Alliant

Consolidated Appropriations Act (CAA)
Prescription Drug Data Collection (RxDC)

Reporting Playbook

Introduction

This guide provides key details to assist your compliance with the CAA pharmacy and health care spending reporting requirements.

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Playbook Overview and Purpose

Pharmacy Reporting or Section 204 Reporting

The Consolidated Appropriations Act of 2020 requires group health plans to report to the Department of Labor (DOL) certain information related to their pharmacy benefit plan and costs, as well as certain overall health care spending information, using a system hosted by the Centers for Medicare and Medicaid Services (CMS) known as the HIOS system (Health Insurance Oversight System). This reporting requirement applies to almost all group health plans, excluding information related to short-term disability plans, retiree-only plans, and account-based plans (HRAs, HSAs, and health FSAs). It also applies to non-federal governmental plans and church plans. Per CMS, this reporting will help to:

- Identify major drivers of increases in prescription drug and health care spending
- Understand how prescription drug rebates impact premiums and out-of-pocket costs
- Promote transparency in prescription drug pricing

Once analyzed, the DOL will publicly publish its findings on drug pricing trends and the impact of prescription drug rebates on patient out-of-pocket costs.

> While the responsibility to report ultimately falls to the group health plan, the rules require that aggregated data be submitted which makes it impractical—if not impossible—for most group health plans to undertake reporting without the support of medical plan insurance carriers, third-party administrators (TPAs), and/or pharmacy benefit managers (PBMs).
>
> Medical plan insurance carriers, TPAs, and PBMs (collectively, vendors) must play a central role here. Ideally, the group health plan's vendors will do the reporting on behalf of the plans for which it provides services. At this stage, however, vendors are not taking a uniform approach to providing support for their clients, and some group health plans will have to submit at least some of the required data.

Key Guidance in this Playbook

This Playbook provides the following guidance as you undertake this initial round of Pharmacy reporting:

- Identifies the data the plan is required to submit
- Outlines next steps based on how the plan is designed (e.g., carved out Rx) and funded
- Step-by-step guidance on accessing the (HIOS) and submitting required data
- FAQs on the basics of the pharmacy reporting requirement

What Information Is Required (aka Data Elements)

The regulatory guidance here uses a good deal of established industry jargon, as well as new terms unique to this particular reporting requirement. This can make understanding the reporting requirements a little difficult. Where possible, we use the terms set forth in the guidance, but provide plain language explanations. Do not hesitate to contact your Alliant representative with questions.

Each year, group health plans (or preferably vendors on their behalf) must submit three separate categories of information:

- One or more plan lists (P1-3)
- Eight data files (D1-D8)
- A narrative response

A plan list identifies the plans in a submission, and provides 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 provide premium and spending information, which the regulations provide should be submitted on an aggregate basis, e.g., all plans within a certain market segment of a particular state. The narrative response should describe the impact of prescription drug rebates on premium and cost sharing. Each reporting entity that submits a data file or a narrative response is required to submit a "plan list." The plan list essentially serves as a table of contents for the data files and the narrative responses. For group health plans, the plan list will be "P2," which is the plan list identifier for employer-based health plans that are non-federal government plans.

The data files contain premium and spending information, and should generally be submitted on an aggregate basis, which is why it makes the most sense for medical plan insurance carriers, third party administrators and PBMs to submit reporting for their clients within each state and market segment. However, as noted above, vendors are not taking a uniform approach to client support. Our understanding of the current solutions is that when there is a medical plan insurance carrier or TPA, and a PBM involved, the medical plan insurance carrier or TPA will most often submit files D1 and D2, as well as the portion of the narrative responses pertaining to that data. The PBM will submit data for Data Files D3-D8 as well as the portion of the narrative response applicable to that data.

