

## **New Guidance and Delayed Enforcement for Prescription Drug Data Collection (RxDC)**

Issue Date: December 2022

On the eve of the requirement for employer sponsored health plans and health insurance carriers to submit prescription drug cost reporting data, the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments), issued new guidance, and provided a submission grace period through January 31, 2023. 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.

### **Background**

The Consolidated Appropriations Act (CAA) passed by Congress in 2021 requires health insurance companies (issuers) and employer-sponsored health plans to annually submit certain information about prescription drugs and health care spending to the Departments. Under previously released guidance, reporting for 2020 and 2021 cost data is due by December 27th, 2022. Thereafter, annual reporting will be due for each calendar year by June 1st of the following year. Reporting for employer-sponsored plans consists of 1 plan file, 8 separate data files, and accompanying narratives. Originally, all the files needed to be submitted electronically to the Centers for Medicare and Medicaid Services (CMS) HIOS system.

### **Who Is Responsible to Submit 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. This will depend on their particular plan administrative arrangements, and the approach their vendors are taking to the reporting requirements. For example, a number of self-funded plan vendors have taken the position that the vendor will 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, ASO fees, and stop-loss costs. If an employer is required to submit their own D1 file, they must also submit a 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 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. Most commonly, some self-insured employers are being told by their vendor that the employer will be responsible for submitting the D1 file. Generally, the regulations require plans and issuers to submit information using the CMS 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.

This change will make it easier for employers who are only submitting the D1 and P2 files because they will not need to go through the relatively cumbersome process of setting up an account in the CMS HIOS system.

### **Other Changes and Clarifications**

The new guidance also contains a number of other clarifications more important to reporting entities such as carriers and claims administrators. These clarifications include allowing multiple submissions by the same reporting entity and submissions by multiple reporting entities for the same plan. Data aggregation rules were also simplified for 2020 and 2021 data. Finally, reporting on certain vaccine data and amounts not applied to the deductible or out-of-pocket maximum were made optional. Again, this data will most likely be reported by carriers and claims administrators, not the employer/plan sponsor.

### **Summary**

As we have said in many of our communications regarding the RxDC reporting requirements, the most important thing an employer can do is to communicate with their vendor to determine if 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.

### **Resources**

The new guidance can be found at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-56>

CMS has set up a RxDC website that contains reporting instructions, templates for the data files, and more at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection>.

CMS also set up a help desk to assist with this process, which can be reached at 1-855-267-1515 or [CMS\\_FEPS@cms.hhs.gov](mailto:CMS_FEPS@cms.hhs.gov).

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