Drug reporting rules present challenges for many

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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 (HHS) will use the information to prepare a biannual, publicly available report. The departments have issued an interim final rule (IFR) detailing the data to report, and the Centers for Medicare & Medicaid Services (CMS) has issued 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. *The latest update to this GRIST reflects CMS FAQs posted through Nov. 7 on its Prescription Drug Data Collection (RxDC) website and adds a new appendix with answers to some common employer questions.*

Overview of RxDC 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 instructions require plans and insurers to report to 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, plan sponsors rarely have access to much of this information. Although the departments acknowledge that the required information resides primarily with plan vendors, the guidance does not meaningfully shift reporting responsibility to vendors — at least for self-funded plans. Employers must ensure all information is reported 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 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 the health plan — must identify impacted vendors, confirm that the vendors will submit required data, verify the reporting is complete and not duplicative, and, in limited instances, self-report data. The current system does not automatically generate a verification for plan sponsors when a report is submitted or accepted without errors.

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 each of the 2020 and 2021 reference years. Beginning with the 2022 reference year, data must be reported by the following June 1.

No general good-faith compliance relief. The departments have not yet provided general 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. Employer advocacy groups have joined with other stakeholders to request general good-faith reporting relief.

Nonenforcement relief limited to average monthly premium information for employers and members. Other than the one-year deferral of enforcement discussed above, the only relief included in the instructions appears to primarily assist *vendors* rather than plan sponsors. Concerned that insurers and third-party administrators (TPAs) will have difficulty obtaining information about the average monthly premiums paid by employers and employees, the departments will not take enforcement actions related to these particular fields only for the 2020 and 2021 reference years. Plan sponsors, which may also have difficulty obtaining cooperation or information from their vendors, would benefit greatly from

broader, general good-faith compliance relief. As background, the instructions define a "member" as anyone enrolled in health coverage, including employees, enrollees, dependents and participants.

Transparency payoff at plan level uncertain. Given the significant effort required, employers may expect long-awaited, unprecedented transparency into prescription drug prices. But the departments' deidentified biannual report to Congress presumably will 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's enactment, that type of plan-level transparency data could give plan sponsors greater insight into the spending of their own plan vs. other plans. The significant differences between the CAA and TiC requirements are discussed more fully in the *Impact on TiC rules* section.

Reporting responsibility

The CAA obligates group health plans and health insurers to do the RxDC reporting, even though a plan's vendors — which may include TPAs, pharmacy benefit managers (PBMs) or other medical plan service providers — actually possess most 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, as they seek 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 reporting entity 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. In some limited instances, self-funded plan sponsors may find that they must self-report some or all of the requested information. 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 submitted on its behalf, and even if the plan's data is aggregated and submitted with many other unrelated plans' data.

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. Self-funded plans do not have any opportunity to shift liability to a vendor under the regulations, although some vendors may provide indemnities for certain errors and omissions.

Assistance from vendors will be critical

Few, if any, employers have sufficient access to the data necessary to satisfy the RxDC 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 level. Employers should

immediately confirm whether their vendor will submit required data directly to CMS on the plan's behalf, and determine specifically whether the vendor is willing to report both plan-specific and aggregate data. All vendors will need to report certain plan-specific information to identify the plans included in their submissions, but vendors may not possess *all* of the plan-specific information required. Vendors also may need to provide plan-level data to those employers that may have to submit the report on their own in certain circumstances (discussed below).

Fully insured plans. The insurer of a fully insured plan presumably will report all aggregate data, since the insurer itself is subject to reporting aggregate data. However, employers sponsoring fully insured plans should confirm this fact, confirm that the insurer has the necessary 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 or indemnify for 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 instructions address a few specific scenarios: reporting a prior vendor's data after a midyear vendor switch, and reporting year-over-year prescription drug cost increases and prior-year rebates after a year-end vendor switch. In each of these situations, the prior vendor may report data for its time servicing the plan or provide that data to the new vendor. CMS FAQs on top 50 drugs and rebates, fees, and other remunerations reiterate that each vendor may report data for its time servicing the plan — even if that results in a in a "disconnect" in the reporting (CMS FAQs 23129 and 23130).

> *Example.* Hudson Ferries Co. sponsors a group health plan that has carved out prescription drug benefits to Alpha Drugs Co., beginning Jan. 1, 2021. Before then, Beta Drugs Inc. was the PBM for Hudson Ferries' plan. Beta is unwilling to provide 2020 data for Alpha to submit, but each PBM will submit aggregate data for its period servicing the plan — i.e., Beta submits 2020 data, and Alpha submits 2021 data. CMS has confirmed this is acceptable, despite creating a "disconnect" in the submissions (for example, Alpha will compile its list of the top 50 drugs with the greatest year-over-year increase using Hudson Ferries' 2021 data but not its 2020 data).

A plan that switches vendors at year-end presumably could rely more broadly on these instructions to allow its prior vendor to either do the reporting or provide data to the employer or its new vendor.

This flexibility is helpful and likely resolves the issue for insured plans. To comply with the reporting obligations, a plan's former insurer presumably would have to report reference-year data — even if it no longer insures a plan as of the reporting deadline — or provide the data to its successor. But because a self-funded plan's vendor is not directly liable for reporting and the instructions do not *require* the prior

vendor to submit or provide the data, the prior vendor may have little incentive to do this reporting or provide relevant data. Self-funded plan sponsors should consider contractually addressing this issue.