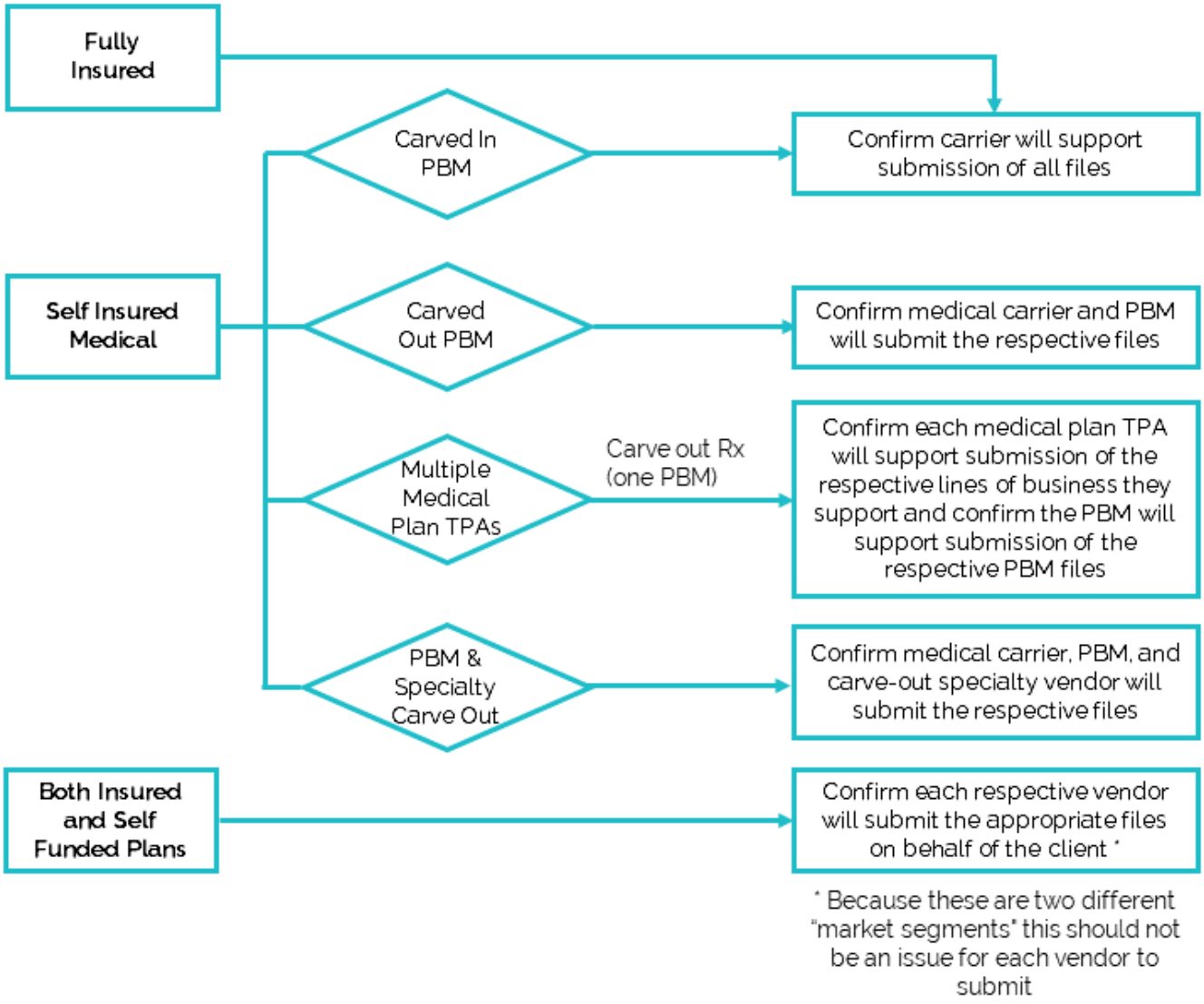
We include screenshots below for a better understanding of the required information and how it is submitted.

12 Required Files

Plan Lists		Data Files		Narrative Response
P1	Individual and Student Market Plan List	**D1**	Premium and Life Years	**One** Word document or PDF addressing the following:
P2	★ Group Health Plan List	**D2**	Spending by Category	• Employer size for self-funded plans
P3	FEHB Plan List	**D3**	Top 50 Most Frequent Brand Drugs	• Wellness Services
		D4	Top 40 Most Costly Drugs	• Drugs missing from the CMS crosswalk
		D5	Top 50 Drugs by Spending Increase	• Drugs covered under hospital or medical benefits
		D6	Rx Totals	• Prescription drug rebate descriptions
		D7	Rx Rebates by Therapeutic Class	• Allocation methods for prescription drug rebates
		D8	Rx Rebates for the Top 25 Drugs	• Impact of prescription drug rebates

KEY: Rx Medical Both Rx and Medical ★ Each reporting entity must submit a P file

Our review of the market to date indicates that reporting solutions will largely depend on the funding and structure of the group health plan. Below is a diagram explaining those solutions and action items based on plan funding and structure.



General Recommendation

As a general recommendation, group health plans should leverage their PBM, medical carriers, and TPAs as applicable and available, to report the data on the plan's behalf. Note, however, that even though PBMs and TPAs will have much of the required information, plan sponsors may still be required to report certain data. Where that is the case, we provide the information on the submission process below.

When Group Health Plans Must Submit in HIOS

A survey of market solutions indicates that the P2 (group health) plan list, the D1 (premiums and life-years) data file, and parts of the narrative response are the most common components that group health plans will be required to submit.

When the medical insurance carrier[1], TPA, or PBM approach require the plan to submit data, it is necessary for the plan to create a HIOS account and submit the information via that platform.

