MZQ CONSULTING LLC
benefits compliance

DEEP DIVE: RXDC REPORTING GUIDE

WHAT IS RXDC REPORTING?

The Consolidated Appropriations Act, 2021 (CAA) creates a new requirement that insurance companies and employer-based health plans submit information about prescription drug and health care spending. Specifically, the federal government is seeking to collect and track information about: (1) spending on prescription drugs that account for the most spending, (2) prescription drugs that account for the most spending, (3) drugs that are prescribed most frequently, (4) prescription drug rebates from drug manufacturers, and (5) premiums and cost-sharing that patients pay.

According to CMS, this information will be used to:

- Identify major drivers of increases in prescription drug and health care spending;
- Understand how prescription drug rebates impact premiums and out-of-pocket costs; and
- Promote transparency in prescription drug pricing.

This information needs to be reported for calendar years 2020 and beyond. The first reports for calendar years 2020 and 2021 are due to CMS by December 27, 2022. After that, they will be due by June 1 annually.

WHAT PLANS ARE REQUIRED TO FILE?

Fully insured and self-funded group health plans, including governmental plans and church plans, must complete RxDC filings. Filings are not required for account-based plans (such as health reimbursement arrangements) or excepted benefit plans (like stand-alone dental/vision plans or short-term limited duration insurance).

For fully insured plans, carriers are legally responsible for the filings. In the case of self-funded plans, plan sponsors must ensure the filings are completed by the appropriate plan vendors. Special care will need to be taken for groups with prescription drug carve-outs because of the enhanced need for coordination discussed below.

HOW DOES THE DATA SUBMISSION PROCESS WORK?

Data will be submitted through an RxDC module in the Health Insurance Oversight System (HIOS) maintained by CMS.

WARNING: IT CAN TAKE UP TO TWO WEEKS TO CREATE AN ACCOUNT TO USE THIS SYSTEM!

Health plans are permitted to use third-party vendors to complete the filings. These vendors, called "reporting entities," can be TPAs, PBMs, or other vendors like MZQ Consulting providing reporting services.

Plans can also rely on multiple vendors to ensure their filings are complete. For example, a plan may use a TPA to submit information about the plan spend, but their PBM to submit the required pharmacy data.

THE JIGSAW PUZZLE

Here's where things get interesting…

For an RxDC Report to be ***complete***, 8 data files must be submitted for each plan. CMS anticipates that in many cases, not all 8 will come from the same source (mainly because of their permissive aggregation rules discussed in more detail below). As a result, every filing includes a list of the plans to which it relates.

CMS intends to use these plan lists as the "key" to completing the puzzle and associating the various forms of data. This will be a big task for CMS, and their instructions direct plans as follows:

> *"Multiple reporting entities should not submit the same data file for a plan, issuer or carrier."*

> *"Each reporting entity must submit one or more plan list files. That is how CMS will know when multiple entities are reporting for the same plan."*

> *"Plans, issuers, carriers, and their reporting entities must work together so that each data file submitted in HIOS contains all required information."*

And, if a plan changes vendor mid-year, the solution is "simple": both vendors can submit on their portion of the year, or they can coordinate the filings…

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

To summarize: 8 complete files must be provided for each plan. Coordination is required… And that's before we address the issue of data aggregation.

DATA AGGREGATION

While it is necessary to ensure data is reported for all plans in all categories, CMS does not intend to complete its analysis at the plan level. The actual analysis will be performed by market segment and state. As such, information is allowed to be submitted in aggregate form.

For this purpose, there are 7 mutually exclusive market segments: the individual market, the student market, the fully insured small group market, the fully insured large group market, self-funded plans offered by small employers (including level-funded plans), self-funded plans offered by large employers, and the Federal Employees Health Benefits Plan.

The rules go on to specify who can aggregate what for these purposes:

- TPAs can aggregate by ***state*** and ***market segment***.
- PBMs can aggregate by ***TPA***, ***state***, and ***market segment***.

But, the information in the prescription drug reporting files (that PBMs are likely to produce) can't be aggregated at a less granular level than the information in the plan spending files (that TPAs are likely to produce).

This basically means the PBM can't aggregate the files if the TPA doesn't aggregate the files. Thus, in a carve-out situation, PBMs will have to be prepared to report at the plan level because they can't guarantee that TPAs will be aggregating (or even reporting data) on behalf of their clients.

