National Compliance Update

USI EMPLOYEE BENEFITS

July 28, 2022

New Prescription Drug Reporting Requirement

As previously reported,[1] Section 204 of the Consolidated Appropriations Act, 2021 ("CAA") requires plan sponsors of group health plans to submit information annually about prescription drugs and health care spending to Centers for Medicare and Medicaid Services ("CMS") on behalf of the Departments of Health and Human Services ("HHS"), Labor ("DOL"), and the Treasury (collectively, the "Departments"). The first deadline is **December 27, 2022**. CMS recently updated guidance related to this reporting requirement that provides some helpful clarification.

WHAT IS REPORTED?

	Data Point	Notes
1.	Plan name	
2.	Plan number	
3.	Plan year	
4.	Employer size	Self-funded plans must elect an option[2]
5.	The plan sponsor's principal place of business	Self-funded plans must elect an option[3]

[1] See USI's Compliance Update, Guidance on Prescription Drug Reporting (November 30, 2021).

[2] Data is aggregated by market segment.

- Fully insured plans use the same market segment that is used for Medical Loss Ratio ("MLR") reporting.
- Self-funded plans determine the number of employees by averaging the total number of all employees employed on business days during the calendar year preceding the reference year, using any reasonable method that takes into account full-time, part-time, and seasonal employees. Examples of reasonable methods include (1) the full-time equivalent method for ACA Employer Penalty purposes; (2) if a TPA is affiliated with an issuer, the counting method used by the issuer for MLR reporting; and (3) if an applicable state method takes into account non-fulltime employees, the applicable state method. Requires a narrative response.

[3] For self-funded plans, the reporting entity should generally report the data in the state where the plan sponsor has its principal place of business. However, when coverage is sponsored by a group trust, association, or multiple employer welfare arrangement ("MEWA"), data is reported in the state where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an "employer" under ERISA section 3(5) for purposes of

6.	Premiums	For self-funded plans, the premium equivalents
7.	Average monthly premiums paid by the employer and the enrollees	
8.	States in which the plan is offered	
9.	Number of enrollees	
10.	50 most common brand prescription drugs dispensed	
11.	50 most costly drugs by total annual spending	
12.	50 drugs with the greatest year-over-year cost increase for the plan	
13.	Total spending by the plan broken down by: 1. Types of cost (e.g., hospital, primary care, specialty care, medical benefit drugs, and other medical costs and services[4]) 2. Plan and enrollee spending on prescription drugs	
14.	Impact on premiums and out-of-pocket costs associated with rebates, fees, or other payments by drug manufacturers to the plan (narrative response)	Includes prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed 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 or coverage from drug manufacturers during the plan year

WHO MUST REPORT?

Employers with fully insured or self-funded (includes level funded) group health plans, including grandfathered plans, church plans subject to the Internal Revenue Code, and governmental plans.

The term “group health plan” does not include excepted benefits such as onsite clinics and accident-only policies. It also does not include account-based plans (e.g., HRAs or health FSAs).

sponsoring the plan) has its principal place of business or the state where the association is incorporated, in the case of an association with no principal place of business.

[4] Includes:

- Radiology and laboratory services that are billed independently by the laboratory
- Non-hospital based skilled nursing and hospice services
- Ambulance services not billed by a hospital facility
- Home health care
- Dental services and supplies
- Vision services and supplies
- Durable medical equipment
- Wellness services billed on a claim (i.e., covered under a plan or policy)
  - Clarification on this item would be welcome.

WHAT PERIODS ARE REPORTED?

Information is reported on a calendar year basis, regardless of plan year. This is referred to as a "reference year."

HOW IS DATA REPORTED?

Data is reported through the RxDC module in the Health Insurance Oversight System ("HIOS"). An account must be created unless the employer:

- already has a HIOS account; or
- is not uploading anything because another vendor is handling the full filing; or
- where the employer is uploading partial data, not including any files.

NOTE: It can take up to two weeks to create an account so plan sponsors should plan accordingly.

The instructions to create a CMS Enterprise Portal and HIOS accounts are in the HIOS Portal User Manual. The instructions for using the RxDC module are in the RxDC HIOS User Manual. To log in to HIOS, go to the CMS Enterprise Portal at https://portal.cms.gov/portal/.

CAN A VENDOR SUBMIT INFORMATION ON THE EMPLOYER'S BEHALF?

Yes.