> *Example.* Liberty Lines Co. sponsors a self-funded calendar-year medical plan. During 2023, Alpha Inc. administers the medical plan (including its prescription drug benefits). Liberty 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 Liberty's medical plan. Although the instructions suggest that Alpha could either report or provide Liberty's data to the new TPA, neither the CAA nor the RxDC reporting guidance *require* that Alpha do so. However, the contract entered into by Alpha and Liberty obligates Alpha to report CAA prescription drug and healthcare spending data to CMS for the 2023 reference year, even though 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 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, such as: • Limited-scope 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
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 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 RxDC 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 (in some cases, that data may be plan-level). In addition, narrative responses are required.

Plan-specific data

Each reporting entity submitting data on behalf of a group health plan must submit a P2 file with plan-specific information. Any data submission without a plan-specific file will be rejected by the Health Insurance Oversight System (HIOS) portal.

The P2 must contain information in the following fields or it will result in a HIOS error:

- Group health plan name and a unique plan identification number
- HIOS plan ID (only for fully insured small-group plans)
- Market segment (for example, the fully insured large-group market)
- Name and employer identification number (EIN) of plan sponsor
- Each state in which the plan or coverage is offered, using two-character state or territorial postal codes (separated by semicolons or “national” where applicable)
- Plan year beginning and end dates

A P2 file must also indicate what data files the reporting entity will submit in the “Included in” fields. For example, a PBM’s P2 file might indicate that the PBM is submitting the D3 through D8 files, but not a D1 or D2 file.

CMS guidance allows reporting entities to use a placeholder for some fields to avoid receiving a HIOS upload error. (For example, the reporting entity could use the starting and end dates of the reference year instead of the starting and end dates of the plan year.) As a result, not *every* P2 has to contain *all* of the plan-specific information listed above. Nevertheless, for each group health plan, the following plan-specific data should be reported on *at least one* P2 file:

- Plan year beginning and end dates
- Each state in which the plan or coverage is offered
- Count of covered members (including dependents) on the last day of the reference year (i.e., Dec. 31); enter “0” if plan terminates before that date

The unique plan identification number required on the P2 file may or may not be same as the Form 5500 plan number for an ERISA plan. Plan sponsors may want to populate the additional field for the Form 5500 plan number on at least one P2 file, especially if the unique plan identification number is not the same as the Form 5500 plan number. Further guidance from CMS on this issue would be helpful.

The P2 is more complex for plans with multiple vendors. CMS has provided examples of how plans with multiple vendors submitting aggregate data should complete the P2 file. See the *Multiple vendors* discussion below. However, plans can reduce the need for CMS to contact entities for follow-up if the reporting entities enter the name and EIN of all reporting entities submitting for the same plan. The P2 ideally should identify the vendor submitting the P2 and any other reporting entities using the following fields:

- Issuer name and EIN
- TPA name and EIN
- PBM name and EIN

Aggregate data

The departments hope that most required data will be reported in the aggregate by an insurer or a vendor. A 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. Restrictions on multiple reporting entities in the instructions would have required many plan sponsors to submit plan-level data themselves, but a subsequent CMS FAQ, discussed below, should allow most employers to rely on their vendors' aggregate submissions.

How aggregation works

The rules allow any entity reporting for multiple plans to submit an aggregated report for its book of business. A CMS FAQ (23159) goes further, stating that each vendor should create only one HIOS submission with data for all of the vendor's clients combined into one of each file type, instead of a different report for each plan administered or insured. This data must be reported by state and market segment.

By state. For the data files, the state is generally determined by a self-funded plan sponsor's principal place of business (which is different from how the state is reported for the P2 file) or the state in which the policy was issued 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 instructions clarify how to categorize various plans within these market segments. Plan data for employers with more than 50 employees generally will be categorized as part of the large-group market. Fully insured plans use the market segment for medical loss ratio (MLR) reporting; four states (California, Colorado, New York and Vermont) use a 100-employee threshold for MLR purposes. Self-funded plans look to the year before the reference year and may use any reasonable method that accounts for full-time, part-time and seasonal employees to determine the average number of employees on business days. Self-funded employers must provide information about how they determined their size in the narrative response if they do not use one of the CMS-approved methods. Level-funded plans — under which the employer pays plan costs up to a certain capped amount — are treated as self-funded. Minimum-premium plans — which have a regular fixed premium or funding payment, often based on past claims experience — are reported as fully insured.

Aggregate data to report

Extensive data will be required in each of four 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 remuneration.
- **Premium spending information:** information about the monthly premiums paid by the employer and members, plus information about total life-years.

See *Appendix A: Aggregate data reporting requirements* for detailed reporting requirements in each category. This data will be reported on eight data files (D files) for each plan.

A few specific aggregate reporting topics are addressed here.

Multiple vendors. Given the breadth of the aggregate data to report, many group health plans will need assistance from multiple vendors, such as insurers, medical TPAs, PBMs and point-solution vendors.

Employers will need to engage *all* vendors with reportable data early in the process to ensure that reporting on the plan's behalf is completed. Fully insured plans should be able to rely on their insurers, which are required to submit aggregate data for their book of business. Recent CMS guidance, described below, should allow more self-funded plans with multiple vendors to rely on their vendors' aggregate data submissions to satisfy most, if not all, of the plan's reporting obligations. However, since the vendors administering a self-funded plan are not directly subject to the RxDC reporting requirements, plans should confirm that each vendor will submit aggregate data by the deadline. Additional steps to ensure compliance are addressed in *Next steps for employers* and *Q&As about specific scenarios*.

Pharmacy benefits administered by PBMs. The instructions minimize the need for a TPA and PBM to coordinate their submissions by separating pharmacy benefit reporting from all other healthcare spending reporting and allowing multiple reporting entities to submit different data files on behalf of the same plan directly to CMS. This greatly simplifies reporting for a plan that has carved out pharmacy benefits to a PBM. The PBM should be able be able to report all required pharmacy information — such as the top 50 (or 25) lists — without coordinating with the TPA of a medical or hospital benefit that may also cover drugs.

