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COMPLIANCE **ALERT**

CMS Issues Revised RxDC Reporting Instructions for Reporting Due June 1

February 23, 2024

Action Required:

- **Employers and plan sponsors should make sure that their plan service providers are using the revised RxDC Instructions when completing their 2023 RxDC reporting requirements.**

The Centers for Medicare & Medicaid Services (CMS) has issued revised reporting instructions ("Instructions") for prescription drug data collection ("RxDC") reporting required under the Consolidated Appropriations Act, 2021 (CAA). The RxDC reporting deadline for the 2023 reference year is just around the corner—June 1, 2024. CMS has also published updated templates and guidance materials on its RxDC Resource Page.

As background, and as explained in prior E-Alerts (here, here and here), the CAA requires that group health plans and health insurance issuers (called "reporting entities") report, on an annual basis, certain prescription drug and healthcare spending information from the prior year (called the "reference year") in a series of data file reports (labeled from D1 to D8) to the Departments of Labor, Health and Human Services, CMS and Treasury (the "Agencies"). The RxDC reporting is completed in coordination with the plan's insurers, third party administrators (TPAs), pharmacy benefit managers (PBMs) and other service providers and is uploaded to a dedicated CMS website called the Enterprise Portal in the CMS Health Insurance Oversight System ("HIOS"). For most employers and plan sponsors, the plans' insurers and service providers will completely handle all of the required RxDC reporting on the plan sponsor's behalf.

What Should Employers and Plan Sponsors Do Next?

Employers and plan sponsors should make sure that they and their plans' service providers are using the revised RxDC Instructions when completing their RxDC reporting for the 2023 reference year. Additionally, it's important to remember that, like last year, there is no good faith relief for this year's filing (for the 2023 reference year).

It's also important to remember that insurance carriers, TPAs, PBMs and other plan service providers have varying rules and requirements, including different deadlines for when information must be provided to them from the plan sponsor, and so, in light of that, it's important to communicate with your plans' different service providers well in advance of the June 1, 2024 deadline, and to speak with your plans' trusted advisors about this year's reporting. ■

↓ Full Explanation Follows ↓

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How do the Revised Reporting Instructions Change the Requirements for RxDC Reporting?

What follows is a summary of some of the key revisions to the Instructions that employers and plan sponsors should be aware of:

- **Sections 5.6 and 5.7:** Most notably, this Section of the Instructions provides that, starting with this year's upcoming reporting, the "aggregation restriction" will be enforced. The "aggregation restriction" rule requires that data submitted in the data files D1 and D3 through D8 must not be aggregated at a "less granular level" than the aggregation level used by the reporting entity that submitted the data in the D2 data file. This change was designed to help the Agencies to better facilitate data analysis for purposes of publishing their biannual public report required under the CAA. Section 5.7 provides helpful examples of how to complete the reporting in compliance with the aggregation restriction rule.
- **Section 8.1:** This Section clarifies that medical devices, nutritional supplements and over-the-counter drugs are excluded from prescription drug lists (that is, excluded from data files D3 through D8) unless the National Drug Code for the product is on the CMS Drug and Therapeutic Class Crosswalk (the Crosswalk spreadsheet is available on the CMS RxDC Resource Page here, in the 3rd bullet down under "Primary Filing Resources").
- **Section 6.1:**
    - Simplifies the calculation of "average monthly premium" so that it is no longer calculated on a per-member basis, as previously required. Starting with the upcoming reporting, plan sponsors should divide the annual premium amounts by 12 instead of dividing by member months when calculating the average monthly premium.
    - Simplifies the calculation of "premium equivalents" by (i) clarifying that premium equivalents may be reported on a cash basis or on a retrospective basis, and (ii) providing additional details on amounts that should be included or excluded from premium equivalents.
- **Section 4.2:** This Section was revised to clarify how to populate the benefit carve-out field in the P2 plan list file.
- **Section 3.6:** This Section provides instructions on how to submit data when the plan list or data files exceed the maximum allowable size limit in HIOS.
- **Section 8.3:** This Section adds a column to the D6 data file to collect prescription drug enrollment information, which will report the total number of member months covered during the reference year under the pharmacy benefit for which pharmacy spending is reported.
- **Section 9.1:** This Section provides instructions to reporting entities on how to report information on retained rebates when exact amounts are unknown.

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In addition to the above, below are helpful reminders from prior rule clarifications made by the Agencies:

- **Reminder (Section 3.3): Multiple Vendors Can Submit Same Data File Type for the Same Plan:** Beginning with last year's RxDC reporting, the Agencies confirmed that while plans are "encouraged" to submit only one data file of each data file type for the same plan, if plan service providers are unable to work together to complete a single data file for a plan, it will be permissible for more than one reporting entity to submit the same data file type on behalf of the same plan. For example, where a plan has separate insurance carriers—one for mental health benefits and one for medical benefits—both insurers can submit a D2 file ("Spending by Category") on behalf of the same plan (the first insurer would report the plan's data relating to mental health benefits and the second would report the plan's data relating to medical benefits). However, it should be noted that multiple reporting entities cannot upload files into the same HIOS submission. Each reporting entity must create its own submission in HIOS.
- **Reminder: No More Good Faith Efforts Relief:** For the 2020 and 2021 reference year's reporting, the Agencies issued guidance indicating that they would not take enforcement action against health plans or issuers that utilized good faith efforts and a reasonable interpretation of the regulations to complete their required reporting. To date, the Agencies have not announced any similar "good faith" relief for reporting for either the 2022 or 2023 reference years.

What Should Employers and Plan Sponsors Do Next?

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Finally, it's also important to remember that insurance carriers, TPAs, PBMs and other plan service providers have varying rules and requirements, including different deadlines for when information must be provided to them from the plan sponsor, and so, in light of that, it's important to communicate with your plans' different service providers well in advance of the June 1, 2024 deadline, and to speak with your plans' trusted advisors about this year's reporting. ■

If you have any additional questions, please call your Corporate Synergies Account Manager or 866.CSG.1719.

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