Prescription Drug (RxDC) Reporting & Other TiC and CAA Requirements for Group Health Plans



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Agenda

- 1. Prescription Drug Data Collection (RxDC) Reporting
 - a. Overview, Applicable Plans and Due Dates
 - b. What's New for 2024 RxDC Reports?
 - c. HIOS Submission Process
 - d. Rules for Aggregating Data Files
 - e. Overview of Plan List and Data Files (P2; D1-D8)
- 2. Transparency in Coverage (TiC) Regulations
 - a. Public and Participant Disclosures
- 3. Consolidated Appropriations Act, 2021 (CAA)
 - d. Other CAA Requirements for Group Health Plans

What is RxDC?

- RxDC is the data collection authorized under Section 204 of Division BB (of Title II) of the CAA
- Applies to:
 - Group health plans (fully insured and self-funded)
 - Health insurers in individual, student, and small and large group markets
 - Federal Employee Health Benefit (FEHB) carriers
- RxDC is not only about prescription drugs, but also:
 - > Average monthly premium, separately for members and employers
 - Spending on healthcare services (separately for hospital, primary care, and specialist care)
 - > Rx spending, utilization, rebates, fees, and remuneration
 - > Impact of Rx rebates on premium and cost sharing
- CMS collects data on behalf of:
 - Departments of Health & Human Services, Labor, and Treasury, and the Office of Personnel Management (OPM)



Applicable Plans and Due Dates

- Which plans are subject to the RxDC reporting requirements?
 - Group health plans (including grandfathered plans)
- Which group health plans are <u>not</u> subject to the RxDC reporting requirements?
 - Excepted benefits (e.g., limited-scope dental or vision offered under separate policies, many EAPs, and fixed indemnity plans)
 - Account-based plans (e.g., HRAs and many gap/bridge plans)
 - Short-term limited-duration insurance (STLDI)
 - Retiree-only plans

Deadlines:

Annual RxDC reports for a given calendar year are due by <u>June 1</u> of the following year (e.g., 2024 reports are due by June 1, 2025)



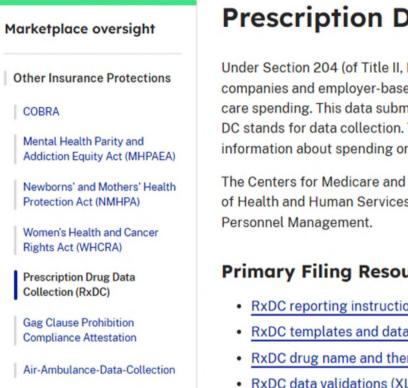
What's New for 2024 RxDC Reports?

- ► No changes to RxDC reporting rules this year, but there were some significant changes beginning last year, including the following:
 - Good faith relief and extensions no longer apply
 - Multiple vendors can also submit the same Data File for the same plan, if needed
 - Similarly, if plan changes vendors mid-year, it is acceptable for the previous vendor to report the data from the period prior to the change, and the new vendor to report the data from the period after the change
 - Updated instructions for populating Carve-Out field in P2
 - Simplified calculation of average monthly premiums in D1
 - Premium equivalents in D1 may be reported on cash basis or retrospective basis, and additional details about amounts included in or excluded from premium equivalents
 - > Added column in D6 to collect Rx enrollment
 - Provided additional detail on reporting info in the prior year columns in D5 and restated rebate columns in D6-D8



CMS RXDC Website

- The CMS.gov Prescription Drug Data Collection (RxDC) website includes reporting instructions, data file templates, HIOS user manual, and other important and helpful information
 - https://www.cms.gov/marketplace/ about/oversight/other-insuranceprotections/prescription-drug-datacollection-rxdc
- Filers must have a Health **Insurance Oversight System** (HIOS) account through the CMS **Enterprise Portal**



Consolidated Appropriations

Act, 2021 (CAA)

Prescription Drug Data Collection (RxDC)

Under Section 204 (of Title II, Division BB) of the Consolidated Appropriations Act, 2021 (CAA), insurance companies and employer-based health plans must submit information about prescription drugs and health care spending. This data submission is called the RxDC report. The Rx stands for prescription drug and the DC stands for data collection. The RxDC report isn't only about prescription drugs. It also collects information about spending on health care services and premium paid by members and employers.

