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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 2020 and 2021 Reference Years

Updated June 28, 2022

Paperwork Reduction Act 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. The time required to complete this information collection is estimated to average 4,731 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. 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.

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Changes from the November 2021 version of the RxDC Instructions

The RxDC reporting instructions have been updated in response to:

- Public comments on the Paperwork Reduction Act package (<u>CMS-10788</u>) related to the interim final rules titled Prescription Drug and Health Care Spending (<u>86 FR 66662</u>), published on November 23rd, 2021
- Help desk inquiries sent to CMS at CMS_FEPS@cms.hhs.gov

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

Plan Lists

- Added definitions for the columns in the plan list files
- Clarified the treatment of non-calendar year plans
- Added columns to the plan list files for reporting entities to indicate which plans are included in the data files

Spending Categories

- Moved the spending category for drugs covered under a medical benefit (medical benefit drugs) from data file D6 Rx Totals to data file D2 Spending by Category
- Eliminated the spending category in D2 for pharmacy benefit drugs
- Combined the spending categories for wellness services and other medical costs and services
- Required that spending on wellness services be restricted to claims-based costs
- Differentiated spending on medical benefit drugs according to whether the drug was separately billed or included as part of a bundled payment arrangement
- Provided additional detail on classifying claims according to spending category

Total Spending

- Specified the circumstances when manufacturer cost-sharing assistance must be subtracted from total spending
- Provided guidance on allocating net payments from any federal or state reinsurance or costsharing reduction arrangement or program

Average Monthly Premium Paid by Members and by Employers

- Clarified how to calculate the average monthly premium
- Changed the term "employee" to "member" in the instructions for calculating average premium per member per months
- Updated instructions with respect to 2020 and 2021 reference year reporting

Prescription Drugs

- Clarified that authorized generics and branded generics are treated as generic drugs for RxDC reporting
- Updated examples to include the RxDC drug codes

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 (the Departments). In addition, the Director of the Office of Personnel Management (OPM) requires Federal Employees Health Benefits carriers (carriers) to submit Section 204 data to HHS. The Centers for Medicare & Medicaid Services (CMS) 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>.

Ree	quir	ed to Submit	No	Not Required to Submit		
•	He	alth insurance issuers offering group coverage	Account-based plans, such as health			
•	He	alth insurance issuers offering individual market		reimbursement arrangements		
	co۱	verage, including:	•	Excepted benefits ² including but not		
	0	Student health plans		limited to:		
	0	Plans sold through the Exchanges		 Short-term limited-duration 		
	0	Plans sold outside of the Exchanges		insurance		
	0	Individual coverage issued through an		 Hospital or other fixed indemnity 		
		association		insurance		
•	Ful	ly-insured and self-funded group health plans,		 Disease-specific insurance 		
	inc	luding:	 Medicare Advantage and 			
	0	Non-federal governmental plans, such as plans		Part D plans		
		sponsored by state and local government	•	Medicaid plans		
	0	Church plans that are subject to the Internal	•	State children's health insurance		
		Revenue Code		program plans		
	0	Federal Employees Health Benefits (FEHB) plans	•	Basic Health Program plans		

1.2 Who must submit the RxDC report?

These requirements apply regardless of whether a plan is considered a grandfathered or grandmothered health plan.³

https://www.cms.gov/files/document/extension-limited-non-enforcement-policy-through-calendar-year-2022.pdf.

¹ The CAA is available at https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf. Section 204 Section 204 of Division BB, Title II starts on page H. R. 133–1737.

² PHS Act 2722(b) and (c), ERISA Section 732, and Code Section 9831.

³ 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 action with respect to certain market requirements. See Bulletin: Extended Non-Enforcement of Affordable Care Act-Compliance With Respect to Certain Policies, available at

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

1.3 When is the deadline?

The last day to submit your data for the 2020 and 2021 reference years is **December 27, 2022**.⁴ The deadline for subsequent reference years is June 1st of the calendar year immediately following the reference year. A **reference year** is the calendar year of the data that is in your RxDC report. For example, the RxDC report for the 2020 reference year means the information in the report is based on what happened in 2020.

What is a Reference Year?

The reference year is the calendar year of the data that is in your RxDC report. For example, the RxDC report for the 2020 reference year means the information in the report is based on what happened in 2020.

1.4 Where can I get help?

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

If you can't find the answer to your question in REGTAP, contact our help desk at 1-855-267-1515 or <u>CMS_FEPS@cms.hhs.gov</u>. Include "RxDC" in the body of the email for faster service. You can typically expect a response within the same day and a full resolution within 1-2 weeks.

REGTAP

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

Help Desk

Contact our help desk at 1-855-267-1515 or <u>CMS_FEPS@cms.hhs.gov</u>. Include "RxDC" in the body of the email for faster service. You can typically expect a response within the same day and a full resolution within 1-2 weeks.

2 Required Files

Plans, issuers, and carriers must submit one or more **plan lists** (P1-P3), **eight data files** (D1-D8), and **a narrative response**.

⁴ The statutory deadlines to submit the RxDC report for the 2020 and 2021 reference years are December 27, 2021 and June 1, 2022, respectively. However, the Departments are deferring enforcement for the 2020 and 2021 reference years if you submit your data by December 27, 2022. See FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Part 49, Q12, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf and https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

2.1 Plan Lists and Data Files

Subject	Plan Lists	Data Files
File Names	 P stands for Plan P1 Individual and student market plan list P2 Group health plan list P3 FEHB plan list 	 D stands for Data D1 Premium and Life-Years D2 Spending by Category 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
Purpose	The plan lists identify the plans in a submission. The plan lists also collect 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 health plans that are not FEHB plans P3 is required for FEHB plans 	All 8 data files are required.
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 are on the CMS website at <u>https://www.cms.gov/CCIIO/Programs-and-</u><u>Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

2.2 Narrative Response

A narrative response is required. Describe the impact of prescription drug rebates on premium and cost sharing in the narrative response. You must also respond regarding the other topics described throughout these instructions. 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.

Optional Supplemental Documents

If you want to provide additional information about your submission, the system will allow you to upload supplemental PDF or Word documents. This is optional.

