

No Surprises Act: Prescription Drug and Health Care Spending Transparency Rule

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Guidance Addresses Reporting Requirements and Provides Enforcement Delay until December 27, 2022



The Consolidated Appropriations Act, 2021 (CAA) required certain federal agencies to issue rules providing for cost transparency and related protections for health coverage under the No Surprises Act portion of the CAA. On November 23, 2021, the Department of Health and Human Services (HHS), together with the Department of Labor (DOL) and the Department of the Treasury (collectively, the Agencies), published an interim final rule entitled Prescription Drug and Health Care Spending.

The transparency requirements under the No Surprises Act (NSA)

The NSA includes several different transparency requirements specifically affecting employer-provided group health coverage:

- Prescription drug and health care spending reporting;
- An advance explanation of benefits (EOB) requirement; and
- Medical/Rx identification (ID) card disclosure requirements.

Prescription drug and health care spending reporting rule and this Alert

The prescription drug and health care spending reporting rule (the “Rule” for the remainder of this Alert) requires health plans and health insurance issuers in the group and individual markets to report certain information about prescription drug and health care spending.[1] The required reporting includes information about health care spending by category, the most frequently covered and expensive prescription drugs, and information about rebates paid by drug manufacturers to plans, issuers, third-party

administrators, and pharmacy benefit managers. The Rule also delays enforcement until the end of 2022.

This Alert focuses on employer-provided group health coverage and addresses who is responsible for the required reporting, how to delegate reporting to a third party, timing, and the required reporting elements.

Other transparency guidance

We covered the advance EOB and medical/Rx ID card disclosure requirements at a high-level in an [earlier alert](#). That alert focused on enforcement delays for those provisions, good-faith compliance, and the Agencies' ongoing efforts to reconcile the NSA's transparency requirements with similar provisions found in a separate set of transparency in health coverage rules (as well as enforcement delays affecting those rules). We do not address these transparency requirements in this Alert.

Reporting requirements

Covered group health plans

The reporting requirements affect both fully insured and self-insured group health plans (almost exclusively medical/Rx plans). The requirements apply to grandfathered plans under the Affordable Care Act, but they do not apply to group health plans consisting solely of excepted benefits^[2] or account-based plans (e.g. health FSAs and HRAs).

Plan sponsors – this is usually the employer – are responsible for complying with the Rule.

- **Fully insured health plans** – The plan sponsor of a fully insured health plan can shift the compliance obligation to the insurance carrier or another third party by mutual written agreement.
- **Self-insured health plans** – The plan sponsor of a self-insured plan can delegate reporting responsibility to a third party administrator (TPA), pharmacy benefit manager (PBM), or other third party by mutual written agreement, but the compliance obligation remains with the plan sponsor. A plan sponsor should protect itself from losses caused by the TPA, PBM, or other third party's negligence or other reporting failures with indemnification language in the written agreement.

Reporting entities

The Rule refers to entities that report data on behalf of a health plan to the Agencies as reporting entities, and a health plan may have multiple reporting entities. For example, a self-insured plan sponsor may contractually delegate health care spending reporting to the medical TPA and prescription drug reporting to a carved-out PBM. In many instances, PBMs have sole knowledge for how plan rebates and other compensation are applied, and are in the best position to report the prescription drug information.

The agencies indicated they intend to make a reporting tool available for use by multiple reporting entities acting on behalf of a single health plan.

Reporting due dates

The Rule requires calendar year reporting without regard to a health plan's actual plan year. Reporting also occurs on a lag basis similar to various other reporting requirements (e.g. Form 5500 reporting and Form 1094/1095 reporting). The Agencies believe that collection of calendar year data will allow for better data validity and trend comparison than mapping data based on different plan years.

- Initial Reporting and Enforcement Delay – Reporting for the 2020 and 2021 calendar years was originally due by December 27, 2021 and June 1, 2022, respectively. The Agencies delayed enforcement for 2020 and 2021 reporting until **December 27, 2022**.
- Subsequent Reporting – Beginning with the 2022 calendar year, reporting is due by **June 1st of the following year**.

Required reporting

Although of little significance to employers sponsoring group health plans, the Rule divides the insurance market into seven different market segments:

1. Individual coverage (excluding the student market);
2. The student health insurance market;
3. Fully-insured small group plans;
4. Fully-insured large group plans (excluding the Federal Employees Health Benefits (FEHB) system);
5. Self-insured plans offered by small employers;
6. Self-insured plans offered by large employers; and
7. The FEHB system.

Specific versus aggregate-level reporting

The Rule generally requires plan sponsors and insurance carriers (or reporting entities acting on their behalf) to report information separately for each medical/Rx plan option in each state offered. However, the Rule allows a reporting entity acting on a plan's behalf to aggregate certain information by state and market segment if the reporting entity is reporting for multiple plans in the state/market segment. This includes plans sponsored by unrelated employers in the state/market segment.

Practical Standpoint: Since most reporting entities will be insurance carriers, TPAs, and/or PBMs, the reporting for most plan options will be specific for certain identification and demographical information and aggregated for spending and other information.

Summary of required reporting data elements

The following is a high-level summary of the required reporting data elements, including data elements that must always be specific to a given plan and data elements reporting entities can aggregate across multiple plans.

Specific reporting information required

1. General information regarding the plan or coverage, including:
 - a) Plan name and other identifying information enabling the Agencies to cross-check with Form 5500 and medical loss ratio reporting information;
 - b) The beginning and end dates of the plan year that ended on or before the last day of the reportable calendar year;
 - c) For each plan option as of the last day of the reportable calendar year, the aggregate number of months for all covered lives divided by twelve (known as life years) by state and market segment; and
 - d) Other enrollment and premium information, including the share of average monthly premium contributions paid by employees and employers.

Aggregate-level reporting information allowed by multiple filer reporting entities for state/market segment

2. Total annual spending, broken down by each health care spending category between participants and plan sponsors.
 - a) Total annual spending – This generally means claims incurred during the reportable calendar year and paid by March 31st of the following year. These amounts include participant cost sharing but exclude rebates, fees, and other remuneration.
 - b) Health care spending categories – These include hospital care; primary care; specialty care, other medical costs (including wellness services), and prescription drug spending.

The existing Rule only addresses this reporting requirement in general terms, and the Agencies indicate they will release detailed guidance in the future.

3. The “Top 50” Lists

- a) The 50 most frequently dispensed brand prescription drugs;
- b) The 50 most costly prescription drugs by total annual spending; and

c) The 50 prescription drugs with the greatest increase in expenditures from the previous year.

4. Rebates, Fees, and Other Remuneration

a) Reporting entities must include the amount of prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or issuer for:

i. each therapeutic class of drugs, as well as for

ii. each of the 25 drugs that yielded the highest amount of rebates (the “Top 25” list); and

b) The impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs. This amount includes bona fide service fees, but it excludes coupons and co-payment cards that do not affect total annual spending.

Definition of prescription drugs: To enable the Agencies to conduct meaningful data analysis and identify prescription drug trends, the Rule requires reporting products with the same name and active ingredient as the same prescription drug even if the products have different dosage strengths, package size, mode of delivery, or manufacturer (for generics).

Client impact & action items

The insurance carriers, TPAs, and/or PBMs will have most of the required reporting data and are in the best position to fulfil the required reporting on behalf of group health plans. In most instances, employers/plan sponsors should contractually delegate reporting to these parties and include indemnification language in the written agreement.

Model form and instructions

The Agencies indicated that they will later release additional instructions and some form of model tool to report the data. The Agencies did not specify a delivery date, and we do not anticipate that it will appear before summer 2022.[3]