Drug reporting rules present challenges for many

In this article

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A new prescription drug reporting mandate, adopted as part of the 2021 Consolidated Appropriations Act (CAA) (Pub. L. No. 116-260), requires group health plans and health insurers to report detailed data about prescription drug pricing (including rebates) and healthcare spending. The first reports are due by Dec. 27, 2022, and annually thereafter. The departments of Labor, Treasury, and Health and Human Services will use the information to prepare a biannual, publicly available report. The departments have issued interim final rules (IFR) detailing the data to report and submission instructions describing the mechanics of the reporting process. This GRIST summarizes the prescription drug reporting rules and identifies compliance challenges facing group health plans.

Overview of CAA prescription drug reporting and transparency

The high cost of prescription drugs is a common source of frustration for many stakeholders in the US healthcare system, including employers sponsoring health plans and plan participants. Employers have supported efforts to make prescription drug pricing — with its web of rebates, discounts and pricing mechanisms — more transparent. Transparency could help address wide price variations, reduce healthcare waste and help individuals make informed choices about their healthcare spending. Mercer has a long-standing commitment to improving healthcare quality, affordability and accessibility for US workers and their families. Price transparency (including the CAA's reporting requirements) is a critical part of that effort.

The No Surprises Act portion of the CAA tackles transparency in prescription drug pricing by requiring group health plans and health insurers to report a wide swath of information about their prescription drug spending. These reports must include information about the impact of complex drug pricing mechanisms — rebates, fees and other remuneration paid by drug manufacturers — on premiums. The submission instructions require plans and insurers to report to the Centers for Medicare & Medicaid Services (CMS) a wide variety of information on overall plan spending beyond prescription drugs, presumably for comparison with prescription drug spending.

Reporting challenges for group health plan sponsors. Unfortunately, group health plan sponsors rarely have access to much of this information. Although the departments acknowledge that the required information resides with plan vendors, the guidance does not meaningfully shift reporting responsibility to vendors — at least for self-funded plans. Employers must coordinate their vendors' information reporting and are liable for all reporting failures, even for vendor-reported data to which employers have no access.

The new reporting requirement is particularly challenging for self-funded group health plan sponsors with multiple vendors and complicated plan designs. Sponsors of self-funded plans — especially those using carve-out and point-solution vendors to administer aspects of their health plans — must identify impacted vendors, coordinate their reporting, and verify that the reporting is complete and not duplicative. The current system does not automatically generate a verification for plan sponsors when a report is submitted or accepted without errors.

No allowance for good-faith compliance relief. To date, the departments have not provided relief for plans and insurers that make good-faith efforts to comply with the law. Such relief in advance of the first reporting deadline would be welcome, given the sweeping nature of the requested data, the departments' acknowledgment that employer plan sponsors do not possess the requested data, as well as the many reporting challenges described in this GRIST.

First reports due Dec. 27, 2022. Plans must report data for each calendar year (referred to as the reference year), beginning with 2020. The CAA originally imposed a Dec. 27, 2021, deadline to report 2020 data, but the departments issued FAQs deferring enforcement for one year. Accordingly, plans must first report data by Dec. 27, 2022, for both the 2020 and 2021 reference years. Beginning with the 2022 reference year, data must be reported by the following June 1.

Transparency payoff at plan level uncertain. Given the significant effort required, employers may expect long-awaited, unprecedented transparency into prescription drug prices. But the department's deidentified biannual report to Congress will presumably focus on national trends, offering employers little visibility into their own plan's prescription drug prices. The departments are encouraging vendors to report CAA prescription drug pricing data in the aggregate. In contrast, the 2020 transparency-in-coverage (TiC) regulations require plan-specific, publicly available prescription drug pricing information in machine-readable files (MRFs). Although the departments put this portion of the TiC regulations on hold after the CAA was enacted, that type of plan-level transparency data could give plan sponsors greater insight into their own plan's spending and the spending of other plans. The significant differences

between the CAA and TiC requirements are discussed more fully in the *Impact on transparency-in-coverage rules* section.

Reporting responsibility

The CAA obligates group health plans and health insurers to do the prescription drug reporting, even though a plan's vendors — which may include third-party administrators (TPAs), pharmacy benefit managers (PBMs) or other medical plan service providers — actually possess the relevant data. While the departments indicated they lacked authority to require data submission by vendors, plans or insurers may enter into written contracts requiring vendors to do the reporting. This appears to be the departments' preferred arrangement.