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, pharmacy benefit manager, 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 to create your CMS Enterprise Portal and HIOS accounts are in the <u>HIOS Portal User</u> <u>Manual</u>. The instructions for using the RxDC module are in the <u>RxDC HIOS User Manual</u>.

3.2 Can a vendor submit information on my behalf?

Yes. Plans, issuers, and carriers can contract with issuers, third-party administrators (TPAs), Pharmacy Benefit Managers (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 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 self-funded 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.

Multiple reporting entities should not submit the *same* data file for a plan, issuer, or carrier. For example, a TPA and PBM should not both submit D2 for the same group health plan. The HIOS system does not automatically prevent duplicate submissions of the same file. CMS will check whether there are duplicate files after the submission deadline.

Each reporting entity must submit one or more plan list files (P1, P2, and/or P3). That is how CMS will know when multiple entities are reporting for the same plan. If you know which reporting entity will also be reporting on behalf of a plan, enter its company name and Employer Identification Number (EIN) in the appropriate columns in the plan list file. CMS will use this information to streamline the reconciliation process when there are multiple reporting entities.

Note: It's not a problem if multiple reporting entities upload different narrative responses on behalf of the same plan, issuer, or carrier.

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. For example, if a TPA uploads D2 and a PBM uploads D4 for the same group health plan, the TPA can see only D2 and the PBM can see only D4. The group health plan cannot see either D2 or D4. The plan should contact its reporting entities directly if the plan wants to see the data uploaded on its behalf.

3.4 What if a vendor can't fill out an entire file?

Plans, issuers, carriers, and their reporting entities must work together so that each data file submitted in HIOS contains all required information. If one reporting entity is responsible for only some of the fields in a data file, it should 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.⁵

3.5 What if a plan changes vendors during the reference year?

If a plan, issuer, or carrier changes vendors during the reference year (such as changing a TPA or PBM), there are two reporting options:

- The previous vendor reports the data from earlier in the year and the new vendor reports the data from later in the year; or
- The previous vendor provides the data to the new vendor and the new vendor reports the entire year of data

Either way, the plan sponsor must ensure that all their data is reported and that it is not double-reported.

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

Currently, 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.

4 Plan List Definitions

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

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 in alphanumeric fields if the string is enclosed by double-quotation marks as text qualifiers. (Ex: "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.

⁵ If there are extenuating circumstances that prevent vendors from working together, contact the help desk at <u>cms_feps@cms.hhs.gov</u>. CMS will get back to you to discuss the situation.

4.1 General Definitions

Members as of 12/31

Location: P1, P2, P3 | Max decimal places: 0 | Must not be blank

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.

Plan Year Beginning and End Dates

Location: P1, P2, P3 | **Format:** MM/DD/YYYY | **Must not be blank** Enter the plan year beginning and end dates.

Individual and Student Markets

Generally, you may enter the first and last day of the reference year. For grandfathered and grandmothered individual market plans, you may alternatively enter the date on which the plan was first offered, and the date on which the plan was closed to new enrollment. For student health plans, you may alternatively enter the plan or policy year, or if the year is not designated in the plan or policy document, then the deductible or limit year used under the coverage.

Group Markets

Enter the actual beginning and end dates of the plan year, even if they fall outside of the reference year. For example, if the plan year is July 1, 2019 through June 30, 2020, enter 07/01/2019 for the beginning date and 06/30/2020 for the end date in the 2020 RxDC report. Since the plan year ended before the end of the reference year, enter 0 for the number of members as of 12/31/2020 in the 2020 RxDC report.

Similarly, if the plan year is July 1, 2020 through June 30, 2021, enter 07/01/2020 for the beginning date and 06/30/2021 for the end date in the 2020 RxDC report. Enter the actual number of members as of 12/31/2020 in the 2020 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 6/30/2020 and another for the plan year that began on 7/1/2020.

Group Health Plan Name	Group Health Plan Number	Market Segment	Plan Year Beginning Pate	Plan Year End Date	Members as of 12/31 of the reference year
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2019	06/30/2020	0

Example: Non-calendar year plan in the 2020 RxDC report.

Group Health Plan Name	Group Health Plan Number	Market Segment	Plan Year Beginning Pate	Plan Year End Date	Members as of 12/31 of the reference year
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2020	06/30/2021	27

Note: In the <u>data files</u> (as opposed to the plan lists), the reporting entity would include only the data related to the 2020 <u>calendar year</u> (e.g. the last six months of the "old" plan and the first six months of the "new" plan).

Market Segment

Location: P1, D1-D8 | Max length 100 characters | Must not be blank Location: P2 | Max length 512 characters | Must not be blank

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

- P1: Enter individual market or student market. Do not enter more than one market segment in a cell.
- P2: 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 semi-colon. Example: Large group market; SF large employer plans. P2 is the only place where you can put more than one market segment in a single cell.
- P3: There isn't a column for market segment because all plans in P3 are FEHB plans.
- D1 D8: Enter individual market, student market, small group market, large group market, SF small employer plans, SF large employer plans, or FEHB plans. Do not enter more than one market segment in a cell.

See Section 5.1 for more information on market segments.

Issuer Name

Location: P2, P3 | **Max Length** 2048 characters 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. If the plan is not insured, leave the cell blank.

Issuer EIN

Location: P2, P3 | Format: 9 digits

Enter the issuer 9-digit EIN. Do not enter the 5-digit HIOS Issuer ID. If a plan uses more than one issuer, enter both in the same cell separated by a semicolon. If the plan is not insured, leave the cell blank.

TPA Name

Location: P2, P3 | Max Length 2048 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 EIN

Location: P2, P3 | **Format:** 9 digits Enter the TPA 9-digit EIN. Do not enter the 5-digit HIOS Issuer ID. If there is more than one TPA, separate them with a semicolon. If a plan doesn't have a TPA, leave the cell blank.

PBM Name

Location: P1, P2, P3 | **Max Length** 2048 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: P1, P2, P3 | **Format:** 9 digits Enter the PBM 9-digit EIN. 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: P1, P2, P3 | 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 a 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.

