

# Departments Provide RxDC Guidance and Delayed Enforcement

January 3, 2023

## Quick Facts

- Starting in 2022, health plans and issuers must annually submit certain information about prescription drug and healthcare spending to the Departments.
- The first report for reference years 2020 and 2021 was due December 27, 2022.
- On December 23, 2022, the Departments released good faith relief for reasonable compliance and a grace period for late reporting.
- The new guidance also included clarification on multiple submissions, submission by email, data aggregation and reporting on vaccines and claim amounts not applied to deductibles.

## Background

Late on December 23, 2022, the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments), issued new guidance, and provided a submission grace period through January 31, 2023, for the new Prescription Drug Data Collection (RxDC) Reporting requirement originally due on December 27, 2022. The Departments will also allow submission of the D1 and P2 files by email instead of through the Centers for Medicare and Medicaid Service (CMS) Health Insurance Oversight System (HIOS) website. In some cases, submission of these files is the responsibility of the employer/plan sponsor.

The Consolidated Appropriations Act (CAA) of 2021 passed by Congress and signed into law on December 27, 2020, requires health insurance companies (issuers) and employer-sponsored health plans to annually submit certain information about prescription drugs and healthcare spending to the Departments. Under previously released guidance, reporting for 2020 and 2021 cost data was due by December 27th, 2022, and then by June 1 annually thereafter. Reporting for employer-sponsored plans consists of one plan file, eight separate data files, and accompanying narrative responses required for certain specific scenarios. Original guidance required all files to be submitted electronically through the HIOS system.

## Who Is Responsible for Submitting Data to CMS?

Employers who sponsor only fully insured health plans will generally be able to rely on their carrier to submit the required reporting. However, employers who sponsor self-funded (or level-funded) plans may have to submit some of the data themselves. What files plan sponsors are required to submit depends on the approach their vendors are taking to the reporting requirements, and agreements in place with various vendors. A common scenario for self-funded plans is for the vendor to submit all files except the D1 file, which the employer must file on their own. The D1 file includes data such as employer/employee contributions, membership data, administrative services only (ASO) fees, and stop-loss costs. If an employer is required to submit their own D1 file, they must also submit a corresponding P2 file that contains additional information about the employer's plan.

## Good Faith Relief and a Grace Period for Data Submission

The Departments recognized that the industry has encountered “*significant operational challenges*” in complying with these reporting requirements. So, for the 2020 and 2021 data submissions (originally due by December 27, 2022), the Departments will not take enforcement action against an employer plan or issuer “*that uses a good faith, reasonable interpretation of the regulations and the Prescription Drug Data Collection (RxDC) Reporting Instructions in making its submission.*” The Departments have also extended a submission grace period and will not consider a plan or issuer to be out of compliance if the submission of 2020 and 2021 data is made on or before January 31, 2023.

## Submission of D1 and P2 Files via Email Allowed

As mentioned above, in certain cases the employer will be required to submit data themselves. Some self-funded employers are being told by their vendors that the employer will be responsible for submitting the D1 file. Generally, the regulations require plans and issuers to submit information using the CMS Health Insurance Oversight System (HIOS) RxDC module. However, under the new guidance, if the employer is submitting only the plan list (P2 file), premium and life-years data (D1 file), and any narrative response, it may submit the file by email to [RxDCsubmissions@cms.hhs.gov](mailto:RxDCsubmissions@cms.hhs.gov) instead of submitting it in HIOS. The name of each file should include the reference year of the submission, the plan list or data file type (e.g., P2, D1), and the name of the group health plan sponsor.

## Other Changes and Clarifications

The new guidance also contains several other clarifications that are important to reporting entities, such as carriers and claims administrators, not the employer/plan sponsor.

## Multiple Submissions

Previous guidance and instructions from CMS stated that vendors should work together to provide one submission per plan. Later guidance stated that, while one submission was still recommended, CMS would accept multiple submissions for the same plan. The newest guidance reiterates that more than one reporting entity may submit the same data file type on behalf of the same plan or issuer, instead of working together to consolidate all the plans or issuer’s data into a single data file for each type of data.

The December 23 guidance reverses course on previous FAQ guidance released in November on duplicate submissions from the same reporting entity. Previous guidance stated that reporting entities should create a submission file, and multiple submissions would be considered duplicates and not accepted by CMS. The December 23 guidance clarifies that while the Departments prefer not to have unnecessary duplication of submissions, and a reporting entity generally should create only one submission in HIOS, “*when a reporting entity submits on behalf of more than one plan or issuer for a reference year, the reporting entity may create more than one submission for that reference year, instead of including the data of all clients within a single set of plan lists and data files for the year. These multiple submissions will be considered valid and not duplicate submissions.*”

## Data Aggregation

Previous guidance and instructions stated that, if multiple reporting entities submit the required data on behalf of one or more plans or issuers in a state and market segment, the data submitted by each of these reporting entities must be aggregated to at least the level used by the reporting entity that submits data on the total annual spending on healthcare services on behalf of those plans or issuers. For 2020 and 2021 data only, a reporting entity submitting the required data may, within each state

and market segment, aggregate at a less granular level than that used by the reporting entity that is submitting the total annual spending data.

## Reporting on Vaccines and Amounts Not Applied to Deductibles

Previous guidance and instructions required plans and issuers to report information on prescription drug names and codes using the [CMS crosswalk](#), which was updated in October 2022 to include vaccines. Reporting entities are permitted but not required to report vaccine codes in the data files. Further, reporting entities are no longer required to report a value for “*amounts not applied to the deductible or out-of-pocket maximum*” and the “*Rx amounts not applied to the deductible or out-of-pocket maximum*” although they are permitted to do so. Reporting entities not reporting this data may leave these data file columns blank.

## Summary

For more information on the RxDC reporting requirements, refer to our previous guidance from [September 2022](#) and [August 2022](#). As stated in previous guidance, employers should communicate with their vendors to determine whether the vendor is taking responsibility for the submission of the required data on behalf of the employer’s plan, and how much, if any, reporting the employer needs to do itself. For employers who need to submit their own D1 and P2 files, the ability to do so via email, instead of through the HIOS system, is a welcome change.

## Important Resources

- [EPIC RxDC Client Webinar](#)
- [CMS Website](#)
- [Regulation](#)
- [CMS Instructions](#)
- [Regtap RxDC FAQs](#)
- [December 23 FAQs](#)

## EPIC Employee Benefits Compliance Services

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