The departments are seeking aggregate, line-of-business data from insurers, TPAs and PBMs to satisfy reporting. Group health plans will want to confirm the extent to which each vendor with reportable data will assist with CAA reporting. The departments note that plans may need to revise vendor contracts to address liability for and accuracy of reporting, as well as how the plan can review the reporting. But regardless of who reports the data, the group health plan will remain liable for any reporting failures or errors, with one narrow exception described below. A group health plan retains this liability, even though the plan may not be able to view what is filed on its behalf, and most of the plan's data likely will be aggregated and filed along with multiple other unrelated plans.

Special rule for fully insured plans. A fully insured plan may shift all liability for reporting failures to the insurer, but only if the employer and insurer execute a written agreement requiring the insurer to report the information in compliance with the IFR. Whether insurers will agree to these terms remains to be seen. Self-funded plans do not have any opportunity to shift liability to a vendor, and the IFR does not provide a rationale for the different treatment.

Assistance from vendors will be critical. Few, if any, employers have sufficient access to the data necessary to satisfy the prescription drug reporting rules. Accordingly, vendors have a key role in the reporting. The departments expect that vendors will report the vast majority of data in an aggregated form rather than at the plan-specific level. Employers should immediately confirm whether their vendor will submit required data on the plan's behalf and determine specifically whether the vendor is willing to report both plan-specific and aggregate data. If a vendor is unwilling to report plan-specific data, an employer needs to determine if another vendor will. Otherwise, an employer may have to report this information on its own.

*Fully insured plans***.** The insurer of a fully insured plan presumably will report all aggregate data, since the insurer is itself subject to the reporting requirement. However, employers sponsoring fully insured plans should confirm this fact, address who will report plan-specific data and sign a written agreement with the insurer reflecting these terms to ensure compliance.

Self-funded plans. Because vendors administering self-funded benefits are not directly subject to the reporting rules, self-funded plan sponsors should contact all relevant vendors to determine the level of

assistance they will provide and work with legal counsel to review contracts to determine the vendor's contractual obligation to assist with reporting and share liability in the event of failure.

Switching insurers or vendors. Employers should consider what will happen if they switch insurers or vendors — whether in the ordinary course of business, due to a corporate transaction or for any other reason. The IFR does not address this issue. A former insurer presumably would have to report reference-year data, even if it no longer insures a plan as of the reporting deadline. But because a self-funded plan's vendor is not directly liable for reporting, self-funded plan sponsors should consider addressing this issue contractually.

> *Example.* XYZ Co. sponsors a self-funded calendar-year medical plan. During 2023, Alpha Inc. administers the medical plan (including its prescription drug benefits). XYZ Co. switches TPAs for the 2024 plan year. By the time reporting for the 2023 reference year is due in June 2024, Alpha is no longer administering XYZ's medical plan. Fortunately, the contract entered into by Alpha and XYZ obligated Alpha to report CAA prescription drug and healthcare spending data to CMS for the 2023 reference year, even if the contract wasn't renewed.

Covered plans

The CAA's drug and healthcare spending reporting requirement applies to a broad swath of health plans, including most employer-sponsored group health plans. The chart below summarizes which types of plans are subject to the CAA's reporting requirement.

Health plans required to report data	Health plans *not* required to report data
Fully insured and self-funded group health plans, including: • Church plans subject to the Internal Revenue Code • Nonfederal governmental plans	Account-based plans, such as: • Health reimbursement arrangements (HRAs) • Individual-coverage HRAs • Health savings accounts • Health flexible spending arrangements
Insurers offering group coverage	Excepted benefits Dental and vision plans Employee assistance programs Hospital or other fixed indemnity insurance Disease-specific insurance Retiree-only plans
Insurers offering individual health plans Public exchange plans Individual plans offered outside public exchanges Student health plans Individual coverage through an association	Medicare Advantage and Part D plans

Health plans required to report data	Health plans *not* required to report data
Grandfathered plans	Medicaid plans
"Grandmothered" plans (certain individual and small-market plans issued before Jan. 1, 2014)	State Children's Health Insurance Program plans
Federal Employees Health Benefits (FEHB) Program plans	Basic Health Program plans

The reporting rules do not expressly exclude expatriate health plans or stand-alone telehealth plans that are permitted during the COVID-19 public health emergency. The departments have been asked to exclude these plans, since their data would not serve the purpose of the prescription drug reporting.