4.2 HIOS Definitions

HIOS Plan ID in P1

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

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 a 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

HIOS Plan ID in P2

Location: P2 | Max length: 2048 characters | May be blank in P2

The HIOS Plan ID field in P2 is applicable only to fully-insured small group health plans that already have HIOS Plan IDs. You can enter more than one HIOS Plan ID in a single cell in P2, if applicable. Separate multiple values with a semicolon. You do not need to create HIOS Plan IDs for group health plans that do not already have HIOS Plan IDs. If your group health plan isn't associated with a HIOS Plan ID, leave this cell blank.

HIOS Plan Name

Location: P1 | 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.

4.3 Group Definitions

Group Health Plan Name

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

Group Health Plan Number

Location: P2 | **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 Form 5500 plan number as the Group Health Plan Number. If you do, 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.

Form 5500 Plan Number

Location: P2 | Max length 25 characters

If applicable, enter the 3-digit plan number reported on the IRS Form 5500 filed with DOL. If there is more than one value, separate them with a semicolon.

Plan Sponsor Name

Location: P2 | **Max length** 2048 characters | **Must not be blank** The term plan sponsor means:

- The employer, for an employee benefit plan that a single employer established or maintains;
- The employee organization in the case of a plan of an employee organization; or

• 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.

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.

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, enter the name of a participating employer as the sponsor. A plan of a controlled group of corporations should enter the name of one of the sponsoring members. In either case, use the same name in all future RxDC reports unless there is a change in sponsorship.

In HIOS, you may upload a supplemental document listing 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 | Max length 25 characters | Must not be blank

Enter the 9-digit employer EIN assigned to the plan sponsor. (Ex: 012345679). 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.

4.4 FEHB Definitions

FEHB Plan Name

Location: P3 | Max Length 2048 characters | Must not be blank

FEHB Contract Number

Location: P3 | Max Length 2048 characters | Must not be blank Enter the FEHB Contract ID.

FEHB Plan Code

Location: P3 | **Max Length** 2048 characters | **Must not be blank** Enter the two-digit FEHB plan code as it appears in the FEHB plan brochure. Separate each two-digit plan code with a semicolon. Ex: 4A; 4B; 4E; 4L.

FEHB Carrier Name

Location: P3 | Max Length 2048 characters | Must not be blank

FEHB Carrier EIN

Location: P3 | Max Length 2048 characters | Must not be blank 9-digit EIN. Include leading zeros if your EIN is fewer than 9 digits. Do not use dashes. Ex: 001234567.

FEHB Affiliate Name

Location: P3 | **Max Length** 2048 characters (If different from the FEHB carrier.) If there is more than one value, separate them with a semicolon.

FEHB Affiliate EIN

Location: P3 | Max Length 2048 characters (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.

5 Data Aggregation

5.1 Market Segment Aggregation

Reporting entities will aggregate data according to market segment. As noted previously, there are 7 market segments: individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

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

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 fullyinsured 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** 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.⁶

For level-funded plans, report the business as self-funded.

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

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

⁶ "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 depends on the size of the employer. 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 all employees employed on business days during the calendar year preceding the reference year. Use any reasonable method that takes into account full-time, part-time, and seasonal employees. Examples of reasonable methods include (1) the full-time equivalent 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 takes into account non-fulltime 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 0.73.⁷ For example, if 40 employees are covered by a plan, then the estimated employer size is 55 (40 ÷ 0.73 = 55). If you use an estimate for employer size for a self-funded plan, describe the method you used in your narrative response. If you use an estimation method other than the one described here, explain why you believe it is a reasonable method.

5.2 State Aggregation

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 multiple employer welfare arrangement (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.

⁷ The divisor is based on estimated take-up rates from the 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 healthcare take-up rate for employers with fewer than 100 employees. See Table 10 at https://www.bls.gov/ncs/ebs/benefits/2021/employee-benefits-in-the-united-states-march-2021.pdf.

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 Employee Retirement Income Security Act of 1974 (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.

5.3 Issuer and TPA Aggregation

Issuers

Within a state and market segment, issuers and their reporting entities must combine the data for all coverage offered by the same issuer.

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.

TPAs and self-funded plans

A TPA reporting on behalf of self-funded plans should, within each state and market segment, combine the data for all self-funded plans on whose behalf it is reporting. A self-funded plan is not required to have a TPA report on its behalf. However, we encourage TPAs to submit RxDC reports on behalf of selffunded plans because it will result in fewer submissions and the total amount of data uploaded into HIOS will be much smaller. The combined data is also more useful because a TPA or PBM can determine the Top Drugs based on a larger sample size.

FEHB carriers

A carrier affiliate or associate such as an issuer, TPA, or other third party such as a vendor or underwriter may be the reporting entity for a FEHB carrier. If a carrier is associated with an issuer, we generally expect that the issuer will report the FEHB line of business in the FEHB market segment of the issuer's submission, rather than the carrier creating a separate submission. Similarly, if a carrier has a contract with a TPA or other third-party vendor, the Departments and OPM expect the TPA or other third-party vendor to report the FEHB line of business data in the FEHB market segment of the TPA's or other third-party vendor's submission.

If a carrier chooses to make its own submission, it needs to make sure that the issuer, TPA, or vendor does not report the same data. If a carrier is associated with more than one issuer, TPA, or vendor, the carrier should aggregate data for plans that share the same issuer, TPA, or vendor. If a carrier offers plans that are not associated with an issuer, TPA, or vendor, the carrier should combine the data for those plans.

PBMs

If a PBM is the reporting entity, the rules for aggregating data by issuer and TPA also apply. For example, if a PBM is reporting data for three issuers, the PBM should aggregate the data separately for each issuer. If a PBM is reporting for 10 self-funded plans that have two different TPAs, the PBM should combine the data for the self-funded plans that share each TPA separately.

