary Continuation of Coverage (TCC) enrollees. You must enter a whole number without decimal places. If a plan year ended before 12/31 of the reference year, enter 0.

Note: In the plan lists, report members as of 12/31 of the reference year. In data file D1, report the average number of members during the reference year, which is called life-years.

FEHB Carrier Name

Location: P3 Column H | Max Length: 2,048 characters | Must not be blank

FEHB Carrier EIN

Location: P3 Column I | **Max Length:** 2,048 characters | **Must not be blank** Enter the 9-digit EIN without dashes. (Example: 012345678.)

Affiliate Name

Location: P3 Column J | **Max Length:** 2,048 characters (If different from the FEHB carrier.) If there is more than one value, separate them with a semicolon. If there isn't an affiliate, leave this cell blank.

Affiliate EIN

Location: P3 Column K | **Max Length:** 2,048 characters (If different from the FEHB carrier.) Enter the 9-digit EIN without dashes. (Example: 012345678.) If there is more than one value, separate them with a semicolon. If there isn't an affiliate, leave this cell blank.

TPA or other Third Party Name

Location: P3 Column L | **Max Length:** 2,048 characters Enter the TPA name. Do not use slashes. If there is more than one TPA, separate them with a semicolon. If a plan doesn't have a TPA, leave the cell blank.

TPA or other Third Party EIN

Location: P3 Column M | Format: 9 digits

Enter the TPA 9-digit EIN without dashes. (Example: 012345678.) If there is more than one TPA, separate them with a semicolon. Do not use dashes. If a plan doesn't have a TPA, leave the cell blank.

PBM Name

Location: P3 Column N| Max Length: 2,048 characters

Enter the PBM name. Do not use slashes. If there is more than one PBM, separate them with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

PBM EIN

Location: P3 Column O | Format: 9 digits

Enter the PBM 9-digit EIN without dashes. (Example: 012345678.) If there is more than one PBM, separate them with a semicolon. If a plan doesn't have a PBM, leave the cell blank.

Included in D1 – D8

Location: P3 Columns P – W | Valid Values: 0 or 1 | Must not be blank

Enter 1 if a plan's data is included in the respective data file in your submission. Enter 0 if the plan's data is not included in the respective data file in your submission. For example, if an issuer is submitting D1 and D2 on behalf of a plan, the issuer should enter 1 in "Included in D1" and "Included in D2" and enter 0 for "Included in D3" through "Included in D8." CMS will use this information to reconcile submissions when more than one reporting entity is submitting on behalf of a plan.

Example: A reporting entity is submitting D1 – D8 on behalf of Plan A and D1 and D2 on behalf of Plans B and C.

FEHB Plan Name	 Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
Plan A	 1	1	1	1	1	1	1	1
Plan B	 1	1	0	0	0	0	0	0
Plan C	 1	1	0	0	0	0	0	0

5 Data Aggregation

5.1 Overview

In the data files (D1 - D8), aggregate the data for plans that are in the same market segment (Section 5.3) and the same state (Section 5.4). Within a state and market segment, you should aggregate data for plans that are associated with the same plan sponsor, issued by the same issuer, administered by the same TPA, or reported by the same reporting entity (Section 5.5). You cannot aggregate the data to a less granular level than the level used by the reporting entity that submits the data in file D2 Spending by Category (Section 5.6).

Note: The aggregation state in D1 – D8 is not the same thing as "states in which the plan is offered" in P2 and P3. See Section 5.4 for more information on determining the aggregation state.

What does it mean to aggregate data?

Aggregating data means that you are combining the information of multiple plans. For example, if a TPA is submitting D2 for three self-funded small employer plans (Plans A, B, C) and two self-funded large employer plans (Plan D and E) in Georgia, the TPA should create D2 as follows:

Company Name	Company EIN	Aggregation State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible or Out-of-Pocket Maximum
TPA Name	TPA EIN	GA	SF small employer plans	Hospital	Sum of Plans A, B, & C	Sum of Plans A, B, & C	Sum of Plans A, B, & C
TPA Name	TPA EIN	GA	SF small employer plans	Primary care	Sum of Plans A, B, & C	Sum of Plans A, B, & C	Sum of Plans A, B, & C
TPA Name	TPA EIN	GA	SF small employer plans	Specialty care	Sum of Plans A, B, & C	Sum of Plans A, B, & C	Sum of Plans A, B, & C
TPA Name	TPA EIN	GA	SF small employer plans	Other medical costs and services	Sum of Plans A, B, & C	Sum of Plans A, B, & C	Sum of Plans A, B, & C
TPA Name	TPA EIN	GA	SF small employer plans	Known medical benefit drugs	Sum of Plans A, B, & C		
TPA Name	TPA EIN	GA	SF small employer plans	Estimated medical benefit drugs	Sum of Plans A, B, & C		
TPA Name	TPA EIN	GA	SF large employer plans	Hospital	Sum of Plans D & E	Sum of Plans D & E	Sum of Plans D & E
TPA Name	TPA EIN	GA	SF large employer plans	Primary care	Sum of Plans D & E	Sum of Plans D & E	Sum of Plans D & E
TPA Name	TPA EIN	GA	SF large employer plans	Specialty care	Sum of Plans D & E	Sum of Plans D & E	Sum of Plans D & E
TPA Name	TPA EIN	GA	SF large employer plans	Other medical costs and services	Sum of Plans D & E	Sum of Plans D & E	Sum of Plans D & E
TPA Name	TPA EIN	GA	SF large employer plans	Known medical benefit drugs	Sum of Plans D & E		
TPA Name	TPA EIN	GA	SF large employer plans	Estimated medical benefit drugs	Sum of Plans D & E		

5.2 Column Names

The first four columns of D1 – D8 are the same:

Company Name

Location: D1–D8 Column A | Max Length: 256 characters | Must not be blank

This column was formerly named Issuer or TPA Name. The purpose of the column has not changed, only the name.

Enter the company name that corresponds to the level of aggregation. Do not enter more than one company name in the same cell. Do not use slashes.

For fully-insured plans, this is usually the name of the issuer. For self-funded plans, this is usually the name of the TPA. If you are not aggregating at the issuer or TPA level within a state or market, enter the name of the company that corresponds with the level of aggregation. For example, if you aggregate data at the plan sponsor, or other reporting entity level, enter the name of the plan sponsor or other reporting entity, respectively.

See Section 5.5 for more information about aggregating data by company.

Company EIN

Location: D1–D8 Column B | Max Length: 9 characters | Must not be blank

This column was formerly named Issuer or TPA EIN. The purpose of the column has not changed, only the name. Enter the 9-digit EIN of the company that corresponds to the level of aggregation. Do not use dashes. (Example: 012345678.) Do not enter more than one EIN in the same cell.

Note: HIOS has been updated to accept EINs with more than one leading zero.

Aggregation State

Location: D1–D8: Column C | Max length: 100 characters | Must not be blank

This column was formerly named State. The purpose of the column has not changed, only the name. Enter the state abbreviation that corresponds with the level of aggregation. Do not enter more than one state in the same cell.

Note: The aggregation state in D1 - D8 is not the same thing as "states in which the plan is offered" in P2 and P3. For self-funded plans, the aggregation state is generally the state where the plan has its principal place of business. For fully-insured plans, the aggregation state is generally the state where the policy was issued. See Section 5.4 for more information on determining the aggregation state.

Market Segment

Location: D1–D8 Column D | Max length: 100 characters | Must not be blank

Valid Values: individual market, student market, small group market, large group market, SF small employer plans, SF large employer plans, FEHB plans. Do not enter more than one market segment in the same cell.

5.3 Market Segment Aggregation

The following table has the names and abbreviations for the market segments. You must use the appropriate abbreviation when you fill out your plan lists and data files. Make sure to use the exact spelling of the abbreviation or you will be unable to upload your data.

Market Segment	Abbreviation
	(not case sensitive)
Individual market (excluding the student market)	Individual market
Student market	Student market
Fully-insured small group market	Small group market
Fully-insured large group market (excluding the FEHB line of business)	Large group market
Self-funded group health plans offered by small employers	SF small employer plans
Self-funded group health plans offered by large employers	SF large employer plans
FEHB line of business	FEHB plans

Note: The market segments are mutually exclusive. Do not report the same data in more than one market segment.

To determine the market segment for a group health plan, determine whether the employer is small or large and whether the plan is fully-insured or self-funded.

Funding Type

A group health plan can be fully-insured, self-funded, or have a combination of funding types. A **fully-insured plan** is a plan for which the insurance risk is transferred to an insurance company. With a **self-funded plan**, the plan sponsor retains the insurance risk, although the plan may be administered by a TPA. Plan sponsors of self-funded plans sometimes purchase stop-loss insurance or other types of reinsurance to mitigate risk (such as level-funded plans). For purposes of reporting, plans with stop-loss insurance coverage are still considered self-funded.

For **mixed-funded plans**, which generally self-fund some benefits and fully insure other benefits, report the self-funded business in the self-funded market segment and the fully-insured business in the fully-insured market segment. For example, if a large employer self-funds the pharmacy benefit of a plan and purchases insurance for the medical benefits, the pharmacy benefits would be attributed to the market segment for self-funded large employer plans and the medical component of the same plan would be attributed to the fully-insured large group market.

For "**minimum premium**" **plans** (MPPs) and similar hybrid arrangements that mimic key aspects of fully-insured arrangements, or that comply with state insurance laws regarding mandated benefits, report the business as fully-insured.¹⁰

For **level-funded plans**, report the business as self-funded. A level-funded plan is a type of self-funded arrangement in which the plan sponsor makes set monthly payments to a service provider to cover estimated claims costs, administrative costs, and premiums for stop-loss insurance for claims that surpass a maximum dollar amount beyond which the plan sponsor is no longer responsible for paying claims (the attachment point). When claims are lower than expected, surplus payments may be refunded at the end of the contract. These arrangements are sometimes referred to as balanced funding or alternative funding.

What if a plan sponsor moves from a fully-insured product to self-funded coverage during the reference year (or vice versa)?

Report the fully-insured business in the small group or large group market segments, as applicable, and the self-funded business in the self-funded small employer or large employer market segments, as applicable.

¹⁰ "Minimum premium" plans generally have regular fixed premium or funding payments, often based on past experience, and limit the plan sponsor's liability for claims.

Employer Size

For group health plans, the market segment (small or large) is based on the number of employees. An employer is generally considered small if it has 50 or fewer employees and large if it has more than 50 employees.

Fully-insured plans

Use the same market segment that you use for Medical Loss Ratio (MLR) reporting.

Self-funded plans

Determine the number of employees by averaging the total number of employees employed on business days during the calendar year preceding the reference year. Include employees that do not have health coverage when you determine the size of the employer. Do not include dependents or retirees when counting the number of employees.

How do I count the number of employees?

Use any reasonable method that accounts for full-time, part-time, and seasonal employees. Examples of reasonable methods include (1) the full-time equivalent employee method described in 26 CFR 54.4980H-2(c); (2) if a TPA is affiliated with an issuer, the counting method used by the issuer for MLR reporting; and (3) if an applicable state method accounts for non-full-time employees, the applicable state method.

If the reporting entity for a self-funded plan doesn't have the necessary information to count the number of employees, the entity may use a reasonable estimate of employer size. A reasonable method to estimate employer size for a self-funded plan is to divide the number of employees in the plan by 0.70.¹¹ For example, if 40 employees are covered by a plan, then the estimated employer size is 57 (40 ÷ 0.70 = 57).

How do I determine employer size if a plan covers more than one employer?

Self-funded multiemployer plans should use the total number of employees employed by the employers that are contributing to the plan pursuant to a collective bargaining agreement.

A self-funded multiple employer welfare arrangement (MEWA) that is considered an employee welfare benefit plan established or maintained by an employer as defined under section 3(5) of the Employee Retirement Income Security Act of 1974 (ERISA)¹² should determine the total number of employees (as defined under ERISA section 3(6)) of the bona fide employer group or association that constitutes the employer under ERISA section 3(5).

¹¹ The divisor is based on estimated take-up rates from the 2023 National Compensation Survey, published by the Bureau of Labor Statistics. A take-up rate is the percentage of workers with access to a plan who participate in the plan. The Departments have used the take-up rate for healthcare benefits for employers with fewer than 100 employees. https://www.bls.gov/ebs/publications/employee-benefits-in-the-united-states-march-2023.htm

¹² See section 3(40) of the Employee Retirement Income Security Act of 1974 (ERISA); see also, e.g., Department of Labor Advisory Opinion 2008–07A, available at <u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resourcecenter/advisory-opinions/2008-07a.pdf</u>; U.S. Department of Labor, Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation (2022), available at <u>https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/mewa-under-erisa-aguide-to-federal-and-state-regulation.pdf</u>.

A self-funded MEWA that is not considered to be an employee welfare benefit plan should determine the number of employees (as defined under ERISA section (3)(6)) of each underlying employer and report data according to whether the employer is a small employer or large employer.

5.4 State Aggregation

Note: In the data files (D1 - D8), report a plan's business in only one state even if the plan is offered in multiple states.

The state aggregation rules for RxDC are like the requirements in the MLR reporting form instructions. In general, a reporting entity should report fully-insured business in the state where the policy was issued. For self-funded plans, the reporting entity should generally report the data in the state where the plan sponsor has its principal place of business. When a plan covers members in multiple states, or when coverage is sponsored by a group trust, association, or MEWA, the reporting entity should follow the instructions below.

Coverage in Multiple States

For self-funded coverage that is not provided through a group trust, association, or MEWA, report the data in the state where the plan sponsor has its principal place of business. For fully-insured plans, report the data in the state where the policy was issued. For individual market business sold through an association, report the data in the state where the certificate of coverage was issued. For FEHB carriers that are not associated with an issuer, TPA, or other third-party vendor and that offer coverage in multiple states, report the data in the state where the policy was issued or where the carrier has its principal place of business.