Required data

A group health plan or insurer must report (or arrange for reporting) two types of data: a small amount of plan-specific information, plus an extensive amount of aggregate data.

Plan-specific data

The following plan-level data must be reported:

- Identifying information for plans, insurers, plan sponsors and any other reporting entities
- Applicable plan year
- Covered participant-beneficiary count on the last day of the reference year
- Each state where the plan or coverage is offered

The health plan sponsor may directly report this information to CMS, or insurers or TPAs may report the information on the sponsor's behalf. If a health plan sponsor is going to report directly to CMS, the sponsor may need to register to use the CMS Enterprise Portal by creating a Health Insurance Oversight System (HIOS) account. The full instructions for creating a CMS Enterprise Portal and HIOS account are in the HIOS Portal User Manual. Additional information is available on the CMS RxDC page; also see the *Reporting process* section.

Aggregate data

Most required data will be reported in the aggregate by an insurer or a vendor. A single self-funded plan could report this data on its own behalf, but the departments expect and encourage TPAs (or other vendors) to report aggregate data on behalf of all plans administered to minimize submissions. CMS also notes that aggregate data will be more useful since the TPA or PBM can determine the top 50 lists based on a larger sample size.

How aggregation works

The rules encourage any entity reporting for multiple plans to submit an aggregated report for its book of business instead of a different report for each plan administered or insured. This data must be reported by state and market segment.

By state. The state is generally determined by a self-funded plan sponsor's principal place of business or the policy situs for a fully insured plan. Special rules apply to health coverage through a multiple-employer welfare association or a group trust.

By market segment. The data reported will be categorized as one of the seven market segments:

- Individual market, except for student plans
- Student market
- Fully insured small-group market
- Fully insured large-group market
- Self-funded small-group market
- Self-funded large-group market
- FEHB

The departments have provided instructions about how to categorize various plans within these market segments. Plan data for employers with more than 100 employees in the prior calendar year generally will be categorized as part of the large-group market. Level-funded plans — where the employer pays plan costs up to a certain capped amount — are treated as self-funded. Minimum-premium plans are reported as fully insured.

Aggregate data to report

Extensive data will be required in each of three categories:

- **Top 50 lists:** the top 50 prescription drugs by highest cost, increase in cost and frequency of dispensing
- **Plan spending information:** total plan spending on healthcare, prescription drugs and premiums, broken down by a number of categories
- **Prescription drug rebate information:** rebate information, including by therapeutic class of drugs and the top 25 prescription drugs with highest rebates and other price concessions.

See the *Appendix: Aggregate data reporting requirements* for detailed reporting requirements in each category. A few specific topics are addressed here.

Rebates. Health plans and insurers must report extensive data on prescription drug rebates, broadly defined as any remuneration relating to drugs prescribed to plan enrollees that is received by or on behalf of the plan or insurer, its PBM, or other service provider. Discounts, chargebacks, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods-in-kind, grants or other price concessions count as rebates, as do bona fide service fees paid by a manufacturer to the PBM. The rebate can be from any source. The reporting must show how rebates defrayed plan costs. If the plan shares all or part of a rebate at the point of sale, then the reporting will need to show how the rebate is allocated. The concept of allocation is not clearly explained in the instructions.

Rebates do not include cost-sharing assistance that manufacturers provide directly to plan enrollees (such as coupons or copay cards). However, manufacturer cost-sharing assistance must be reported as part of total annual spending to the extent (i) the health plan or insurer knows about the assistance, and (ii) it reduces spending by the plan or its enrollees. For example, a manufacturer's cost-sharing assistance that is not applied to the deductible or out-of-pocket maximum would reduce the plan's reported total annual spending.

Multiple vendors. Given the breadth of the aggregate data to report, many group health plans will need assistance from multiple vendors. Employers with multiple TPAs and PBMs will need to engage *all* vendors early in the process to ensure that reporting on the plan's behalf is completed.

The rules confirm that multiple vendors may report data for one plan but do not require that TPAs and PBMs work together to compile the top 50 (or 25) drug lists. Instead, the PBM can compile these lists without coordinating with the TPA of a medical or hospital benefit that may also cover drugs — for example, the drugs provided to patients while admitted to a hospital. But in other instances, the instructions appear to implicitly require vendor collaboration.