Aggregation Restriction

Pursuant to 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 that:

- If the data submitted in D2 IS NOT aggregated by the issuer or TPA (that is, the reporting entity for D2 reports the data separately for each group health plan), the data in D1, D3, D4, D5, D6, D7, and D8 must also be reported separately for each plan.
- If the data submitted in D2 IS aggregated (that is, not reported at the plan level), then the reporting entities for the other data files can *choose* whether they want to report information at the plan level or at the aggregate level. The reporting entities for the other data files don't have to make the same decision for each of the other files. For example, if D2 is at the aggregate level, a reporting entity could choose to submit D1 at the plan level and D4 at the aggregate level.

5.4 Examples of Aggregate Reporting

Below are examples of aggregated data files.

Example 1: Issuer reports for fully-insured plans

Note on Terminology: In HIOS, a 5-digit HIOS Issuer ID is assigned to an issuer in a specific state in which it operates. Therefore, if an insurance company that has a unique 9-digit EIN operates in multiple states, it will have multiple HIOS Issuer IDs. In these instructions, for simplicity, the term "issuer" refers to the insurance company at the EIN level when that is appropriate in context, such as in the examples below.

Issuer A reports total spending in California in the individual, small group, and large group markets, andin Washington for the individual and student markets.Issuer or TPA EINStateMarket SegmentTotal SpendingTotal Cost Sharing

Issuer or TPA EIN	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 in 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.

Issuer or TPA EIN	State	Market Segment	Total Spending	Total Cost Sharing
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EIN for Issuer X	CO	Individual market	\$10,437	\$1,404
EIN for Issuer X	CO	Small group market	\$333,803,307	\$39,962,932
EIN for Issuer X	CO	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.

Issuer or TPA EIN	State	Market Segment	Total Spending	Total Cost Sharing
EIN for Issuer B	CO	Individual market	\$58,971,803	\$9,304,571
EIN for Issuer B	CO	Small group market	\$338,403	\$35,147
EIN for Issuer B	CO	FEHB plans	\$728,966,601	\$88,562,152
EIN for Issuer B	CO	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
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.

Issuer or TPA EIN	State	Market Segment	Total Spending	Total Cost Sharing
EIN for TPA C	KY	SF small employer plans	\$162,827,074	\$17,407,842
EIN for TPA C	KY	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 self-funded plans administered by TPA F, TPA G, and Issuer D. (See Section 9.2 for information about allocating prescription drug rebates across plans, issuers, carriers, states, and markets.)

EIN	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	CO	Small group market	\$10,714	\$2,278
EIN for Issuer D	CO	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 TPA G	СТ	SF large employer plans	\$776,632	\$296,518

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 has employees in Nevada, Utah, and Arizona. In each state, employees can choose among several options. Some of the options are fullyinsured through Issuer H and some of the plans are self-funded and administered by TPA I. To help facilitate data analysis and identify duplicate submissions, the first column should be the EIN of the issuer or TPA of the plans, rather than the EIN of the plan sponsor. (If a self-funded plan is self-administered and doesn't use a TPA, then you can use the EIN of the plan sponsor.)

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

6 Premium and Life-Years

Use the definitions in this section to report premium and life-years in D1 Premium and Life-Years.

Life-years

Location: D1 | 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, and FEHB annuitants are all considered members.

To calculate life-years, you must first calculate member months.

To calculate member months:

- 1. Count the number of members covered on a given day of each month of the reference year
- 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
- 2. Round the resulting number to the 8th decimal place

Example: Calculating member months and life-years

Date	Members covered by the plan on the given date
January 1, 2020	882
February 1, 2020	872
March 1, 2020	884
April 1, 2020	921
May 1, 2020	924
June 1, 2020	923
July 1, 2020	925
August 1, 2020	916
September 1, 2020	907
October 1, 2020	906
November 1, 2020	902
December 1, 2020	869
Total Member Months	10,831
# of Life-Years (Total member months / 12)	902.58333333

Earned premium (fully-insured coverage)

Location: D1 | Max decimals: 8

Earned premium means all money paid by a member, policyholder, subscriber, and/or plan sponsor as a condition of the member receiving 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.

Premium equivalents (self-funded coverage)

Location: D1 | Max decimals: 8

For self-funded plans and other arrangements that do not rely exclusively or primarily on premiums, report the premium equivalent amounts representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, Administrative Services Only (ASO) and other TPA fees, and stop-loss premiums. An employer with a self-funded plan may use, as the total cost of providing and maintaining coverage, the same costs that are taken into account for purposes of calculating COBRA premiums (minus the 2% administration charge, if applicable).

ASO and other TPA fees paid

Location: D1 | Max decimals: 8

Report the ASO and other fees paid to the TPA. This amount should also be included in Premium Equivalents.

Stop loss premium paid

Location: D1 | Max decimals: 8

Report the stop loss premium paid to the insurer. This amount should also be included in Premium Equivalents.

Average monthly premium paid by members

Location: D1 | Max decimals: 8

Report the average monthly premium per member per month (PMPM) paid by members.

Include:

- Premium paid by members
- APTCs
 - Premium equivalents paid by members for self-funded coverage

Exclude:

- Premium paid by employers or other plan sponsors on behalf of members.
- Premium equivalents paid by employers or other plan sponsors on behalf of members

Formula:

Total premium paid by members Average monthly premium paid by members = -Total member months

To calculate average monthly premium paid by members at the aggregate level (EIN, state, market segment), you have two options:

- Calculate the amount for each plan and then take the weighted average across plans in the aggregation level, using member months as the weight; or
- Calculate the amount using total level data from all the plans in the aggregation level.

Average monthly premium paid by employers

Location: D1 | Max decimals: 8

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

Include:

- Premium paid by employers and other plan sponsors on behalf of members (including dependents).⁸
- Premium equivalents for self-funded coverage.
- Premium paid by group trust, association, or MEWA plans if separate employers or other plan sponsors make premium contributions.

⁸ For FEHB plans, the amount paid by the employer is the government contribution within the meaning of Title 5 USC Chapter 89.

Exclude:

• Premium paid by members

Formula:

 $Average monthly premium paid by employers = \frac{Total premium paid by employers}{Total member months}$

To calculate the value at the aggregate level (EIN, state, market segment), you have two options:

- Calculate the amount for each plan and then take the weighted average across all plans in the aggregation level, using member months as the weight; or
- Calculate the amount using total level data from all the plans in the aggregation level.