Employer Business through Group Trust, Association, or MEWA

For health coverage provided to plans through a group trust or MEWA, report the data in the state where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an "employer" under ERISA section 3(5) for purposes of sponsoring the plan) has its principal place of business or the state where the association is incorporated, in the case of an association with no principal place of business.

How do I determine the principal place of business?

You may use any reasonable method to determine the principal place of business for purposes of these prescription drug reporting requirements. For example, you could use the state where the plan is administered, the state whose laws govern the plan, or the state where most employees reside, work, or receive care.

Note: The principal place of business for purposes of state aggregation must be in the U.S.

5.5 Company Aggregation

In the data files, you have several choices on how to aggregate data to the company level. Within a state and market segment, you may aggregate data using the following approaches (if they are not precluded by the Aggregation Restriction in Section 5.6):

- All coverage associated with the same plan sponsor
- All coverage issued by the same issuer
- All coverage administered by the same TPA
- All coverage reported by the same reporting entity
- All coverage offered by the same FEHB carrier¹³

¹³ If a carrier is affiliated or associated with an issuer, TPA, or other third-party such as a vendor or underwriter, we generally expect that the issuer, TPA, or other third-party will include the carrier's business in the FEHB market segment of

Generally, we expect reporting entities to aggregate at the issuer or TPA level. If you are not aggregating to the issuer or TPA level, enter the name and EIN of the company associated with the aggregation level. For example, if you are aggregating to the plan sponsor level, enter the name and EIN of the plan sponsor.

It's acceptable to aggregate to different levels on different data files, as noted in Section 5.6. It is also acceptable to aggregate to different levels within the same data file. For example, if you are reporting for multiple self-funded plans, you may aggregate and report at the plan sponsor level for some plans and aggregate and report for the other plans at the TPA level within the same data file.

If a parent company has subsidiaries with separate EINs, may I report according to the parent company EIN? If the same coverage is offered for all subsidiary companies, you may report according to the parent company EIN.

Dual-contract health insurance coverage

If in-network benefits and out-of-network benefits are provided by separate but <u>affiliated</u> issuers, data may be reported separately for each type by issuer **or** combined and reported by the issuer that provides the in-network coverage.

If two <u>unaffiliated</u> issuers provide coverage as part of a package, the issuers must report the data separately. For example, if one issuer provides inpatient coverage and an unaffiliated issuer provides outpatient coverage, the submission for the first issuer should contain only the information about the inpatient coverage and the submission for the other issuer should contain only information about the outpatient coverage.

5.6 Aggregation Restriction

Note: Starting with the RxDC report for the 2023 reference year, the aggregation restriction will no longer be suspended. Enforcement of the aggregation restriction will facilitate data analysis for the purposes of developing the biannual public report required under section 9825(b) of the Code, section 725(b) of ERISA, and section 2799A–10(b) of the PHS Act.

What is the aggregation restriction?

Under 26 CFR 54.9825-5T(b)(2)(i), 29 CFR 2590.725-3(b)(2)(i), and 45 CFR 149.730(b)(2)(i), the data submitted in files D1 and D3 – D8 must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submitted the data in file D2 Spending by Category.

This means:

- If the data submitted in D2 is aggregated according to the plan sponsor EIN, the data in D1, D3, D4, D5, D6, D7, and D8 must also be aggregated according to the plan sponsor EIN.
- If the data submitted in D2 is aggregated according to the Issuer or TPA EIN (or some other level that is not the plan sponsor level), then the reporting entities for D1, D3, D4, D5, D6, D7, and D8 may choose to aggregate at the same level used in D2 or to aggregate according to the plan sponsor EIN. The reporting entities for D1, D3, D4, D5, D6, D7, and D8, D7, and D8 do not have to make the same decision. For example, if D2 is at the TPA level, the reporting entity for D1 could aggregate at the plan sponsor level and the reporting entity for D4 could aggregate at the TPA level.

its submission, rather than the carrier creating a separate submission. If a carrier chooses to make its own submission, it needs to make sure that the issuer, TPA, or other third party does not report the same data.

When more than one reporting entity is submitting D2 on behalf of the same plan, issuer, or carrier, the reporting entity that submitted D2 at the most granular level shall serve as the aggregation level to use for the purposes of the aggregation restriction.

5.7 Examples of Aggregate Reporting

Below are examples of aggregated data files. Not all columns are shown.

Example 1: Issuer reports for fully-insured plans

Issuer A reports total spending in California in the individual, small group, and large group markets, and in Washington for the individual and student markets.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
EIN for Issuer A	CA	Individual market	\$177,141,997	\$21,733,552
EIN for Issuer A	CA	Small group market	\$8,419,411	\$1,099,238
EIN for Issuer A	CA	Large group market	\$23,735,387	\$3,061,628
EIN for Issuer A	WA	Individual market	\$168,409	\$22,107
EIN for Issuer A	WA	Student market	\$377,582	\$55,690

Example 2: Issuer reports for multiple issuers that are subsidiaries of the same holding group Issuer X, Issuer Y, and Issuer Z are part of the same holding group. Issuer X reports on behalf of itself and also on behalf of Issuer Y and Issuer Z.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
EIN for Issuer X	CO	Individual market	¢10.427	\$1,404
	0	Inuiviuuai Inai Ket	\$10,437	\$1,404
EIN for Issuer X	СО	Small group market	\$333,803,307	\$39,962,932
EIN for Issuer X	СО	Large group market	\$107,047,027	\$15,617,091
EIN for Issuer X	ID	Large group market	\$219,568	\$26,072
EIN for Issuer X	WY	Large group market	\$73,114	\$9,362
EIN for Issuer Y	PA	Small group market	\$7,234,076	\$1,002,860
EIN for Issuer Y	PA	Large group market	\$231,331,535	\$27,706,578
EIN for Issuer Y	NY	Small group market	\$7,234,076	\$1,009,009
EIN for Issuer Y	NJ	Small group market	\$23,375,484	\$2,696,362
EIN for Issuer Z	NJ	Small group market	\$1,781,722	\$240,568

Example 3: Issuer reports for fully-insured plans, FEHB plans, and self-funded plans

Issuer B both sells insurance and provides administrative services for self-funded plans. Issuer B reports total spending in Colorado in the individual, small group, and large group markets and for self-funded large employer plans; in Idaho in the individual, small group, and large group markets; and in Wyoming for self-funded large employer plans. Issuer B is also associated with an FEHB carrier and reports for FEHB plans in Colorado.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
EIN for Issuer B	СО	Individual market	\$58,971,803	\$9,304,571
EIN for Issuer B	СО	Small group market	\$338,403	\$35,147
EIN for Issuer B	СО	FEHB plans	\$728,966,601	\$88,562,152
EIN for Issuer B	СО	SF large employer plans	\$219,568	\$30,149
EIN for Issuer B	ID	Individual market	\$150,268	\$23,162
EIN for Issuer B	ID	Small group market	\$25,441,865	\$3,912,450

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
EIN for Issuer B	ID	Large group markets	\$1,295,869	\$168,839
EIN for Issuer B	WY	SF large employer plans	\$170,953,419	\$26,331,955

Example 4: TPA reports for self-funded plans

TPA C reports total spending for self-funded small employers and self-funded large employers in multiple states.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
EIN for TPA C	КҮ	SF small employer plans	\$162,827,074	\$17,407,842
EIN for TPA C	КҮ	SF large employer plans	\$404,143,910	\$51,431,354
EIN for TPA C	LA	SF small employer plans	\$370,421	\$49,929
EIN for TPA C	MI	SF small employer plans	\$455,249,960	\$70,231,411
EIN for TPA C	MI	SF large employer plans	\$1,077,284,699	\$142,352,400
EIN for TPA C	MN	SF large employer plans	\$2,386,062	\$307,850

Example 5: PBM reports data on behalf of fully-insured plans and self-funded plans

A PBM reports prescription drug rebates for fully-insured plans offered by Issuer D and Issuer E and for selffunded plans administered by TPA F, TPA G, and Issuer D. Issuers D and E and TPA F are aggregating their D2s at the issuer/TPA level. TPA G is aggregating its D2 at the TPA level for its self-funded small employer plan clients, and at the plan sponsor level for its only two self-funded large employer plan clients M and N. (See Section 9.2 for information about allocating prescription drug rebates across plans, issuers, carriers, states, and markets.)

Company EIN	Aggregation State	Market Segment	Total Rx Spending under Pharmacy Benefit	Total Rebates, Fees and Other Remuneration
EIN for Issuer D	СО	Individual market	\$210	\$65
EIN for Issuer D	СО	Small group market	\$10,714	\$2,278
EIN for Issuer D	СО	Student market	\$2,962,333	\$669,043
EIN for Issuer D's TPA Business	СО	SF small employer plans	\$4,483	\$1,372
EIN for Issuer D	WY	Large group market	\$1,296	\$456
EIN for Issuer E	PA	Small group market	\$205,705	\$45,212
EIN for Issuer E	PA	Large group market	\$5,142,346	\$1,445,822
EIN for TPA F	NY	SF small employer plans	\$186,672	\$45,212
EIN for TPA F	NJ	SF small employer plans	\$1,460,734	\$483,284
EIN for TPA G	СТ	SF small employer plans	\$4,095,437	\$897,556
EIN for Plan Sponsor M	СТ	SF large employer plans	\$435,422	\$212,306
EIN for Plan Sponsor N	СТ	SF large employer plans	\$341,210	\$84,212

Example 6: Plan sponsor self-reports for fully-insured plans and self-funded plans

An employer with 10,000 employees is headquartered in Nevada and offers several plans that employees can choose from. Some plans are fully-insured; some plans are self-funded.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
Plan Sponsor EIN	NV	Large group market	\$ 9,619,527	\$1,119,521
Plan Sponsor EIN	NV	SF large employer plans	\$34,540,901	\$5,485,786

It is also acceptable for the plan sponsor to report using the name and EIN of the issuer and TPA, respectively.

Company EIN	Aggregation State	Market Segment	Total Spending	Total Cost Sharing
Issuer EIN	NV	Large group market	\$ 9,619,527	\$1,119,521
TPA EIN	NV	SF large employer plans	\$34,540,901	\$5,485,786

See Section 6.2 for additional reporting examples when a plan has multiple issuers or multiple TPAs.

6 D1 Premium and Life-Years

Data file D1 collects combined information about a plan's medical and pharmacy benefits. If a plan has a carveout benefit, you have two options:

- Preferred option: One reporting entity combines information for all benefits and submits one D1 file.
- More than one reporting entity submits D1 on behalf of the plan. When CMS compiles the files, the combined information should account for all of a plan's benefits.

The second option is not preferred because life-years cannot be fully reconciled if some members do not have coverage under all benefits. There is also an increased risk of double-reporting when multiple D1 files are submitted.

6.1 Definitions

Use the definitions in this section to report medical and pharmacy benefit premium and life-years in D1 Premium and Life-Years. Columns E and F are monthly averages, column G is an average annual amount, and columns H – K are annual totals.

Average Monthly Premium Paid by Members Column E	Average Monthly Premium Paid by Employers Column F	Life Years Column G	Earned Premium Column H	Premium Equivalents Column I	Admin Fees Paid (included in Premium Equivalents field) Column J	Stop Loss Premium Paid (included in Premium Equivalents field) Column K
Monthly Average	Monthly Average	Annual Average	Annual Total (fully-insured plans)	Annual Total (self-funded plans)	Annual Total (self-funded plans)	Annual Total (self-funded plans)

Average Monthly Premium

Note: Prior to the 2023 reference year, average premium was calculated on a per-member-per-month basis. Starting with the 2023 reference year, the monthly average is not on a per-member basis. This means you should divide annual premium amounts by 12 instead of dividing by member-months when calculating the average monthly premium.

Average monthly premium paid by members

Location: D1 Column E | Max decimals: 8

Report the average monthly premium (or premium equivalents) paid by members during the reference year.

Calculate the average monthly premium (or premium equivalent) by taking the total annual premium (or premium equivalents) paid by members during the reference year and dividing by 12. You should divide by 12 even if the coverage was not in effect for the entire calendar year.

Include:

- Premium or premium equivalents paid by members for medical and pharmacy coverage (See definition of premium equivalents below.)
- Advance premium tax credits (APTCs) in the individual and fully-insured small group markets
- Member payments for COBRA coverage, including the 2% administrative fee
- Spousal and tobacco surcharges

Exclude: Premium or premium equivalents paid by employers or other plan sponsors on behalf of members.

Average monthly premium paid by employers

Location: D1 Column F | Max decimals: 8

Not applicable in the individual or student markets. For group health plans and FEHB plans, report the average monthly premium paid by employers or other plan sponsors on behalf of members.

Calculate the average annual premium (or premium equivalent) by taking the total annual premium (or premium equivalents) paid on behalf of members and dividing by 12. You should divide by 12 even if the coverage was not in effect for a member or members for the entire reference year.

Include:

- Premium or premium equivalents paid by employers and other plan sponsors on behalf of members (including dependents) for medical and pharmacy coverage.¹⁴
- Premium or premium equivalents paid by group trust, association, or MEWA plans if separate employers or other plan sponsors make premium contributions.

Exclude: Premium or premium equivalents paid by members.

Should premium paid for coverage of an owner of an S-Corporation or Partnership be counted as amount paid by a member or an amount paid by an employer?

If the owner works for the business and pays their premium out of personal funds, report the premium as an amount paid by a member.

How should I report premium paid for coverage of a sole proprietor or other small business where the coverage only covers the owner and/or the owner's spouse?