- Information about prescription drugs covered by the pharmacy benefit will be reported on files **D3 through D8.** No information about drugs covered by the medical plan will be reported on files D3 through D8.
- Information about prescription drugs covered under a medical benefit (such as drugs provided to patients while admitted to a hospital), as well as healthcare spending not related to prescription drugs (such as hospital, specialty and primary care spending), must be reported on the **D2 file**.
- Both the TPA and PBM must submit a **P2 file**, and CMS (FAQ 23127) has provided a sample P2 file in which a TPA identifies the PBM (and vice versa). While this is how CMS says the TPA and PBM *should* complete their P2 files, some may be unwilling to list the other on their aggregate submission. CMS doesn't address whether the plan is *required* to submit a P2 listing its vendors in this instance, but some plans may want to do so to ensure compliance, particularly if they have to submit another file (e.g., the D1 file).

*Multiple TPAs, multiple PBMs or point solutions***.** Many self-funded plans have more than one vendor with reportable data for the same *type* of file. For example, a self-funded plan that carves out behavioral health benefits will have two vendors with reportable healthcare spending data for the plan's D2 file. Likewise, a self-funded plan offering multiple benefit packages may have multiple TPAs or PBMs with reportable data for the same data file type.

A CMS FAQ (23128) confirms that the agency will accept multiple data files *of the same type* (e.g., two or more D2 files, each with information about total annual healthcare spending) from the same group health plan, if "extenuating circumstances" exist. The FAQ "instructs reporting entities to contact the CMS help desk at CMS_FEBS@cms.hhs.gov if there are 'extenuating circumstances' that prevent vendors from working together to submit a unique file for each data file type."

This is a welcome change from the instructions, which limited each group health plan to eight data files and would have required plan sponsors to step in and combine plan data if vendors were unwilling to do so.

CMS provides several examples in which multiple vendors submit the same data file *type* for one plan. In each example, the plan-specific P2 files connect the plan with the multiple data files submitted by its vendors.

> *Example.* Empire Co. sponsors a self-funded plan, offering a medical benefit administered by Alpha Co., with behavioral health coverage carved out and administered by Epsilon Inc. CMS assumes that both Alpha and Epsilon will submit a D1 and a D2 file. On the CMS sample P2 file, Alpha and Epsilon each identify the other by name and EIN. The Empire Co. plan must provide Alpha with Epsilon's name and EIN (and vice versa) to include on the P2 each submits or submit a P2 file itself to alert CMS that Alpha and Epsilon are submitting the same file type on the plan's behalf.
>
> *Example.* Big Apple Co. sponsors a group health plan that offers employees two fully insured benefit packages: one option insured by Alpha Insurance Co. and a second insured by Delta Insurance Co. CMS assumes that Beta and Delta will each submit a D2 file (presumably, each also would submit the remaining data files (D1 and D3 through D8), but that isn't specified in the example). On the P2 file, each insurer would use distinct names and numbers for each Big Apple benefit package. Alternatively, Big Apple's plan can submit a P2 file identifying the two insurers submitting data on the plan's behalf. CMS states that if a plan does not ensure that its vendors use different plan names and numbers or that CMS receives a P2 file listing of all of the plan's vendors, the agency "would need to follow up with the reporting entities to determine whether duplicate data has been submitted."

CMS has not given an example of "extenuating circumstances" that prevent a plan's vendors from working together to produce one file. Since few, if any, vendors have been willing to work together to submit data files, perhaps *all* plans will be able to demonstrate extenuating circumstances, but clarification would be helpful. Plan sponsors should document what their vendors are willing to do for the submission. Whether plans *must* contact the CMS help desk before relying on multiple data files is unclear. CMS likely is aware of the situation and probably wouldn't want to receive emails from every plan with vendors unwilling to combine data, but confirmation would be helpful.

Aggregation restriction. The IFR and the instructions include an aggregation restriction, which could reduce the number of plans able to rely on their PBM's aggregate submission of pharmacy data. The instructions state that pharmacy data submitted in files D1 and D3 through D8 may not be aggregated "at a less granular level" than the D2 file. This means that if the D2 file, which reports all healthcare spending other than the pharmacy benefit, is not aggregated "by the issuer or TPA" but is instead submitted at the plan level, all files requiring pharmacy benefit data must also be submitted at the plan level. As discussed in the *Multiple vendors* discussion above, recent CMS FAQs should allow most plans to rely on their vendors' aggregate D2 files, blunting the impact of the aggregation restriction. But there may be some plans — for example, those administered by a medical TPA unwilling to submit aggregate data — who must submit a plan-level D2 file. Relief from the aggregation restriction would be helpful.

Premiums. Plans and insurers must report information about premiums, including the average monthly premiums paid by the employer and members, on the D1 file, subject to the limited enforcement relief discussed above (see *Nonenforcement relief limited to average monthly premium information for employers and members*). The premium amount for a fully insured plan is calculated using 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. The instructions allow self-funded plans to use the same costs that are taken into account for calculating COBRA rates (minus the 2% administrative fee) as the total cost of providing and maintaining coverage. However, stop-loss premiums must still be reported on a separate line in the D1 file. Some required premium information, such as stop-loss premiums or monthly amounts paid by employees and the employer, is probably known only by the employer. Employers should prepare to either provide this information to the reporting entity (to the extent that the vendor lacks this data and will accept it) or consider self-reporting the premium information.

Rebates. Health plans and insurers must report extensive data on prescription drug rebates, broadly defined as any remuneration relating to drugs prescribed to members and 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 members (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) the assistance reduces spending by the plan or its members. 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.