How do I compute the weighted average?

To calculate the weighted average monthly premium paid by members:

- 1. Calculate the average monthly premium paid by members for each plan in the aggregation level (formula box above)
- 2. For each plan, multiply the amount in Step 1 by the number of member months in the plan
- 3. Calculate the sum of the amount in Step 2 for all plans in the aggregation level
- 4. Calculate the sum the number of member months for all plans in the aggregation level
- 5. Divide the amount in Step 3 by the amount in Step 4

Use the same method to calculate the weighted average monthly premium paid by employers.

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

Average monthly premium paid by enrollees and average monthly premium paid by employers are data elements required by Section 204 of the CAA and the Prescription Drug and Health Care Spending interim final rules (86 FR 66662). Generally, if you are reporting on behalf of a group health plan or FEHB plan, you must obtain this information from the plan.

For the 2020 and 2021 reference years only

If you have obtained the required information, you must report it. However, the Departments recognize there may be significant challenges to obtain information about employer premium contributions, especially when a contractual relationship began before the passage of the CAA. Accordingly, the Departments will not take enforcement action related to the requirement to report average monthly premium paid by employers versus members for the 2020 and 2021 reference years if those data elements are reported in RxDC report for the 2022 reference year and all future reference years.

7 Spending

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 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.) For the 2020 and 2021 reference years, you may choose to use a valuation date that is later than March 31.

7.1 Definitions

Total spending

Location: D2, D3, D4, D5, 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, 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 Prescription drug rebates, fees, and other remuneration (In other words, total spending is net of prescription drug rebates, fees, and other remuneration.) Manufacturer cost-sharing assistance, to the extent known 	 Ineligible claims, such as duplicate claims, recovered claims overpayments, third- party liabilities (e.g., coordination of benefits claims), and any other claims that are denied under the policy's or plan's terms Payments for services other than medical care (e.g., 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 Charges or payments from state or federal risk adjustment programs

Total cost sharing

Location: D2, D3, D4, D5, D7, D8 | **Max decimals:** 8 Include cost sharing when you report Total Spending, and also as a separate data element.

Include in Total Cost	Subtract	Exclude
Sharing		
 Deductibles, coinsurance, and copays, including amounts that may have 	 Cost sharing paid by a member's secondary insurance, to the extent known 	 Cost sharing reductions the issuer paid on behalf of the member under federal or state cost-sharing reduction

Include in Total Cost Sharing	Subtract	Exclude
been paid through a health savings or reimbursement account	 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. 	 programs (include these amounts in total spending but not in total cost sharing) Premium Manufacturer cost-sharing assistance

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 information is available.

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

Location: D2 | 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:

- Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary
- 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.⁹

7.2 Spending Categories

Location: D2 | 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.

Spending Category	Abbreviation (Not case sensitive)
Hospital	Hospital
Primary care	Primary care
Specialty care	Specialty care
Other medical costs and services	Other medical costs and services
Medical benefit drugs: known amounts (informational)	Known medical benefit drugs
Medical benefit drugs: estimated amounts (informational)	Estimated medical benefit drugs

⁹ 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

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. (This is a change from the instructions published on November 23, 2021.)

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 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. These include but not 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 	 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
performed by a primary care provider	amounts in other medical
• Administration of medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service.	costs and services)

Primary Care Taxonomy Codes

Taxonomy Code	Taxonomy Provider Type	Taxonomy Classification	Taxonomy Specialty
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
20800000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PEDIATRICS	NOT APPLICABLE
2080A0000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PEDIATRICS	ADOLESCENT MEDICINE
208D00000X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	GENERAL PRACTICE	NOT APPLICABLE
2083P0901X	ALLOPATHIC & OSTEOPATHIC PHYSICIANS	PREVENTIVE MEDICINE	PUBLIC HEALTH & GENERAL 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
	PRACTICE NURSING		
363L00000X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	NOT APPLICABLE
	PRACTICE NURSING		
363LA2200X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	ADULT HEALTH
	PRACTICE NURSING		
363LC1500X	PHYSICIAN ASSISTANTS AND ADVANCED	COMMUNITY HEALTH	NOT APPLICABLE
	PRACTICE NURSING		
363LF0000X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	FAMILY
	PRACTICE NURSING		
363LG0600X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	GERONTOLOGY
	PRACTICE NURSING		
363LP0200X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	PEDIATRICS
	PRACTICE NURSING		
261QS1000X	AMBULATORY HEALTH CARE FACILITIES	CLINIC/CENTER	STUDENT HEALTH
363LP2300X	PHYSICIAN ASSISTANTS AND ADVANCED	PRIMARY CARE	NOT APPLICABLE
	PRACTICE NURSING		
363LW0102X	PHYSICIAN ASSISTANTS AND ADVANCED	NURSE PRACTITIONER	WOMEN'S HEALTH
	PRACTICE NURSING		
207Q00000X	ALLOPATHIC & OSTEOPATHIC	FAMILY MEDICINE	NOT APPLICABLE
	PHYSICIANS		
364SA2200X	NURSING SERVICE PROVIDERS	CLINICAL NURSE	ADULT HEALTH
		SPECIALIST	
364SC1501X	NURSING SERVICE PROVIDERS	CLINICAL NURSE	COMMUNITY HEALTH
		SPECIALIST	
364SF0001X	NURSING SERVICE PROVIDERS	CLINICAL NURSE	FAMILY HEALTH
		SPECIALIST	
364SP0200X	NURSING SERVICE PROVIDERS	CLINICAL NURSE	PEDIATRICS
		SPECIALIST	

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 	 Amounts reported in hospital, primary care, or other medical costs and
and are not considered primary care providers as defined above	servicesDental services (report in
 Chiropractors, podiatrists, optometrists, and physical, occupational, and speech therapists that are not billed as part 	Other medical costs and services)
of hospital or facility services	Laboratory and radiology services associated with

	Include in Specialty Care	Exclude
•	Doctor's office or outpatient care center services provided by specialists	specialty care in a doctor's office or outpatient care
•	Hospital-based specialist services only if the specialist independently bills for those services	center that are billed independently by the
•	Administration of medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service.	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:	 Amounts reported in hospital, primary care, or specialty care
 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 Durable medical equipment Wellness services billed on a claim. Do not include wellness services that are not covered services under a plan or policy. For the purposes of the RxDC report, wellness services are defined as activities primarily designed to implement, promote, and improve health. 	 Claims with a valid revenue code on the UB-04 form. Wellness services not billed on a claim

Medical benefit drugs: known amounts (informational)

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.