- Insured plans may enter into a written agreement with their carriers to transfer responsibility and liability for reporting to the carrier which USI recommends.
- Self-funded plans may enter into a written agreement with their third-party administrator ("TPA"), pharmacy benefit manager ("PBM"), or other vendor to fulfill reporting function on behalf of the plan; however, the plan sponsor remains liable for any failures.

An entity that submits some or all required information is called a "reporting entity." Reporting entities may charge additional fees for compiling and filing the data.

A plan, issuer, or carrier can allow multiple reporting entities to submit on its behalf. For example, a self-funded group health plan may contract with a TPA to submit the Spending by Category data file and separately contract with a PBM to submit the Top 50 Most Costly Drugs file. Plans, issuers, carriers, and their reporting entities must work together so that each data file submitted in HIOS contains all required information. If one reporting entity is responsible for only some of the fields in a data file, it should fill out those fields and then give the data file to the other reporting entity to complete the remaining information before submitting the data file in HIOS.

Some of the above-listed data points may not be known by the issuer, TPAs, PBMs, or other vendors. Employers should be prepared to receive a request for information from the carrier, TPA, or PBM and either timely provide the information or prepare to do a partial filing.

USI Note. Some carriers, TPAs, and PBMs have started to release information as it relates to this reporting. For example:

- UnitedHealthcare has indicated they will submit the full report for fully insured business. For self-funded business:
  - UnitedHealthcare will submit the full report where coverage is integrated with UnitedHealthcare (includes UMR and All Savers), except employer will submit P2, D1 for UHC/ASO key accounts, national accounts, public sector cases and Surest/Bind plans (UHC handles the rest).
  - If UHC is not the PBM (carve-out, including OptumRx Direct) or stop loss administrator, plan sponsors must ensure their vendors submit the appropriate files.
  - See specific UHC reporting details here, "CAA FAQ," Pharmacy Benefits and Cost Reporting (page 98), July 11, 2022. https://www.uhc.com/content/dam/uhcdotcom/en/HealthReform/PDF/Provisions/reform-CAA-external-faq.pdf.
- CVS (a PBM) offers an option where it will submit certain data files (D3-D8) on behalf of the plan, but the employer remains responsible for submitting all Plan Files, Data Files D1-D2, and the narrative response (likely in coordination with the medical plan TPA).

If a plan, issuer, or carrier changes vendors during the reference year (such as changing a TPA or PBM), there are two reporting options:

1. The previous vendor reports the data from earlier in the year and the new vendor reports the data from later in the year; or
2. The previous vendor provides the data to the new vendor and the new vendor reports the entire year of data.

Either way, the plan sponsor must ensure that all their data is reported and that it is not double reported.

For mixed-funded plans, which generally self-fund some benefits and fully insure other benefits, the self-funded business is reported in the self-funded market segment and the fully insured business is reported in the fully insured market segment. For example, suppose a large employer self-funds the pharmacy benefit of a plan and purchases insurance for the medical benefits. In this case, the pharmacy benefits would be attributed to the market segment for self-funded large employer plans and the medical component of the same plan would be attributed to the fully insured large group market.

Currently, CMS does not have a mechanism to notify plans, issuers, or carriers when data has been submitted on their behalf. To confirm submission, plans should contact their reporting entities directly.

WHAT IF A PLAN SPONSOR MOVES FROM A FULLY INSURED PRODUCT TO SELF-FUNDED COVERAGE IN THE MIDDLE OF THE REFERENCE YEAR (OR VICE VERSA)?

The fully insured business is reported in the small group or large group market segments and the self-funded business is reported in the self-funded small employer or large employer market segments.

WHEN IS THE DEADLINE?

The last day to submit data for the 2020 and 2021 reference years is **December 27, 2022**. The deadline for subsequent reference years is **June 1st** of the calendar year immediately following the reference year. So, June 1, 2023, is the second deadline, reporting calendar year 2022 information.

WHAT IS THE PENALTY FOR NONCOMPLIANCE?

The penalty is $100 per affected individual. In addition, the DOL can enforce compliance.

IS THERE ANY RELIEF?

For the 2020 and 2021 reference years only, the Departments 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 those data elements are not available and they are reported for the 2022 reference year and all future reference years.

WHERE DO I GO FOR ADDITIONAL INFORMATION?

For additional information on the requirements, please visit: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

There remain many unanswered questions with respect to this reporting. Hopefully, the Departments will issue further guidance before the due date.

Issuers, TPAs, PBMs, and other third-party vendors are expected to be reaching out to plan sponsors in the coming months.