Wellness. The CAA explicitly lists "other medical costs, including wellness services" as a subcategory of total annual healthcare spending information to report. The IFR does not define wellness services, but the instructions state that for purposes of this reporting, wellness services are "activities primarily designed to implement, promote, and improve health." CMS's initial instructions would have required reporting by a wide range of wellness programs, but the updated instructions pare back the wellness services subject to reporting by providing the following guidelines:

- Only wellness services "billed on a claim" should be reported.
- Only wellness services covered under a plan or policy should be reported.
- Wellness services should be reported with other medical costs and services rather than as a separate line item.

A CMS FAQ (23094) focuses on whether a wellness service was "billed on a claim." For example, a gift card for completing a smoking-cessation program that was *not* billed on a claim should not be reported, while the cost of a nicotine patch placement, for which the medical provider submits a claim, should be reported on the D2 file. Employers should identify which benefits are wellness services, determine which of those are covered by a plan and billed on a claim, and identify who will do the reporting.

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. Multiple reporting entities can submit a narrative response for the same plan, but the following seven topics should be addressed (if applicable):

- Employer size for self-funded plans (applicable only if the size is based on an estimate and not an actual count)
- Net payments from federal or state reinsurance or cost-sharing reduction programs
- Drugs missing from the CMS crosswalk
- Medical benefit drugs
- Prescription drug rebate descriptions
- Allocation methods for prescription drug rebates (applicable only if the method is not one approved in the instructions)
- Impact of prescription drug rebates

The narrative response is causing some confusion for plan sponsors:

- What level of response will be considered sufficient is unclear. CMS has not provided a template for the narrative response and has offered sample language for only the sixth topic — allocation methods for prescription drug rebates.
- Although the instructions state that *all* topics must be addressed, two topics may be unnecessary, as discussed above.
- Plan sponsors may reasonably expect that TPAs and PBMs would submit narrative responses — some topics fall squarely within the expertise of service providers (e.g., drugs missing from the CMS crosswalk). But a few topics may require some coordination, at least for self-funded plan sponsors:
  - Self-funded plans should confirm that a vendor intends to submit a narrative response about how the employer's size was determined.
  - CMS asks for detailed information on how rebates impact premiums, out-of-pocket costs, tier assignments in the formulary, and the removal of generic drugs from the formulary, plus how that

impact varies by market segment or plan type. Plan sponsors should confirm that the vendor submitting the plan's pharmacy data is providing an adequate narrative response to this question.

Optional supplemental document. The RxDC application allows but does not require reporting entities to submit an optional supplemental narrative providing additional information, perhaps to document any extenuating circumstances related to vendor submissions. The document must be in .docx or .pdf format.

Reporting process

All data submissions are through the HIOS module on the CMS Enterprise Portal. The reporting entity will need a HIOS account, and two or more individuals will need to sign up for access. The CMS RxDC page provides technical instructions on how to create a HIOS account and submit data. A CMS FAQ (23107) confirms that a group health plan needs a HIOS account *only* if it is submitting data itself.

Confirming vendor compliance. If a vendor reports data on behalf of a group health plan, the plan cannot access the vendor's submission and won't receive electronic confirmation of the vendor's submission from the CMS system. Plan sponsors — particularly if they will be liable for any reporting errors or failures — should seek confirmation of the submission directly from the reporting entity (or entities). Plan sponsors should also consider asking for a copy or "cut" of the data submitted on the plan's behalf, along with the date submitted, to demonstrate compliance. This is discussed further under *Impact on TiC rules*.

Enforcement

Neither the CAA nor the IFR describes how the departments must enforce the new CAA reporting requirement. The departments presumably will use 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 HHS will enforce federal requirements if a state fails to do so.

HHS is proposing a different construct for enforcing the RxDC 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 would be welcome.

Use of reported data

The departments will use the reported data to prepare a public report about prescription drug reimbursements and pricing and the role of prescription drugs in premium increases. The departments'

first report is due 18 months after deadline for the first submission of data from plans and insurers—presumably June 2023. The departments must issue a report every other year thereafter.

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 TiC rules

Less than two months before the CAA became law, the departments issued 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 overlapping and duplicative 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 RxDC 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
Scope of data	Typically, aggregate data for an insurer's, a PBM's or a vendor's book of business	Plan-level information

Because the MRFs would have contained the *plan-level* pricing information about *all* covered drugs, employers likely would have learned more about their plan's prescription drug pricing from the TiC 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 RxDC 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 reporting entity 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 RxDC 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 group health plans subject to the reporting requirement, and all internal sources and vendors with required data.
  - Consider which point solutions fit within the definition of wellness services for reporting purposes.
  - Determine what wellness information is reportable (i.e., billed on a claim and part of a plan or policy), and where to obtain that information (for example, through a wellness vendor, TPA/insurer and/or the employer).
  - Review whether any point solutions that are not wellness programs are an excepted benefit or an account-based plan or are otherwise excludable from the submission.
- Review and revise applicable vendor contracts to ensure compliance with the CAA RxDC reporting obligation. Ensure that the contracts:
  - Allow for the necessary flow of data so the vendor can provide data to the plan sponsor and report CAA information as needed, including after termination of the contract.
  - Require assistance with reporting and sufficiently protect the plan sponsor and plan in the event of a reporting failure (for example, by indemnification, performance guarantee or other contractual provisions).
- Confirm that the insurer of any fully insured plan will report all required aggregate data. Ask the insurer if it will report plan-specific data as well. Ensure that the insurer has agreed in writing to do this reporting.
- For self-funded plan sponsors, determine your submission strategy, including the level of assistance needed from each administrator of a self-funded benefit.
  - Decide whether to:
    - Rely on vendors to submit the required aggregate data and plan-specific data on your behalf.