Complete the column for Total Spending (including cost sharing). You are not required to complete the Total Cost Sharing or Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum columns for this informational category.

Medical benefit drugs: estimated amounts (informational)

Location: D2 | **Max decimals:** 8 | **Abbreviation:** Estimated medical benefit drugs Report the estimated portion of bundled or alternative payment arrangements (or other non-fee-forservice 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. If you report estimated amounts, explain the circumstances and describe the method you used in the Narrative Response.

Complete the column for Total Spending (including cost sharing). You are not required to complete the Total Cost Sharing or Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum columns for this informational category.

EIN	State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible and/or Out-of- Pocket Maximum
123456789	ND	Individual market	Hospital	\$1,240,100	\$183,990	\$10,920
123456789	ND	Individual market	Primary Care	\$459,300	\$10,200	\$890
123456789	ND	Individual market	Specialty Care	\$873,300	\$340,000	\$2,680
123456789	ND	Individual market	Other medical costs and services	\$428,800	\$165,900	\$8,550
123456789	ND	Individual market	Known medical benefit drugs	\$211,560		
123456789	ND	Individual market	Estimated medical benefit drugs	\$145,556		

Example: Data aggregated by spending category

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.

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.

8.2 Drug Aggregation

Prescription drug definition

For the purposes of RxDC reporting, a prescription drug is defined as a set of National Drug Codes¹⁰ (NDCs) that are grouped together by name and ingredient. This means that NDCs with the same

¹⁰ 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.

ingredient are grouped together even if they have different strengths, dosage forms (ex: capsule, tablet, liquid), routes of delivery (ex: oral, injection), 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 or as 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: 2048 | Drug Code Max Length: 100

The RxDC drug name for brand prescription drugs is the combination of the ingredient name and the brand name.¹¹ 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.¹² 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	Labeler	Brand	Strength, Dosage Form, and	RxDC	RxDC
NDC		Indicator	Package	Drug Name	Drug Code
000939	Teva	Generic°	375 mg/1, 120 capsule, extended	mesalamine	R005258201
22489	Pharmaceuticals		release in 1 bottle		01000
540920	Takeda	Generic°	1.2 g/1, 120 tablet, delayed release	mesalamine	R005258201
10001			in 1 bottle		01000
597620	Greenstone LLC	Generic°	400 mg/1, 180 capsule, delayed	mesalamine	R005258201
11701			release in 1 bottle		01000
597620	Greenstone LLC	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R005258201
11803			box		01000

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

¹¹ 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.

¹² 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.

606870	American Health	Generic	400 mg/1, 20 blister pack in 1 box,	mesalamine	R005258201
55632	Packaging	20	unit-dose		01000
625590	ANI	Generic°	4 g/60mL, 7 bottles in 1 box	mesalamine	R005258201
42007	Pharmaceuticals				01000
692381	Amneal	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R005258201
27403	Pharmaceuticals		carton		01000
699180	Amring	Generic	1000 mg/1, 30 suppositories in 1	mesalamine	R005258201
56030	Pharmaceuticals		box		01000
707711	Cadila Healthcare	Generic	800 mg/1, 10 tablet, delayed	mesalamine	R005258201
11002			release in 1 blister pack		01000
707711	Cadila Healthcare	Generic [^]	800 mg/1, 10 tablet, delayed	mesalamine	R005258201
35302			release in 1 blister pack		01000
433530	Aphena Pharma	Brand	375 mg/1, 2160 capsule, extended	mesalamine	R005258201
88479	Solutions		release in 1 bottle	[Apriso]	01001
656490	Salix	Brand	375 mg/1, 1 bottle in 1 carton	mesalamine	R005258201
10301	Pharmaceuticals			[Apriso]	01001
000235	Allergan, Inc.	Brand	800 mg/1, 180 tablet, delayed	mesalamine	R005258201
90118			release in 1 bottle	[Asacol]	01002
589140	Allergan, Inc.	Brand	1000 mg/1, 3 suppository, 1 box	mesalamine	R005258201
50101				[Canasa]	01003
000235	Allergan, Inc.	Brand	400 mg/1, 180 capsule, delayed	mesalamine	R005258201
85318			release in 1 bottle	[Delzicol]	01004
500903	A-S Medication	Brand	400 mg/1, 180 capsule, delayed	mesalamine	R005258201
00200	Solutions		release in 1 bottle	[Delzicol]	01004
540920	Takeda	Brand	1.2 g/1, 120 tablet, delayed release	mesalamine	R005258201
47601			in 1 bottle	[Lialda]	01005
540920	Takeda	Brand	250 mg/1, 240 capsules in 1 bottle	mesalamine	R005258201
18981				[Pentasa]	01006
000370	Meda	Brand	4 g/60mL, 7 bottles, with	mesalamine	R005258201
02207	Pharmaceuticals		applicator in 1 carton	[Rowasa]	01007
000370	Meda	Brand	4 g/60mL, 28 bottles, dispensing in	mesalamine	R005258201
06603	Pharmaceuticals		1 carton	[Rowasa]	01007

° Authorized generic; [^] Branded generic

Example: Data aggregated by RxDC drug name

lssuer or TPA 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

Therapeutic classes

Location: D7 | Must not be blank Therapeutic Class Max Length: 2,048 | 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.¹³ 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. Ex: 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>.

lssuer or TPA EIN	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

Where can I download the CMS Drug and Therapeutic Class Crosswalk File?

The crosswalk file is available on the CMS website at <u>https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection</u>.

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, you should assign the prescription drug a RxDC drug name using the naming method described in Section 8.2. You should also assign a unique RxDC drug code. If the CMS crosswalk is missing the RxDC therapeutic class name for an NDC, you should use the FDA Established Pharmacologic Class (EPC) (or combination of EPCs) that you believe is most accurate. Provide information about the missing NDC or missing therapeutic class in your Narrative Response.