The RxDC reporting instructions state that if the group health plan does not have the details needed for file D1, the Departments will not take enforcement action related to the 2020 and 2021 reference years (the initial reporting period) as long as file D1 is included for the 2022 reference year (due June 1, 2023) and all future reference years.

Registering in HIOS

If you are required to submit data, please register with the HIOS system as quickly as possible. CMS indicates it can take up to two weeks to create the appropriate accounts. If you already have a HIOS account this will not apply to you.

To register, follow the steps outlined in the HIOS Portal RxDC Quick Reference Guide (PDF). This "how to" document will walk you through the multiple steps required to access the Prescription Drug Data Collection (RxDC) Module where data can be submitted.

If you have questions about setting up your account, contact the CMS help desk at CMS_FEPS@cms.hhs.gov or 1-855-267-1515.

For faster service, send your question by email and include "RxDC HIOS Question" in the body of the email with a brief description of the issue.

Populating Files

CMS has provided pre-designed templates for group health plan use. The RxDC file templates and data dictionary can be found here.

[1] Note that for fully insured medical plans with pharmacy benefits included in that design, the medical plan insurance carrier should generally handle all aspects of pharmacy reporting.

Populating Plan List P2

Whenever a group health plan submits data, they must submit file P2. Each row should have a unique combination of the Group Health Plan Number, plan year beginning date, and plan sponsor EIN.

The RxDC instructions, which you should have readily available when preparing the report, provide that each reporting entity must submit a plan list file. That is how CMS will know when multiple entities are reporting for the same group health 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. You can ask your medical plan insurance carrier/TPA and PBM for their EIN number(s) and official name.

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.

Note 3: 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

Completing file P2

Template	Column Name	Data Type	Instructions
P2: Group Health Plan List	Group Health Plan Name	varchar(512)	This is the group health plan's name. **The Plan Name is 1a on the Form 5500[2].**
P2: Group Health Plan List	Group Health Plan Number	varchar(25)	Enter a unique plan identification number. You may use numbers, letters, or punctuation marks (except for slashes). You may use the plan number from your accounting system, the Form 5500 Plan Number (if you file it), the plan sponsor EIN (if the plan sponsor only has one plan), or create a new identification number to enumerate the plans in the plan list. If you use the Form 5500 plan number as the Group Health Plan Number, you must also enter the Form 5500 plan number in the Form 5500 Plan Number column. That is, the Form 5500 Plan Number would be in two columns-- the Group Health Plan Number column *and* the Form 5500 Plan Number column. If you use the plan sponsor EIN as the Group Health Plan Number, you must also enter the plan sponsor EIN in the Plan Sponsor EIN column. That is, the plan sponsor EIN would be in the Group Health Plan Number column *and* the Plan Sponsor EIN column.
P2: Group Health Plan List	Carve-Out Description	varchar(2048)	Previously, this column was used to collect the HIOS Plan ID from issuers offering fully-insured small group health plans. Starting with the 2022 reference year, this column will be used to collect information about carve-out benefits when multiple reporting entities are reporting information about the same plan. A benefit carve-out is a benefit administered, offered, or insured by an entity that is different than the entity that administers, offers, or insures the majority of the plan's other benefits. If a reporting entity is reporting information only for a carve-out benefit, such as a prescription drug benefit or a behavioral health benefit, please describe the benefit carve-out. This field is free form and you can enter up to 2,048 characters. You may enter a long description or a short description. Examples of a short description include "Medical except for mental health services only" or "prescription drug benefit carve-out" and "Inpatient hospital only." This column is not mandatory for the 2022 reference year. Plans without pharmacy benefits: If you are submitting on behalf of a plan that does not cover pharmacy benefits (and therefore a PBM or other reporting entity will not be submitting D3 – D8 for that plan), enter "This plan does not include pharmacy benefits." This will let CMS know that we shouldn't expect D3 – D8 for that plan.

[2] Non-federal governmental group health plans and church plans do not submit a Form 5500 filing but should have some documentation of the group health plan name.