> *Example.* A self-funded plan sponsor has a carved-out prescription drug benefit. Most of the prescription drug data will reside with the PBM, but some data (like annual healthcare service costs and plan premiums) will reside with the medical TPA. The PBM and medical TPA may collaborate on a report submitted by one entity or may separately report the plan's data. Neither the rules nor the instructions explicitly state that the PBM and TPA *must* collaborate, but the instructions state that the vendors should not each submit the same data file for the same plan. A total of eight data files must be submitted for the plan, and some data files may require input from more than one entity. For example, one data file (the "D2") asks for spending information on the health plan and pharmacy benefit, so submitting one D2 would require coordination between the PBM and TPA. Since this seems at odds with permitting multiple submissions, confirmation from the departments would be helpful. The preamble to the regulations states that the departments intend to build a system allowing multiple entities to report different subsets of information for the same plan, so perhaps this issue will be resolved in the future.

The instructions are not clear as to how an employer with multiple TPAs for different self-funded coverage packages will submit data. The instructions say that multiple reporting entities should not submit the same data file for a plan but do not specify how a plan with more than one TPA or PBM should submit data. The HIOS system currently doesn't automatically prevent duplicate submissions of

the same file, but CMS intends to check for duplicate files after the submission deadline. Additional guidance from the departments on how to file in these situations would be useful.

Employers may also have point-solution vendors (such as for fertility or telehealth benefits) with data that must be reported. Employers should identify all vendors that might have reportable data and ensure each vendor is reporting all aggregate data, or make other arrangements to report required data. Again, additional guidance on how to file in these situations would be welcome.

Wellness programs. The CAA explicitly lists "other medical services, including wellness programs" as a subcategory of total annual healthcare spending information to report. Given the wide variety of programs described under the "wellness" umbrella, practitioners wondered *which* wellness programs or expenses must be reported. In fact, some wellness vendors may be unaware that prescription drug reporting includes wellness programs.

The IFR does not define wellness programs, but the instructions state that wellness expenses for services primarily designed to implement, promote, and increase health and wellness should be reported. One example provided is a public health education campaign conducted with state or local health departments, which suggests that reporting is not limited to wellness plans that can be classified as medical. (Other examples provided are wellness/lifestyle coaching programs designed to achieve specific and measurable improvements, coaching programs for those with chronic disease, and coaching or education programs and health promotion activities to change behavior.)

The instructions carve out from reporting the cost of a wellness service or activity that is not a quality improvement expense (as defined by medical loss ratio (MLR) rules). While insurers may have experience classifying costs under the MLR rules, employers with uninsured programs will find it challenging to apply these instructions to the wide variety of wellness programs offered to employees.

Employers might argue that an uninsured wellness program independent of a group health plan is not subject to reporting, since the reporting obligation applies to insurers and group health plans. But the instructions appear to require reporting on such a program, stating that a wellness expense that cannot be "tied to" a plan, insurer, state or market segment should be reported using a "reasonable method" to allocate the expense across states and market segments.

Employers should review their full array of wellness programs, analyze whether cost reporting is required, and determine whether the insurer or vendor administering the program will do the reporting. The instructions specify that actual rewards, incentives, bonuses or cost-sharing reductions that are not reflected in premiums or claims must be reported. Arguably, this could include a tobacco surcharge or an annual physical incentive. The administrative fees of a wellness program appear to be excluded. Only wellness incentives actually paid out need to be reported; plan sponsors need not report the value of unearned incentives. Employers should consider whether their TPAs or PBMs would have access to this information, and if not, prepare to report it or provide to the vendor to include with its reporting.

Premiums. Plans and insurers must report information about premiums, including the average monthly premiums paid by the employer and enrollees. The premium amount for a fully insured plan is calculated based on MLR rules. For self-funded plans, the IFR defines the premium as the total cost of providing

and maintaining coverage, including claims, administrative fees and stop-loss premiums. Some of the required premium information, such as stop-loss premiums or monthly amounts paid by the employee and employer, is probably known only by employer plan sponsor. Employers should prepare to provide this information to the reporting vendor or to self-report premium information.

Narrative response data

In addition to the plan-specific and aggregate data files, plans and insurers must submit a separate narrative response file in either .docx or .pdf format that provides seven explanations on some of the contents and how they were calculated, including:

- Employer size for self-funded plans
- Wellness services description
- Drug rebate descriptions, allocation methods, and impact on plan premiums and out-of-pocket costs

A template for the narrative response has not been provided.