If only the owner and/or the owner's spouse are covered by a fully-insured policy, you may treat the policy as an individual market policy and you do not have to report whether the amount is paid by a member versus paid by an employer.

What if I don't know the amount of premium paid by members versus employers?

Section 204 of the CAA, and the Prescription Drug and Health Care Spending interim final rules (86 FR 66662) require premium information to be reported separately according to amounts paid by members and amounts paid by employers. Generally, if you are reporting on behalf of a group health plan or FEHB plan, you must obtain this information from the plan. If the plan does not provide you this information, then the plan must submit its own P2 and D1 to CMS.

¹⁴ For FEHB plans, the amount paid by the employer is the government contribution within the meaning of 5 U.S.C. 8906.

If you are unable to obtain all necessary information to calculate average monthly premium paid by members and average monthly premium paid by employers from a plan, you should:

- Exclude the plan when calculating average monthly premium paid by members and average monthly premium paid by employers in columns E and F
- Include the plan when calculating life years, earned premium, premium equivalents, admin fees, and stop-loss premium in columns G K

Life-years

Location: D1 Column G | Max decimals: 8

Life-years are the average number of members throughout the year. As noted above, the term **member** means a person who has health coverage, regardless of whether the coverage is associated with an insurance policy, a group health plan, or an FEHB plan. For example, enrollees, dependents, participants, beneficiaries, COBRA participants, retirees (except for retirees in a retiree-only plan), and FEHB annuitants are all considered members. To calculate life-years, you must first calculate member months, as noted below.

To calculate member months:

- 1. Count the number of members covered on a given day of each month of the reference year, and
- 2. Add the number of members from Step 1 to calculate total member months for the reference year.

To calculate life-years:

- 1. Divide member months by 12, and
- 2. Round the resulting number to the 8th decimal place.

Example: Calculating member months and life-years

	inoritins and me years			
Date	Members covered by the plan on the given date			
	by the plan on the given date			
January 1, 2023	882			
February 1, 2023	872			
March 1, 2023	884			
April 1, 2023	921			
May 1, 2023	924			
June 1, 2023	923			
July 1, 2023	925			
August 1, 2023	916			
September 1, 2023	907			
October 1, 2023	906			
November 1, 2023	902			
December 1, 2023	869			
Total Member Months	10,831			
# of Life-Years	002 5822222			
(Total member months / 12)	902.58333333			

If you are reporting for multiple plans, add the number of life-years for each plan and report the total amount for all plans.

Earned premium (fully-insured coverage)

Location: D1 Column H | Max decimals: 8

Report total annual earned premium. Earned premium means all money paid by a member, policyholder, subscriber, and/or plan sponsor as a condition of the member receiving medical or pharmacy coverage. Earned

premium includes any fees or other contributions associated with the health plan. For FEHB plans, earned premium means the member and government shares of premium.

Report earned premium on a direct basis, without factoring in reinsurance. Include advance payments of the premium tax credit (APTCs), if applicable. Do not reduce the amount of earned premium to reflect state or federal MLR rebates. Do not include stop-loss premium.

Premium equivalents (total plan cost for self-funded coverage)

Location: D1 Column I | Max decimals: 8

For self-funded plans and other arrangements that do not rely exclusively or primarily on premiums, report the total annual premium equivalent amounts representing the total cost of providing and maintaining coverage for all members.

Premium equivalents may be reported on a cash basis or on a retrospective basis.

Include:

- Medical and pharmacy claims costs (you may use either paid claims or incurred claims)
- Administrative costs, including fees that self-funded plans paid to an ASO, TPA, PBM, or other entity administering a plan
- Stop-loss premiums
- Network access fees, such as preferred provider organization (PPO) fees
- Payments made under capitation contracts with providers for benefits covered under the plan

Subtract:

- Stop-loss reimbursements¹⁵
- Prescription drug rebates that were received and retained¹⁶ by the group health plan during the reference year, regardless of whether the payment is retrospective or prospective

Exclude:

- Amounts paid by Medicare
- Premium equivalents that will be reported by a different reporting entity (for example, if a different reporting entity will report premium equivalents for a pharmacy carve-out or stop-loss purchased from an outside vendor)
- Amounts related to Flexible Spending Arrangements (FSAs), Health Savings Accounts (HSAs), Medical Savings Accounts (MSAs), and HRAs (such as contributions, reimbursements, or administrative costs)
- Amounts related to excepted benefits, including Employee Assistance Programs (EAPs)
- Contributions to a trust that are not contributions for claims incurred but not yet reported
- Copays and coinsurance paid by members

To calculate total annual premium equivalents, an employer with a self-funded plan may use, as the total cost of providing and maintaining coverage, the same *types* of costs that are taken into account for purposes of calculating COBRA premiums (minus the 2% administration charge, if applicable). Report total annual costs, not

¹⁵ For the purposes of calculating premium equivalents, it is acceptable to subtract stop-loss reimbursements based on all amounts received during the reference year or based only on amounts attributable to the claims within the reference year that gave rise to reimbursements.

¹⁶ See Section 9.1 for more information regarding retained rebates.

the COBRA rate. Report the total dollar amount actually paid for the reference year, rather than the amounts used to set the COBRA rate.

Should I include premium or premium equivalents for members of an Employee Group Waiver Plan (EGWP)?

You have the option to include premium or premium equivalents for members of an EGWP if the member is covered by a medical plan that is not a retiree-only plan, though it is not required.¹⁷ Similarly, you may include premium or premium equivalents paid for additional pharmacy benefits that are not covered by the EGWP. Premium and premium equivalents for EGWP members should be net of subsidies and reimbursements. Please make reasonable efforts to ensure that the data reported in D2 – D8 is consistent with how EGWP data is reported in D1.

Note: If a reporting entity for D3 – D8 is unable or unwilling to exclude EGWP prescription drug plans (EGWP-PDPs), then the reporting entity(ies) for D1 and D2 may include information for EGWP-PDP members even if the members are covered by a retiree-only medical plan.

Admin fees paid

Location: D1 Column J | Max decimals: 8

Report total annual administrative fees (such as claims processing fees) that self-funded plans paid to an ASO, TPA, PBM, or other entity administering a self-funded plan. This amount should also be included in Premium Equivalents.

If a group health plan's staff, rather than a TPA, performs some of these functions, the plan may, but is not required to, include a pro-rata portion of these costs in premium equivalents.

Exclude (to the extent possible)¹⁸:

- Fees for FSA administration, wellness programs, or financial or clinical analytics
- Fees paid by the TPA to an external party unless they are pass-through payments from the group health plan

Stop-loss premium paid

Location: D1 Column K | Max decimals: 8

Report the total annual stop-loss premium paid by the plan to the stop-loss insurer. This amount should also be included in Premium Equivalents. Do not include premium for stop-loss purchased by an issuer.

6.2 D1 Example

If you are reporting at the plan sponsor level for a plan that has more than one issuer or more than one TPA, you have two reporting options:

- 1. Aggregate the data for multiple issuers (or multiple TPAs) within a state and market and enter the plan sponsor name in the Company Name field, or
- 2. Aggregate the data separately for each issuer or TPA and enter the name of the issuer or TPA in the Company Name field.

For example, suppose Plan Sponsor A offers a fully-insured plan where Issuer 1 insures a behavioral health benefit and Issuer 2 insures the other benefits. Suppose Plan Sponsor A also has a self-funded plan where TPA 1

 $^{^{17}}$ Cf. FAQs about Affordable Care Act Implementation (Part XI), available at

https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xi.pdf.

¹⁸ The Departments recognize that some reporting entities rely on financial coding systems with limitations with respect to identifying each fee on the exclusion list.

administers the medical benefit, TPA 2 administers the pharmacy benefit, and Plan Sponsor A purchases stoploss coverage from Issuer 1.

Note 1: You may leave cells blank in columns E-K if a different entity will report the data. However, all reporting entities must enter values for columns A – D.

Note 2: Stop-loss premium should be reported in the self-funded market segment.

Comp Name (Col A)	Agg State (Col C)	Mkt Sgmt (Col D)	Avg Monthly Prm Paid by Mmbrs (Col E)	Life-Years (Col G)	Earned Prm (Col H)	Prm Equiv (Col I)	Admin Fees (Col J)	Stop-loss Prm (Col K)
Plan Sponsor A	GA	Large group market	Add annual amts from Issuers 1 & 2 and then divide by 12	Combined life-yrs from Issuers 1 & 2. (Don't double- count members covered by both benefits.)	Sum of prm paid to Issuer 1 & Issuer 2			
Plan Sponsor A	GA	SF large employer plans	Add annual amts from TPAs 1 & 2 (including mmbr portion of TPA fees & stop-loss) and then divide by 12	Combined life-yrs from TPAs 1 & 2. (Don't double- count members covered by both benefits.)		Total plan costs including Admin fees & stop-loss.	Sum of fees paid to TPAs 1 & 2	Stop-loss prm paid to Issuer 1

Option 1: Plan Sponsor Level (not all columns shown)

Reporting Option 2: Issuer and TPA Level (Not all columns shown.)

Comp Name (Col A)	Agg State (Col C)	Mkt Sgmt (Col D)	Avg Monthly Prm Paid by Mmbrs (Col E)	Life-years* (Col G)	Earned Prm (Col H)	Prm Equiv (Col I)	Admin Fees (Col J)	Stop-loss Prm (Col K)
lssuer 1	GA	Large group market	Avg for Issuer 1	Life-yrs covered by Issuer 1	Prm paid to Issuer 1			
lssuer 2	GA	Large group market	Avg for Issuer 2	Life-yrs covered by Issuer 2	Prm paid to Issuer 2			
TPA 1	GA	SF large employer plans	Avg under TPA 1 (including mmbr portion of TPA fees)	Life-yrs under TPA 1		Total plan costs including TPA fees for the medical benefit	Total fees paid to TPA 1	
TPA 2	GA	SF large employer plans	Avg under TPA 2 (including mmbr portion of TPA fees)	Life-yrs under TPA 2		Total plan costs including TPA fees for the pharmacy benefit	Total fees paid to TPA 2	
lssuer 1	GA	SF large employer plans	Avg mmbr portion of stop-loss	Life-yrs covered by stop-loss		Stop-loss prm paid to Issuer 1		Stop-loss prm paid to Issuer 1

*When reporting entities use Option 2, CMS will not be able to calculate total life-years without double-counting members covered by more than one benefit.

7 D2 Spending by Category

Data file D2 collects information related to a plan's medical benefit(s). Do not include information related to a plan's pharmacy benefit(s).

Report data related specifically to the reference year and paid or received through March 31 of the calendar year immediately following the reference year. For accounting purposes, this is sometimes referred to as "incurred in 12, paid or received in 15." For example, for the 2023 reference year, include claims incurred during 01/01/2023 – 12/31/2023 and paid or received through March 31, 2024.

For non-calendar plan years, include only the portion of experience that was incurred during the reference year and paid or received through March 31 of the following calendar year.

7.1 Definitions

Total spending

Location: D2 Column F | Max decimals: 8

Report allowed claims with dates of service during the reference year. Allowed claims are the total payments made under the plan or policy to health care providers on behalf of members. This includes fee-for-service and capitated payments. Report claims on a direct basis (that is, before reinsurance or stop-loss reimbursements, unless specifically stated otherwise in these instructions).

Include in Total Spending	Subtract	Exclude
 Payments by the plan, issuer, or carrier Cost sharing paid by members Claims liability, including claims incurred during the reference year but not paid or not reported as of March 31 of the year following the reference year (such as claims reported but still in the process of adjustment or payment) 	 Net payments from any federal or state reinsurance or cost-sharing reduction arrangement or program (not applicable for self-funded plans) Prescription drug rebates, fees, and other remuneration, to the extent known and only if they are related to coverage under the plan's medical benefit Prescription drug rebates, fees, and other remuneration that are expected but have not yet been received, to the extent known and only if they are related to coverage under the medical benefit Manufacturer cost-sharing assistance, to the extent known and only if it is related to coverage under the plan's medical benefit 	 Ineligible claims, such as duplicate claims, recovered claims overpayments, and any other claims that are denied under the policy's or plan's terms Payments by Medicare Third-party liabilities paid by other entities, such as coordination of benefits claims Payments for services other than medical care, such as medical management, quality improvement, and fraud detection and recovery expenses Active life reserves (policy reserves, contract reserves, contingency reserves, or any kind of reserves except traditionally defined reserves for claims incurred but not reported) or change in such reserves Contributions to a trust that are not contributions for claims incurred but not yet reported Charges or payments from state or federal risk adjustment programs

Total cost sharing

Location: D2 Column G | Max decimals: 8

Include cost sharing when you report Total Spending, and also as a separate data element.

Include in Total Cost Sharing	Subtract	Exclude
 Deductibles, coinsurance, and copays, including amounts that may have been paid through an FSA, HSA, MSA, or HRA, and regardless of whether the amount was applied to the deductible or out-of- pocket maximum 	 Cost sharing paid by a member's secondary insurance, to the extent known Prescription drug rebates, fees, and other remuneration that are passed to members at the point-of-sale, if not already accounted for as reduced cost sharing amounts paid by members, and only if they are related to coverage under the medical benefit 	 Cost sharing reductions the issuer paid on behalf of the member under federal or state cost-sharing reduction programs (include these amounts in total spending but not in total cost sharing) Premium Manufacturer cost-sharing assistance

Amounts not applied to deductible or out-of-pocket maximum

Location: D2 Column H | Max decimals: 8

Report billed amounts that were (1) not applied to a member's deductible or out-of-pocket maximum, (2) not paid by the plan, issuer, or carrier, and (3) not included in Total Spending.