The Centers for Medicare and Medicaid Services is collecting the RxDC report on behalf of the Departments of Health and Human Services, the Department of Labor, the Department of Treasury, and the Office of

Primary Filing Resources

- RxDC reporting instructions (PDF)
- RxDC templates and data dictionary (ZIP)
- RxDC drug name and therapeutic class crosswalk (XLSX)
- RxDC data validations (XLSX)

Other Resources

- · Frequently Asked Questions (PDF)
- Training Resource Directory (PDF)
- RxDC YouTube Playlist
- Federal Regulation

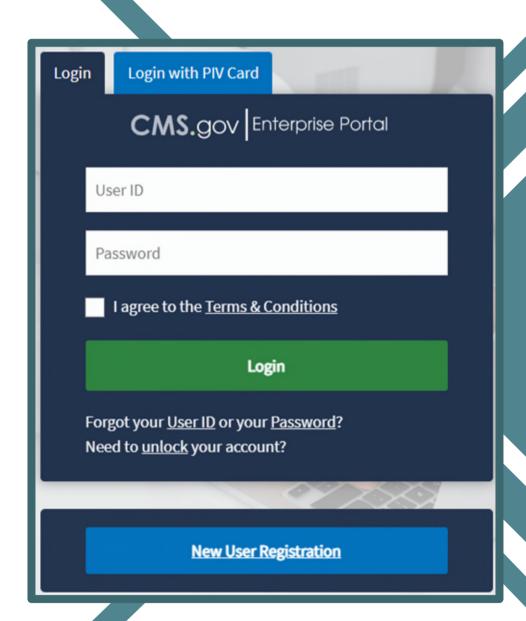
HIOS Manuals

- · HIOS Access Guide for RxDC Users (PDF)
- RxDC HIOS Module User Manual (PDF)
- · Click here to submit your data in the CMS Enterprise Portal



HIOS Submission Process

- Submit Data Files through the RxDC module in the Health Insurance Oversight System (HIOS)
 - To log in to HIOS, go to the CMS Enterprise Portal
- If you are submitting the Data Files, you must have an HIOS account
 - It can take up to two weeks to create your accounts. Don't wait until the last minute!
- ► Instructions to create HIOS accounts are in the HIOS Access Guide for RxDC Users
- Instructions for using the RxDC module are in the RxDC HIOS Module User Manual
- Select "New User Registration"
 - Application = HIOS
- Save files in Comma Separated Values (CSV) format before uploading them to HIOS





RxDC Reporting Entities

- ► Plans can have one or more vendors (*aka*, "reporting entities") submit on their behalves
- ➤ Some reporting entities submit all files on behalf of a plan; others, for example, may ask plans to submit P2 and D1 data files
- How do I know if I have to submit P2 and D2:
 - In general, if your insurer, TPA, or PBM sent you a survey or questionnaire to collect information about plan numbers, premium, or funding types, it is likely that they are reporting P2 and D1 on your behalf



Plan Lists and Data Files

Subject	Plan Lists	Data Files
File Names	 P stands for Plan P1 Individual and student market plan list P2 Group health plan list P3 FEHB plan list 	 D stands for Data D1 Premium and Life-Years D2 Spending by Category D3 Top 50 Most Frequent Brand Drugs D4 Top 50 Most Costly Drugs D5 Top 50 Drugs by Spending Increase D6 Rx Totals D7 Rx Rebates by Therapeutic Class D8 Rx Rebates for the Top 25 Drugs
Purpose	The plan lists identify the plans in a submission. The plan lists also collect plan-level information required by statute, such as the beginning and end dates of the plan year, the number of members, and the states in which the plan or coverage is offered.	The data files collect premium and spending information at an aggregate level.
Requirement	 P1 is required for plans in the individual or student market P2 is required for employer-based health plans that are not FEHB plans P3 is required for FEHB plans 	All 8 data files are required.