8.3 Rx Utilization

Use the following definitions to report prescription drug utilization.

¹³ 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.

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 | Integer

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.

8.4 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, 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 (see options below) Prescription drug rebates, fees, and other remuneration (In other words, total spending is net of prescription drug rebates, fees, and other remuneration.) Manufacturer cost-sharing assistance, to the extent known 	 Ineligible claims, such as duplicate claims, recovered claims overpayments, third- party liabilities (e.g., coordination of benefits claims), and any other claims that are denied under the policy's or plan's terms Payments for services other than medical care (e.g., 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

Include in Rx Total Spending	Subtract	Exclude
		 reported) or change in such reserves 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 a health savings or reimbursement account 	 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 	 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) 	

Include in Rx Cost Sharing	Subtract	Exclude	
	accounted for as reduced cost	Premium	
	sharing amounts paid by	 Manufacturer cost-sharing 	
	members.	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:

- Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary
- 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.

D3 Top 50 Most Frequently Dispensed Brand Name Drugs

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 for the issuer or TPA.
 - 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.
- 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.

- Create a table with the top 50 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.¹⁴
 - 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 for the issuer or TPA.
- 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 state, market segment, and EIN of the issuer or TPA.
 - 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 2020, exclude the drug from D5 in the 2020 RxDC report and in the 2021 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.

Include all plans and coverage in your calculations, even if the plan or coverage was not in effect for both years. For example, if you are calculating the increase in spending from 2020 to 2021 and a plan was only effective in 2020, you should include the plan in your 2020 total even though it isn't in the 2021 total.

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

¹⁴ When we say the "EIN of the issuer or TPA", this is a shorthand way of referring to the EIN of the relevant issuer, TPA, carrier, or plan according to the Aggregation section above. Similarly, "market" or "market segment" includes the FEHB line of business, where applicable.

• 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.)

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

- 1. 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 for the reference year 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.
- 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.
 - Use the dollar amount increase, not the percent increase.
- 5. Create a table with the top 50 drugs and include a row for every state, market segment, and EIN of the issuer or TPA.
 - 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.

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.
 - \circ 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 state, market segment, and EIN of the issuer or TPA.
 - 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.

9 Rebates, Fees, and Other Remuneration

9.1 Definitions

Pharmacy benefit manager

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.

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:

- Manufacturer rebates received by plans, issuers, or carriers and not passed through to any member or entity
- 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

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:
 - Bona fide service fees
 - o Discounts
 - Chargebacks
 - Cash discounts
 - Free goods contingent on a purchase agreement
 - Up-front payments
 - 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.

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 2021 RxDC report, there would be one column for total rebates for 2021 (as of 3/31/2022) and another column for restated rebates for 2020 (restated as of 3/31/2022). This field is required starting with the RxDC report for the 2021 reference year.

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

As noted in Section 8.5, 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 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.)

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.

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

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

Method	Description	Reasonable?	Explanation
	prescription drug based on the number of		differences in
	members enrolled in the plan, issuer, or		utilization and
	carrier as a percent of the total number of		spending on rebate
	members enrolled in all the PBM's plans,		eligible drugs across
	issuers or carriers.		plans or issuers.
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		differences in
	of claims under the plan, issuer, or carrier		utilization and
	as a percent of the total number of claims		spending on rebate
	received under all the PBM's plans,		eligible drugs across
	issuers or carriers. Thus, allocation is		plans or issuers.
	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.

Employer size for self-funded plans

Did you use actual counts or estimates to determine the size of the employer for self-funded plans? Describe your estimation method if you used estimates.

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

If applicable, describe how you accounted for net payments from federal or state reinsurance and costsharing 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, provide the RxDC drug name and therapeutic class that you used.

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 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 4.2.
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	Valid Values:
		Individual market
		Student market
		Do not enter more than one value.
Members as of 12/31	Integer	The number of enrollees on the last day of the reference 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 and Life	Integer	Valid Values:
Years?		0
(1= Yes; 0 = No)		1
Included in D2 Spending by Category?	Integer	Valid Values:
Included in D2 Spending by Category?		0
(1= Yes; 0 = No)		1

Paperwork Reduction Act 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. The time required to complete this information collection is estimated to average 4,731 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. 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.

P1 Column Name	Field Type	Instructions
Included in D3 Top 50 Most Frequent Integer		Valid Values:
Brand Drugs?		0
(1= Yes; 0 = No)		1
Included in D4 Top 50 Most Costly	Integer	Valid Values:
Drugs?		0
(1= Yes; 0 = No)		1
Included in D5 Top 50 Drugs by	Integer	Valid Values:
Spending Increase?		0
(1= Yes; 0 = No)		1
Included in D6 Rx Totals?	Integer	Valid Values:
(1 = Yes; 0 = No)		0
(1- 163, 0 - 110)		1
Included in D7 Rx Rebates by	Integer	Valid Values:
Therapeutic Class?		0
(1= Yes; 0 = No)		1
Included in D8 Rx Rebates for the Top	Integer	Valid Values:
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 Effective 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.
HIOS Plan ID String		Fully-insured small group plans only. Enter the 14-digit HIOS Plan ID(s). Do not use dashes. Ex: 12345NY1234567. You may enter more than one value in the same cell. If there is more than one value, separate them with a semicolon.
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.

P2 Column Name	Field Type	Instructions
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. ¹⁵ 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	<u>Valid Values</u> : Small group market Large group market SF small employer plans SF large employer plans For mixed-funded plans, enter both markets and separate them with a semicolon.
Plan 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 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	Integer	The number of members with coverage, including 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.

¹⁵ In these instructions, the term "State" includes the District of Columbia and the U.S. territories. For Federal Employee Health Benefit (FEHB) plans, you must report data for the territories. For other plans, reporting on territories is optional.