Include in Amounts not applied to deductible or out-of- pocket max	Exclude
 The difference between the billed amount and the allowed amount for claims from out-of-network providers (balance billing) Denied claims for services within a covered benefit category, such as: Physical therapy service denied because the member has exceeded the plan's or policy's quantitative limit for physical therapy services Comprehensive vision exam denied because the member has exceeded the maximum annual benefit for vision services Ceramic inlay denied because the procedure code is not covered under the plan's or policy's dental benefit An otherwise covered service denied because it did not meet the plan's or policy's criteria for medical necessity Manufacturer cost-sharing assistance for drugs covered under the medical benefit that is not counted toward a member's deductible or out-of-pocket maximum as part of an accumulator adjustment program.¹⁹ 	 Denied claims for services that are not within a covered benefit category (such as a denied dental claim when a plan does not cover dental services) Denied claims due to a provider error, such as double-billing, submitting the wrong insurance form, or using an incorrect procedure code Claims initially denied and subsequently paid on appeal during the same reference year or the three months following the reference year (in this circumstance, report the paid amount in total spending). PPO discounts

¹⁹ A copay accumulator program, sometimes referred to as accumulator adjustment or maximizer program, is a policy under which the value of manufacturer cost-sharing assistance amounts, such as coupons or copay cards, are not applied to a member's deductible and/or out-of-pocket maximum.

7.2 Spending Categories

Location: D2 Column E | Max length: 256 characters | Must not be blank

The following table has the spending category names and abbreviations. You must use the abbreviation when you fill out data file D2. Make sure to use the exact spelling of the abbreviation or you will be unable to upload your data.

Abbreviation (Not case sensitive)
Hospital
Primary care
Specialty care
Other medical costs and services
Known medical benefit drugs
Estimated medical benefit drugs

Mutual Exclusiveness and Double-Reporting

The hospital, primary care, specialty care, and other medical costs and services spending categories are mutually exclusive of each other and *include* known and estimated spending on medical benefit drugs billed under those categories. Spending on medical benefit drugs must also be reported in the respective categories for medical benefit drugs. This means that medical benefit drug spending is "double-reported."

Capitation

Total spending includes spending for partial and full capitated services. You must estimate the portion of spending for capitated services that is attributable to each spending category and allocate it accordingly.

Pharmacy Benefit Drugs

Do NOT report spending on pharmacy benefit drugs anywhere in D2 Spending by Category.

Hospital

Location: D2 | Max decimals: 8

Report spending on services provided by hospitals to members and billed by the facility.

Include in Hospital	Exclude
 All inpatient and outpatient facility services billed by the facility, including: Any claim meeting one or more of the following criteria: A. Place of Service codes 21, 31, 32, 33, 34, 51, 56, or 61 B. Medicare Severity Diagnosis-Related Group (MS-DRG) code C. All claims with revenue codes 010X – 021X, or a valid revenue code on the UB-04 form and a CPT/HCPCS code. Below are examples of hospital spending: Revenue codes 036X, 048X, 049X, 079X and CPT/HCPCS codes 10004-69999 Revenue codes 045X and CPT/HCPCS codes 99281-99292 Revenue codes 015, 0125, 0135, 0145, 0155, 0235, and 0650 – 0659 (hospice) Revenue codes 0560 – 0609 (home health) Revenue codes 0540 – 0549 (ambulance) Revenue code 0981 (Emergency Department) Room and board, ancillary charges, services of resident providers, inpatient pharmacy, hospital-based nursing home and hospice care, and any other services billed by hospitals Services provided in psychiatric and substance abuse hospitals Facility services for medical, surgical, lab, radiology, therapy, maternity, skilled nursing, and other services that are billed by the facility Include outpatient care, emergency services, or ambulance services only if billed by the facility Medications dispensed by an institutional pharmacy and administered on-site as part of a medical service, covered under a medical benefit. These include but are not limited to CPT/HCPCS codes J0000–J9999. 	 Any medication covered under the pharmacy benefit Amounts reported in primary care, specialty care, or other medical costs and services Provider services if independently billed Laboratory and radiology services that are billed independently by the laboratory (report these amounts in other medical costs and services)

Primary care

Location: D2 | Max decimals: 8

Report spending on clinical health care services provided by a primary care provider in a doctor's office or outpatient care center. For the purposes of the RxDC report, a primary care provider is, generally, a provider who (1) has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; and (2) is accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

Include in Primary Care	Exclude
 Services billed with the following CPT/HCPCS codes and taxonomy codes: 99381-99397, 99460-99464 99202-99215, 99304-99350, G0402, G0438, G0439 and one of the taxonomy codes in the table below Clinical health care services provided by other clinicians, such as nurse practitioners, clinical nurse specialists, or physician assistants, in a primary care setting Obstetrics and gynecology clinical health care services if performed by a primary care provider On-site administration of medications as part of a clinical health care service. 	 Amounts reported in hospital, specialty care, or other medical costs and services Laboratory and radiology services provided in a primary care setting that are billed independently by the laboratory (report these amounts in other medical costs and services)

Primary Care Taxonomy Codes

Primary Care T Taxonomy	Taxonomy Specialty			
Code	Taxonomy Provider Type	Taxonomy Classification	reaction y specially	
163WC1500X	NURSING SERVICE PROVIDERS	REGISTERED NURSE	COMMUNITY HEALTH	
163WG0000X	NURSING SERVICE PROVIDERS	REGISTERED NURSE	GENERAL PRACTICE	
207QA0505X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	FAMILY PRACTICE	ADULT MEDICINE	
207RG0300X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	INTERNAL MEDICINE	GERIATRIC MEDICINE	
207QA0000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	FAMILY PRACTICE	ADOLESCENT MEDICINE	
207QG0300X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	FAMILY MEDICINE	GERIATRIC MEDICINE	
207R00000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	INTERNAL MEDICINE	NOT APPLICABLE	
207RA0000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	INTERNAL MEDICINE	ADOLESCENT MEDICINE	
208000000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PEDIATRICS	NOT APPLICABLE	
2080A0000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PEDIATRICS	ADOLESCENT MEDICINE	
2080A00000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	GENERAL PRACTICE	NOT APPLICABLE	
208200000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PREVENTIVE MEDICINE	PUBLIC HEALTH & GENERAL	
20031 05017	ALLOI ATTIC & OSTEOI ATTIC TITSICIANS		PREVENTIVE MEDICINE	
261QC1500X	AMBULATORY HEALTH CARE FACILITIES	CLINIC/CENTER	COMMUNITY HEALTH	
261QR1300X	AMBULATORY HEALTH CARE FACILITIES	CLINIC/CENTER	RURAL HEALTH	
261QP2300X	AMBULATORY HEALTH CARE FACILITIES	CLINIC/CENTER	PRIMARY CARE	
363A00000X	PHYSICIAN ASSISTANTS AND ADVANCED	PHYSICIAN ASSISTANT	NOT APPLICABLE	
	PRACTICE NURSING			
363AM0700X	PHYSICIAN ASSISTANTS AND ADVANCED	PHYSICIAN ASSISTANT	MEDICAL	
363L00000X	PRACTICE NURSING PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	NOT APPLICABLE	
303L00000X	PRACTICE NURSING	NURSE PRACTITIONER		
363LA2200X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	ADULT HEALTH	
	PRACTICE NURSING			
363LC1500X	PHYSICIAN ASSISTANTS AND ADVANCED	COMMUNITY HEALTH	NOT APPLICABLE	
2621 50000				
363LF0000X	PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE NURSING	NURSE PRACTITIONER	FAMILY	
363LG0600X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	GERONTOLOGY	
	PRACTICE NURSING			
363LP0200X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	PEDIATRICS	
264.064.000				
261QS1000X	AMBULATORY HEALTH CARE FACILITIES	CLINIC/CENTER	STUDENT HEALTH	
363LP2300X	PHYSICIAN ASSISTANTS AND ADVANCED PRACTICE NURSING	PRIMARY CARE	NOT APPLICABLE	
363LW0102X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	WOMEN'S HEALTH	
	PRACTICE NURSING			
207Q00000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	FAMILY MEDICINE	NOT APPLICABLE	
364SA2200X	NURSING SERVICE PROVIDERS	CLINICAL NURSE SPECIALIST	ADULT HEALTH	
364SC1501X	NURSING SERVICE PROVIDERS	CLINICAL NURSE SPECIALIST	COMMUNITY HEALTH	
364SF0001X	NURSING SERVICE PROVIDERS	CLINICAL NURSE SPECIALIST	FAMILY HEALTH	
364SP0200X	NURSING SERVICE PROVIDERS	CLINICAL NURSE SPECIALIST	PEDIATRICS	

Specialty care

Location: D2 | Max decimals: 8

Report spending on clinical health care services provided by specialists. A specialist is, generally, a provider that focuses on a specific area of medicine or a group of patients to diagnose, manage, prevent, or treat certain types of diseases, symptoms, and conditions.

Include in Specialty Care	Exclude
 All professional services not inclusive of primary care, including the following: Providers that have training in a specific area of health care and are not considered primary care providers as defined above Chiropractors, podiatrists, ophthalmologists, and physical, occupational, and speech therapists that are not billed as part of hospital or facility services Doctor's office or outpatient care center services provided by specialists Hospital-based specialist services only if the specialist independently bills for those services On-site administration of medications as part of a clinical health care service. 	 Amounts reported in hospital, primary care, or other medical costs and services Dental services (report in Other medical costs and services) Laboratory and radiology services associated with specialty care in a doctor's office or outpatient care center that are billed independently by the laboratory (report these amounts in other medical costs and services)

Other medical costs and services

Location: D2 | Max decimals: 8

Report spending for all other professional and facility clinical health care services and equipment not reported as hospital, primary care, or specialty care.

Include in Other medical costs and services	Exclude
 Report spending for all other professional and facility clinical health care services and equipment not reported as hospital, primary care, or specialty care. Examples as follows: Radiology and laboratory services that are billed independently by the laboratory (Radiology: 70000–79999; laboratory and pathology: 36415; 36416; 80000–89999) Non-hospital based skilled nursing and hospice services Ambulance services not billed by a hospital facility Home health care Dental services and supplies Vision services and supplies (except for amounts billed by an ophthalmologist, which should be reported in Specialty Care) Durable medical equipment Medications covered under a medical benefit and not already reported in the hospital, primary care, or specialty care spending categories Wellness services billed on a claim. 	 Amounts reported in hospital, primary care, or specialty care Claims with a valid revenue code on the UB-04 form. Wellness services not billed on a claim

Which wellness services should I include in the RxDC report?

For the purposes of the RxDC report, wellness services are defined as activities primarily designed to implement, promote, and improve health. If a wellness service is billed on a claim, include it in the "Other medical costs and services" spending category in data file D2 Spending by Category. If a wellness service is not billed on a claim or is not a covered service under a plan or policy, do not include it anywhere in the RxDC report.

Example of a wellness service billed on a claim

A member sees a provider for the placement of a nicotine patch to help with smoking cessation, and the provider submits a claim for providing this service (for example, using codes CPT 1036f and S4990). Report the amount in the "Other medical costs and services" spending category in data file D2 Spending by Category.

Example of a wellness service not billed on a claim

A member receives a gift card for completing a smoking cessation program. Do not include this wellness service from the RxDC report.

Medical benefit drugs: known amounts reported in hospital, primary care, specialty care, and other medical costs and services

Location: D2 | Max decimals: 8 | Abbreviation: Known medical benefit drugs

Report spending on drugs covered under a medical benefit that are separately billed or otherwise known exactly. The amounts reported here are also included in the hospital, primary care, specialty care, or other medical costs and services categories.

Note: You are not required to complete the Total Cost Sharing or Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum columns for the medical benefit drug spending categories.

Medical benefit drugs: estimated amounts reported in hospital, primary care, specialty care, and other medical costs and services

Location: D2 | Max decimals: 8 | Abbreviation: Estimated medical benefit drugs

Report the estimated portion of bundled or alternative payment arrangements (or other non-fee-for-service amounts) that can be attributed to drugs covered under a medical benefit. The amounts reported must also be reported in the hospital, primary care, specialty care, or other medical costs and services categories. You must estimate spending on prescription drugs included in the bundle or other alternative payment arrangement in good faith and to the best of your ability. You may use any reasonable method to estimate the amounts.

If you report estimated amounts, describe the estimation method you used in the Narrative Response.

Note: You are not required to complete the Total Cost Sharing or Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum columns for the medical benefit drug spending categories.

7.3 D2 Example

Example: Individual market data from Issuer A aggregated by spending category for North Dakota and South Dakota

Company Name	Company EIN	Agg State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible or Out-of-Pocket Maximum
Issuer A	123456789	ND	Individual market	Hospital	3580521.90	401066.37	2996850.61
Issuer A	123456789	ND	Individual market	Primary Care	602438.96	75794.03	500619.57
Issuer A	123456789	ND	Individual market	Specialty Care	1418977.71	193444.03	1060628.03
Issuer A	123456789	ND	Individual market	Other medical costs and services	751875.43	186265.76	474019.32
Issuer A	123456789	ND	Individual market	Known medical benefit drugs	478610.92		
Issuer A	123456789	ND	Individual market	Estimated medical benefit drugs	14556.00		

Company Name	Company EIN	Agg State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible or Out-of-Pocket Maximum
Issuer A	123456789	SD	Individual market	Hospital	4570611.94	378986.37	4111798.51
Issuer A	123456789	SD	Individual market	Primary Care	409930.85	94257.97	301538.7
Issuer A	123456789	SD	Individual market	Specialty Care	1073888.69	218862.36	716278.03
Issuer A	123456789	SD	Individual market	Other medical costs and services	563733.18	116404.78	407365.13
Issuer A	123456789	SD	Individual market	Known medical benefit drugs	549538.92		
Issuer A	123456789	SD	Individual market	Estimated medical benefit drugs	322523.12		

8 Prescription Drug Reporting

8.1 Prescription Drug Coverage

Medical benefit drugs

Location: D2

Report information about prescription drugs covered under a medical benefit in D2. You must estimate the portion of bundled or alternative payment arrangements that can be attributed to medical benefit drugs in good faith and to the best of your ability. Include information for pharmaceutical supplies, medical devices, nutritional supplements, and OTCs in the appropriate spending category in D2 if the products are covered under a plan's medical benefit.