			Note: Leave this field blank if you are reporting all information about the plan.
P2: Group Health Plan List	Form 5500 Plan Number	varchar(1024)	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. The Plan Number is 1b on the Form 5500. Non-federal governmental group health plans and church plans do not submit a Form 5500 filing. If you don't have a Form 5500 Plan Number, leave this field blank. If you're not sure if you have a Form 5500 Plan Number, you can look it up using the Form 5500 search tool on the Department of Labor website at https://www.efast.dol.gov/5500search.
P2: Group Health Plan List	States in which the plan is offered	varchar(200)	Enter the states and territories in which the plan or coverage is offered using two-character state postal code. If there is more than one state or territory, separate them with a semicolon. 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 one or more territories, enter "National" as well as the two-character postal code for the applicable territories, separated by a semicolon. For example: National; PR; GU. For purposes of RxDC reporting, a plan is considered "offered" in a state if a person living or working in that state would be eligible to obtain coverage under the plan. Self-funded plans may enter "National" if a person living or working in any state would be eligible to obtain coverage under the plan. Note 1: This column, "States in which the plan is offered" in plan list P2, is not the same thing as "Aggregation State" in the aggregate data files (D1 – D8). 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. Note 2: If multiple vendors submit on behalf of the same plan, issuer, or carrier, only one of them is required to report the states in which the plan is offered.
P2: Group Health Plan List	Market Segment	varchar (512)	The market segment for almost all Alliant clients required to submit reporting will be "Self-funded group health plans offered by large employers"— this is a client with more than 50 members (i.e., an employer is "small" if it has 50 or fewer employees and "large" if it has more than 50 employees). **Most clients should list: "SF large employer plan."** Valid Values: • Individual market • Student market • Small group market • Large group market

			• SF small employer plans • SF large employer plans • FEHB plans If a plan is partially insured and partially self-funded, enter both market segments in the same cell, separated by a semicolon. Example: Large group market; SF large employer plans. **Note: P2 is the only place where you can put more than one market segment in a single cell. Do not enter more than one value for market segment in data files D1 – D8.**
P2: Group Health Plan List	Plan Year Beginning Date	date	Should be listed in MM/DD/YYYY format. Most clients will list both 01/01/2022. Enter the actual beginning date of the plan year, even if they fell outside of the reference year. The plan year may be the year in the plan document of a group health plan, the deductible or limit year used under the plan, or the policy year. Note: When multiple vendors submit on behalf of the same plan, at least one vendor must enter the beginning and end dates of the plan year. The other vendors may enter the beginning and end dates of the plan year, or the first and last day of the portion of the reference year for which they are submitting data. How do I fill out the plan list for plans with non-calendar plan years? Suppose for example that the plan year is July 1, 2021, through June 30, 2022. Enter 07/01/2021 for the beginning date and 06/30/2022 for the end date in the 2022 RxDC report. Because the plan year ended before the end of the reference year, enter 0 for the number of members as of 12/31/2022 in the 2022 RxDC report. Similarly, if the plan year is July 1, 2022, through June 30, 2023, enter 07/01/2022 for the beginning date and 06/30/2023 for the end date in the 2022 RxDC report. Enter the actual number of members as of 12/31/2022 in the 2022 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 6/30/2022 and another for the plan year that began on 7/1/2022.
P2: Group Health Plan List	Plan Year End Date	date	Should be listed in MM/DD/YYYY format. Most clients will list 12/31/2022 and 12/31/2021 for each file). Use two rows in the plan list file if a plan has a non-calendar plan year and renews during the calendar year. (One row for the plan year that ended in the reference year and another for the plan year that began during the reference year).
P2: Group Health Plan List	Members as of 12/31 of the reference year	int	This is the number of members with coverage, including dependents, on the last day of the reference year (not the plan year). 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 ended before the last day of the reference year, enter 0. For the purposes of these instructions, the term "member" means a person who has health coverage, regardless of whether the coverage is associated with an insurance policy, a group health plan, or an FEHB plan. For example, enrollees, dependents, participants, beneficiaries, and FEHB annuitants are all considered members. Retirees and COBRA participants, including their dependents, also are considered members if they are covered by a plan that is not a retiree-only plan.
P2: Group Health Plan List	Plan Sponsor Name	varchar(2048)	For plans filing Form 5500, use the same plan sponsor name identified in the Form 5500. For non-federal governmental plans, the definition of plan sponsor is set forth below, but is usually named in the plan-related documents and agreements, as well as employee and participant facing communications. The term plan sponsor means: • The employer, for an employee benefit plan that a single employer established or maintains. Note: A plan of a controlled group of corporations generally is a single-employer plan and should enter the name of the parent corporation or other member of the group considered the sponsor. • 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. (Alternatively, you may use a separate row in the plan list for each plan sponsor.) *Multiple-Employer Plans* If an association or other entity is not the plan sponsor, you may enter the name of a participating employer. Use the same name in future RxDC reports unless there is a change in sponsorship. In HIOS, you may upload a supplemental document with the names and EINs of the participating employers and/or sponsoring members of the multi-employer plan. This is optional.
P2: Group Health Plan List	Plan Sponsor EIN	varchar(2048)	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. **For reference, the EIN is 2b on the Form 5500.**