While it is clearly CMS's goal that data be reported at an aggregate level, this likely won't be practical in many circumstances. **MZQ Consulting recommends plans sponsors elect plan level reporting where: (1) they have a prescription drug carve-out, or (2) they changed TPAs or PBMs during a plan year.**

WHAT INFORMATION NEEDS TO BE INCLUDED?

All RxDC filings must include a list of the plans covered by the filing. For employer-plan purposes, this will be using a file named P2.

For each plan included in each submission, the P2 file includes:

- Group Health Plan Name
- Group Health Plan Number
- HIOS Plan ID
- Form 5500 Plan Number
- States in which the plan is offered
- Market Segment
- Plan Year Beginning Date
- Plan Year End Date
- Members as of 12/31 of the Reference Year
- Plan Sponsor Name
- Plan Sponsor EIN
- As applicable:
  - Issuer Name
  - Issuer EIN
  - TPA Name
  - TPA EIN
  - PBM Name
  - PBM EIN

- Indicators as to which of the required data files (described below) are included in the submission

8 data files also need to be submitted for each plan. These files are described in detail below.

D1—PREMIUM AND LIFE YEARS

File D1 includes the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State
- Market Segment
- Average Monthly Premium Paid by Members
  Total premium paid by members/total member months
- Average Monthly Premium Paid by Employers
  Total premium paid by employers/total member months
- Life Years

  To calculate:

  1. Count number of members (including dependents) as of a given day of each month.
  2. Add number of members each month of the year, then divide by 12
  3. Round to the 8th decimal place (yes, we think that's a little much too…)
- Earned Premium (for fully insured plans only)
- Premium Equivalents
  Include claims cost, administrative costs, ASO and other TPA fees, and stop loss premiums. COBRA rates (less the 2% admin fee) may be used.
- ASO/TPA Fees Paid
- Stop Loss Premium Paid

D2—SPENDING BY CATEGORY

File D2 includes the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State
- Market Segment
- Spending Category
- Total Spending

  This amount should include:

  - Payments by the plan, issuer, or carrier
  - Cost sharing paid by members
  - Claims liability (including claims incurred during the reporting year but not paid or reported as of March 31 of the following year)

  This amount should NOT include:

  - Payments from any federal or state reinsurance or cost-sharing reduction program
  - Prescription drug rebates, fees, or other renumeration
  - Manufacturer cost-assistance
  - Ineligible claims, duplicate claims, recovered claims overpayments, etc.
- Total Cost Sharing

  This amount should include:

  - Deductibles, coinsurance, and copayments

  This amount should NOT include:

  - Cost sharing paid by a member's secondary insurance
  - Prescription drug rebates, fees, or other renumeration
  - Cost sharing reductions the member paid on behalf of any federal or state reinsurance or cost-sharing reduction program
  - Premiums
  - Manufacturer cost-sharing assistance
- Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum

  Billed amounts that were not:

  - Applied to a member's deductible or out-of-pocket max;
  - Not paid by the plan, issuer, or carrier; and
  - Not included in total spending

  This amount should include:

  - Disallowed amounts for non-covered services or prescription drugs not on a plan or coverage's formulary
  - Cost-sharing amounts not applied to the deductible or out-of-pocket maximum

SPENDING CATEGORIES

Reporting is required in the following categories

HOSPITAL

All inpatient and outpatient facility services billed by the facility, including:

- Any claims with: a Place of Service Code of 21, 31, 32, 33, 34, 51, 56, or 61
- Medicare Severity Diagnosis-Related Group (MS-DRG) code
- All claims with revenue codes 010X-021X, or a valid revenue code on the UB-04 form and a CPT/HCPCS Code. Examples include (1) revenue codes 036X, 048X, 049X, 079X and CPT/HCPCS codes 10004-69999 and (2) revenue codes 045X and CPT/HCPCS codes 99281-99292
- Room and board, ancillary charges, services of resident providers, inpatient pharmacy, hospital-based nursing home and hospice care, and any other services billed by hospitals
- Services provided in psychiatric and substance abuse hospitals
- Facility services for medical, surgical, lab, radiology, therapy, maternity, skilled nursing, and other services that are billed by the facility
- Outpatient care, emergency services, or ambulance services only if billed by the facility
- Medications dispensed by an institutional pharmacy and administered on-site as part of a medical service. These include but are not limited to CPT/HCPCS codes J0000-J9999

The following should not be included:

