Transparency Becomes Clearer: Departments Issue Regulations for Reporting Prescription Drug and Health Care Spending

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Employers that sponsor self-insured group health plans and health insurance issuers for fully insured plans will have to report information for prescription drug benefits and health care spending no later than December 27, 2022, for the 2020 and 2021 calendar years. After December 27, 2022, an annual file must be submitted by June 1 for the prior calendar year.

Background

The Departments of Labor, Treasury, and Health and Human Services (the Departments) posted interim final regulations with request for comments (IFR) in the *Federal Register* on November 23, 2021, primarily related to the prescription drug file requirement under the Consolidated Appropriations Act, 2021 (the CAA). The purpose of this guidance is to enhance transparency on how prescription drugs contribute to the cost of health coverage. Comments must be submitted to the Departments no later than January 24, 2022.

A variety of transparency-related requirements under the Affordable Care Act (ACA) and CAA were delayed or required to be implemented under a good faith standard on August 20, 2021, through frequently asked questions (FAQs) Part 49. The requirements outlined in this bulletin pertain solely to the CAA prescription drug file addressed in FAQ No. 12. While the focus of the report is the impact of prescription drug costs, hospital and medical data also must be submitted in a process referred to as the "Section 204 data submission." The prescription drug Machine Readable File requirement under the ACA has not yet been addressed by the Departments, and it is currently unclear how these two rules will intersect.

Who Must Report and Contract Requirements

The Section 204 data submission applies to both self-insured and fully insured group health plans, regardless of whether the plan is grandfathered under the ACA, including:

- Group health plans that are subject to ERISA;
- Non-federal governmental plans subject to the Public Health Services Act;
- Church plans;
- Individual health insurance coverage, including coverage offered in the individual market, through or outside a government exchange;
- Student health insurance; and

- Federal Employees Health Benefits carriers, applicable to federal government plans (not addressed in detail in this bulletin).

The Section 204 data submission does not apply to:

- Health reimbursement arrangements or other account-based group health plans;
- Excepted benefits (e.g., most dental/vision benefits); or
- Short-term limited duration insurance.

The Departments anticipate that most employers will delegate the Section 204 data reporting requirement. A self-insured group health plan is permitted to delegate its Section 204 data submission responsibility to a third party, such as a health plan administrator (TPA) and pharmacy benefit manager (PBM). The plan, however, must have a written agreement specifying that the third party is handling the reporting on the group health plan's behalf. The employer/plan sponsor will apparently remain responsible even though the TPA and/or PBM is permitted to handle on the employer's behalf. For fully insured group health plans, the plan may satisfy the requirement if the health insurance issuer handles the reporting and a written agreement is in place. The Departments propose that in an insured arrangement with a written agreement in place, the insurer, not the employer/plan sponsor, will be responsible for compliance.

Report Timing

Plan data is submitted for the "reference year," which is the calendar year before the data is submitted. As noted above, plan data for 2020 and 2021 do not have to be submitted until December 27, 2022. (Since data reporting is based on the calendar year, the group health plan's plan year does not factor into the timing of reporting.) After 2022, a plan must report by each June 1 — e.g., for the 2022 calendar year, the filing deadline is June 1, 2023.

Report Content

The technical details of the Section 204 data submission will be included in the instructions that accompany the data submission mechanism.

Different reporting entities may be utilized for different categories of required information. For example, if a self-funded group health plan engages a TPA to report health care spending and a PBM to report prescription drug spending, the Departments will need to verify that both reporting entities reported the data and included the data for the plan.

Aggregate Reporting

The most complex requirement appears to be aggregate reporting. The Departments are contemplating requiring information to be aggregated for multiple plans, then submitted separately for each state. In addition, if there are multiple reporting entities that submit the required data related to one or more plans or issuers in a state and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by

the reporting entity that submits the data on total annual spending on health care services on behalf of the plan or coverage. For insured plans, experience with respect to each fully insured policy generally must be included on the report for the state where the contract was issued. For self-insured plans, experience must be included on the report for the state where the plan sponsor has its principal place of business.

Plan Level Required Information

Plans and issuers must ensure that the information that they report or that is reported on their behalf includes the following identifying information at the plan or coverage level:

- Name, Federal Employer Identification Number, and other relevant identification numbers for the plan, issuer, plan sponsor, and any other reporting entity;
- The beginning and end dates of the plan year that ended on or before the last day of the reference year (the calendar year that is being reported);
- The number of participants, beneficiaries, and enrollees, as applicable, covered on the last of the reference year; and
- The state in which the plan or coverage is offered.

Information for Each State and Market Segment

The following information must be reported with respect to the plans or coverage for each state and market segment for the reference year:

1. Prescription Drug Data. Prescription drug information applicable to the pharmacy benefit (not the hospital benefit), such as:

- The 50 brand prescription drugs most frequently dispensed by pharmacies;
- The 50 most costly prescription drugs; and
- The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year.

Further, with respect to the prescription drug data requirements, for each such drug, prescription drug spending and utilization must be reported including:

- Total annual spending by the plan or coverage;
- Total annual spending by the participants enrolled in the plan;
- The number of participants with a paid prescription drug claim;
- Total dosage units dispensed; and
- The number of paid claims.

2. Annual Health Care Spending. Plans and issuers must separately report total annual spending on health care services by the plan or coverage, and total annual spending on health care services by participants 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, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and
- Other medical costs, including wellness services.

3. Premium Amounts. Average monthly premium amount paid by plan sponsors and average monthly premium amount paid by participants, as well as related data must be reported. This amount includes "premium equivalent" information for self-insured group health plans, representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

4. Prescription Drug Rebates and Fees. The data also must include prescription drug rebates, fees, and "other remuneration" paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs in the plan. These amounts must be reported for each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan from drug manufacturers during the plan year.

Ultimately, the Departments will publish a report with information on reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases, with information that is aggregated. This report must be published no later than 18 months after the date on which plans are required to report.

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