AON

Round 2: RxDC Data Due June 1 With More Challenges for Employers

February 2023

Employers sponsoring group health plans must prepare for the next Prescription Drug Data Collection (RxDC) submission, due June 1, 2023. Plans must submit more information regarding how the plan splits payments between the employer and the employee, and the responsible government agencies are less likely to offer relief. All employers, including those with fully insured medical or prescription drug benefits, should begin planning their approach to fulfilling this regulatory requirement as soon as possible, in case there are gaps in what the plan vendors will provide. The RxDC submission includes medical, prescription drug, and premium/premium equivalent information and likely will require assistance from more than one vendor.

This Aon bulletin discusses:

- RxDC Submission Date

- Changes From the Initial Submission

- Refresher on the RxDC Submission

- Impact on Employers and Next Steps

RxDC Submission Date

The RxDC process requires employer group health plans and insurers to report medical, prescription drug, and premium/premium equivalent data to the Centers for Medicare and Medicaid Services (CMS) for calendar years (reference years) regardless of plan or policy year. For the 2022 reference year, the RxDC submission is due June 1, 2023.

For the first submission, the Department of Labor (DOL), Treasury, and Health and Human Services (the Departments) granted relief by extending the original December 27, 2022, deadline to January 31, 2023. Currently there is no indication that there will be relief for this second submission.

Changes From the Initial Submission

Submission Requires More Information, Including Employer- and Employee-Paid Premiums/Premium Equivalents

The RxDC submission requires group health plans report the total premium or premium equivalent, as applicable, the premium/premium equivalent paid by the employer, and the premium/premium equivalent paid by employees (members). CMS granted relief for the first submission and did not require this data because it would require greater coordination among industry participants. CMS has

indicated that it expects group health plans to report this data for the 2022 reference year and future submissions.

Vendors Are Changing Their Approaches in Response to New Requirements

Medical third-party administrators (TPAs), pharmacy benefit managers (PBMs), and insurers learned more about what RxDC requires, and most of these vendors are implementing changes in the data that they will collect and the services that they will provide. It is possible some vendors will decline to submit some data on behalf of group health plans, leaving that task to the employer plan sponsor. In addition, CMS has indicated that different vendors can supply data for a single "D" file for a single employer-sponsored group health plan; however, the data must be coordinated and cannot be duplicative. This is complicated because some vendors are doing more and others are doing less than what they submitted during the 2020/2021 submission. The D1 File, which reports premium equivalent information, is particularly complicated for self-insured employers who have prescription drug coverage or other benefits "carved-out" because the medical TPA likely does not have the complete data for that file.

Tighter Timeline for Producing Information and Submission

The 2022 RxDC submission requires group health plans and insurers to report data regarding actual claims paid in 2022 by June 1, 2023. This includes a three-month runout period ending March 31 for some of the medical and prescription drug spending data, leaving little time between closing the year, processing the data, preparing for submission, and actual submission. This was not an issue when the deadline was at the end of the year, but this regular deadline leaves little time for plans to prepare and submit.

The Full Extent of Changes Are Not Yet Known

CMS released initial guidance for the 2020/2021 submission in December 2021 with a major update to the instructions in June 2022. Subsequently, CMS issued more guidance in Frequently Asked Questions (FAQs) and in public webinars through January 2023. CMS has indicated that there will be a major update to the CMS instructions for the 2022 submission as well as more informal guidance, but CMS has not provided the industry with timing regarding when they will issue new instructions. Any significant changes to the instructions may result in plan sponsors scrambling to meet the new requirements with little time before the June 1, 2023, submission deadline.

Refresher on the RxDC Submission

Plans and Insurers Subject to the RxDC Submission Requirements

The RxDC submission requirements apply to:

- Group health plans subject to ERISA;

- Non-federal governmental plans subject to the Public Health Service Act;

- Church plans subject to the Internal Revenue Code;

- Individual health insurance;

- Student health insurance; and

- Federal Employees Health Benefits carriers.

The RxDC submission requirements do not apply to:

- Flexible spending accounts, health reimbursement arrangements, other account-based group health plans, and health savings accounts;

- Excepted benefits (e.g., most dental/vision benefits and employee assistance plans, hospital, and other fixed indemnity insurance);

- Short-term limited duration insurance;

- Retiree-only medical plans (i.e., separate IRS Form 5500 and plan document from actives); and

- Medicare Advantage and Part D plans.

An employer sponsoring a fully insured plan can enter into a written agreement with the insurer to transfer responsibility and liability for the RxDC submission to the insurer. While an employer sponsoring a self-insured plan can enter into a written agreement with the TPA and PBM to make the RxDC submission, the responsibility and liability remain with the employer.

Penalties for noncompliance include excise taxes of up to $100 per day per participant. A $500,000 limit to the penalty applies when errors are due to reasonable cause and not to willful neglect. The DOL can audit and bring civil suits against the plan for noncompliance.

Elements of the RxDC Submission

The RxDC submission includes almost a dozen files of data and plan information, as well as "Narrative Responses" that explain how certain data was derived. The RxDC submission comprises at least one of three Plan Files and eight Data Files.

Plan Files. The Plan Files are as follows:

- **Plan File 1 (P1)—Individual Plans.** This file applies only to individual health insurance plans and student health plans.