Reporting process

All data must be reported to CMS. The submission will be through the prescription drug data collection (RxDC) module, known as the Enterprise Portal. The reporting entity will need a HIOS account.

Confirming vendor compliance. If a vendor reports data on behalf of a group health plan, the group health plan cannot access the vendor's filing, nor will the plan receive electronic confirmation of the vendor's filing from the CMS system. Plan sponsors should seek verification directly from the reporting entity (or entities) to confirm the reporting — particularly if the plan sponsor will be liable for any reporting errors or failures. Plan sponsors should also consider asking for a copy or "cut" of the data submitted on their behalf, along with the date submitted, to demonstrate compliance. This is discussed further in the *Impact on transparency-in-coverage rules* section.

Enforcement

Neither the CAA nor the IFR describes how the departments must enforce the new CAA reporting requirement. The departments presumably will look to existing enforcement measures to ensure compliance by insurers and group health plans (with the potential for daily IRS penalties of $100 per participant for noncompliance). Under the Public Health Service Act, states have enforcement authority over insurers, but the Department of Health and Human Services (HHS) will enforce federal requirements if a state fails to do so.

HHS is proposing a different construct for enforcement of the new CAA prescription drug reporting requirement. Referring to its proposed air ambulance surprise-billing regulations, HHS seeks direct enforcement authority over reporting by insurers, instead of leaving enforcement to state insurance departments — unless the department receives notice that a state intends to enforce the reporting

requirement. HHS reasons that since the reporting will take place on an HHS website, states won't have access to the reported data necessary to assess compliance. Resolution of the enforcement issue is expected in final regulations later this year.

Use of reported data

The departments will use the reported data to prepare a publicly available report about prescription drug reimbursements and pricing, and the role of prescription drugs in premium increases. The first report is due within 18 months of the first submission of data, and the departments must issue a report every other year thereafter. The 18-month timeframe appears to be triggered by the original statutory reporting deadline — Dec. 27, 2021 — which means that the departments' first report would be due before May 27, 2023.

The report will be posted on the internet, with data aggregated to eliminate any individually identifiable or plan-specific information. The departments expect the reported data will help identify excessive drug pricing due to market concentration, promote generic drugs and address the cost impact of drug manufacturer rebates.

Impact on transparency-in-coverage rules

Less than two months before the CAA became law, the departments issued the TiC regulations, which — like the CAA — obligate health plans and insurers to disclose prescription drug information. One section of the TiC regulations requires health plans and insurers to publicly post machine-readable files (MRFs) disclosing certain prescription drug pricing information. Though the prescription drug MRF requirement was slated to begin with the 2022 plan year, the departments have indefinitely deferred enforcement of this provision (and have encouraged states to do the same). Given concerns about overlap and duplication between the TiC and CAA prescription drug disclosures, the departments are considering whether the TiC prescription drug MRF requirement remains appropriate.

Although the TiC regulations and the CAA both aim to increase transparency in prescription drug pricing, the chart below identifies some key differences between the two sets of reporting requirements.

Key differences	CAA prescription drug reporting	TiC regulations
Governing statute	CAA	Affordable Care Act
Information to report	Cost data on top 50 drugs, healthcare services, rebates and other information	MRFs containing negotiated rates and historical net prices for all covered drugs
Reporting method	Reported confidentially through CMS web portal	Posted on plan's public website
Frequency of reporting	Annually for prior reference year	Updated monthly

Key differences	CAA prescription drug reporting	TiC regulations
Scope of data	Typically, aggregate data for an insurer's, a PBM's or a vendor's book of business	Plan-specific information

Because the MRFs would have contained the *plan-specific* pricing information about *all* covered drugs, employers likely would have learned more about their plan's prescription drug pricing from the TiC prescription drug disclosures. In contrast, most vendors are expected to report aggregated CAA-required prescription drug information for each of seven market segments and may or may not provide a copy of that information to plan sponsors.

Although the prescription drug reporting rules don't require a vendor to provide its aggregated report to each plan sponsor, an employer can always ask its vendor for a copy. A plan sponsor may be able to argue, depending on the facts and circumstances, that a particular TPA, PBM, carrier or other service provider *must* disclose its report under the CAA's broker/consultant provisions. Whether such an argument will succeed is unclear, since the guidance available to date doesn't address this issue.