    - Submit plan-specific data on your own, but rely on vendors to submit the required aggregate data.
    - Submit all required information on your own, using plan-level rather than aggregate data (this may depend on whether a particular vendor will provide the necessary data to you).
  - If a vendor is reporting on your behalf:
    - Confirm that each vendor will report all required aggregate data on the plan's 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 a vendor is unwilling to submit aggregate data, confirm that the vendor will provide the necessary plan level data with sufficient time for you to report.
- Take additional steps if a group health plan intends to rely on multiple vendors' aggregate data submissions:
  - Document the extenuating circumstances preventing the submission of a single data file for the plan.
  - Develop a strategy to ensure that plan-specific information is properly submitted.
    - Plans with multiple vendors may need to provide information to vendors so each reporting entity can identify the plan's other vendors by name and EIN on the P2 file. Vendors administering separate benefit packages may be able to simply use distinct plan names and numbers on the P2 instead of identifying other vendors. To avoid CMS follow-up, at least one P2 should list all of the plan's vendors and their EINs. If the plan's vendors are unwilling to submit such a P2, the plan sponsor could consider submitting a complete P2 for the plan.
  - Risk-averse plan sponsors should discuss with legal counsel whether to take additional steps to ensure compliance, such as:
    - Submit a P2 file to document all of the plan's vendors.
    - Contact the CMS help desk about any extenuating circumstances.
    - Include an optional supplemental document explaining extenuating circumstances.
- Determine whether to submit any data directly to CMS. Consultation with legal counsel about the plan's specifics may be required. If submitting data directly, designate two or more individuals to apply for a HIOS account as soon as possible, and take the necessary additional steps to establish roles and register an organization to connect those accounts.
  - While most employers should be able to rely on their vendors' submissions, some vendors with reportable data may be unwilling to submit aggregate data to CMS.

  - In some situations, the plan sponsor may need to prepare and/or submit the P2 and/or D1 files on the plan's behalf. For example:
    - Some TPAs may be unwilling to submit a D1 file on a plan's behalf.
    - Some TPAs may be unwilling to accept data from the plan sponsor (like the plan number or stop-loss premium paid), causing the P2 and/or D1 files to be incomplete.
    - Some plan sponsors may decide to submit their own P2 file because they either disagree with the vendor's reporting strategy or want to ensure CMS has an accurate list of the plan's vendors.
    - Some plan sponsors may wish to submit narratives specifically addressing the plan.
  - Some plan sponsors may *want* to submit plan-level data. If each of the plan's vendors are willing to provide plan-level data for the plan sponsor to submit, the sponsor will gain greater transparency into the plan's healthcare and prescription drug costs. Unfortunately, getting all of a plan's vendors to agree to provide plan-level data may be difficult at this point.
- Monitor each vendor's or insurer's process to comply by the applicable deadline. Ask the vendor to provide verification of data submitted to CMS.
- Document and keep records of data prepared for your plan's submission, along with communications from vendors or other experts related to the submission. This may be necessary to show good-faith compliance with submission requirements or to provide additional information to CMS.
- 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. Stakeholder groups have requested broad good-faith compliance relief, among other things, from the departments. Employers will need to review and comply with any additional guidance issued.

Related resources

Non-Mercer resources

- Prescription drug data collection (RxDC) (CMS)
- Prescription drug data collection (RxDC) FAQs (CMS, Nov. 7, 2022)
- Prescription drug data collection (RxDC) reporting instructions (CMS, June 29, 2022, replacing an earlier Dec. 16, 2021, version)
- Interim final rule with request for comments (Federal Register, Nov. 23, 2021)
- FAQs about ACA and 2021 CAA 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)
- TiC 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

- Recent CMS FAQs simplify RxDC reporting (Sept. 29, 2022)
- Updated CMS instructions limit Rx reporting for wellness services (Sept. 8, 2022)
- New employer Rx reporting mandate is quickly approaching (Aug. 25, 2022)
- 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)

Note: Mercer is not engaged in the practice of law, accounting or medicine. Any commentary in this article does not constitute and is not a substitute for legal, tax or medical advice. Readers of this article should consult a legal, tax or medical expert for advice on those matters.

Appendix A: Aggregate data reporting requirements

The following reporting requirements come from the IFR and the 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 members • Number of members with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Determine by number of paid claims during reference year. • Use the CMS crosswalk file to identify which drugs are brand name. • Include manufacturer cost-sharing assistance. • Report only drugs covered by a pharmacy benefit; exclude drugs covered under a nonpharmacy benefit.
Top 50 most costly drugs	D4	• Total annual plan spending • Total annual spending by members • Number of members with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Determine by total annual spending (by plan sponsor and members) for each drug, net of rebates. • Include manufacturer cost-sharing assistance. • Report only drugs covered by a pharmacy benefit; exclude drugs covered by a nonpharmacy benefit.

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 members • Number of members 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 members) in reference year and immediately preceding year. • Include only drugs approved by the Food and Drug Administration (FDA) for marketing or emergency use for entire reference year and preceding year. • Include manufacturer cost-sharing assistance. • Report only drugs covered by the pharmacy benefit; exclude drugs covered by a nonpharmacy benefit.
Plan spending information			
Total annual healthcare spending	D2	• Hospital costs • Primary care costs • Specialty care costs • Prescription drug costs • Other medical costs and services • Known medical benefit drugs (e.g., separately billed) • Estimated medical benefit drugs (e.g., bundled or other alternative payment arrangements)	• Do not report pharmacy benefits on the D2. • Report drugs covered under nonpharmacy benefits in relevant hospital or medical category (and presumably broken down into known and estimated categories). • Calculate total annual spending according to instructions (e.g., net of rebates and excluding manufacturer cost-sharing assistance and payments for services other than medical care, such as medical management, quality improvement or fraud detection). • Include claims incurred during the reference year but not paid or reported as of March 31 of the following year (for 2021 and 2022 reference years, can choose later valuation date).