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Aggregated Data Files

- ► If a reporting entity submits data on behalf of more than one plan in a state, the reporting entity may aggregate data in its D1-D8 Data Files
- Aggregation is by (1) <u>State</u>, (2) <u>Market Segment</u>, and
 (3) <u>Reporting Company</u>
- Aggregation restriction now applies:
 - Data submitted in D1 and D3–D8 data files must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submitted the D2 (Spending by Category) data file
 - This means that if the data submitted in D2 is not aggregated by issuer or TPA, the data in D1 and D3-D8 must also be reported separately for each plan
 - If the data submitted in D2 is aggregated, then the reporting entities for the other data files can choose whether to report at the plan level or aggregate level



Aggregated Data Files

Aggregation by (1) State, (2) Market Segment, and (3) Reporting Company:

(1) By State – which state?

- Fully insured plan: State where contract was issued
- Self-funded plan: State where plan sponsor has its principal place of business
 - Level-funded = Self-funded
- MEWA: For a "plan" MEWA, generally the place where the group or association has its principle place of business

(2) By Market Segments:

- Individual market, except for student plans
- Student market
- Fully insured, small-group
- Fully insured, large-group
- Self-funded, small-group
- Self-funded, large-group
- Federal Employee Health Benefits (FEHB)

(3) By Reporting Company:

Usually aggregated at carrier or TPA level, but could be aggregated at plan sponsor, PBM, or other company level



Data Files (P2 and D1-D8)

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 - Rx Totals

D7 – Rebates by Therapeutic Class



P2: Group Health Plan List

Plan-Specific Information

Identifying information (e.g., name, EIN and other relevant identification numbers) for the plan, plan sponsor, and plan's reporting entities

Each state in which the plan is offered

Beginning and end dates of the plan year that ended on or before the last day of the reference year

Number of participants and beneficiaries covered on the last day of the reference year

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

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D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

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P2: Group Health Plan List

Group Health Plan Name (Required)	Group Health Plan Number (Required)	Carve-Out Description	Form 5500 Plan Number (if known)	States in which the plan is offered	Market Segment (Required)	Plan Year Beginning Date (MM/DD/YYYY)	Plan Year End Date (MM/DD/YYYY)	Members as of 12/31 of the Reference Year
ABC Health Plan	SFC12345	Pharmacy only	501	National	SF large employer plans	01/01/2024	12/31/2024	227

Plan Sponsor Name (Required)	Plan Sponsor EIN (Required)	Issuer Name	Issuer EIN	TPA Name	TPA EIN	PBM Name	PBM EIN
ABC, LLC	12-3456789	Sun Life	98-7654321	Cigna	55-555555	Express Scripts	99-9999999

Included in DI. Premium and Life Years? (I∷Yes; 0 = No)	Included in D2 Spending by Category? (J≈Yes; 0 ≈ No)	Included in D3 Top 50 Most Frequent Brand Drugs? (1:: Yes; 0:: No)	Included in D4 Top 50 Most Costly Drugs? (1:= Yes; 0 = No)	Included in D5 Top 50 Drugs by Spending Increase? (1:= Yes; 0 = No)	Included in D6 Rx Totals? (1=Yes; 0 = No)	Included in D7 Rx Rebates by Therapeutic Class? (1:= Yes; 0 = No)	Included in D8 Rx Rebates for the Top 25 Drugs? (1=Yes; 0 = No)
1	1	1	1	1	1	1	1

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

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P2: Group Health Plan List

Group Health Plan Name (Required)	Group Health Plan Number (Required)	Carve-Out Description	Form 5500 Plan Number (if known)	States in which the plan is offered	Market Segment (Required)	Plan Year Beginning Date (MM/DD/YYYY)	Plan Year End Date (MM/DD/YYYY)	Members as of 12/31 of the Reference Year
ABC Health Plan	SFC12345	Pharmacy only	501	National	SF large employer plans	07/01/2023	06/30/2024	0
ABC Health Plan	SFC12345	Pharmacy only	501	National	SF large employer plans	07/01/2024	06/30/2025	227

Non-Calendar Year Plans

- ► Example: Plan year is July 1 June 30. When completing the 2024 calendar year RxDC report, use two rows in the P2 file:
 - 1. One row for the plan year that ended on 6/30/2024; and
 - 2. Another for the plan year that began on 7/1/2024.
- Enter the actual number of members as of 12/31/2024 in the second row and zero members in the first row.

