COMPLIANCE ALERT

CMS Provides Updated RxDC Reporting Instructions

April 3, 2023

Quick Facts

- The next round of prescription drug data collection (RxDC) reporting is due June 1, 2023.
- On March 27, 2023, the Centers for Medicare and Medicaid Services (CMS) released updated instructions for reference year 2022.
- The updated instructions provide clarity on many pending issues and answer questions from the first round of reporting.
- The new guidance did not provide good faith relief or a grace period for the 2022 reference year.

Background

The first round of RxDC reporting, as required by the Consolidated Appropriations Act of 2021 was initially due December 27, 2022, and was later extended to January 31, 2023. The second round of reporting will be due June 1, 2023. This is an annual reporting requirement which, going forward, will be due June 1 of the year following the calendar year being reported, also known as the reference year. Since the interim final rules were released in November 2021, CMS has provided various guidance and instructions to assist reporting entities. On March 27, 2023, CMS issued **updated instructions** for 2022 reference year reporting.

The 2022 reference year instructions provide an outline of the most significant changes from the previous year's instructions. Those changes are:

- Specified that RxDC reporting requirements do not apply to retiree-only plans. (Section 1.4)
- Clarified reporting with respect to US territories. (Section 1.5)
- Added an option for multiple vendors to submit the same data file on behalf of the same plan, issuer, or carrier. (Section 3.3)
- Added an option for a reporting entity to create multiple submissions in the Health Insurance Oversight System (HIOS) for the same reference year. (Section 3.5)
- Rearranged plan list instructions to separately address P1, P2, and P3. (Section 4)
- Replaced the column for HIOS Plan ID in plan list P2 with a column to collect information about benefit carve-outs. (Section 4.2)
- Renamed columns A and B in the data files (D1 – D8) from "Issuer or TPA (third-party administrator) Name" and "Issuer or TPA EIN (Employer Identification Number)" to "Company Name" and "Company EIN" to reflect the fact that you may choose to aggregate data at the plan sponsor, carrier, reporting entity, or other company level, rather than only the issuer or TPA level. The purpose of these columns has not changed, only the names. (Section 5.2)

- Renamed column C in the data files (D1 – D8) from “State” to “Aggregation State” to more clearly differentiate from the column labeled “States in which the plan is offered” in plan lists P2 and P3. The purpose of this column has not changed. (Section 5.2)
- Extended suspension of the aggregation restriction. (Section 5.6)
- Renamed column J in D1 from “ASO (administrative services only)/TPA Fees Paid” to “Admin Fees Paid” to reflect that self-funded plans pay administrative fees to other types of companies, such as PBMs. The purpose of the column has not changed. (Section 6.1)
- Specified 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. (Section 6.1.)
- Specified that stop-loss reimbursements should be subtracted from premium equivalents in D1. (Section 6.1)
- Specified that stop-loss reimbursements should not be subtracted from total spending in D2. (Section 7.1)
- Specified that rebates expected but not yet received should be subtracted from total spending. (Section 7.1 for drugs covered under a medical benefit and Section 8.4 for drugs covered under a pharmacy benefit.)
- General edits for clarity.

Many of these updates are discussed in detail below.

Plan and Data File Updates

Retirees and Retiree Plans

CMS clarified in the new instructions that reporting does not apply to retiree-only plans. A retiree-only plan is one that covers retirees and less than two active employees as plan participants. Retirees that are not part of a retiree-only plan should be included in member counts but should not be included when determining whether an employer is a large or small employer.

US Territories

The updated instructions clarify that plans, issuers, and carriers must report RxDC data for all 50 states, the District of Columbia (D.C.), and the US territories. In the instructions, the term “State” includes all 50 states, D.C., and the territories. Previous instructions stated that reporting in US territories was optional.

States Where Coverage is Offered

The Plan Files require a list of the “states where the plan or coverage is offered”. Reporting entities should enter the 2-character state abbreviation and separate multiple states with a semicolon. If a plan is offered in every state and in D.C., enter “National”. If a plan is offered nationally and 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 that “states where the plan or coverage is offered” is different from state information required on the D1 file. The D1 files require the reporting entity to list the state where the plan sponsor has its

principal place of business or where the plan is situsted. Reporting entities should only enter one state in this field and use the 2-character state abbreviation.