Pharmacy benefit drugs

Location: D3, D4, D5, D6, D7, D8

Report information about prescription drugs covered under the pharmacy benefit in data files D3, D4, D5, D6, D7, and D8. Include compounded drugs covered under a pharmacy benefit in D6 but not in D3, D4, D5, D7, or D8.

Include spending on pharmaceutical supplies, medical devices, nutritional supplements, and OTCs in D6 if covered by a pharmacy benefit. **Do not** include spending on pharmaceutical supplies, medical devices, nutritional supplements, and OTCs in D3, D4, D5, D7, or D8 unless the National Drug Code ²⁰ (NDC) for the product is in the CMS Drug and Therapeutic Class Crosswalk ("CMS crosswalk") at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

Should I include information about prescriptions filled outside of the U.S.?

Plans, issuers, and carriers should make their own determination on whether to include information about prescriptions filled in other countries.

²⁰ The Food & Drug Administration (FDA) assigns a unique National Drug Code to each pharmaceutical product manufactured, prepared, propagated, compounded, or processed for sale in the United States.

Prescription drug definition

For the purposes of RxDC reporting, a prescription drug is defined as a set of NDCs that are grouped together by name and ingredient. This means that NDCs with the same ingredient are grouped together even if they have different strengths, dosage forms (example: capsule, tablet, liquid), routes of delivery (example: oral, intravenous, inhaled), labeler names (manufacturer, re-packager, or distributor), or package types or sizes. For example, if the same active ingredient is available as both a tablet and a liquid, both forms are considered the same drug for RxDC reporting, unless they have different brand names.

Drug names and codes

Location: D3, D4, D5, D8 | Must not be blank Drug Name Max Length: 2,048 | Drug Code Max Length: 100

The RxDC drug name for brand prescription drugs is the combination of the ingredient name and the brand name.²¹ The brand name is enclosed in brackets. Specifically, the format of the RxDC drug name is: ingredient name [brand name]. For generic drugs, the RxDC drug name is just the ingredient name. For the purposes of RxDC reporting, branded generics and authorized generics are treated the same as unbranded generics.²² Thus, the RxDC drug name for branded generics and authorized generics is just the ingredient name.

If an NDC has more than one ingredient, the RxDC drug name contains all ingredients. The ingredients are separated from each other using a pipe symbol ("|") with a space on both sides of the pipe symbol. For example, the RxDC drug name for a generic drug with two ingredients is: ingredient 1 | ingredient 2. The RxDC drug name for a brand prescription drug with two ingredients is: ingredient 1 | ingredient 2 [brand name]. The ingredients are listed in alphabetic order.

Each RxDC drug name has a unique RxDC drug code. The RxDC names and codes are in the CMS Drug and Therapeutic Class Crosswalk at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

11-Digit NDC	Labeler	Brand	Strength, Dosage Form, and	RxDC	RxDC
		Indicator	Package	Drug Name	Drug Code
00093922489	Teva	Generic°	375 mg/1, 120 capsule, extended	mesalamine	R00525820101000
	Pharmaceuticals		release in 1 bottle		
54092010001	Takeda	Generic°	1.2 g/1, 120 tablet, delayed	mesalamine	R00525820101000
			release in 1 bottle		
59762011701	Greenstone LLC	Generic°	400 mg/1, 180 capsule, delayed	mesalamine	R00525820101000
			release in 1 bottle		
59762011803	Greenstone LLC	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R00525820101000
			box		
60687055632	American Health	Generic	400 mg/1, 20 blister pack in 1	mesalamine	R00525820101000
	Packaging		box, unit-dose		
62559042007	ANI	Generic°	4 g/60mL, 7 bottles in 1 box	mesalamine	R00525820101000
	Pharmaceuticals				

Example: Crosswalk from NDC to RxDC drug name and code (excerpt for mesalamine)

²¹ For the purposes of RxDC reporting, the Departments generally use the brand name and active ingredient name from RxNorm. RxNorm is a standardized drug naming convention for clinical drugs produced by the U.S. National Library of Medicine. See https://www.nlm.nih.gov/research/umls/rxnorm/index.html for more information about RxNorm.

²² Branded generics are marketed under a brand name but go through the same FDA approval process as unbranded generics. Branded generics and unbranded generics may only be sold after the brand prescription drug loses marketing exclusivity. Authorized generics are created by makers of brand prescription drugs under the same New Drug Approval (NDA) authorization as the original brand prescription drug. Authorized generics may be marketed before the brand prescription drug loses marketing exclusivity.

11-Digit NDC	Labeler	Brand	Strength, Dosage Form, and	RxDC	RxDC
-		Indicator	Package	Drug Name	Drug Code
69238127403	Amneal	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R00525820101000
	Pharmaceuticals		carton		
69918056030	Amring	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R00525820101000
	Pharmaceuticals		box		
70771111002	Cadila	Generic	800 mg/1, 10 tablet, delayed	mesalamine	R00525820101000
	Healthcare		release in 1 blister pack		
70771135302	Cadila	Generic [^]	800 mg/1, 10 tablet, delayed	mesalamine	R00525820101000
	Healthcare		release in 1 blister pack		
43353088479	Aphena Pharma	Brand	375 mg/1, 2160 capsule,	mesalamine	R00525820101001
	Solutions		extended release in 1 bottle	[Apriso]	
65649010301	Salix	Brand	375 mg/1, 1 bottle in 1 carton	mesalamine	R00525820101001
	Pharmaceuticals			[Apriso]	
00023590118	Allergan, Inc.	Brand	800 mg/1, 180 tablet, delayed	mesalamine	R00525820101002
			release in 1 bottle	[Asacol]	
58914050101	Allergan, Inc.	Brand	1000 mg/1, 3 suppository, 1 box	mesalamine	R00525820101003
				[Canasa]	
00023585318	Allergan, Inc.	Brand	400 mg/1, 180 capsule, delayed	mesalamine	R00525820101004
			release in 1 bottle	[Delzicol]	
50090300200	A-S Medication	Brand	400 mg/1, 180 capsule, delayed	mesalamine	R00525820101004
	Solutions		release in 1 bottle	[Delzicol]	
54092047601	Takeda	Brand	1.2 g/1, 120 tablet, delayed	mesalamine	R00525820101005
			release in 1 bottle	[Lialda]	
54092018981	Takeda	Brand	250 mg/1, 240 capsules in 1	mesalamine	R00525820101006
			bottle	[Pentasa]	
00037002207	Meda	Brand	4 g/60mL, 7 bottles, with	mesalamine	R00525820101007
	Pharmaceuticals		applicator in 1 carton	[Rowasa]	
00037006603	Meda	Brand	4 g/60mL, 28 bottles, dispensing	mesalamine	R00525820101007
	Pharmaceuticals		in 1 carton	[Rowasa]	

° Authorized generic; ^ Branded generic

Example: Data aggregated by RxDC drug name (not all columns shown)

Company EIN	State	Market segment	RxDC Drug Name	RxDC Drug Code	Number of paid claims
123456789	CA	Individual Market	mesalamine	R00525820101000	9,744
123456789	CA	Individual Market	mesalamine [Apriso]	R00525820101001	3,904
123456789	CA	Individual Market	mesalamine [Asacol]	R00525820101002	5,642
123456789	CA	Individual Market	mesalamine [Canasa]	R00525820101003	2,145
123456789	CA	Individual Market	mesalamine [Delzicol]	R00525820101004	6,015
123456789	CA	Individual Market	mesalamine [Lialda]	R00525820101005	8,983
123456789	CA	Individual Market	mesalamine [Pentasa]	R00525820101006	198
123456789	CA	Individual Market	mesalamine [Rowasa]	R00525820101007	1,703

Note: To reduce file size, you may leave RxDC Drug Name blank, as long as RxDC Drug Code is populated.

Therapeutic classes

Location: D7 | Must not be blank

Therapeutic Class Max Length: 2,048 characters | Class Code Max Length: 100 characters

A therapeutic class is a group of drugs that have a similar mechanism of action or treat the same condition. For example, mesalamine, balsalazide, olsalazine, and sulfasalazine are medications used to reduce inflammation in the lining of the intestine. Therefore, they are assigned the same RxDC therapeutic class name,

Aminosalicylate.²³ If an NDC has more than one ingredient and those ingredients belong to different therapeutic classes, the RxDC therapeutic class name is the combination of the therapeutic classes. The therapeutic classes are listed alphabetically and separated from each other using a pipe symbol ("|"), with a space on both sides of the pipe symbol. (Example: Therapeutic Class 1 | Therapeutic Class 2.)

Each RxDC therapeutic class has a unique RxDC class code. The RxDC names and codes are in the CMS Drug and Therapeutic Class Crosswalk at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

Company EIN	Agg State	Market Segment	RxDC Therapeutic Class	RxDC Class Code	Number of paid claims
123456789	CA	Individual market	Corticosteroid	E01755760101	5,567
123456789	CA	Small group market	Corticosteroid	E01755760101	7,389
123456789	CA	Large group market	Corticosteroid	E01755760101	15,011
123456789	CA	Individual market	Anti-epileptic Agent	E01757530101	5,136
123456789	CA	Small group market	Anti-epileptic Agent	E01757530101	14,034
123456789	CA	Large group market	Anti-epileptic Agent	E01757530101	9,333

Example: Data aggregated by therapeutic class (not all columns shown)

Note: To reduce file size, you may leave RxDC Therapeutic Class blank, as long as RxDC Class Code is populated.

CMS Crosswalk

The CMS Drug and Therapeutic Class Crosswalk ("CMS crosswalk") contains the RxDC drug code and therapeutic class code for each NDC. The CMS crosswalk file is available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

What if an NDC is missing from the CMS Drug and Therapeutic Class Crosswalk?

If the CMS crosswalk is missing an NDC for a prescription drug that was dispensed during the reference year (and the missing NDC is not for a pharmaceutical supply, medical device, nutritional supplement, or OTC drug), you should assign an RxDC drug name using the naming method described earlier in this Section 8.1. If the ingredient or ingredient/brand name combination is already in the RxDC crosswalk, use the existing RxDC drug name and drug code. If the ingredient or ingredient/brand name combination lis already in the RxDC crosswalk, use the CMS crosswalk (and the missing NDC is not for a pharmaceutical supply, medical device, nutritional supplement, or OTC drug), create a unique RxDC drug code using a method of your choosing. Assign the drug to the most appropriate RxDC therapeutic class based on existing RxDC therapeutic class names and codes.

If you include data in D3, D4, D5, D7, or D8 for NDCs that are not in the CMS crosswalk, upload a supplemental document in HIOS to identify the RxDC drug name, RxDC drug code, RxDC therapeutic class name, and RxDC Code that you used for each NDC. The supplemental file should be a CSV or Excel file.

11-Digit NDC	RxDC Drug Name	RxDC Drug Code	RxDC Therapeutic Class	RxDC Class Code

Note: Do not create additional RxDC drug names for pharmaceutical supplies, medical devices, nutritional supplements, or OTC drugs.

²³ For the purposes of RxDC reporting, we generally group drugs by therapeutic class according to their FDA Established Pharmacologic Class (EPC). See <u>https://www.fda.gov/industry/structured-product-labeling-resources/pharmacologic-class</u> for more information on EPCs.

8.2 Rx Utilization

Use the following definitions to report prescription drug utilization.

Number of paid claims

Location: D3, D4, D5, D7, D8 | **Max decimals:** 8 The number of claims paid for prescriptions filled during the reference year.

Number of members with a paid claim

Location: D3, D4, D5, D7, D8 | **Max decimals:** 0 The number of members with at least one paid claim for a prescription filled during the reference year.

Total dosage units

Location: D3, D4, D5, D7, D8 | Max decimals: 8

The total number dosage units dispensed during the reference year. Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

8.3 Rx Enrollment

Location: D6 Column E | Max decimals: 8

New for 2023: Report the total number of member months covered during the reference year under the pharmacy benefit for which you are reporting pharmacy spending. Calculate member months as described in the definition of life-years in Section 6.1. For example, if 100 members were covered for 12 months and another 10 members were covered for only one month, the total number of member months would be 1,210.

If you are reporting information about a carved-out benefit and a different reporting entity (or entities) will report on the plan's other benefit(s), include only the members covered by the carved-out benefit for which you are reporting.

8.4 Rx Spending

Total spending and total cost sharing are net of prescription drug rebates, fees, and other remuneration. The definitions in this section are the same as the definitions in Section 7.

Rx Total Spending

Location: D3, D4, D5, D6, D7, D8 | Max decimals: 8

Report allowed claims with dates of service during the reference year. Allowed claims are the total payments made under the plan or policy to health care providers on behalf of members. Report claims on a direct basis (that is, before reinsurance and stop-loss reimbursements, unless specifically stated otherwise in these instructions).