- Any medication covered under the pharmacy benefit
- Amounts reported in primary care, specialty care, or other medical costs and services
- Provider services if independently billed
- Laboratory and radiology services that are billed independently by the laboratory (report these amounts in other medical costs and services)

PRIMARY CARE

A primary care provider is a provider who (1) has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine, and (2) is accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

The following should be included:

- Services billed with the following CPT/HCPCS codes and taxonomy codes: 99381-99397, 99460-99464, 99202-99215, 99304-99350, G0402, G0438, G0439, and any one of the taxonomy codes further specified by CMS
- Clinical health care services provided by other clinicians, such as nurse practitioners, clinical nurse specialists, or physician assistants, in a primary care setting
- Obstetrics and gynecology clinical health care services if performed by a primary care provider
- Administration of medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service

The following should not be included:

- Amounts reported in hospital, specialty care, or other medical costs and services
- Laboratory and radiology services that are billed independently by the laboratory (report these amounts in other medical costs and services)

SPECIALTY CARE

A specialist is generally a provider that focuses on a specific area of medicine or a group of patients to diagnose, manage, prevent, or treat certain types of diseases, symptoms, and conditions.

This category includes all professional services (other than primary care), including:

- ✔ Providers that have training in a specific area of health care and are not considered primary care providers
- ✔ Chiropractors, podiatrists, optometrists, and physical, occupational, and speech therapists that are not billed as part of hospital or facility services
- ✔ Doctor's office or outpatient care center services provided by specialists
- ✔ Hospital-based specialist services only if the specialist independently bills for those services
- ✔ Administration of medications dispensed by an institutional pharmacy and administered on-site as part of a clinical health care service

The following should not be included:

- ✔ Amounts reported in hospital, primary care, or other medical costs and services
- ✔ Dental services (report these as other medical costs)
- ✔ Laboratory and radiology services that are billed independently by the laboratory (report these amounts in other medical costs and services)

OTHER MEDICAL COSTS AND SERVICES

Spending for all other professional and facility clinical health care services and equipment not reported as hospital, primary care, or specialty care.

This category includes:

- ✔ Radiology and laboratory services that are billed independently by the laboratory (radiology: 70000–79999; laboratory and pathology: 36415; 36416; 80000–89999)
- ✔ Non-hospital based skilled nursing and hospice services
- ✔ Ambulance services not billed by a hospital facility
- ✔ Home health care
- ✔ Dental services and supplies
- ✔ Vision services and supplies
- ✔ Durable medical equipment
- ✔ Wellness services billed on a claim

The following should not be included:

- ✔ Amounts reported in hospital, primary care, or specialty care

MEDICAL BENEFIT DRUGS (KNOWN AMOUNTS)

Spending on drugs covered under a medical benefit that are separately billed or otherwise known exactly. These amounts are also reported under hospital, primary care, specialty care, or other medical costs and services as applicable. The "Total Cost Sharing" and "Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum" do not have to be completed for this category.

MEDICAL BENEFIT DRUGS (ESTIMATED AMOUNTS)

The estimated portion of bundled or alternative payment arrangements attributable to drugs covered under a medical benefit. Estimates should be made in good faith "to the best of your ability."

These amounts are also reported under hospital, primary care, specialty care, or other medical costs and services as applicable. The "Total Cost Sharing" and "Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum" do not have to be completed for this category.

D3—TOP 50 MOST FREQUENT BRAND DRUGS

D4—TOP 50 MOST COSTLY DRUGS

D5—TOP 50 BY SPENDING INCREASE

Files D3, D4 & D5 include the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State
- Market Segment
- Drug Name
  For brand name drugs: ingredient [brand name]
  For generic drugs: ingredient
- Drug Code
  CMS has published a crosswalk from NDC to RxDC drug codes
- Frequency/Cost/Spending Increase Rank
- Number of Paid Claims
- Number of Members with a Paid Claim
- Number of Dosage Units
  Dosage unit means the smallest unit in which the Rx is administered or dispensed (e.g., pill, capsule, mL, etc.)
- Total Spending
  Net rebates, fees, or other remuneration
- Total Cost Sharing
  Deductibles, coinsurance, and copayments
- Manufacturer Cost-Sharing Assistance
  Provide amounts paid through manufacturers assistance programs on behalf of members (like coupons or copay cards) to the extent available