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

Clarification on Multiple Submissions

Multiple Submissions from the Same Reporting Entity

For reference years 2020 and 2021, CMS stated that reporting entities should not make more than one submission to the Health Insurance and Oversight System (HIOS) and later provided some transition relief. The 2022 reference year instructions provide relief stating that "a reporting entity may make multiple submissions in HIOS if the content of the submissions is mutually exclusive." In other words, if a reporting entity makes multiple submissions in HIOS, the submissions should not include duplicate data. The instructions refer reporting entities to the RxDC HIOS Manual for correcting duplicate submissions. Despite this relief, CMS discourages reporting entities from making multiple submissions in HIOS.

Multiple Data Files of the Same File Type

Multiple vendors can be reporting entities submitting data on the plan's behalf. However, since HIOS cannot identify duplicate information, reporting entities should not submit reports consisting of the same data. CMS uses the Plan Files to identify when multiple entities are reporting for the same plan. Reporting entities also reporting on behalf of a plan should enter the company name and Employer Identification Number (EIN) in the appropriate columns on the plan list file. CMS will use this information to streamline the reconciliation process when there are multiple reporting entities. The RxDC instructions confirm that uploading different narrative responses on behalf of the same plan, issuer, or carrier by multiple reporting entities is permitted.

In the RxDC instructions released on March 27, 2023, CMS stated that reporting entities are encouraged to work together to submit only one data file of each type for the same plan, issuer, or carrier. 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 data for the entire year.

Clarification on Calculating Premiums

Employer and Member Premiums

Employers must report the average monthly premium (per member, per month, or PMPM) paid by employers on behalf of members which includes the premium equivalent amounts for self-funded

plans. CMS provided this formula as a basic framework for determining the premium in the 2020 and 2021 reference year instructions:

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

Additionally, employers must report the average monthly premium per member, per month paid by members, which includes the premium equivalent amounts paid by members of self-funded plans. CMS provided this formula as a basic framework for determining the premium in the 2020 and 2021 reference year instructions:

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

In the updated instructions released on March 27, 2023, CMS provides additional instructions calculating the premium. CMS states that calculating the average monthly premium using the table below, taken from the CMS instructions, may be helpful. If reporting for only a partial year, complete only the rows applicable to the period when the plan was active. While the table CMS provides in the instructions is not required, it may be helpful in determining the information required in this data field.

Month	Member Count (including dependents & including members that paid zero premium)	Total Premium (or premium equivalents) Paid by Members	Total premium (or premium equivalents) Paid by Employers (Note: For self-funded plans, this is total plan costs minus premium paid by members.)
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			
Total	Total A	Total B	Total C

Next, use the totals to calculate average monthly premium paid by members and average monthly premium paid by employers as follows:

Average Monthly Premium Paid by Members = Total B divided by Total A

Average Monthly Premium Paid by Employers = Total C divided by Total A

Note that there is no longer transition relief for providing employer and member premiums. For reference years 2020 and 2021 only, CMS provided nonenforcement relief related to the requirement to report the average monthly premium paid by employers versus members. As of the date of the publication of this alert, there is no indication that transition relief for employer and employee contributions has been extended for the 2022 reference year. Employers should expect to provide this information.

Premium Equivalent Amounts

Self-funded plans must report the annual premium equivalent amounts representing the total cost of providing and maintaining coverage for all members on the D1 file. In the 2020 and 2021 reference year instructions, CMS stated that self-funded plans should report premium equivalent rates (PERs). PERs generally reflect projected claims costs that employers expect to pay in the upcoming plan year. CMS later informally stated that they wanted employers to report actual, not projected claim costs.

In the instructions released on March 27, 2023, CMS clarifies the amounts employers are required to report. CMS states that the Departments recognize that there are various funding arrangements for self-funded plans, and the calculation of premium equivalents is not always straightforward. Entities should report amounts that best represent the total cost of providing and maintaining coverage for the reference year. Therefore, actual costs on a retrospective basis should be used instead of funding levels whenever possible. CMS changed the verbiage in the instructions from “premium equivalent rates” to “premium equivalent amounts.” Hopefully, the new guidance will clarify confusion around this data field and the information required for submission.