			A multiple-employer plan or plan of a controlled group of corporations should use the EIN of the entity identified in the Plan Sponsor Name field. *What if I don't know the plan sponsor EIN?* You must report the plan sponsor EIN. If you don't know the EIN, you must obtain the information from the plan sponsor. CMS uses the plan sponsor EIN to reconcile submissions made by multiple reporting entities on behalf of the same plan.
P2: Group Health Plan List	Issuer Name	varchar(2048)	If there is more than one issuer, enter both in the same cell separated by a semicolon. **If the plan is not insured (i.e., if the plan is self-insured), leave the cell blank.** Self-funded plans: • For self-funded plans with stop-loss coverage, enter the name of the stop-loss carrier. • For self-funded plans that use an issuer as a TPA or ASO provider, do NOT enter the name of the issuer here. Instead, enter the name of the issuer providing the TPA/ASO services in the "TPA Name" column. • If an issuer provides stop-loss and also provides TPA/ASO services to a self-funded plan, enter the name of the issuer in the "Issuer Name" column and in the "TPA Name" column. • **Otherwise, leave the "Issuer Name" column blank.**
P2: Group Health Plan List	Issuer EIN	varchar(2048)	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 (i.e., self-insured), leave the cell blank.**
P2: Group Health Plan List	TPA Name	varchar(2048)	Enter the name of the TPA and/or ASO. Do not use slashes. If there is more than one TPA or ASO, separate their names with a semicolon. If a plan doesn't have a TPA or an ASO provider, leave the cell blank.
P2: Group Health Plan List	TPA EIN	varchar(2048)	Enter the 9-digit EIN of the company you entered in the TPA Name field. Do not use dashes. (Ex: 012345678.). If there is more than one TPA, separate them with a semicolon. If a plan doesn't have a TPA, leave the cell blank.
P2: Group Health Plan List	PBM Name	varchar(2048)	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.
P2: Group Health Plan List	PBM EIN	varchar(2048)	Enter the PBM 9-digit EIN without dashes. (Ex: 012345678.). If there is more than one PBM, separate them with a semicolon. If a plan doesn't have a PBM, leave the cell blank.
P2: Group Health Plan List	Included in D1 Premium and Life Years? (1= Yes; 0 = No)	smallint	Enter 1 if a plan's data is included in the respective data file in your submission. Enter 0 if the plan's data is not included in the respective data file in your submission.

			List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D2 Spending by Category? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D3 Top 50 Most Frequent Brand Drugs? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D4 Top 50 Most Costly Drugs? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D5 Top 50 Drugs by Spending Increase? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D6 Rx Totals? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D7 Rx Rebates by Therapeutic Class? (1= Yes; 0 = No)	smallint	List 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.
P2: Group Health Plan List	Included in D8 Rx Rebates for the Top 25 Drugs? (1= Yes; 0 = No)	smallit	Select 1 (yes) if you will be submitting the referenced file or 0 (no) if you will not be submitting the referenced file.

Populating file D1 (Premium and Life Years).

Refer to page 30 of the RxDC Reporting Instructions for instructions on how to report premium and life-years in data file D1.

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

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

Template	Column Name	Data Type	Instructions
D1: Premium and Life Years	Company Name	varchar(256)	Enter the name of the Plan Sponsor. This should be the same as the P2 file. Do not enter more than one value.
D1: Premium and Life Years	Company EIN	varchar(9)	Enter the Plan Sponsor 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. **The EIN is 2b on the Form 5500.**
D1: Premium and Life Years	Aggregation State	char(2)	Enter the 2-character state or territory postal code. Ex: NY. Do not enter more than one value**.** **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.** **For fully-insured plans, report the data in the state where the policy was issued.**
D1: Premium and Life Years	Market Segment	varchar(100)	The market segment for almost all clients will be "Self-funded group health plans offered by large employers" – this is a client with more than 50 members (i.e., an employer is "small" if it has 50 or fewer employees and "large" if it has more than 50 employees). For other market segments, refer to question 8 in the FAQs below.
D1: Premium and Life Years	Average Monthly Premium Paid by Members	numeric(24,8)	See the Reporting Instructions, page 31, for how to calculate average monthly premium.
D1: Premium and Life Years	Average Monthly Premium Paid by Employers	numeric(24,8)	See the Reporting Instructions, pages 31-32, for how to calculate average monthly premium.
D1: Premium and Life Years	Life Years	numeric(24,8)	Life years are the average number of members throughout the year. Enrollees, dependents, participants, beneficiaries are all members.