Employers interested in their own plan's transparency data may want to ask their vendor to provide their plan's information disaggregated from the CAA report. An employer could consider negotiating for this disaggregated data as part of its vendor contract.

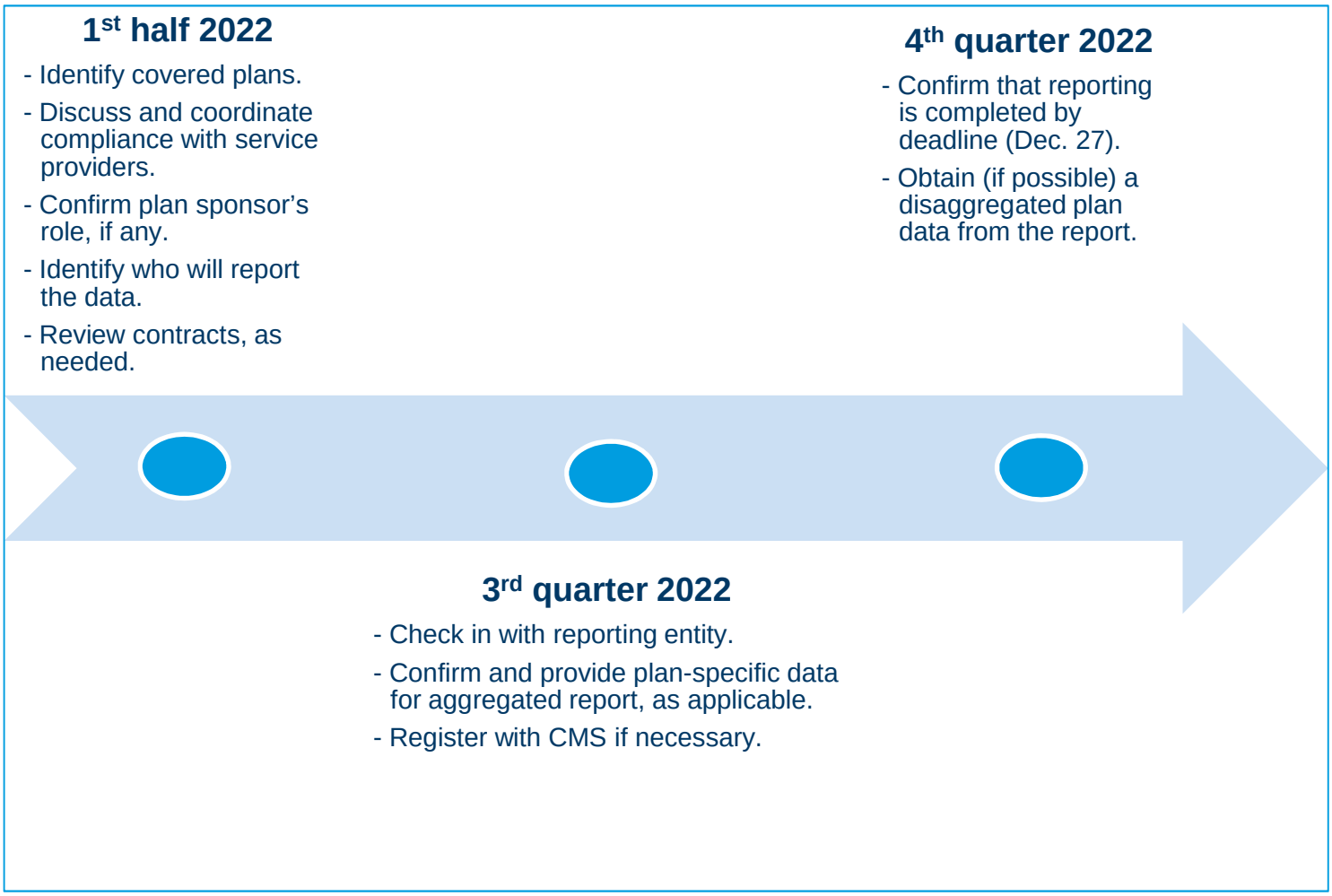
Next steps for employers

To comply with the CAA's prescription drug reporting requirement, most employers will need significant assistance from their vendors, since vendors — not employers — possess the necessary data. Here are some steps to prepare:

- Identify all plans subject to the reporting requirement, and all internal sources, vendors and wellness programs with required data.
- Confirm that the insurer of any fully insured plan will report all required aggregate data. Ask the insurer how it will report plan-specific data as well. Ensure that the insurer has agreed in writing to do this reporting.
- For self-funded plans, determine how you will file, including the level of assistance needed from each administrator of a self-funded benefit. Multiple vendors may have the required data that needs to be coordinated.
  - Decide whether to:
    - Rely on vendors to file the required aggregate data and plan-specific data on your behalf.
    - File plan-specific data on your own, but rely on vendors to file the required aggregate data.

