Asher, Gittler & D'Alba, Ltd.
Release: Volume 42 No. 50

EBSA PRESCRIPTION DRUG INTERIM FINAL RULE

On November 23, 2021, four federal agencies, including the Employee Benefits Security Administration ("EBSA"), issued an Interim Final Rule ("Rule"), effective December 23, 2021, entitled "Prescription Drug and Health Care Spending." The Rule applies to health plans and health insurance issuers, including ERISA Health and Welfare Plans, whether insured or self-funded ("Plans"). The Rule implements provisions of the Consolidated Appropriations Act, 2021 ("Act"), passed on December 27, 2020.

The Rule requires Plans to submit extensive information regarding medical coverage, treatment, prescription drugs, and other data. The information that must be submitted is set forth in the Attachment.

The Rule states that a forthcoming form, issued by the Secretaries, will guide reporting. However, the Rule itself does contain some logistical and technical reporting guidelines. First, the Rule provides that the "reference year" for which a Plan must submit data refers to the calendar year preceding the calendar year in which the data submission is due, even if the Plan has a different Plan year. For prescription drugs, the Plan's reporting must differentiate between Brand Prescription Drugs and others, and prescription drugs are grouped together by name and ingredient without differentiating by dosage strength or package size. The Departments will, but have not yet, create a uniform list of "therapeutic classes" composed of drugs with similar mechanisms of action that treat similar conditions. Generally, a Plan may aggregate the data it reports, and a third party may be retained to submit the data. Finally, the reporting deadline for calendar years 2020 and 2021 has been set at December 27, 2022; after that, June 1 will be the reporting deadline for the previous calendar year's data. While much guidance is still forthcoming, the Rule allows Plans to begin identifying and calculating what they will eventually have to report.

Attachment

Information that must be submitted by a Plan pursuant to the Act and the Rule:

- Plan "demographic" information:
  - The beginning and end dates of the Plan year;
  - The number of participants, beneficiaries, and enrollees covered on the last day of the "reference year" (the calendar year immediately before the year in which the information must be submitted); and
  - The states where the coverage is offered.

- Spending on health care services:
  - Hospital costs (including for prescription drugs prescribed at the hospital);
  - Health care provider costs;
  - Prescription drug costs (see below); and
  - Other costs.

- Prescription drug costs, with data setting forth, by market segment:
  - The 50 most frequently dispensed prescription drugs, with the total number of paid claims for each;
  - The 50 most costly prescription drugs by total annual spending net of rebates, with that amount; and
  - The 50 prescription drugs with the greatest increase in Plan expenditures year-over-year, with the amount of that increase.

- Further, for both the Plan's 50 most frequently dispensed Brand Prescription Drugs, and for each therapeutic class of drug, the Plan must report:
  - Total annual spending on the drug by the Plan;
  - Total annual spending by participants, beneficiaries, and enrollees;
  - The number of participants, beneficiaries, and enrollees with a paid claim;
  - The total dosage units dispensed; and
  - The number of paid claims.

- Additionally, the Plan must report:
  - The average monthly premiums paid by participants, beneficiaries, and enrollees;
  - The average monthly premiums paid by employers.
- Finally, the Plan must disclose all rebates, fees, and any other monies paid by drug manufacturers to the Plan (or its administrators or service providers), including bona fide service fees and remuneration from any source, as well as what effect, if any, they had on costs or premiums.

ASHER, GITTLER & D'ALBA, LTD.
200 West Jackson Boulevard, Suite 720
Chicago, IL 60606 – 312.263.1500

Dated: December 20, 2021

This release informs you of items of interest in the field of labor relations. It is not intended to be used as legal advice or opinion.

U.S. News & Report's Best Law Firms Designation is for Chicago Tier 1 rankings in Employment Law (Individuals), Labor Law (Union), and Litigation (Labor and Employment) and a National Tier 2 ranking in Litigation (Labor and Employment).