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 members • Number of members with a paid prescription drug claim • Total dosage units dispensed • Number of paid claims	• Report all prescription drug spending by only a pharmacy benefit. • Most recent version of the D6 does not appear to include the last four items (newly omitting total member spending).
Premium spending information			
Premium spending and life-years	D1	• Average monthly premium paid by employer** • Average monthly premium paid by members** • 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 total months of coverage for participants and beneficiaries divided by 12. • Self-funded plans report administrative services organization or TPA fees and stop-loss premiums paid).
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	• Report for a pharmacy benefit only. • 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 members • Number of members 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 members 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 a pharmacy benefit; exclude drugs covered by a nonpharmacy benefit. • 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)			
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 members • Number of members 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 members 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 a pharmacy benefit; exclude drugs covered by a nonpharmacy benefit. • Must restate total rebates from the prior reference year as of March 31 of the reporting year.
Method used to allocate rebates, fees and other remuneration	None	Not applicable	• Requires a narrative response. • Consult Section 9.2 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 percentage 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 10 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 – Impact of rebates on tier assignments in the formulary – Quantitative estimate of the impact, if possible

* The instructions provide that each plan must submit the aggregate data in eight "D" files.

** Nonenforcement relief for 2020 and 2021, subject to conditions.

Appendix B: Common employer Q&As

As the first RxDC reporting deadline approaches, employers sponsoring group health plans have many questions. Below are some common Q&As reflecting the guidance available to date. First are general Q&As about the mechanics of RxDC reporting, followed by Q&As addressing using hypothetical situations to demonstrate how reporting works.

General Q&As

Question 1. For the first RxDC submission, are the data for reference years 2020 and 2021 combined into one submission or submitted separately?

Answer 1. Separate submissions are required for each reference year**.** Keep in mind that a reference year is the calendar year, not the plan year. Even noncalendar-year plans must submit calendar-year data. CMS provides special rules for noncalendar-year plans in the instructions.

Question 2. When can data be submitted? Once submitted, can data be revised or corrected?

Answer 2. Data may be entered now with a "save-in-progress" feature, so a reporting entity doesn't have to complete the submission in one session. However, once data is submitted (i.e., "submit" is clicked and the submission status is marked "complete"), the reporting entity may have to work with the RxDC help desk at cms_feps@cms.hhs.gov to make corrections, unless or until CMS provides another process for corrections.

Question 3. Meeting the Dec. 27, 2022, deadline may be a challenge for some. Can employers submit data after that date?

Answer 3. Employers should submit data by the Dec. 27, 2022, deadline. Current guidance, including the instructions, doesn't address whether or how data for 2020 and 2021 can be submitted after that date. Stakeholders have urged the departments to leave the reporting system open and provide a 30-day grace period for late or revised submissions after the Dec. 27, 2022, deadline, when extenuating circumstances exist.

Question 4. Will most employers sponsoring group health plans (especially if self-funded) have to prepare files with plan-specific information (the P2) and premium spending information (the D1) themselves?

Answer 4. Probably not. Insured plan sponsors should be able to rely on their insurer to submit the P2 and D1 files (see Q&As 6 and 7). With regard to self-funded plans, many plan sponsors should be able to rely on their TPA to submit the P2 and D1 files. Many vendors will submit the P2 and D1 files on behalf of self-funded plans, although the vendor may need some information to do so (see discussion below).

In some situations, the plan sponsor may need to prepare and/or submit the P2 and D1 files or provide data to the TPA to prepare those files:

- Some TPAs may be unwilling to submit the D1 or a P2 with all required plan-specific information on a plan's behalf.
- Some plan sponsors may prefer to submit their own P2 to ensure compliance (see Q&As 7 and 11).
- Some of the P2 and D1 data (like the plan number) may be known only to the plan sponsor. The plan sponsor will need to provide this data to its vendors. Because *all* reporting entities must submit a P2, even a plan sponsor that intends to submit its own P2 and D1 may have to provide some information to its vendor for the *vendor's* P2 submission.

Question 5. If a plan sponsor must submit one or more data files (e.g., because a TPA, PBM or other vendor will not), what is the process?

Answer 5. The RxDC Quick Reference Guide is the primary resource for accessing HIOS through the CMS Enterprise Portal. Here are the major steps:

- At least two individuals per reporting entity (including a submitting plan sponsor) must obtain an active HIOS account because at least two role approvers are required. These individuals must go through the new user registration process on the CMS Enterprise Portal.
- When selecting an application, request access to the HIOS application.
- To verify identity, users must provide personally identifiable information (including Social Security number) and answer questions about their credit report. Users must also set up a device for multifactor authentication every time they log into HIOS.
- Once approved, a user must request a role and create an organization. Users should have the plan sponsor's EIN available to confirm whether the organization already exists in HIOS. If not, the user will need to provide high-level plan information.
- The major roles for RxDC reporting are company administrator (able to edit organization information), at least two organization role approvers (able to approve or deny roles) and RxDC submitter (able to submit RxDC data). An individual may have more than one role.

Other useful RxDC resources include:

- RxDC HIOS User Manual
- HIOS Portal User Manual

Section 3.1 of the instructions indicates that the registration process may take up to two weeks to create accounts and warns: "Don't wait until the last minute!"