Include in Rx Total Spending	Subtract	Exclude
 Payments by the plan, issuer, or carrier Cost sharing paid by members Claims liability, including claims incurred during the reference year but not paid or not reported as of March 31 of the year following the reference year (such as claims reported but still in the process of adjustment or payment) 	 Net payments from any federal or state reinsurance or cost-sharing reduction arrangement or program (not applicable to self-funded coverage) Prescription drug rebates, fees, and other remuneration (In other words, total spending is net of prescription drug rebates, fees, and other remuneration) Prescription drug rebates, fees, and other remuneration that are expected but have not yet been received Manufacturer cost-sharing assistance, to the extent known 	 Ineligible claims, such as duplicate claims, recovered claims overpayments, and any other claims that are denied under the policy's or plan's terms Payments by Medicare Third-party liabilities paid by other entities, such as coordination of benefits claims Payments for services other than medical care (Example: medical management, quality improvement, fraud detection and recovery expenses) Active life reserves (policy reserves, contract reserves, contingency reserves, or any kind of reserves except traditionally defined reserves for claims incurred but not reported) or change in such reserves Contributions to a trust that are not contributions for claims incurred but not yet reported Charges or payments from state or federal risk adjustment programs

How do I account for net payments from federal or state reinsurance and cost-sharing reduction programs when I report spending on prescription drugs?

Option 1

Determine the exact amount of net payments from federal or state reinsurance and cost-sharing reduction programs attributable to specific drug claims, and use these amounts when reporting spending at the drug level. If you choose Option 1, note the accounting method you used in the narrative response.

Option 2

Use a reasonable method to allocate net payments from federal or state reinsurance and cost-sharing reduction programs to the drug level. For example, you could allocate the amounts according to the ratio of spending at the drug level divided by total spending on medical and pharmacy claims at the aggregate level, either for all enrollees or for only the reinsurance-covered or CSR-eligible enrollees, as applicable. If you choose Option 2, describe the allocation method you used in the narrative response and explain why you think it is reasonable.

Option 3

You may choose to account for net payments from federal or state reinsurance and cost-sharing reduction programs attributable to drug spending in the narrative response, rather than subtracting the amounts from drug spending reported in data files D3 – D8. If you choose Option 3, the narrative response must include the total amount of net payments from federal or state reinsurance and cost-sharing reduction programs, as applicable, allocated or attributable to prescription drugs, separately for each state and market segment. The

reporting entity that submits D3 – D8 can be different than the reporting entity that submits the narrative response.

Rx Cost Sharing

Location: D3, D4, D5, D7, D8 | Max decimals: 8

Note: Report cost sharing as a stand-alone data element and include it when you report total spending.

Include in Rx Cost Sharing	Subtract	Exclude
 Deductibles, coinsurance, and copays, including amounts that may have been paid through an FSA, HSA, MSA, or HRA, and regardless of whether the amount was applied to the deductible or out-of-pocket maximum 	 Cost sharing paid by a member's secondary insurance, to the extent known Prescription drug rebates, fees, and other remuneration that are passed to members at the point-of-sale, if not already accounted for as reduced cost sharing amounts paid by members 	 Cost sharing reductions the issuer paid on behalf of the member under federal or state cost-sharing reduction programs (include these amounts in total spending but not in total cost sharing) Premium Manufacturer cost-sharing assistance

Rx Manufacturer cost-sharing assistance

Location: D3, D4, D5, D7, D8 | Max decimals: 8

Report manufacturer cost-sharing assistance amounts paid on behalf of members, such as coupons or copay cards, to the extent the information is available.

Rx Amounts not applied to deductible or out-of-pocket maximum

Location: D6 | Max decimals: 8

Report billed amounts that were (1) not applied to a member's deductible or out-of-pocket maximum, (2) not paid by the plan, issuer, or carrier, and (3) not included in Rx Total Spending.

Include:

- Denied claims for prescription drugs that are not on a plan or coverage's formulary (unless the prescription is subsequently filled with a generic version or alternate brand version of the same drug)
- Cost-sharing amounts not applied to the deductible or out-of-pocket maximum. For example, if manufacturer cost-sharing assistance is not counted towards a member's deductible or out-of-pocket maximum as part of an accumulator adjustment program, include it here.

8.5 Top Drug Lists

Exclude drugs covered under a non-pharmacy benefit when you create the four RxDC top drug tables. If there are ties when you rank the top drugs, use the number of members with a paid claim as the tie breaker. If there is still a tie, choose one of the other utilization or spending measures to break the tie.

Note: A PBM or other reporting entity may determine the top 50 or top 25 drugs using the data of all plans in the same state and market segment even if the PBM is reporting data at the plan sponsor, issuer, or TPA level within the state and market segment.

Use the following steps to create the Top 50 Most Frequent Brand Name Drugs table.

- 1. For each RxDC brand name drug, calculate the total number of paid claims in a state and market by adding the number of paid claims for every NDC associated with the RxDC brand drug name.
 - Only count paid claims for prescriptions filled during the reference year.
 - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market segment.
 - CMS will indicate which drugs are considered brand name drugs in the CMS Drug and Therapeutic Class Crosswalk File or provide instructions for you to determine which drugs are considered brand name drugs.
- 2. Rank the drugs in each state and market segment according to number of paid claims, sorted in descending order. Using this ranking, identify the 50 brand name drugs with the highest number of paid claims. **Note:** A rank value of 1 means the drug is the most frequently prescribed brand name drug.
- 3. Create a table with the top 50 drugs and include a row for every aggregation state, market segment, and aggregation company.
 - This means that there will be 50 rows for every state, market segment, and EIN combination.
- 4. For each row, report the number of paid claims and the other utilization and spending variables in the file layouts.

D4 Top 50 Most Costly Drugs

Use the following steps to create the Top 50 Most Costly Drugs table.

- 1. For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other remuneration, in the state and market segment by summing total spending for every NDC associated with the RxDC drug name.
 - Use the definition of Total Spending in Section 7.1 above.
 - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market segment.
- 2. Rank the drugs in the state and market segment according to total spending, sorted in descending order, and identify the 50 drugs with the greatest total spending. **Note:** A rank value of 1 means that the drug has the greatest value for total spending.)
- 3. Create a table with the top 50 drugs and include a row for every aggregation state, market segment, and aggregation company.
 - This means that there will be 50 rows for every state, market segment, and EIN combination.
- 4. For each row, report total spending and the other utilization and spending variables in the file layouts.

D5 Top 50 Drugs with the Greatest Increase in Spending

Exclude prescription drugs if they were not approved for marketing, or issued an Emergency Use Authorization (EUA), by the Food and Drug Administration for the entire reference year *and* for the entire calendar year immediately preceding the reference year. For example, if a drug was introduced in 2022, exclude the drug from D5 in the 2022 RxDC report and in the 2023 RxDC report. The CMS Drug and Therapeutic Class Crosswalk will be updated to indicate the year in which a drug was first approved for marketing or issued an EUA.

Use the following steps to create D5 Top 50 Drugs with the Greatest Increase in Spending.

- For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other price concessions, in the state and market segment by summing total spending <u>for the reference year</u> for the NDCs associated with the RxDC drug name.
 - Use the definition of Total Spending in Section 7.1 above.

- Only include NDCs if they were approved for marketing or issued an EUA for the entire reference year and for the entire year prior to the reference year.
- If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market segment.
- 2. For each RxDC drug, calculate total spending, net of prescription drug rebates, fees, and other price concessions, in the state and market segment <u>for the year prior to the reference year</u> by summing total spending for the NDCs associated with the RxDC drug name.
 - Use the definition of Total Spending in Section 7.1 above.
 - Only include NDCs if they were approved for marketing or issued an EUA for the entire reference year and for the entire year prior to the reference year.
 - If you are reporting on behalf of multiple group health plans, include all of them when calculating the total in the state and market for the issuer or TPA.
- 3. For each RxDC drug, calculate the increase in total spending by subtracting total spending in the state and market segment for the year prior to the reference year (the amount from Step 2) from total spending in the state and market segment for the reference year (the amount from Step 1).
 - If spending on a drug increased from one year to the next, the difference will be a positive number. If spending on a drug decreased from one year to the next, the difference will be a negative number.
- 4. Rank the drugs in each state and market segment according to the increase in total spending (the amount from Step 3), sorted in descending order. Identify the 50 drugs with the greatest increase in total spending. A rank value of 1 means the drug has the greatest increase in total spending.
 - \circ $\;$ $\;$ Use the dollar amount increase, not the percent increase.
- 5. Create a table with the top 50 drugs and include a row for every aggregation state, market segment, and aggregation company.
 - \circ This means that there will be 50 rows for every state, market segment, and EIN combination.
- 6. For each row, report total spending in the reference year, total spending in the year prior to the reference year, the increase in total spending, and the other utilization and spending variables in the file layouts.

What if my client had a different reporting entity last year?

There are two reporting options:

- The previous reporting entity includes the client's data in the prior year column of their report, assuming they are still reporting on behalf of other clients; or
- You obtain prior year data from the previous reporting entity and include it in the prior year column of your report.

Note: There will be a disconnect between the current year and prior year columns because the set of clients in the current year columns is different from the set of clients in the prior year column.

What if an NDC is mapped to a different RxDC drug code or therapeutic class code than it was in the prior year?

When CMS updates the crosswalk each year, it's possible for an NDC to be assigned to a different RxDC drug code or therapeutic class. If the mapping of an NDC changes from one year to the next, there are two reporting options:

- Use the prior year crosswalk for the prior year data and the current year crosswalk for the current year data, or
- Use the current year crosswalk for both years.

D8 Top 25 Drugs with the Greatest Amount of Rebates

Use the following steps to create the Top 25 by Rx Rebates table.

- 1. For each RxDC drug, calculate total rebates, fees, and other remuneration in the state and market segment by summing total rebates, fees, and other remuneration for every NDC associated with the RxDC drug name.
 - Use the definition of Total Rebates, Fees, and Other Remuneration in Section 9.1 below.
 - If Rx rebates, fees, and other remuneration cannot be measured at the NDC level, use a reasonable method to allocate rebates, fees, and other remuneration to the NDC level. See Section 9.2 below for more information about allocation methods.
- 2. Rank the drugs in the state and market segment according to total rebates, fees, and other remuneration, sorted in descending order. Identify the 25 drugs with the greatest amount. A rank value of 1 means the drug has the greatest amount of total rebates, fees, and other remuneration.
- 3. Create a table with the top 25 drugs and include a row for every aggregation state, market segment, and aggregation company.
 - This means that there will be 25 rows for every state, market segment, and EIN combination.
- 4. For each row, report prescription drug rebates, fees, and other remuneration, as well as the utilization, spending, and other associated Rx rebate variables in the file layouts.

What if I'm reporting for multiple clients and receive multiple Top 50 or Top 25 lists instead of claims-level data?

If your clients provide a Top 50 or Top 25 list without claims-level data for all drugs, do not add the spending and utilization to re-calculate a new Top 50 or Top 25 based on the lists from multiple clients. For example, if you receive the top 50 most costly drug list from two plan sponsors, do not add spending on drugs on both lists to re-calculate a new list of the top 50 most costly drugs, even if the plans are in the same state and market segment and have the same issuer or TPA. Instead, "stack" the top 50 lists and report the plan sponsor name and EIN in columns A and B of the data file.

Example of							
Company Name	Company EIN	Agg State	Market Segment	Drug Name	Drug Code	Spending Increase Rank	 Total Spending
Plan Sponsor A	EIN of Plan Sponsor A	ОН	small group market	levothyroxine	R00105820101000	1	196660.90
Plan Sponsor A	EIN of Plan Sponsor A	ОН	small group market	semaglutide [Ozempic]	R19913020101001	2	134362.70
Plan Sponsor A	EIN of Plan Sponsor A	ОН	small group market				
Plan Sponsor A	EIN of Plan Sponsor A	ОН	small group market	sumatriptan	R00374180101000	50	11229.21
Plan Sponsor B	EIN of Plan Sponsor B	NJ	sf large employer plans	adalimumab [Humira]	R03273610101001	1	603041.60
Plan Sponsor B	EIN of Plan Sponsor B	NJ	sf large employer plans	lanadelumab [Takhzyro]	R20556410101001	2	469190.50
Plan Sponsor B	EIN of Plan Sponsor B	NJ	sf large employer plans				
Plan Sponsor B	EIN of Plan Sponsor B	NJ	sf large employer plans	mepolizumab [Nucala]	R17205970101001	50	6401.44

Example of "stacked" Top 50 list

9 Rebates, Fees, and Other Remuneration

9.1 Definitions

Rebates retained by PBMs

Location: D7, D8 | Max decimals: 8

Include:

- Manufacturer rebates received by PBMs and not passed through to any member or entity
- Amounts received directly from a manufacturer or indirectly from a pharmacy, wholesaler, or other entity
- Include rebate amounts that are expected but have not yet been received if the PBM will retain the expected amounts

Rebates retained by plans/issuers/carriers

Location: D7, D8 | Max decimals: 8

Include (to the extent known):

- Manufacturer rebates received by plans, issuers, or carriers and not passed through to any member or entity, including rebates that are retained and used to reduce future premiums
- Amounts received directly from a manufacturer or indirectly from a PBM, pharmacy, wholesaler, or other entity
- Rebate amounts that are expected but have not yet been received if the plan, issuer, or carrier will retain the expected amounts
- Rebate guarantee amounts. A rebate guarantee amount is a payment received from a PBM to account for the difference between the rebate amount guaranteed by a PBM, as likely delineated in the contract between the two parties, and the actual rebate amount received from a drug manufacturer.

Note: If a PBM or other reporting entity is unable to obtain complete information regarding the rebates, fees, and other remuneration received or retained by a plan, issuer, or carrier, the reporting entity may report only the rebates, fees, and other remuneration from any sources known to the reporting entity, and may assume that known amounts received by the plan, issuer, or carrier were retained by the plan, issuer, or carrier.