			See the Reporting Instructions, pages 32-33, for how to calculate life years.
D1: Premium and Life Years	Earned Premium	numeric(24,8)	For fully insured plans.
D1: Premium and Life Years	Premium Equivalents	numeric(24,8)	For self-funded plans. Please see details on pages 33-35 of the Reporting Instructions. *Updated to specify that prescription drug rebates should be subtracted from premium equivalents in D1 regardless of whether the rebate received in the reference year is retrospective or prospective* *Updated to specify that stop-loss reimbursements should be subtracted from premium equivalents in D1*
D1: Premium and Life Years	Admin Fees Paid (included in the Premium Equivalents field)	numeric(24,8)	For self-funded plans. Note this is a subcategory or breakout of the premium equivalent. *This column was formerly named ASO and other TPA fees paid. The purpose of the column has not changed, only the name.*
D1: Premium and Life Years	Stop Loss Premium Paid (included in the Premium Equivalents field)	numeric(24,8)	For self-funded plans. Note this is a subcategory or breakout of the premium equivalent.

Populating the Narrative Response

The narrative response can be created and saved as a Word document or a PDF. The narrative response provides context for the data files submitted. There are six areas that are addressed in the Narrative Response. A description of each is included in the instructions.

1. Net payments from federal or state reinsurance or cost-sharing reduction programs
2. Drugs missing from the CMS crosswalk
3. Medical benefit drugs
4. Prescription drug rebate descriptions
5. Allocation methods for prescription drug rebates
6. 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.

The medical TPA or PBM should respond to Items 1-5 because those items are included in the respective data files; therefore, no action is needed for employers for these items. For self-insured clients that have a carved-out PBM, the only item that PBMs may not respond to is the bolded portion of item 6, the impact of prescription rebates (above). If the employer is not submitting any files to HIOS, we do not believe the employer would need to create a HIOS ID just to submit this information as part of a Narrative Response. If the employer is submitting one of the data files (most likely file D1), and the current PBM has specifically stated they will not respond to this portion of the Narrative Response, the employer may choose to respond.

The most common response to this question would be to state that rebates ultimately help reduce member costs. Rebates paid by the PBM from pharmaceutical manufacturers are utilized to reduce member medical premiums. For those clients that provide members with point-of-sale rebates (this is a less common strategy), the response would be that these rebates are shared with members at the point of sale and thus reduce member costs in that way. This would only impact self-insured clients as the medical TPAs often do not share rebates with its clients.

See Section 10 of the Reporting Instructions for more information on the narrative response.

Before your Submit: Plan and Data File Requirements

Follow these instructions when preparing your submission:

- Your files must be in Comma Separated Value (CSV) format.
- The order of the columns in your file must exactly match the order of the columns in the data dictionary.
- 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 use slashes (“/”) in alphanumeric fields. HIOS won’t accept text with slashes because data with slashes requires additional security screening that would slow down processing time. The exception is that you can use slashes in the column headers and in date fields.
- You can use commas in a text field if there are quotation marks on both sides of the text. Ex: “Company ABC, Inc.”
- Excel will automatically insert the quotation marks for you when you save a file in CSV format. For example, you can enter Company ABC, Inc in the template without quotation marks and Excel will convert it to “Company ABD, Inc” when you save it as a CSV file. Without the quotation marks, HIOS won’t know whether a comma is part of a text string or is a delimiter between columns.

- Do not use more than 8 decimal places in numeric fields. Ex: 0.6666666666 should be rounded to 0.66666667

You can generate your own CSV files using the Data Dictionary or you can create them using the RxDC templates provided by CMS. If you use the Excel templates provided by CMS, remember to save your files in CSV format before uploading them into HIOS. Note: the colors in the RxDC templates make the template easier to read. They do not convey meaning.

To create a CSV file from Excel:

- Open the workbook you want to save.
- Click File > Save As.
- Pick the place where you want to save the workbook.
- In the Save As dialog box, navigate to the location you want.
- Click the arrow in the Save as type box and pick CSV comma delimited

Narrative Response

The narrative response file format must be Portable Document Format (.pdf) or Microsoft Word (.doc or .docx).

Optional Supplemental Documents

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

Submitting files in HIOS

To access HIOS, visit https://portal.cms.gov.

To submit the files in HIOS, follow the instructions starting on page 9 of the HIOS Portal User Manual.

Frequently Asked Questions

1. Which plans are obligated to comply with the CAA Rx Reporting law?

   This reporting requirement essentially applies to all clients and only excludes claims from Medicare, Medicaid, short-term disability, retiree-only plans, and account-based plans (HRAs, HSAs, health FSAs). Note that retiree-only plans may not encompass all retiree coverage, but includes only those plans that are designed, documented, and administered to cover only retirees, and must have fewer than two active participants on the plan. Plans may have their vendors submit on their behalf where possible, but ultimately the responsibility falls with the client.

2. When is the deadline?

   December 27, 2022 is the submission deadline for reference years 2020 and 2021. For the 2022 reference year submission and beyond, submissions will be due on June 1 for the preceding year. Therefore, the 2022 submission is due on June 1, 2023 and, similarly, reporting will be due on the June 1st following each reference year thereafter.