Q&As about specific scenarios

Question 6. Tradewind Winery Inc. sponsors a fully insured group health plan for its employees. The plan, which includes prescription drug coverage, has been insured by Alpha Insurance Co. since 2017. How will Tradewind submit its RxDC reporting?

Answer 6. Because this plan is fully insured, Tradewind should be able to rely on Alpha for probably all of the reporting. Both Alpha and Tradewind are subject to the RxDC rules, and Alpha must submit aggregate data for its plans. Tradewind should confirm the following with Alpha:

- Will Alpha submit on Tradewind's behalf all of the plan-specific data required?
- Does Alpha need any information from Tradewind — such as information about employee and employer monthly premiums — to submit aggregate data?
- Has Alpha agreed in writing to complete the RxDC reporting for Tradewind? A written agreement is how Tradewind can shift RxDC reporting liability to Alpha.

Question 7. What if Tradewind offers its employees one plan with a choice of two fully insured benefit package options, each insured by a different insurance company? Can each insurer submit separate reports?

Answer 7. Yes. Each insurer presumably will separately report all aggregate data, and Tradewind should be able to rely on its insurers for most, if not all, reporting.

- Each of Tradewind's insurers is subject to RxDC reporting and must submit aggregate data for the its insured plans.
- CMS will accept multiple data files of the same type from the same group health plan if "extenuating circumstances" prevent the plan's vendors from working together.
  - CMS provided an example of one plan with two insured benefit package options. In CMS's example, each insurer submits data for its insured benefit package option, using different plan names and numbers for different benefit packages.

Key compliance steps for Tradewind include:

- Document the extenuating circumstances preventing the submission of a single set of data files.
- Confirm that each vendor will submit aggregate data to CMS on Tradewind's behalf and has all the plan-specific data needed to submit aggregate data.
- Enter into a written agreement with each vendor.
- Ensure that each vendor uses a different plan name and number for each benefit package in its submission.

  - If the vendors use the *same* group health plan name and number, Tradewind should ensure that all P2 files (certainly at least one P2 file) identify all plan vendors. Tradewind may be able to provide the information to one of its vendors to submit to CMS, or Tradewind could submit its own P2 file identifying its vendors.

- Confirm with legal counsel whether additional steps are required to rely on the vendors' aggregate submissions. For example, a plan sponsor that wants to take a more conservative approach might want to submit its own P2 file, contact the RxDC help desk about the extenuating circumstances or submit an optional supplemental document explaining the extenuating circumstances.

Question 8. Since 2017, Spirits Bottling Inc. has sponsored one group health plan with two benefit package options:

- **A fully insured package identical to the one described in Q&A 6**
- **A self-funded package, including prescription drug coverage, administered by Beta TPA Co.**

How will Spirits submit its RxDC reporting?

Answer 8. Spirits should be able to rely on its insurer and TPA to report most — if not all —data on the employer's behalf.

- Like Tradewind in Q&A 6, Spirits should be able to rely on Alpha for the fully insured option's submission.
- Unlike an insurer, Beta isn't *required* to report Spirits' data for the self-funded option to CMS. However, most TPAs will submit data to CMS for any plan they administer, so Spirits should ask Beta the same questions asked of Alpha. One key difference: Even if Beta signs a contract agreeing to do the reporting, Spirits remains legally responsible for any failures.
  - Beta may ask Spirits to submit the P2 file with certain plan-specific information or the D1 file with premium spending information.
  - Beta also could provide Spirits all of the self-funded data to submit to CMS (this might be mandatory or optional).
- Spirits apparently doesn't have to combine the data for its insured and self-funded benefit options.
- Spirits should take the key compliance steps listed in the response to Q&A 7.

Note: This Q&A assumes that Spirits doesn't have carve-out or point-solution vendors with reportable data.

Question 9. Cool Quenchers Corp. sponsors the Cool Quenchers Health & Welfare Plan, which submits a Form 5500 under plan number 501. The plan offers employees one medical benefit option — a preferred provider organization (PPO) administered by Beta TPA Co. Cool Quenchers has carved out prescription drug coverage and contracts with a PBM, Gamma Rx Inc., to administer the plan's pharmacy benefits. Cool Quenchers hasn't changed any vendors in recent years and doesn't contract with any other carve-out or point-solution vendors.

How will Cool Quenchers submit its RxDC reporting?

Answer 9. Cool Quenchers should be able to rely on its TPA and PBM to report most data on the corporation's behalf.

- As discussed in Q&A 8 above, a TPA like Beta isn't *required* to report aggregate data for its self-funded clients. The same is true for PBMs managing the pharmacy benefits of a self-funded plan. However, most TPAs and PBMs will probably submit aggregate data for their book of business directly to CMS. Cool Quenchers should be able to rely on Beta's and Gamma Rx's aggregate book-of-business data submissions but should confirm this understanding in writing.
- Beta and Gamma Rx don't need to coordinate — each will submit separate data files.
  - Gamma Rx will likely report information about prescription drugs covered by the pharmacy benefit on files D3 through D8 for its book of business.
  - Beta will likely report all other required health plan information (including prescription drugs covered under a medical benefit) in the aggregate for its book of business on the D2 file.
- Just as in Q&A 8, Cool Quenchers may have to submit some plan-specific or premium spending information itself or provide that information to Beta or Gamma Rx.
- What if either Beta or Gamma Rx refuses to submit aggregate data to CMS?
  - If Beta won't submit aggregate data for Cool Quenchers and it must submit the D2 file reporting its own plan-level data, then Cool Quenchers won't be able to rely on Gamma Rx's aggregate submission. This is because of the **aggregation restriction** discussed in the *Aggregate data to report*.
  - The aggregation restriction works in only one direction. If Gamma Rx won't submit aggregate data for Cool Quenchers, Cool Quenchers has a choice: either rely on Beta's aggregate submission or submit Beta's plan-level data.