D6—RX TOTALS

File D6 includes the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State
- Market Segment
- Total Rx Spending under Pharmacy Benefit
- Rx Amounts Not Applied to Deductible and/or Out-of-Pocket Maximum
- Bona Fide Service Fees
  Fair market value for services performed on behalf of the manufacturer that the manufacturer would otherwise perform
- PBM Spread Amounts
  Difference between what the plan paid to the PBM and what the PBM paid to the manufacturer
- Total Rebates/Fees/Other Remuneration
- Restated Prior Year Rebates/Fees/Other Remuneration

D7—RX REBATES BY THERAPEUTIC CLASS

File D7 includes the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State
- Market Segment
- Therapeutic Class Name
- Therapeutic Class Code
- Number of Paid Claims
- Number of Members with a Paid Claim
- Number of Dosage Units
- Total Spending
- Total Cost Sharing
- Manufacturer Cost-Sharing Assistance
- Rebates Retained by PBM
- Rebates Retained by Plan/Issuer/Carrier
- Rebates Passed to Member at POS
- Net Transfer of Fees and Other Remuneration from Manufacturer to Plan/Issuer/Carrier
- Net Transfer of Fees and Other Remuneration from Pharmacy to Plan/Issuer/Carrier
- Total Rebates/Fees/Other Remuneration
- Restated Prior Year Rebates/Fees/Other Remuneration

D8—RX REBATES FOR THE TOP 25 DRUGS

File D8 includes the following data elements:

- Issuer or TPA Name
- Issuer or TPA EIN
- State

- ✔ Market Segment
- ✔ Drug Name
- ✔ Drug Code
- ✔ Rebate Rank
- ✔ Number of Paid Claims
- ✔ Number of Members with a Paid Claim
- ✔ Number of Dosage Units
- ✔ Total Spending
- ✔ Total Cost Sharing
- ✔ Manufacturer Cost-Sharing Assistance
- ✔ Rebates Retained by PBM
- ✔ Rebates Retained by Plan/Issuer/Carrier
- ✔ Rebates Passed to Member at POS
- ✔ Net Transfer of Fees and Other Remuneration from Manufacturer to Plan/Issuer/Carrier
- ✔ Net Transfer of Fees and Other Remuneration from Pharmacy to Plan/Issuer/Carrier
- ✔ Total Rebates/Fees/Other Remuneration
- ✔ Restated Prior Year Rebates/Fees/Other Remuneration

"REBATE" GLOSSARY

Rebates Retained by PBMs —

Manufacturer rebates received by PBMs and not passed through to any member or entity;

Amounts received directly from a manufacturer or indirectly from a pharmacy, wholesaler, or other entity; and

Rebate amounts that are expected but have not yet been received if the PBM will retain the expected amounts.

Rebates Retained by Plans/Issuers/Carriers —

Manufacturer rebates received by plans, issuers, or carriers and not passed through to any member or entity;

Amounts received directly from a manufacturer or indirectly from a PBM, pharmacy, wholesaler, or other entity;

Rebate amounts that are expected but have not yet been received if the plan, issuer, or carrier will retain the expected amounts; and

Rebate guarantee amounts.

Rebates Passed to Members at POS —

Manufacturer rebates passed through (rather than retained by PBMs or plans/issuers/carriers) to members at the point of sale (POS) (Do not include manufacturer cost-sharing assistance).

Net Transfer of Fees and Other Remuneration from Manufacturer to Plan/Issuer/Carrier —

Price concessions, fees, and other remuneration provided to a plan, issuer, carrier, or PBM, directly or indirectly. For example, include the following amounts:

- ▸ Bona fide service fees (discounts, chargebacks, cash discounts)
- ▸ Free goods contingent on purchase agreement (up-front payments)
- ▸ Coupons
- ▸ Goods in kind
- ▸ Free or reduced-price services
- ▸ Grants
- ▸ Other price concessions or similar benefits

Also include fees and other remuneration that is expected but not yet transferred.

Do not include any remuneration, coupons, or price concessions for which the full value is passed on to the member.

Net Transfer of Fees and Other Remuneration from Pharmacy to Plan/Issuer/Carrier —

Report the amounts described above (in the data element for the net transfer of other remuneration from manufacturers to issuers, plans, carriers, and PBMs) except that the amount reported here should be the net transfer from pharmacies, wholesalers, and other entities, rather than from manufacturers.

Report net amounts.

Total Rebates/Fees/Other Remuneration —

The sum of the previous 5 data elements.