    - File all required information on your own rather than using aggregate data (this may depend on whether a particular vendor will provide the necessary data to you for filing purposes).
  - Give special consideration to the above decision if the plan uses more than one TPA or PBM for different benefit packages. The third option immediately above may be the preferred method for self-funded plans with complex, multiple vendor plans.
  - Confirm that each relevant vendor will either provide the necessary data for you to report or report all required aggregate data on your behalf, and coordinate submission strategy if necessary.
    - If a vendor is reporting on your behalf, request disaggregated data from the vendor. The instructions suggest that a plan "should contact its reporting entities directly if the plan wants to see the data uploaded on its behalf."
  - If you intend to file the entire report or plan-specific data directly, register with CMS.
  - Review what wellness incentive information needs to be reported and where to obtain that information (for example, through a wellness vendor, TPA/insurer and/or the employer).
- Monitor each vendor's or insurer's process to comply by the applicable deadline. Ask the vendor to provide verification of the data submitted to CMS.
- Review and revise vendor contracts to ensure compliance with the CAA prescription drug reporting obligation. Ensure that the contracts:
  - Allow for the necessary flow of data so the vendor can provide data to you and report CAA information as needed, including after termination of the contract.
  - Sufficiently require assistance with reporting and protect the plan sponsor and plan in the event of a reporting failure (for example, by indemnification, performance guarantee or other contractual provisions).
- Watch for additional guidance and possible litigation. The departments sought comments on the entire IFR, and indicated that they intend to issue final regulations promptly upon receipt of such comments. Employers will need to review and comply with any additional guidance when issued.

The following page has a suggested timeline of important employer activities for the remainder of 2022 — the reference year for which the first reports will be due.



Related resources

Non-Mercer resources

- Prescription drug data collection (RxDC) (CMS)
- Prescription drug data collection (RxDC) reporting instructions (CMS, Dec. 16, 2021)
- Interim final rules with request for comments (Federal Register, Nov. 23, 2021)
- FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 implementation part 49 (DOL, HHS and Treasury, Aug. 20, 2021)

- Request for information regarding reporting on pharmacy benefits and prescription drug costs (Federal Register, June 23, 2021)
- Section 204, Title II, Division BB of the 2021 CAA (Congress, Dec. 27, 2020)
- Transparency-in-coverage regulations for group health plans and health insurance issuers (Federal Register, Nov. 12, 2020)

Mercer Law & Policy resources

- Mercer, ERIC provide more input on CAA prescription drug reporting (Jan. 28, 2022)
- Mercer, ERIC comment on CAA prescription drug reporting rules (July 23, 2021)
- Mercer comments on proposed transparency-in-coverage rules (Jan. 31, 2020)

Other Mercer resources

- Comments in response to Healthy Future Task Force Affordability Subcommittee RFI (Feb. 4, 2022)
- Comments on prescription drug reporting RFI (Mercer and ERIC, Jan. 24, 2022)
- Regulators clarify implementation timeline of transparency provisions (Aug. 25, 2021)
- Comments on proposed transparency-in-coverage regulations (Jan. 29, 2020)

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Appendix: Aggregate data reporting requirements

The following reporting requirements come from the IFR and Appendix A of the reporting instructions.

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Top 50 lists			
Top 50 most frequently dispensed brand name drugs	D3	• Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Determine by number of paid claims during reference year. • Use CMS crosswalk file to identify which drugs are brand name. • Include manufacturer cost-sharing assistance. • Report only drugs covered by pharmacy benefit; exclude drugs covered under a nonpharmacy benefit (such as drugs administered in a provider setting and covered by medical plan).
Top 50 most costly drugs	D4	• Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Determine by total annual spending for each drug (by plan sponsor and enrollees), net of rebates. • Include manufacturer cost-sharing assistance. • Report only drugs covered by pharmacy benefit; exclude drugs covered by a nonpharmacy benefit (such as drugs administered in a provider setting and covered by medical plan).