To calculate premium equivalent amounts (PEAs), an employer with a self-funded plan may use, as the total cost of providing and maintaining coverage, the same **types** of costs that are considered for purposes of calculating COBRA premiums (minus the 2% administration charge, if applicable). This does not mean employers should report the actual COBRA rate, but rather to report the total dollar amount actually paid for the reference year.

Plans should include:

- Claims costs
- Administrative costs, including ASO and other TPA fees
- Stop-loss premiums
- Network access fees, such as preferred provider organization (PPO) fees
- Payments made under capitation contracts with providers for benefits covered under the plan
- Stop-loss reimbursements
- Prescription drug rebates received by the group health plan during the reference year, regardless of whether the payment is retrospective or prospective

Plans should exclude:

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

Admin Fees Paid

Employers should report total administrative fees paid for a self-funded plan for the reference year, including the premium equivalents amount in the D1. This field should be left blank for a fully insured

plan. This column was previously called ASO/TPA fees paid. CMS notes in the instructions that the purpose of the column has not changed, only its name for clarification.

Included in this field are administrative fees paid by a self-funded plan to an ASO, TPA, or other entity administering a self-funded plan. Excluded from reporting are fees for FSA administration, wellness programs, or financial or clinical analytics.

Additional Updates

Carve-Outs

A benefit carve-out is a benefit administered, offered, or insured by an entity that is different from the entity that administers, offers, or insures most of the plan's other benefits. Stop-loss, prescription drug benefits, and mental health benefits are common plan carve-outs.

Starting with the 2022 reference year, carved-out benefits will be listed on the P2 file, replacing the column that previously was used to collect HIOS plan IDs for fully insured plans. The information will be used to collect information about carve-out benefits when multiple reporting entities are reporting on information about the same plan. If a reporting entity is reporting information only for a carve-out benefit, such as a prescription drug benefit or a behavioral health benefit, the benefit carve-out should be described in the P2 field. The P2 field is a free-form field that allows up to 2,048 characters. CMS requests a short description of the carved-out benefit in this field, such as "medical except for mental health services only" or "prescription drug benefit carve-out." CMS has provided some relief for this reporting field, stating in the instructions that this field is not mandatory for the 2022 reference year.

Carve-out benefits are also reported in the D1 file. Employers reporting carve-outs have two reporting options:

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

CMS discourages using option two 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.

Companies No Longer in Business

While there is still very little guidance on how to handle reporting following a merger or acquisition, the updated instructions released on March 27, 2023, provide some guidance for plans and issuers that terminate during a reference year. The instructions state that, for self-funded terminated plans, reporting entities may choose to include or exclude the business associated with the terminated plan.

Proposed Collection Comment Request

Along with the updated RxDC instructions, CMS released a Proposed Collection Comment Request on March 27, 2023. Comments regarding the "burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden."

Comments may be submitted electronically through **http://www.regulations.gov** or to the Office of Strategic Operations and Regulatory Affairs Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850 by May 26, 2023.

Summary

The updated instructions released in March provide much-needed clarity for many pending issues and questions. The RxDC reporting responsibility lies with the group health plan sponsor, but their carriers, TPAs, and PBMs will have most of the information necessary to submit the required data on behalf of employer-sponsored plans. Because there are some data elements that these vendors do not keep on file, some coordination with plan sponsors will be required. Employers should be aware of what information the reporting entities will submit on their behalf, whether they need multiple reporting entities to complete the submission, and should confirm with vendors that the data was submitted in advance of the due date. Employers that need to submit files on their own should register with the HIOS soon. HIOS credentialing requires multiple steps and can take several weeks to complete.

EPIC is monitoring any developments with this new requirement to determine how we can best assist our clients and will release additional resources as more information becomes available.

EPIC Employee Benefits Compliance Services

For further information on this or any other topic, please contact your EPIC benefits consulting team.