- **Plan File 2 (P2)—Group Health Plans.** Employers that sponsor group health plans must submit information such as the plan name, plan number, and the number of members covered by the plan on December 31 of the reference year. Employers will want to ensure that the vendors who are submitting Data Files have the correct information for the associated P2 File by legal plan. CMS prefers a roadmap between vendors as part of this P2 File submission.

- **Plan File 3 (P3)—Federal Employee Health Plan (FEHB) Plans.** This file applies only to the FEHB.

Data Files. The Data Files contain the medical plan and prescription drug plan information that plans must disclose in the RxDC submission. The Data Files, including the entities that are able to create and submit the data, are as follows:

- **Data File 1 (D1)**—Information on premium/premium equivalents, employee contributions, and covered life years.

  - **Who Will Submit the D1.** Some insurers and medical TPAs will not create this file, or they will not collect the information necessary to complete this file. It is very important to understand what information an insurer or medical TPA will have to create these files; if there is a gap, the employer plan sponsor must fill it by submitting a supplemental D1 File. For example, if prescription drug benefits are carved out to a PBM, the premium data maintained by the medical TPA or insurer may not be complete since it may not incorporate the value of the prescription drug benefit.

  - **Email Submission Unclear.** For the 2020/2021 reference years' submission, CMS provided last-minute relief to employers in Department FAQs Part 56 that allowed employers to submit the D1 to CMS via email instead of the Health Insurance Oversight System (HIOS). This alternative submission method may not be permitted for 2022 but again, the industry is awaiting CMS's updated instructions.

  - **Additional Data Is Required for This File for 2022.** Specifically, employers must include Average Monthly Premium Paid by Members and Average Monthly Premium Paid by Employer(s) as defined by the RxDC Manual.

- **Data File 2 (D2)**—Information on health care spending by category. Medical insurers and TPAs will create and submit this file.

Insurers and PBMs covering prescription drugs will create and submit the following Data Files:

- **Data File 3 (D3)**—Top 50 most frequently dispensed brand name drugs.

- **Data File 4 (D4)**—Top 50 most costly drugs.

- **Data File 5 (D5)**—Top 50 drugs with the greatest spending increase.

- **Data File 6 (D6)**—Total prescription drug spend, fees paid, and rebates received.

- **Data File 7 (D7)**—Prescription drug rebates by therapeutic class.

- **Data File 8 (D8)**—Prescription drug rebates for the top 25 drugs.

Narrative Response. The Narrative Response is a Word or PDF document by a reporting entity that explains how the reporting entity derived the information in the Data Files. For employers submitting D1, the Narrative Response explains and describes how a self-insured employer calculates the employer size to determine whether the employer is a large group employer or small group employer. If the employer used estimates, the employer must describe the estimation method. Similarly, insurers, TPAs, and PBMs must submit a Narrative Response for their Data Files.

Submitting the Plan Files and Data Files to CMS

On or before the submission due date, the reporting entities for a plan—employers (or their designee such as a consultant or benefits administrator), PBMs, TPAs, and insurers (or a combination of them)—must upload the Plan Files and Data Files onto CMS's HIOS platform. A plan's RxDC submission must

include at least one Plan File and all eight Data Files. HIOS will not accept a submission comprised of Data File(s) without a corresponding Plan File. Multiple plans sponsored by the same plan sponsor should be filed at the same time by the same reporting entity. While Department FAQs Part 56 provided relief for the 2020/2021 submission that permitted multiple submissions by the same reporting entity, it is possible that new CMS instructions will not permit multiple submissions by the same reporting entity. CMS will use the P2 File to link all the applicable Data Files to the plan sponsor.

A plan's submission is complete when CMS has received the applicable Plan File, all eight Data Files, and the Narrative Responses. Only the entity that submits the Data Files via HIOS can access the submission. Employers must rely on PBMs, medical TPAs, and medical insurers' assurances that their files have been submitted to CMS.

Impact on Employers and Next Steps

This submission may be more difficult due to the greater stringency for reporting from CMS, the additional data required, and the fast-changing guidance and industry response. Employer plan sponsors must begin preparing the 2022 submission soon and remain alert to changes in the submission requirements. Many vendors have already announced their data collection efforts, but the anticipated change in guidance from the Departments or CMS could require vendors to ask for more information or require employers to submit their own data.

Next Steps

Fully insured plans. If not already done, employers should enter into written agreements with the insurers to shift responsibility for RxDC compliance to the insurer. Employers should then monitor the insurers to ensure compliance. If an insurer states that they will not submit a Data File on behalf of the plan (e.g. D1), the responsibility may fall back to the employer depending on the terms of the written agreement.

Self-insured plans. Employers whose plans have either a self-insured medical component, a self-insured prescription drug component, or both, should enter into written agreements with TPAs and PBMs to require them to create and submit RxDC Data Files. These employers should also determine whether they must create or submit any RxDC Data Files themselves. Employers with self-insured plans must monitor their TPAs and PBMs to ensure a timely and complete RxDC submission. Any failure to report any of the required data is a liability of the employer plan sponsor, so it is important to understand if there are any gaps in information being reported to CMS.

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