Restated Prior Year Rebates/Fees/Other Remuneration —

Restate total rebates and other remuneration from the prior reference year as of 3/31 of the calendar year following the current reference year (that is, incurred in 12 months, paid or received in 27 months).

So, for example, in the 2021 RxDC report, there would be one column for total rebates for 2021 (as of 3/31/2022) and another column for restated rebates for 2020 (restated as of 3/31/2022).

A reasonable method must be used to allocate rebates. The following methods are considered reasonable:

- **Based on dosage units**—allocate rebates received for multiple drugs based on total dosage units for each drug as a percent of total drug spending for all the prescription drugs for which the rebate was received.
- **Based on total drug spending**—allocate rebates received for multiple drugs based on total drug spending for each drug as a percent of total drug spending for all the prescription drugs for which the rebate was received.
- **Based on billed rebate amounts**—rebates received for a specific drug are allocated to a plan, issuer, or carrier and 11-digit NDC based on the rebate amounts billed to the pharmaceutical manufacturer for the specific plan, issuer, or carrier and drug as a percent of the total rebate amount billed to the pharmaceutical manufacturer for all the PBM's plans or issuers.
- **Based on plan's brand drug spending**—rebate amounts received for multiple drugs are allocated to a plan, issuer, or carrier based on the total drug spend for drugs under the plan, issuer, or carrier as a percent of the total drug spend for brand drugs under all of the PBM's plans or issuers, and further to a prescription drug based on the NDC-specific total drug spend under the plan, issuer, or carrier as a percent of the total drug spend for brand drugs under the plan, issuer, or carrier.

The following methods are not considered reasonable:

- **Based on enrollment**—rebates received for multiple drugs are allocated to a plan, issuer, or carrier for prescription drugs based on the number of members enrolled in the plan, issuer, or carrier as a percent of the total number of members enrolled in all the PBM's plans, issuers or carriers.
- **Based on the number of paid claims**—rebates received for multiple drugs are allocated to a plan, issuer, or carrier for prescription drugs based on the number of claims under the plan, issuer, or carrier as a percent of the total number of claims received under all the PBM's plans, issuers or carriers. Thus, allocation is based on the total number of claims for all the drugs rather than the number of claims received for each drug.

NARRATIVE RESPONSES

Plans must also provide written answers to the following questions. These answers are uploaded to HIOS in Word or PDF format.

Employer size for self-funded plans

Did you use actual counts or estimates to determine the size of the employer for self-funded plans? Describe your estimation method if you used estimates.

Net payments from federal or state reinsurance or cost-sharing reduction programs

If applicable, describe how you accounted for net payments from federal or state reinsurance and cost sharing reduction programs.

Drugs missing from the CMS crosswalk

If the CMS crosswalk is missing an NDC for a drug that was prescribed during the reference year and covered under the pharmacy benefit, provide the RxDC drug name and therapeutic class that you used.

Medical benefit drugs

Describe how you estimated the portion of bundled or alternative payment arrangements that can be attributed to drugs covered under a medical benefit (as reported in D2). Describe allocation methods, if applicable.

Prescription drug rebate descriptions

Describe the types of rebates, fees, and other remuneration that you included or excluded in the Rx Totals, Rx Rebates by Therapeutic Class, and Rx Rebates for the Top 25 Drugs. Explain any negative values for rebates, fees, or other remuneration.

Allocation methods for prescription drug rebates

Describe the methods you used to allocate prescription drug rebates, fees, and other remuneration. If you used an allocation method other than one of the methods described as reasonable, your description must include enough detail for CMS to evaluate whether the method is reasonable.

Impact of prescription drug rebates

Describe the impact of rebates, fees, and other remuneration on premium and out-of-pocket costs in your narrative response. Provide as much detail as possible. Describe how and why the impact may vary based on the market segment or for particular types of plans, such as high deductible health plans. Describe the impact of prescription drug rebates on the tier assignment of prescription drugs in the formulary, or the removal of generic equivalents from a formulary. If possible, provide a quantitative estimate of the impact.

A FINAL THOUGHT

This guide outlines the exceedingly complex calculations and process that will be required to implement RxDC reporting. We anticipate that this program will get off to a bumpy start this fall. It is our hope that CMS will work closely with plan sponsors, TPAs, and PBMs to help facilitate compliance. Notably, however, the reporting deadlines have already been delayed once, so it would be prudent to be actively preparing for this reporting NOW.

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