Rebates passed to members at POS

Location: D7, D8 | Max decimals: 8

Include:

• Manufacturer rebates passed through (rather than retained by PBMs or plans/issuers/carriers) to members at the point of sale (POS)

Exclude:

• Manufacturer cost-sharing assistance

Net transfer of other remuneration from manufacturers to plans/issuers/carriers/PBMs

Location: D7, D8 | Max decimals: 8

Report *net* amounts. For example, if transfers from manufacturer to a PBM exceed transfers from the PBM to manufacturer, report a positive number. If transfers from a PBM to the manufacturer exceed transfers from the manufacturer to the PBM, report a negative number.

Include:

- Price concessions, fees, and other remuneration provided to a plan, issuer, carrier, or PBM, directly or indirectly. For example, include the following amounts:
 - $\circ \quad \text{Bona fide service fees} \\$
 - Discounts

- Chargebacks
- o Cash discounts
- Free goods contingent on a purchase agreement
- Up-front payments
- o Coupons
- Goods in kind
- Free or reduced-price services
- o Grants
- Other price concessions or similar benefits
- Fees and other remuneration that are expected but not yet transferred.

Exclude:

• Any remuneration, coupons, or price concessions for which the full value is passed on to the member.

Net transfer of other remuneration from pharmacies to issuers/plans/carriers/PBMs

Location: D7, D8 | Max decimals: 8

Report the amounts described above (in the data element for the net transfer of other remuneration from manufacturers to issuers, plans, carriers, and PBMs) except that the amount reported here should be the net transfer from pharmacies, wholesalers, and other entities, rather than from manufacturers.

Report *net* amounts. For example, if transfers from pharmacies to a PBM exceed transfers from the PBM to pharmacies, report a positive number; if transfers from a PBM to pharmacies exceed transfers from pharmacies to the PBM, report a negative number.

Total rebates, fees, and other remuneration

Location: D7, D8 | Max decimals: 8

Sum of the previous five data elements. That is, the sum of "Rebates retained by PBMs," "Rebates retained by plans/issuers/carriers," "Rebates passed to members at POS," and "Net transfer of other remuneration from manufacturers to plans/issuers/carriers/PBMs."

Restated prior year rebates, fees, and other remuneration

Location: D7, D8 | Max decimals: 8

Restate total rebates and other remuneration from the prior reference year as of 3/31 of the calendar year following the current reference year (that is, incurred in 12 months, paid or received in 27 months). So, for example, in the 2023 RxDC report, there would be one column for total rebates for 2023 (as of 3/31/2024) and another column for restated rebates for 2022 (restated as of 3/31/2024).

What if my client had a different reporting entity last year?

There are two reporting options:

- The previous reporting entity includes the client's data in the prior year column of their reference year report (assuming they are still reporting on behalf of other clients); or
- You obtain prior year data from the previous reporting entity and include it in prior year column of your report.

Note: There will be a disconnect between the current year column and the restated prior year column. (Because the set of clients in the current year columns is different from the set of clients in the prior year column.)

Bona fide service fees

Location: D6 | Max decimals: 8

Bona fide service fees are fees that a manufacturer pays to a PBM that:

- Represent fair market value for a bona fide, itemized service performed on behalf of the manufacturer. These are services that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and
- Are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Bona fide service fees include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).

PBM spread amounts

Location: D6 | Max decimals: 8

The PBM spread is the difference between the amount the plan, issuer, or carrier paid to the PBM and the amount the PBM paid to manufacturers, wholesalers, pharmacies, or other vendors. For example, if plans paid \$250 to the PBM, and the PBM paid \$200 to manufacturers, wholesalers, pharmacies, or other vendors, the PBM spread amount would be \$50.

Include:

- amounts for all drugs furnished through the PBM.
- amounts paid to retail, mail-order, and other pharmacies.

If a plan, issuer, or carrier uses pass-through pricing to pay PBMs, use zero for the PBM spread amount. If a plan, issuer, or carrier uses lock-in pricing to pay PBMs, report the difference between the lock-in price and the price ultimately received by the pharmacy.

9.2 Allocation Methods

Use a reasonable method to allocate rebates, fees, and other remuneration if they cannot be tied to a specific prescription drug for a specific EIN, state, and market segment.

Method	Description	Reasonable?	Explanation
Based on	Allocate rebates received for multiple drugs	Yes	Appropriately accounts
dosage units	based on total dosage units for each drug as a		for differences in a
	percent of total drug spending for all the		specific drug's
	prescription drugs for which the rebate was		utilization across plans
	received.		and issuers.
Based on	Allocate rebates received for multiple drugs	Yes	Approximates
total drug	based on total drug spending for each drug as a		differences in
spending	percent of total drug spending for all the		utilization and spending
	prescription drugs for which the rebate was		on rebate eligible
	received.		drugs.
Based on	Rebates received for a specific drug are	Yes	Appropriately accounts
billed rebate	allocated to a plan, issuer, or carrier and 11-		for differences in a
amounts	digit NDC based on the rebate amounts billed		specific drug's
	to the pharmaceutical manufacturer for the		utilization across plans
	specific plan, issuer, or carrier and drug as a		or issuers.
	percent of the total rebate amount billed to		
	the pharmaceutical manufacturer for all the		
	PBM's plans or issuers.		

Here are examples of reasonable and unreasonable methods to allocate prescription drug rebates.

Method	Description	Reasonable?	Explanation
Based on	Rebate amounts received for multiple drugs	Yes, but only if	Accounts for
plan's brand	are allocated to a plan, issuer, or carrier based	the PBM receives	differences in
drug	on the total drug spend for drugs under the	rebates only for	utilization and spending
spending	plan, issuer, or carrier as a percent of the total	brand drugs.	on rebate-eligible drugs
	drug spend for brand drugs under all of the		across plans or issuers.
	PBM's plans or issuers, and further to a		
	prescription drug based on the NDC-specific		
	total drug spend under the plan, issuer, or		
	carrier as a percent of the total drug spend for		
	brand drugs under the plan, issuer, or carrier.		
Based on	Rebates received for multiple drugs are	No	Does not sufficiently
enrollment	allocated to a plan, issuer, or carrier for		approximate
	prescription drug based on the number of		differences in
	members enrolled in the plan, issuer, or carrier		utilization and spending
	as a percent of the total number of members		on rebate eligible drugs
	enrolled in all the PBM's plans, issuers, or		across plans or issuers.
	carriers.		
Based on the	Rebates received for multiple drugs are	No	Does not sufficiently
number of	allocated to a plan, issuer, or carrier for		approximate
paid claims	prescription drugs based on the number of		differences in
	claims under the plan, issuer, or carrier as a		utilization and spending
	percent of the total number of claims received		on rebate eligible drugs
	under all the PBM's plans, issuers, or carriers.		across plans or issuers.
	Thus, allocation is based on the total number		
	of claims for all the drugs rather than the		
	number of claims received for each drug.		

Describe the method you used in the narrative response. If you used an allocation method other than one of the methods described as reasonable in the table above, include enough detail for CMS to evaluate whether the method is reasonable.

Also describe the methods you used to allocate fees or other remuneration in the narrative response. Some allocation methods, such as allocation based on the number of paid claims, are considered unreasonable for allocating rebates but might, based on the support that you provide in the narrative response, be considered reasonable for allocating fees.

10 Narrative Response

Address the following topics in your narrative response. Save your narrative as a Word document or pdf before uploading it into HIOS.

Net payments from federal or state reinsurance or cost-sharing reduction programs

Issuers that paid into or received payments from federal or state reinsurance programs or cost-sharing reduction programs should describe how they accounted for net payments from federal or state reinsurance and cost-sharing reduction programs. (See Section 8.4.)

Drugs missing from the CMS crosswalk

If the CMS crosswalk is missing an NDC for a drug that was prescribed during the reference year and covered under the pharmacy benefit, please use the "Upload supplemental document" feature in HIOS to upload an Excel or CSV table with the RxDC drug name and drug code that you used or created, as well as the therapeutic

class name and code, for each missing NDC. that you used (or created for each missing NDC. The supplemental file should be a table with the following layout:

11-Digit NDC	RxDC Drug Name	RxDC Drug Code	RxDC Therapeutic Class	RxDC Class Code

Medical benefit drugs

Describe how you estimated the portion of bundled or alternative payment arrangements that can be attributed to drugs covered under a medical benefit (as reported in D2). Describe allocation methods, if applicable.

Prescription drug rebate descriptions

Describe the types of rebates, fees, and other remuneration that you included or excluded in the Rx Totals, Rx Rebates by Therapeutic Class, and Rx Rebates for the Top 25 Drugs. Explain any negative values for rebates, fees, or other remuneration.

Allocation methods for prescription drug rebates

Describe the methods you used to allocate prescription drug rebates, fees, and other remuneration. If you used an allocation method other than one of the methods described as reasonable in the Section 9.2 above, your description must include enough detail for CMS to evaluate whether the method is reasonable.

Impact of prescription drug rebates

Describe the impact of rebates, fees, and other remuneration on premium and out-of-pocket costs in your narrative response. Provide as much detail as possible. Describe how and why the impact may vary based on the market segment or for particular types of plans, such as high deductible health plans. Describe the impact of prescription drug rebates on the tier assignment of prescription drugs in the formulary, or the removal of generic equivalents from a formulary. If possible, provide a quantitative estimate of the impact.

11 Appendix A: File Layouts for the RxDC Report

11.1 Plan Lists

P1 Individual and Student Market Plan List

Note: Each row in P1 should have a unique combination of HIOS Plan ID and plan year beginning date.

P1 Column Name	Field Type	Instructions	
HIOS Plan Name	String	Do not enter more than one value.	
HIOS Plan ID	String	14-digit HIOS Plan ID. Ex: 12345NY1234567. Do not enter	
		more than one value.	
		Note: Some grandfathered plans and student health plans	
		currently don't have HIOS IDs. If a plan doesn't have a HIOS	
		Plan ID, follow the instructions in Section 4.1.	
Plan Year Beginning Date	Date	MM/DD/YYYY	
		Do not enter more than one value.	
Plan Year End Date	Date	MM/DD/YYYY	
		Do not enter more than one value.	
Market Segment	String	<u>Valid Values</u> :	
		Individual market	
		Student market	
		Do not enter more than one value.	
Members as of 12/31 of	Integer	The number of enrollees on the last day of the reference	
the reference year		year. If a plan ended before the last day of the reference	
		year, enter 0.	
PBM Name	String	If there is more than one value, separate them with a	
		semicolon.	
PBM EIN	String	9-digit EIN. Include leading zeros if your EIN is fewer than 9	
		digits. Do not use dashes. Ex: 001234567. If there is more	
		than one value, separate them with a semicolon.	
Included in D1 Premium	Integer	Valid Values:	
and Life Years?		0	
(1= Yes; 0 = No)		1	
Included in D2 Spending by	Integer	Valid Values:	
Category?		0	
(1= Yes; 0 = No)		1	
Included in D3 Top 50 Most	Integer	Valid Values:	
Frequent Brand Drugs?		0	
(1= Yes; 0 = No)	1.1		
Included in D4 Top 50 Most	Integer	Valid Values:	
Costly Drugs?		0	
(1= Yes; 0 = No)	laterer	1 Velid Velvee	
Included in D5 Top 50	Integer	Valid Values:	
Drugs by Spending Increase?		0	
(1= Yes; 0 = No)		1	
(1 - 165, 0 - 100)	Integer	Valid Valuas	
Included in D6 Rx Totals?	Integer	Valid Values:	
(1= Yes; 0 = No)		0	
		1	

P1 Column Name	Field Type	Instructions
Included in D7 Rx Rebates	Integer	Valid Values:
by Therapeutic Class?		0
(1= Yes; 0 = No)		1
Included in D8 Rx Rebates	Integer	Valid Values:
for the Top 25 Drugs?		0
(1= Yes; 0 = No)		1

P2 Group Health Plan List

Each row should have a unique combination of Group Health Plan Number, plan year beginning date, and plan sponsor EIN.

P2 Column Name	Field Type	Instructions	
Group Health Plan Name	String	Do not include FEHB plans.	
Group Health Plan Number	String	Enter a unique plan identification number. You can use the identification number in your own database or any other numbering sequence as long as there is a unique plan ID number for every plan. You may use the Form 5500 Plan Number.	
Carve-out Description	String	 Valid values: Pharmacy only Behavioral health only Fertility only Specialty drugs only Hospital only This plan does not include pharmacy benefits Medical only Other Leave blank if you are reporting on the majority of the plan's benefits as well as a carved-out benefit. 	
Form 5500 Plan Number	String	If applicable, enter the 3-digit plan number reported on the IRS Form 5500 filed with the Department of Labor. If there is more than one value, separate them with a semicolon.	
States in which the plan offered	String	Enter the state(s) in which the plan or coverage is offered using 2-character state postal code. ²⁴ If there is more than one state, separate them with a semicolon. For example: AL; AK; MA. If a plan is offered in every state and in DC, enter "National". If a plan is offered nationally and also in the territories, enter "National" as well as the 2-character postal code for the territories, separated by a semicolon. For example: National; PR; GU.	
Market Segment	String	Valid Values: Small group market Large group market SF small employer plans SF large employer plans	

²⁴ In these instructions, the term "State" includes the District of Columbia and the U.S. territories.

