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HHS Releases Updated Drug Data Collection (RxDC) Reporting Instructions in Advance of June 1, 2024, Deadline

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Under Section 204 of the Consolidated Appropriations Act, 2021 (CAA), referred to as "The No Surprises Act" (NSA), all employer-sponsored health plans must satisfy certain transparency requirements by reporting annual prescription drug and health care spending data (often referred to as the Prescription Drug Data Collection (RxDC) report). The RxDC report is not only about prescription drugs. It also collects information about spending on health care services and premiums paid by members and employers. The instructions for 2024 announce the end to the non-enforcement period for the disaggregated reporting requirement, meaning some group health plans may need or want to report data at the employer level rather than relying on aggregated reporting by pharmacy benefit managers (PBMs) or other vendors, including third party administrators (TPAs) and administrative services only providers (ASOs) as permitted in prior years. Plan sponsors need to prepare now and watch for information requests from vendors assisting with their RxDC reporting.

Background

The RxDC requirement applies to all employer-sponsored health plans as well as health insurance providers in both the individual and group markets. RxDC reporting requirements do not apply to retiree-only plans, account-based plans such as health reimbursement arrangements (HRAs) and excepted benefit plans such as limited-scope dental and vision plans, hospital or other fixed indemnity insurance, and disease-specific insurance.

The RxDC data is reported to the U.S. Department of Labor (DOL), the Department of the Treasury (Treasury), and the Department of Health and Human Services (HHS) (collectively, the "federal agencies") annually. The RxDC report is intended to aid the federal agencies in monitoring prescription drug and healthcare spending trends for possible regulatory approaches to control costs and for a biannual, publicly available report. The ongoing deadline for the annual report is June 1 for the "reference year," which is the

calendar year immediately preceding the calendar year in which the RxDC is due. Accordingly, the deadline for submitting 2023 calendar year data is June 1, 2024.

Updates for 2023 Reporting

HHS previously released step-by-step data submission instructions to submit data for the 2020, 2021, and 2023 reference years through the RxDC module in the Health Insurance Oversight System (HIOS). Revised instructions for the reporting due on June 1, 2024, are mostly consistent with prior years, however, one significant change is the new enforcement of the "aggregation restriction" beginning with the 2023 reference year.

For 2023 reporting, pharmacy benefit data must be reported at the "most granular" level the employer's medical data is reported on File D2, meaning that the data submitted in File D1 and Files D3 through D8 cannot be aggregated at a less granular level than the data submitted in File D2. For example, if the medical data in File D2 is aggregated according to the plan sponsor Employer Identification Number (EIN), then data in files D1 and D3 through D8 must be aggregated according to plan sponsor EIN. In other words, the aggregation restriction will limit the ability of plans to have their vendors report medical premium and life years data on file D1 and the pharmacy benefit data reported on files D3 through D8 "at a less granular level" than the medical benefit data reported on file D2.

Employers with robust group health plans will likely have more than one entity reporting information on File D2, such as carve-out surgery or wellness solutions. These add-on benefits will report information which may not be included as part of the group health plan's general medical data captured by the TPA or ASO. Because the instructions state that the most granular level D2 submitted on behalf of an employer dictates how the aggregation restriction applies, plan sponsors with a carve-out vendor providing employer level data on File D2 for medical benefits will trigger employer level reporting for all of the group health plan's remaining D files (D1 and D3-D8). If all medical reporting is at the vendor level, then the remaining reporting may be at the plan level or aggregated at the vendor level.

Access to the plan level data may be a benefit to those employers that want more information on their prescription drug spending. The pharmacy reporting on Files D3 through D8 includes information not normally available to plan sponsors, including the PBM profit margin, information on certain prescription drug rebates and manufacturer cost-sharing assistance. Even if the group health plan's most granular medical files on D2 are at the vendor level, the employer may still choose to have the pharmacy data reported at the plan level. This option may provide employers with key insight into their pharmacy spend that has otherwise been unavailable and provide a valuable tool in monitoring expenses to meet fiduciary oversight of the group health plan.

Other significant changes in the instructions for the 2023 reference year reporting include:

- Medical devices, nutritional supplements, and over the counter (OTC) drugs are generally excluded from prescription drug lists with exceptions for products on the CMS Drug and Therapeutic Class Crosswalk (Section 8.1)
- A simplified calculation of the average monthly premium is provided using the total annual premium divided by 12 instead of the average monthly premium on a per-member basis (Section 6.1)

- A simplified calculation of premium equivalents is allowed by removing restrictions on reporting on a cash basis and using paid claims rather than incurred claims (Section 6.1)
- Additional details are provided about amounts that should be included or excluded from premium equivalents (Section 6.1)
- Instructions are provided to reporting entities to report information on retained rebates when exact amounts are unknown (Section 9.1)

Failure to comply with the RxDC reporting requirements falls under Internal Revenue Code Section 4980D penalties, resulting in a $100 per day fine for each day of non-compliance.

Employer Action Items

- Complete the next annual RxDC reporting by June 1, reporting data from calendar year 2023 (regardless of the health plan's plan year).
- Employers with fully insured health plans should follow up with their insurance carriers to confirm that the RxDC report has been timely filed, while requesting a copy of the documentation for their plan records.
- Employers with self-insured health plans (including level-funded plans) are responsible for timely filing the RxDC report. If employers rely on their TPA, PBM, or ASO to submit the report on their behalf, they should follow up with their TPA, PBM, or ASO to confirm that the report has been timely filed, while requesting a copy of the documentation for their plan records.
- Provide any information requested by insurance carrier, TPA, PBM, or ASO needed to submit the RxDC report on the employer's behalf.
- Confirm whether data must be reported on a plan level or aggregated basis and consider whether to request that the pharmacy data on Files D3 through D8 be reported on a plan level basis to access additional details on the pharmacy benefit spend for the reference year.