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Top 50 lists (cont'd)			
Top 50 drugs by spending increase (in dollar amount, not percentage)	D5	For reference year and preceding year: • Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Determine by dollar increase, not percentage increase. • Use difference between annual spending (by plan sponsor and enrollees) in reference year and immediately preceding year. • Include only drugs that were FDA-approved for marketing or emergency use authorization for entire reference year and preceding year. • Include manufacturer cost-sharing assistance. • Report only drugs covered by pharmacy benefit; exclude drugs covered by a nonpharmacy benefit (such as drugs administered in a provider setting and covered by medical plan).
Plan spending information			
Total annual healthcare spending	D2	• Hospital costs • Primary care costs • Specialty care costs • Prescription drug costs • Other medical costs, including wellness services	• Calculate total annual spending net of rebates, and exclude payments for services other than medical care (e.g., medical management, quality improvement or fraud detection). • Include claims incurred during reference year, but not paid or reported as of March 31 of following year (i.e., still in adjustment process). • Report drugs covered under nonpharmacy benefits in relevant hospital or medical category; report pharmacy benefits in prescription drug category. • Include manufacturer cost-sharing assistance.

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Plan spending information (cont'd)			
Prescription drug spending	D6	• Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Report all prescription drug spending by pharmacy benefit or nonpharmacy benefit. • D6 does not ask for last three subcategories, so where to report them is unclear.
Premium spending and life-years	D1	• Average monthly premium paid by employer • Average monthly premium paid by enrollees • Total of life-years • Total annual premium amount and total number of life-years	• Include amounts paid by plan sponsors like employee organizations that may not directly employ participant in average employer contribution. • Calculate life-years as the total months of coverage for participants and beneficiaries, divided by 12.
Prescription drug rebate information			
Total rebates, fees and other remuneration	D6	• Total annual reporting (not by drug) • Difference between what plan pays PBMs and what PBMs pay to pharmacies (the "spread") • Bona fide service fees that manufacturer pays to a PBM	• Include spending by nonpharmacy benefit (good-faith effort required where cost is difficult to determine, as in bundled or alternative payment arrangements). • Must restate total rebates from the prior reference year as of March 31 of the reporting year.

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Prescription drug rebate information (cont'd)			
Prescription drug rebates by therapeutic class	D7	For each therapeutic class of prescription drugs: • Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims • Rebates, excluding bona fide service fees, passed through to the plan or insurer • Rebates, excluding bona fide service fees, passed to plan enrollees at the point of sale – Manufacturer cost-sharing assistance is reported separately. • Rebates, excluding bona fide service fees, retained by PBMs	• Must use therapeutic class name and code. • Report only drugs covered by pharmacy benefit; exclude drugs covered by a nonpharmacy benefit (such as drugs administered in a provider setting).

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Prescription drug rebate information (cont'd)			
Top 25 prescription drugs with highest rebates and other price concessions for the reference year	D8	For each drug: • Total annual plan spending • Total annual spending by enrollees • Number of enrollees with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims • Rebates, excluding bona fide service fees, passed through to the plan or insurer • Rebates, excluding bona fide service fees, passed to plan enrollees at the point of sale – Manufacturer cost-sharing assistance is reported separately. • Rebates, excluding bona fide service fees, retained by PBMs	• Must rank top 25 rebated drugs. • Report only drugs covered by pharmacy benefit; exclude drugs covered by a nonpharmacy benefit (such as drugs administered in a provider setting and covered by medical plan).
Method used to allocate rebates, fees and other remuneration	None	Not applicable	• Requires a narrative response. • Consult Section 7.2 of the instructions for examples of reasonable allocation methods. For example, allocating rebates for multiple drugs based on total dosage units for each drug as a percent of total drug spending is reasonable, but allocating rebates based on plan enrollment is unreasonable.

Data to report for the reference year	Data file name*	Data subcategories to report	Key details
Prescription drug rebate information (cont'd)			
Impact of rebates on premiums and cost sharing	None	Not applicable	• Requires a narrative response. • See Section 8 of the instructions for details on how rebates may impact premiums and out-of-pocket costs, including: – Differences in the impact by market segment or plan type and reasons for those differences – The impact of rebates on tier assignments in the formulary – A quantitative estimate of the impact, if possible