3. What is a reference year and is it the same as the plan 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. A reference year is not the same as the plan year so non-calendar plan years will be required to submit data that spans two plan years.

4. What are the high-level "rules" for the submission of the required files?

   Each reporting entity should submit a P file. For group health plans, this will be file P2 (Group Health Plan List).

   The government's intention was that PBMs, medical carriers and TPAs would share data among one another to support the submission of only one data file (i.e., one D2 file, one D3 file, etc.) per client per market segment and state. However, vendors have been reluctant to share and receive data in that manner. Note that TPAs may be more willing to receive data as that is the nature of their business.

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

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

Multiple reporting entities can submit portions of a plan's narrative response.

5. What is a reporting entity?

A reporting entity is an entity that submits some or all required information (e.g., whoever is submitting whether that is the medical carrier, TPA, PBM or plan).

6. What is meant by data aggregation?

Reporting entities, to the extent possible, will aggregate data according to market segment (see below). Plans will simply submit their data and designate the appropriate market segment.

The market segments are mutually exclusive; therefore, the same data should not be reported in more than one market segment.

7. What are the reporting market segments?

Below is a table that highlights the market segments. Per the instructions, an employer is generally considered small if it has 50 or fewer employees and large if it has more than 50 employees. This applies regardless of the state's group insurance size designation, e.g., in states where groups under 100 are considered small group.

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

- **For plans with different funding mechanisms**, which self-fund some benefits and fully insure other benefits, report the self-funded business in the self-funded market segment and the fully insured business in the fully insured market segment
- **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

- **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
- **Level-funded plans:** Report the business as self-funded

8. What is meant by state aggregation rules?

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.

9. What is the aggregation restriction and when does it apply?

Starting with reporting for the 2023 reference year (due June 1st, 2024) the instructions indicate that the "aggregation restriction" will no longer be suspended. The aggregation restriction says that 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, for example, a plan's D2 aggregates data at the plan sponsor EIN level, then the D1 and D3-D8 data must also be aggregated according to the plan sponsor EIN. If the data in D2 is aggregated according to Issuer or TPA EIN (or some level that is not the plan sponsor level), then the reporting entities for D1 and D3-D8 may choose to aggregate at the same level as used in the D2 or may choose to aggregate according to the plan sponsor EIN. In the latter scenario, the reporting entities for each D1, D3-D8 file may choose different approaches for each file. As discussed in this playbook, in most scenarios, employers will need to rely on vendors for the data reported in files D1 and D3-D8, but may need to report their own D2 with data likely aggregated at the plan sponsor EIN level. While we encourage employers to understand what reporting is performed on their behalf, we think it infeasible, due to the lack of data access, for employers to report on the D1 and D3-D8 on their own and carriers, TPAs, or other reporting entities may be reluctant or unable to aggregate at the plan level. For now, this remains an area where further agency guidance would be welcome.

10. What if the plan does not have the details needed for file D1 (Premium and Life-Years)?

For the 2020 and 2021 reference years only, if plans have the required information, they must report it. However, the Departments will not take enforcement action related to the requirement to report the average monthly premium paid by employers versus members for the 2020 and 2021 reference years if those data elements are reported in the RxDC report for the 2022 reference year (due June 1, 2023) and all future reference years (June 1 each year thereafter).

11. For file D1 (Premiums and Life Years) what if the plan has a separate vendor for medical and stop loss?

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

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

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

12. What is the difference between the P files?

    Plan files (P) contain plan level identifiers and other information requested by the government.

    They are considered keys to the Data files (D) that will be submitted. P files are market segment specific and request different pieces of information.

    - 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

    Group health plans will submit a P2 file.

13. What if a plan is with a different TPA or PBM now than they had for the initial reference years?

    Group health plans should reach out to their last PBM or TPA to determine how it will support reporting for those plans.

14. What if the plan sponsor acquired a company during a reference year?

    Where a plan sponsor has acquired a company with a separate group health plan, we recommend they contact the acquired company's previous PBM and/or medical carrier or TPA, as applicable, for the prior vendor to submit data for the period during which they were that plan's PBM/TPA/medical carrier. The acquired entity's vendors should ideally submit the data in a fashion consistent with the rest of the data for the respective period they were the vendor (e.g., same EIN, market segment, state).

15. Can two different vendors submit data on the plan's behalf for the same timeframe and EIN but for different groups? (Ex: Plan Sponsor A has 10 groups total that are managed by two different PBM vendors, but all come under the same EIN during the same time period. Plan Sponsor A has nine groups managed by PBM vendor one and one group managed by PBM vendor two.)

    Yes. The vendors should use the Group Health Plan Name and Group Health Plan Number fields in the P2 file to indicate which plans they are reporting on behalf of.

16. In an acquisition, what if the acquired entity did not transition into the acquiring entity's group, but maintained a separate plan for a time period?

