Health Plan Disclosure Requirements for Prescription Drugs

Under the Affordable Care Act (ACA) transparency-in-coverage (TiC) rules and provisions of the Consolidated Appropriations Act, 2021 (CAA), group health plan sponsors must both disclose and report detailed information regarding a plan's prescription drug coverage and costs. There is significant overlap under the two sets of disclosure rules, which has led to confusion regarding compliance. The confusion is even greater since the rules impose two required components for prescription drug cost disclosure – an annual report (Report) to the Centers for Medicare & Medicaid Services (CMS) and a mandatory machine-readable file (MRF).

The Report deadline was originally set for last year, but the Departments that enforce the rules delayed the deadline until December 27, 2022. Also, because there is significant overlap in the rules regarding prescription drug costs, the Departments delayed the prescription drug MRF requirement indefinitely pending further regulation and guidance.

Recent CMS guidance provided some technical clarifications to certain required Report elements, but it also sparked more confusion among plan sponsors as to applicable deadlines. The recent guidance merely clarified certain highly specific content elements; it did not change the compliance date for either the Report or the MRF.

Annual Report and Machine-Readable File

Virtually all group health plans – insured and self-funded alike – must file the Report. However, health reimbursement arrangements (HRAs), including individual coverage HRAs, and other account-based plans will not need to report. The Report will be due starting December 27, 2022, for plan information for 2020 and 2021 calendar years. Subsequent years will be reported by June 1 each year (i.e., 2022 information reported by June 1, 2023).

Group health plans can require relevant service providers or carriers to file these reports. The Departments caution, however, that a plan will remain liable for any reporting failure even if it transfers its reporting responsibility to a carrier, pharmacy benefit manager (PBM), or third-party administrator (TPA).

Similarly, non-grandfathered plans also will need to make a prescription drug MRF publicly available to detail the in-network negotiated rates and historical net prices for all covered prescription drugs by the plan at the pharmacy-location level. This MRF requirement mirrors the MRFs already required to be created and posted for non-prescription drug information effective July 1, 2022. There currently is no announced deadline for this MRF requirement. The Departments have noted that they will not enforce the requirement until they issue further guidance.

Report Details

Plans (or their carriers or another third party) will file Reports through the CMS's RxDC module in the Health Insurance Oversight System (HIOS). A plan sponsor will need to coordinate with a carrier or other vendor who already has HIOS access or will need to apply for its own credentials and access.

Plans generally must provide:

- Plan name and number
- Plan sponsor and principal place of business
- Plan year start and end dates
- Number of participants, beneficiaries, or enrollees
- Each state in which the plan is offered
- The 50 most frequently dispensed brand name prescription drugs, and the total number of paid claims for each
- The 50 most costly prescription drugs by total annual spending
- The annual amount spent by the plan for each such drug
- The 50 prescription drugs with the greatest increase in plan expenditures from the plan year preceding the reported plan year, and, for each such drug, the change in amounts expended by the plan in each such plan year
- Total spending on health care services by the plan broken down by the type of costs, including:
    - Hospital costs
    - Health care provider and clinical service costs, for primary care and specialty care separately
    - Costs for prescription drugs
    - Other medical costs, including wellness services
- Spending on prescription drugs by the plan and by participants, beneficiaries, and enrollees

- The average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees
- Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, including the amount paid for each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amounts of rebates and other remuneration under the plan from drug manufacturers during the plan year
- Any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration

Recent guidance indicates the Departments recognize there may be significant challenges to obtain information about employer premium contributions, especially when a contractual relationship began before the passage of the CAA. So, the Departments have announced that they will not take enforcement action related to the requirement to report average monthly premium paid by employers versus members for the 2020 and 2021 reference years if that data is reported in the RxDC report for the 2022 reference year and all future reference years.

The new guidance also clarifies that prescription drug rebates, fees, and other remuneration received for prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan, from all sources (e.g., pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor) must be included as well as discounts, chargebacks or rebates, cash discounts, and coupons.

In the PBM context, a plan must report:

- Manufacturer rebates received by PBMs and not passed through to any member or entity
- Amounts received directly from a manufacturer or indirectly from a pharmacy, wholesaler, or other entity
- Rebate amounts that are expected but have not yet been received if the PBM will retain the expected amounts

Plans also must report:

- Manufacturer rebates received by plans, issuers, or carriers and not passed through to any member or entity
- Amounts received directly from a manufacturer or indirectly from a PBM, pharmacy, wholesaler, or other entity
- Rebate amounts that are expected but have not yet been received if the plan, issuer, or carrier will retain the expected amounts

The Report also should disclose manufacturer rebates passed through (rather than retained by PBMs, plans, issuers, or carriers) to members at the point of sale.

Due Dates

All plans will report information for the previous calendar year even if a plan has a non-calendar plan year. As noted above, the Departments have announced that they will not start enforcing the Department reporting requirements until December 27, 2022. Plan sponsors should already be planning for the delayed deadline to ensure that they have the necessary info to report for 2020 and 2021 reference years (i.e., calendar years).

Conclusion

Plan sponsors should already be working to have a process in place to meet the December 27, 2022, deadline for reporting prescription drug information to CMS through the HIOS system. Though there is no set timetable for complying with the prescription drug MRF requirement, plan sponsors can take solace in the fact that the requirement (aside from specific content) should be somewhat easier to navigate given the similar MRFs already in place. We will monitor developments and provide actionable updates as the Departments issue further guidance.