P2 Column Name	Field Type	Instructions
		For mixed-funded plans, enter both markets and separate
		them with a semicolon.
Plan Year Beginning Date Date		MM/DD/YYYY
		If a plan has a non-calendar plan year and renews during the
		calendar year, use two rows in the plan list file. (One row for
		the plan year that ended in the reference year and another
		for the plan year that began during the reference year.)
Plan Year End Date	Date	MM/DD/YYYY
		If a plan has a non-calendar plan year and renews during the
		calendar year, use two rows in the plan list file. (One row for
		the plan year that ended in the reference year and another
		for the plan year that began during the reference year.)
Members as of 12/31 of	Integer	The number of members with coverage, including
the reference year		dependents, on the last day of the reference year. If a plan
		ended before the last day of the reference year, enter 0.
Plan Sponsor Name	String	Enter the plan sponsor or client name. If there is more than
		one value, separate them with a semicolon.
Plan Sponsor EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer
		than 9 digits. Do not use dashes. Ex: 001234567. If there is
		more than one value, separate them with a semicolon.
Issuer Name	String	If there is more than one value, separate them with a
		semicolon.
Issuer EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer
		than 9 digits. Do not use dashes. Ex: 001234567. If there is
		more than one value, separate them with a semicolon.
TPA Name	String	If there is more than one value, separate them with a
		semicolon.
TPA EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer
		than 9 digits. Do not use dashes. Ex: 001234567. If there is
		more than one value, separate them with a semicolon.
PBM Name	String	If there is more than one value, separate them with a
		semicolon.
PBM EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN is fewer
		than 9 digits. Do not use dashes. Ex: 001234567. If there is
		more than one value, separate them with a semicolon.
Included in D1 Premium	Integer	Valid Values:
and Life Years?		0
(1= Yes; 0 = No)	1	
Included in D2 Spending by	Integer	Valid Values:
Category?		0
(1= Yes; 0 = No)	laterer	1 Velid Velvee
Included in D3 Top 50 Most	Integer	Valid Values:
Frequent Brand Drugs?		0
(1= Yes; 0 = No)	المحمد	
Included in D4 Top 50 Most	Integer	Valid Values:
Costly Drugs?		0
(1= Yes; 0 = No)		1

P2 Column Name	Field Type	Instructions
Included in D5 Top 50	Integer	Valid Values:
Drugs by Spending		0
Increase?		1
(1= Yes; 0 = No)		
Included in D6 Rx Totals?	Integer	Valid Values:
		0
(1= Yes; 0 = No)		1
Included in D7 Rx Rebates	Integer	Valid Values:
by Therapeutic Class?		0
(1= Yes; 0 = No)		1
Included in D8 Rx Rebates	Integer	Valid Values:
for the Top 25 Drugs?		0
(1= Yes; 0 = No)		1

P3 FEHB Plan List

Each row should have a unique combination of FEHB contract number, FEHB plan code, and plan year beginning date.

P3 Column Name	Field Type	Instructions	
FEHB Plan Name	String		
FEHB Contract Number	String	Enter the FEHB Contract ID.	
FEHB Plan Code	String	Enter the three-digit FEHB plan code as it appears in the FEHB plan brochure. Separate each three-digit plan code with a semicolon. Ex: 511; 512.	
States in which the plan is offered	String	Enter the states and territories in which the plan is offered using the 2-character postal code. If there is more than one state or territory, separate them with a semicolon. For example: AL; AK; MA. If a plan is offered in every state and DC, enter "National". If a plan is offered nationally and also in the territories, enter "National" as well as the 2-characte postal code for the territories, separated by a semicolon. F example: National; PR; GU.	
Plan Year Beginning Date	Date	MM/DD/YYYY Do not enter more than one value.	
Plan Year End Date	Date	MM/DD/YYYY Do not enter more than one value.	
Members as of 12/31 of the reference year	Integer	The number of FEHB covered individuals, including dependents, on the last day of the reference year. If the plan ended before the last day of the reference year, enter 0.	
FEHB Carrier Name	String		
FEHB Carrier EIN	String	9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567.	
Affiliate Name	String	(If different from the FEHB carrier.) If there is more than one value, separate them with a semicolon.	
Affiliate EIN	String	(If different from the FEHB carrier.)	

P3 Column Name	Field Type	Instructions		
		Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.		
TPA or Other Third-party Name	String	(If different from the FEHB carrier.) If there is more than one value, separate them with a semicolon.		
TPA or Other Third-party EIN	String	(If different from the FEHB carrier.) Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.		
PBM Name	String	(If different from the FEHB carrier.) If there is more than one value, separate them with a semicolon.		
PBM EIN	String	(If different from the FEHB carrier.) Enter the 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567. If there is more than one value, separate them with a semicolon.		
Included in D1 Premium and Life Years? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D2 Spending by Category? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D3 Top 50 Most Frequent Brand Drugs? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D4 Top 50 Most Costly Drugs? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D5 Top 50 Drugs by Spending Increase? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D6 Rx Totals? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D7 Rx Rebates by Therapeutic Class? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		
Included in D8 Rx Rebates for the Top 25 Drugs? (1= Yes; 0 = No)	Integer	Valid Values: 0 1		

11.2 Data Files

D1 Premium and Life Years

Each row in D1 must have a unique combination of EIN, state, and market segment.

D1 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan
		sponsor, or reporting entity as applicable. Do not
		enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state or territory postal code.
		Ex: NY. Do not enter more than one value.
Market Segment	String	<u>Valid Values</u> :
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Average Monthly Premium	Numeric	
Paid by Members		
Average Monthly Premium	Numeric	
Paid by Employers		
Life Years	Numeric	
Earned Premium	Numeric	For fully-insured plans.
Premium Equivalents	Numeric	For self-funded plans.
Admin fees Paid (included in	Numeric	For self-funded plans.
the Premium Equivalents field)		
Stop-loss Premium Paid	Numeric	For self-funded plans.
(included in the Premium		
Equivalents field)		

D2 Spending by Category

Each row in D2 must have a unique combination of EIN, state, market segment, and spending category.

D2 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan
		sponsor, or reporting entity as applicable. Do not
		enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
		not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market

D2 Column Name	Field Type	Instructions
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Spending Category	String	Valid Values:
		Hospital
		Primary Care
		Specialty Care
		Other medical costs and services
		Known medical benefit drugs
		Estimated medical benefit drugs
		Do not enter more than one value.
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Amounts Not Applied to	Numeric	
Deductible and/or Out-of-		
Pocket Maximum		

D3 Top 50 Most Frequent Brand Drugs

Each row in D3 must have a unique combination of EIN, state, market segment, and drug code.

D3 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan
		sponsor, or reporting entity as applicable. Do not
		enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
		not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Drug Name	String	Enter the drug name from the CMS crosswalk file. Do
		not enter more than one value.
Drug Code	String	Enter the drug code from the CMS crosswalk file. Do
		not use NDC. Do not enter more than one value.
Frequency Rank	Integer	Valid Values: 1-50. Do not enter more than one
		value.
Number of Paid Claims	Integer	

D3 Column Name	Field Type	Instructions
Number of Members with a Paid	Integer	
Claim		
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing	Numeric	
Assistance		

D4 Top 50 Most Costly Drugs

Each row in D4 must have a unique combination of EIN, state, market segment, and drug code.

Field		
D4 Column Name	Туре	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan
		sponsor, or reporting entity as applicable. Do not
		enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
		not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Drug Name	String	Enter the drug name from the CMS crosswalk file. Do
		not enter more than one value.
Drug Code	String	Enter the drug code from the CMS crosswalk file. Do
		not use NDC. Do not enter more than one value.
Cost Rank	Integer	Valid Values: 1-50. Do not enter more than one
		value.
Number of Paid Claims	Integer	
Number of Members with a Paid	Integer	
Claim		
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing	Numeric	
Assistance		

D5 Top 50 Drugs by Spending Increase

Each row in D5 must have a unique combination of EIN, state, market segment, and drug code.

D5 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier,
	C	plan sponsor, or reporting entity as applicable. Do
		not enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your
. ,	U	EIN has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
	0	not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Drug Name	String	Enter the drug name from the CMS crosswalk file.
		Do not enter more than one value.
Drug Code	String	Enter the drug code from the CMS crosswalk file.
		Do not use NDC. Do not enter more than one
		value.
Spending Increase Rank	Integer	Valid Values: 1-50. Do not enter more than one
		value.
Number of Paid Claims	Integer	
Number of Members with a Paid	Integer	
Claim		
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing	Numeric	
Assistance		
Prior Year Number of Paid Claims	Integer	
Prior Year Number of Members	Integer	
with a Paid Claim		
Prior Year Number of Dosage Units	Numeric	
Prior Year Total Spending	Numeric	
Prior Year Total Cost Sharing	Numeric	
Prior Year Manufacturer Cost-	Numeric	
Sharing Assistance		
Dollar Increase in Total Spending	Numeric	

D6 Rx Totals

Each row in D6 must have a unique combination of EIN, state, and market segment.

D6 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan sponsor, or reporting entity as applicable. Do not enter more than one value.

D6 Column Name	Field Type	Instructions
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
		not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Rx Enrollment	Numeric	
Total Rx Spending under	Numeric	
Pharmacy Benefit		
Rx Amounts Not Applied to	Numeric	
Deductible and/or Out-of-		
Pocket Maximum		
Bona Fide Service Fees	Numeric	
PBM Spread Amounts	Numeric	
Total Rebates/Fees/Other	Numeric	
Remuneration		
Restated Prior Year	Numeric	
Rebates/Fees/Other		
Remuneration		

D7 Rx Rebates by Therapeutic Class

Each row in D7 must have a unique combination of EIN, state, market segment, and therapeutic class code.

D7 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier, plan
		sponsor, or reporting entity as applicable. Do not
		enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your EIN
		has fewer than 9 digits. Do not use dashes. Ex:
		001234567. Do not enter more than one value.
Aggregation State	String	Enter the 2-character state postal code. Ex: NY. Do
		not enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans

D7 Column Name	Field Type	Instructions
		Do not enter more than one value.
Therapeutic Class Name	String	Enter the therapeutic class name from the CMS
		crosswalk file. Do not enter more than one value.
Therapeutic Class Code	String	Enter the therapeutic class code from the CMS
		crosswalk file. Do not enter more than one value.
Number of Paid Claims	Integer	
Number of Members with a	Integer	
Paid Claim		
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing	Numeric	
Assistance		
Rebates Retained by PBM	Numeric	
Rebates Retained by	Numeric	
Plan/Issuer/Carrier		
Rebates Passed to Member at	Numeric	
POS		
Net Transfer of Fees and	Numeric	
Other Remuneration from		
Manufacturer to		
Plan/Issuer/Carrier		
Net Transfer of Fees and	Numeric	
Other Remuneration from		
Pharmacy to		
Plan/Issuer/Carrier		
Total Rebates/Fees/Other	Numeric	
Remuneration		
Restated Prior Year	Numeric	
Rebates/Fees/Other		
Remuneration		

D8 Rx Rebates for the Top 25 Drugs

Each row in D8 must have a unique combination of EIN, state, market segment, and drug code.

D8 Column Name	Field Type	Instructions
Company Name	String	Enter the name of the issuer, TPA, FEHB carrier,
		plan sponsor, or reporting entity as applicable. Do
		not enter more than one value.
Company EIN	String	Enter the 9-digit EIN. Include leading zeros if your
		EIN has fewer than 9 digits. Do not use dashes.
		Ex: 001234567. Do not enter more than one
		value.
Aggregation State	String	2-character state postal code. Ex: NY. Do not
		enter more than one value.
Market Segment	String	Valid Values:
		Individual market
		Student market
		Small group market

D8 Column Name	Field Type	Instructions
		Large group market
		SF small employer plans
		SF large employer plans
		FEHB plans
		Do not enter more than one value.
Drug Name	String	Enter the drug name from CMS crosswalk file. Do
		not enter more than one value.
Drug Code	String	Enter the drug code from the CMS crosswalk. Do
		not use NDC. Do not enter more than one value.
Rebate Rank	Integer	Valid Values: 1-25. Do not enter more than one
		value.
Number of Paid Claims	Integer	
Number of Members with a Paid	Integer	
Claim		
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing	Numeric	
Assistance		
Rebates Retained by PBM	Numeric	
Rebates Retained by	Numeric	
Plan/Issuer/Carrier		
Rebates Passed to Member at POS	Numeric	
Net Transfer of Fees and Other	Numeric	
Remuneration from Manufacturer		
to Plan/Issuer/Carrier		
Net Transfer of Fees/Other	Numeric	
Remuneration from Pharmacy to		
Plan/Issuer/Carrier		
Total Rebates/Fees/Other	Numeric	
Remuneration		
Restated Prior Year	Numeric	
Rebates/Fees/Other		
Remuneration		

11.3 File Requirements

What file format should I use?

You must use Comma Separated Value (CSV) format for your plan lists and data files. You can generate your own CSV files or you can create them using the RxDC templates provided by CMS.

Where is the Data Dictionary and the RxDC templates? The RxDC data dictionary and templates are on the CMS website at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

Follow these instructions when preparing your submission:

- Your files must be in CSV format. If you use the Excel templates provided by CMS, save your files in CSV format before uploading them into HIOS.
- The order of the columns in your file must exactly match the order of the columns in the file layouts.
- The first row of your file should contain the column names. Your data should start on the second row.
- You can use letters, numbers, and the following special characters in non-numeric fields: (){}[] & ~!; @ # \$ % + = |.
- Do not use commas or dollar signs in numeric fields. Only numbers and decimals are allowed. You should remove numeric formatting in Excel before saving your file in CSV format.
- Do not use slashes ("/") in alphanumeric fields. HIOS won't accept text with slashes because data with slashes requires additional security screening that would slow down processing time. The exception is that you can use slashes in the column headers and in date fields.
- You can use commas in a text field if there are quotation marks on both sides of the text. Ex: "Company ABC, Inc."
 - Excel will automatically insert the quotation marks for you when you save a file in CSV format. For example, you can enter Company ABC, Inc in the template without quotation marks and Excel will convert it to "Company ABD, Inc" when you save it as a CSV file. Without the quotation marks, HIOS won't know whether a comma is part of a text string or is a delimiter between columns.
- Do not use more than 8 decimal places in numeric fields. Ex: 0.6666666666666666 should be rounded to 0.666666667.

The maximum file size for each CSV file is 200 megabytes.