    In this case, the reporting entity can use two rows in the P2 file – one for the main plan and the other for the 'acquired' plan. In the data files (D1 – D8), the reporting entity can combine the information for the plans unless they are in different states or market segments.

17. What if the plan's PBM works with a rebate aggregator and the rebate aggregator is not prepared to submit on our behalf?

    In this case, the PBM should submit all of the data on the plan's behalf that they have in their possession. If the rebate aggregator that is contracted with the PBM is unable to submit the data, the plan should complete a portion of the narrative response and note that their rebate aggregator is unable to submit rebate data at this time.

18. What if after best efforts my medical plan insurance carrier or TPA, PBM and stop loss vendors are not able to submit all data on my company's behalf?

    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.

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

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

20. Can multiple vendors submit the same data file type?

    Plans, issuers, carriers, and their reporting entities are encouraged to work together to submit only one data file of each data file type for the same plan, issuer, or carrier. For example, if one reporting entity is responsible for only some of the fields in a data file, it might fill out those fields and then give the data file to the other reporting entity to complete the remaining information before submitting the data file in HIOS. However, if entities are unwilling or unable to work together, more than one reporting entity may submit the same type of data file on behalf of the same plan, issuer, or carrier. For example, if a plan has two issuers, one for behavioral health benefits and another for other medical benefits, then both issuers can submit D2 on behalf of the plan. The first issuer's D2 would include the plan's data related to behavioral health benefits. The second issuer's D2 would include the plan's data related to

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

21. Which wellness services should be included in the RxDC report?

The CMS FAQs state that if a wellness service is billed on a claim, the medical plan insurance carrier or TPA can include it in the 'Other medical costs and services' spending category in data file D2 Spending by Category. If a wellness service is not billed on a claim, it does not need to be included in the RxDC report.

Example of a wellness service billed on a claim:

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

Example of a wellness service not billed on a claim:

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

22. What if the group health plan is a non-calendar year plan? How does this work for the data (D) files?

In the data files (as opposed to the plan lists), the reporting entity would include only the data related to the reference year for which you are reporting. For example, if the plan was active in 2021 and 2022 and your client is reporting for 2022, the plan only needs to report for the portions of 2022 when the plan was active.

23. What about non-calendar year plans and the P2 file?

For the P2 file, enter the plan year's actual beginning and end dates, even if they fall outside of the reference year.

Enter the actual beginning and end dates of the plan year, even if they fell outside of the reference year.

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

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

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

Suppose for example that the plan year is July 1, 2021, through June 30, 2022. Enter 07/01/2021 for the beginning date and 06/30/2022 for the end date in the 2022 RxDC report. Because the plan year ended before the end of the reference year, enter 0 for the number of members as of 12/31/2022 in the 2022 RxDC report.

Similarly, if the plan year is July 1, 2022, through June 30, 2023, enter 07/01/2022 for the beginning date and 06/30/2023 for the end date in the 2022 RxDC report. Enter the actual number of members as of 12/31/2022 in the 2022 RxDC report. 16 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 6/30/2022 and another for the plan year that began on 7/1/2022.

Non-calendar year plan in the 2022 RxDC report:

Group Health Plan Name	Group Health Plan Number	Market Segment	Plan Year Beginning Date	Plan Year End Date	Members as of 12/31 of the reference year
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2021	06/30/2022	0
Jane's Furniture Health and Welfare Plan	501	Small group market	07/01/2022	06/30/2023	27

24. Where can I get additional help?

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

You can also sign up for email announcements and register for training webinars at Registration for Technical Assistance Portal (REGTAP) at https://regtap.cms.gov/rxdc.php.

If you can't find the answer to your question in REGTAP, contact our help desk at 1-855-267-1515 or CMS_FEPS@cms.hhs.gov. 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): https://regtap.cms.gov/rxdc.php

25. How/Where do group health plans submit the required data?

HIOS is an application within the CMS Enterprise Portal: https://portal.cms.gov/portal/

References

CMS CCIIO Product Page
https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

Regulation
https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending

RxDC Reporting Instructions
https://regtap.cms.gov/reg_librarye.php?i=3860

Templates
https://regtap.cms.gov/reg_librarye.php?i=3863

RxDC Crosswalk
https://regtap.cms.gov/reg_librarye.php?i=3861

Health Insurance Oversight System (HIOS) Prescription Drug Data Collection (RxDC) User Manual
https://regtap.cms.gov/reg_librarye.php?&i=3862

HIOS Portal RxDC Quick Reference Guide (PDF)
https://regtap.cms.gov/reg_librarye.php?&i=4019

CMS RxDC Reporting Frequently Asked Questions (PDF)
https://regtap.cms.gov/documents/rxdcfaq.pdf

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