Question 10. Same facts as Q&A 9, except the Cool Quenchers Health & Welfare Plan offers employees two medical coverage options:

- **A PPO administered by Beta TPA Co.**
- **A PPO administered by Delta TPA Co.**

For both options, Cool Quenchers has carved out prescription drug coverage and contracts with Gamma Rx Inc. to administer the pharmacy benefits. How will Cool Quenchers submit its RxDC reporting?

Answer 10. Cool Quenchers should be able to rely on its vendors to report most (if not all) data on its behalf. When two TPAs administer different benefit package options, the answer to Q&A 7 (one plan with two *insured* benefit package options) generally applies, except as follows:

- Unlike insurers, Beta and Delta are not *required* to submit aggregate data. Cool Quenchers should confirm that Beta and Delta will timely submit to CMS aggregate data files that include Cool Quenchers' data.
- What if Beta or Delta won't submit aggregate data for Cool Quenchers? As discussed in Q&A 9, Cool Quenchers won't be able to rely on Gamma Rx's aggregate submission because of the **aggregation restriction** in the rules.

With respect to Gamma Rx, just as in Q&A 9, Gamma Rx will probably submit aggregate data for its book of business directly to CMS and report that information on files D3 through D8.

- If the aggregation restriction applies, Gamma Rx's data would need to be reported at the plan level.

Question 11. Same facts as Q&A 9 but instead of carving out prescription drug coverage, Cool Quenchers has carved out behavioral health coverage and contracts with Epsilon Inc. to administer those benefits. How will Cool Quenchers submit its RxDC reporting?

Answer 11. Although this scenario seems similar to the one in Q&A 9, different issues arise when behavioral health benefits rather than pharmacy benefits are carved out.

- As stated in Q&A 9, most TPAs and PBMs probably will submit aggregate data for their book of business directly to CMS, although they are not required to do so. Whether other carve-out vendors with reportable data are prepared to submit aggregate data for their book of business directly to CMS is unclear. Cool Quenchers will have to confirm with Epsilon.
- Unlike the situation in Q&A 9 (where Beta and Gamma Rx each have data for different file types), both Beta TPA and Epsilon have healthcare spending information that must be reported on the same file type (the D2 file). But Beta and Epsilon should be able to submit separate D2 files. As discussed in Q&A 7, CMS recently confirmed that multiple reporting entities may submit the same data file type

(here, the D2 file) for the same plan if extenuating circumstances prevent the vendors from working together.

  - CMS provides an example in which a plan's TPA and behavioral health carve-out vendor, when submitting separate D2 files, must identify the other by name and EIN in the P2 file.

Key compliance steps for Cool Quenchers include:

- Document the extenuating circumstances that prevent submitting a single D2 file.
- Confirm that each vendor will submit aggregate data on a D2 file to CMS on Cool Quencher's behalf.
  - If either Beta TPA or Epsilon refuses to submit aggregate data to CMS, Cool Quenchers should confirm whether both will submit plan-level data to CMS. Cool Quenchers may have to submit the data itself through HIOS.
- Confirm whether Beta TPA or Epsilon will submit the plan-specific and premium spending information.
  - If not, Cool Quenchers will have to submit that information on the P2 and D1 files.
- Provide the name and EIN of Beta TPA to Epsilon, and vice versa.
  - If Cool Quenchers does not provide this information, Cool Quenchers will have to submit a P2 in HIOS to alert CMS that both Beta and Epsilon are submitting the same data file type on the employer's behalf.
- Enter into a written agreement with each vendor.
- Confirm with legal counsel whether additional steps are required to rely on the vendors' aggregate submissions. For example, a plan sponsor that wants to take a more conservative approach might want to submit its own P2 file, contact the RxDC help desk about the extenuating circumstances or submit an optional supplemental document explaining the extenuating circumstances.

Note: While a behavioral health carve-out vendor almost certainly has reportable data, many point-solution vendors do not have reportable data. Each point solution should be analyzed separately.

Question 12: Same facts as Q&A 9, except Cool Quenchers contracts with Gamma Rx Inc. to administer pharmacy benefits beginning Jan. 1, 2021. Before then, Sigma Scripts Corp. had administered the plan's pharmacy benefits. Beta TPA, Gamma Rx and Sigma Scripts are willing to submit aggregate data on their clients' behalf. Can Cool Quenchers rely on that aggregate reporting despite changing PBMs in 2021?

Answer 12. The guidance Q&A 9 should not change just because Cool Quenchers switched PBMs for 2021; Cool Quenchers should still be able to rely on its TPA's and PBMs' aggregate reporting. The instructions provide two options for submitting data after a change in vendors:

- **Option 1.** Each vendor can submit data for its period servicing the plan — i.e., Sigma Scripts submits 2020 data, and Gamma Rx submits 2021 data. CMS has confirmed this option is acceptable, despite creating a "disconnect" in the submissions (for example, Gamma Rx will compile its list of the top 50 drugs with the greatest year-over-year increase using Cool Quenchers' 2021 data but not its 2020 data).
- **Option 2.** Sigma Scripts can provide data to Gamma Rx, which will then submit data for both 2020 and 2021 on Cool Quenchers' behalf.

PBMs are unlikely to agree to Option 2 but *should* agree to Option 1. Cool Quenchers should reach out to its vendors to confirm that Sigma Scripts will submit the 2020 data as part of its aggregate submission and Gamma Rx will submit the 2021 data.