P2 Column Name	Field Type	Instructions		
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. 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 and Life Years?	Integer	Valid Values: 0		
(1= Yes; 0 = No)		1		
Included in D2 Spending by Category? Integer (1= Yes; 0 = No)		Valid Values: 0 1		
Included in D3 Top 50 Most Frequent	Integer	Valid Values:		
Brand Drugs?		0		
(1= Yes; 0 = No)		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	Integer	Valid Values:		
Spending Increase?	_	0		
(1= Yes; 0 = No)		1		
Included in D6 Rx Totals?	Integer	Valid Values:		
(1 = Yes; 0 = No)		0		
		1		
Included in D7 Rx Rebates by	Integer	Valid Values:		
Therapeutic Class?		0		
(1= Yes; 0 = No)		1		

P2 Column Name	Field Type	Instructions
Included in D8 Rx Rebates for the Top	Integer	Valid Values:
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 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 two-digit FEHB plan code as it appears in the FEHB plan brochure. Separate each two-digit plan code with a semicolon. Ex: 4A; 4B; 4E; 4L.
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 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.
Plan Beginning Date	Date	MM/DD/YYYY Do not enter more than one value.
Plan End Date	Date	MM/DD/YYYY Do not enter more than one value.
Members as of 12/31 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	Integer	Valid Values:
Years?		0
(1= Yes; 0 = No)		1
Included in D2 Spending by Category?	Integer	Valid Values:
(1= Yes; 0 = No)		0
(1- 103, 0 - 100)		1
Included in D3 Top 50 Most Frequent	Integer	Valid Values:
Brand Drugs?		0
(1= Yes; 0 = No)		1
Included in D4 Top 50 Most Costly	Integer	Valid Values:
Drugs?		0
(1= Yes; 0 = No)		1
Included in D5 Top 50 Drugs by	Integer	Valid Values:
Spending Increase?		0
(1= Yes; 0 = No)		1
Included in D6 Rx Totals?	Integer	Valid Values:
(1 = Yes; 0 = No)		0
(1 - 103, 0 - 100)		1

P3 Column Name	Field Type	Instructions	
Included in D7 Rx Rebates by	Integer	Valid Values:	
Therapeutic Class?		0	
(1= Yes; 0 = No)		1	
Included in D8 Rx Rebates for the Top Integer		Valid Values:	
25 Drugs?		0	
(1= Yes; 0 = No)		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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
		applicable. Do not enter more than one value.
Issuer or TPA 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.
State	String	Enter the 2-character state or territory 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.
Average Monthly Premium Paid by Members	Numeric	
Average Monthly Premium Paid by Employers	Numeric	
Life Years	Numeric	
Earned Premium	Numeric	For fully-insured plans.
Premium Equivalents	Numeric	For self-funded plans.

D1 Column Name	Field Type	Instructions
ASO/TPA Fees Paid (included in the Premium	Numeric	For self-funded plans.
Equivalents field)		
Stop Loss Premium Paid (included in the	Numeric	For self-funded plans.
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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan
		sponsor, as applicable. Do not enter more than one value.
Issuer or TPA 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.
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.
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.

D2 Column Name		Instructions
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum	Numeric	

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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
	_	applicable. Do not enter more than one value.
Issuer or TPA 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.
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	
Number of Members with a Paid Claim	Integer	
Number of Dosage Units	Numeric	

D3 Column Name	Field Type	Instructions
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	

D4 Top 50 Most Costly Drugs

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

D4 Column Name	Field Type	Instructions
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
		applicable. Do not enter more than one value.
Issuer or TPA 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.
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 Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	

D4 Column Name	Field Type	Instructions
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	

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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
		applicable. Do not enter more than one value.
lssuer or TPA 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.
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.
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 Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	

D5 Column Name	Field Type	Instructions
Manufacturer Cost-Sharing Assistance	Numeric	
Prior Year Number of Paid Claims	Integer	
Prior Year Number of Members with a Paid	Integer	
Claim		
Prior Year Number of Dosage Units	Numeric	
Prior Year Total Spending	Numeric	
Prior Year Total Cost Sharing	Numeric	
Prior Year Manufacturer Cost-Sharing Assistance	Numeric	
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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
		applicable. Do not enter more than one value.
Issuer or TPA 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.
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.
Total Rx Spending under Pharmacy Benefit	Numeric	
Rx Amounts Not Applied to Deductible and/or	Numeric	
Out-of-Pocket Maximum		

D6 Column Name	Field Type	Instructions
Bona Fide Service Fees	Numeric	
PBM Spread Amounts	Numeric	
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other	Numeric	
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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as
		applicable. Do not enter more than one value.
Issuer or TPA 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.
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.
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 Paid Claim	Integer	

D7 Column Name	Field Type	Instructions
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	
Rebates Retained by PBM	Numeric	
Rebates Retained by Plan/Issuer/Carrier	Numeric	
Rebates Passed to Member at POS	Numeric	
Net Transfer of Fees and Other Remuneration	Numeric	
from Manufacturer to Plan/Issuer/Carrier		
Net Transfer of Fees and Other Remuneration	Numeric	
from Pharmacy to Plan/Issuer/Carrier		
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other	Numeric	
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
Issuer or TPA Name	String	Enter the name of the issuer, TPA, FEHB carrier, or plan sponsor, as applicable. Do not enter more than one value.
Issuer or TPA 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.
State	String	2-character state 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

D8 Column Name	Field	Instructions
	Туре	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
	Ũ	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 Claim	Integer	
Number of Dosage Units	Numeric	
Total Spending	Numeric	
Total Cost Sharing	Numeric	
Manufacturer Cost-Sharing Assistance	Numeric	
Rebates Retained by PBM	Numeric	
Rebates Retained by Plan/Issuer/Carrier	Numeric	
Rebates Passed to Member at POS	Numeric	
Net Transfer of Fees and Other Remuneration from	Numeric	
Manufacturer to Plan/Issuer/Carrier		
Net Transfer of Fees/Other Remuneration from	Numeric	
Pharmacy to Plan/Issuer/Carrier		
Total Rebates/Fees/Other Remuneration	Numeric	
Restated Prior Year Rebates/Fees/Other Remuneration	Numeric	

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 are the RxDC templates?

The RxDC 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.
- 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.
- 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.