



Employer Health Plans Face December 27 Deadline for Submitting Rx Data to CMS

August 2022

Employers sponsoring group health plans must begin preparing for the first Prescription Drug Data Collection (RxDC), which is due on December 27, 2022. 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 Dates;
- Plans and Insurers Subject to the RxDC Submission Requirements;
- Elements of the RxDC Submission—Plan Files, Data Files, and Narrative Responses;
- Submitting the Plan Files, Data Files, and Narrative Responses to The Centers for Medicare & Medicaid Services (CMS); and
- Impact on Employers. This bulletin addresses certain compliance issues, including:
 - Collecting and filing data from the pharmacy benefit manager (PBM) and third-party administrator (TPA);
 - Change in vendors;
 - Plan year changes;
 - Terminated plans;
 - Non-federal governmental plans, church plans, and small plans;
 - Entering into written agreements for fully insured plans; and
 - Entering into written agreements for self-insured plans.
- Evolving Guidance

Note: Aon will release its proposed RxDC solution shortly for employers needing additional support in meeting the RxDC submission requirements (also referred to as “Section 204 reporting”).

RxDC Submission Dates

The RxDC process requires employer group health plans and insurers to report medical, prescription drug, and premium/premium equivalent data to the CMS for calendar years (“reference years”). The first RxDC submission is due December 27, 2022, for both the 2020 and 2021 reference years.



Thereafter, the RxDC submission is due June 1 after the end of the reference year (e.g., the 2022 reference year submission is due June 1, 2023).

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; 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 in the plan up to \$500,000. The Department of Labor can audit and bring civil suits against the plan for noncompliance.

Elements of the RxDC Submission

The RxDC submission includes almost a dozen sets of data and plan information, as well as “Narrative Responses” explaining how certain data was derived. The RxDC submission comprises three Plan Files and eight Data Files.

Plan Files

The Plan Files are as follows:

- **Plan File 1 (P1).** 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' Data Files have the correct information for the P2 File by plan.
- **Plan File 3 (P3).** This file applies only to the Federal Employee Health Plan.

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 create and submit the data, are as follows:

- **Data File 1 (D1)**—Information on premium/premium equivalents, employee contributions, and covered life years. If the plan is fully insured, the insurer will create and submit the file. If the plan is self-insured, however, at least some medical TPAs have announced they will not create and submit the file, in which case the employer must create and submit the file, likely with support from their actuary or consultant.
- **Data File 2 (D2)**—Information on health care spending by category. Medical insurers and TPAs will create and submit this file.

The following Data Files will likely be created and submitted by health insurers and PBMs:

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

Narrative Responses

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 determines 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, Data Files, and Narrative Responses to CMS

On or before the submission date, the reporting entities for a plan—employers, PBMs, TPAs, and insurers (or a combination of them)—must upload the Plan Files and Data Files onto CMS's Health Insurance Oversight System (HIOS) platform. A plan's RxDC submission must include one Plan File and all eight Data Files. HIOS will not accept a submission comprised of D File(s) without a corresponding P File. Multiple plans sponsored by the same plan sponsor can be filed at the same time 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 RxDC 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

Collecting and filing data from the PBM and TPA. Some PBMs and medical TPAs are offering to submit Data Files on behalf of the group health plan or, alternatively, provide the employer with the Data Files to submit. While most employers will find it more convenient for the PBM and TPA to submit the Files on their behalf, an employer may have to submit the Files if the data must be combined with other vendors' data (e.g., if there has been a change in PBM or TPA in the middle of a reference year.)

Some employers may not have a choice and will have to submit Data Files sent to them from vendors. For example, some of the data requires a year-over-year cost comparison, requiring the current vendor to possess cost data from the prior year. Thus, a vendor may not be willing to submit data for the December 27 submission if the vendor was not the vendor in 2019, 2020, and 2021, or is no longer the vendor in 2022. The vendor will instead send the employer the Data Files and leave the task of submission to the employer.

Change in vendors. If there has been a change in PBM, medical insurer, or medical TPA between 2019 and December 2022, employers must determine which vendors will produce and submit 2020 and 2021 Data Files, and whether the employer must submit Data Files to CMS itself.

Plan year changes. Short plan years and changing plan years in 2020 and 2021 will require special attention to ensure correctly reporting information on Plan Files.

Terminated plans. Nothing in guidance suggests that a plan terminated after January 1, 2020, does not need to submit an RxDC submission. Continuing employers or successor employers must prepare RxDC submissions for terminated plans that existed in 2020 or 2021.

Non-federal governmental plans, church plans, and small plans. Many vendors are planning to use Form 5500 information for creating Plan Files to attach to their Data Files. Non-federal governmental plans, church plans, and small ERISA plans that do not have Form 5500 filings should ensure that vendors have plan information for creating Plan Files.



Entering into written agreements for fully insured plans. 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.

Entering into written agreements for 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, if possible, 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.

Evolving Guidance

There are aspects of the RxDC submission that still require clarification from CMS. Some details around the process may change in the coming months.

Resources

The RxDC submission manual can be found [here](#).



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