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



D1: Premium & Life Years

Company Name	Company EIN	Aggregation State	Market Segment	Average Monthly Premium Paid by Members	Average Monthly Premium Paid by Employers

Aggregation could be at the plan sponsor, carrier, reporting entity, or other company level

			Admin Fees Paid	Stop Loss Premium
Life Years	Earned Premium	Premium Equivalents	(included in the	Paid (included in the
Life feats	(fully-insured plans)	(self-funded plans)	Premium Equivalents	Premium Equivalents
			field)	field)
•				

Life Years (and Member Months):

To calculate Member Months:

- 1. Count the number of covered lives on a given day of each month of the reference year.
- 2. Add the number of members from Step 1 to calculate total member months for the reference year.

To calculate Life Years:

- Divide the Member Months by 12.
- 2. Round the resulting number to the 8th decimal point.

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

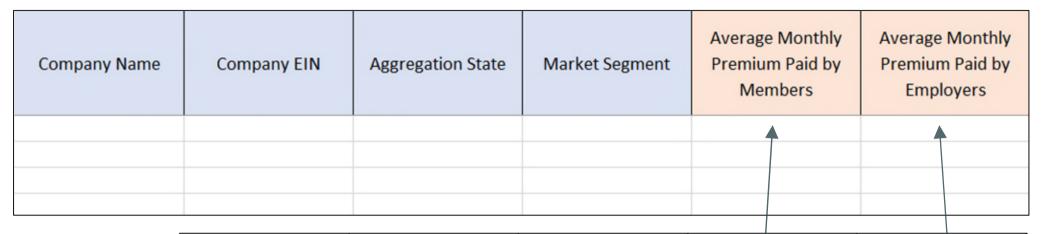
D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



D1: Premium & Life Years





Premium Equivalents = Total cost of providing coverage, including claims costs, administrative costs, Administrative Services Only (ASO) and other TPA fees, and stop-loss premiums.

Employers with self-funded plans may use, as the total cost of providing coverage, the same costs that are taken into account for purposes of calculating COBRA premiums (minus the 2% administration charge, if applicable)

Stop loss reimbursements should be subtracted from Premium Equivalents

Rx rebates received in the reference year should be subtracted from Premium Equivalents, regardless of whether the rebate received is retrospective or prospective

Average Monthly
Premium Paid by
Member = Total
Premium Equivalents
paid by members for
the year / 12

Average Monthly
Premium Paid by
Employers = Total
Premium Equivalents
paid by employers
for the year / 12

Prior to the 2023 reference year, average premium was calculated on a per-member-per-month basis. Starting with the 2023 reference year, this was changed to longer be on a per-member basis.

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

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D4 – Top 50 Most Costly

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D6 - Rx Totals

D7 – Rebates by Therapeutic Class



D2: Spending by Category

Company Name	Company EIN	Aggregation State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible and/or Out- of-Pocket Maximum
Cigna	55-555555	AL	SF large employer plans	Hospital			
Cigna	55-555555	AL	SF large employer plans	Primary care			
Cigna	55-555555	AL	SF large employer plans	Specialty care			
Cigna	55-555555	AL	SF large employer plans	Other medical costs and services			
Cigna	55-555555	AL	SF large employer plans	Known medical benefit drugs		[Leave blank]	[Leave blank]
Cigna	55-555555	AL	SF large employer plans	Estimated medical benefit drugs		[Leave blank]	[Leave blank]

- ► Report data related specifically to the reference year and paid or received through March 31 of the calendar year immediately following the reference year. For accounting purposes, this is sometimes referred to as "incurred in 12, paid or received in 15."
- ► Hospital, Primary care, Specialty care, and Other medical costs and services spending categories are mutually exclusive of each other and include known and estimated spending on medical benefit drugs billed under those categories. Spending on medical benefit drugs must also be reported in the respective categories for medical benefit drugs. This means that medical benefit drug spending is "double-reported."
- Medical benefit drugs = Drugs covered under a medical benefit (drugs covered under a pharmacy benefit need not be reported in D2; they are reported in D3-D8)

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

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D2: Spending by Category

Company Name	Company EIN	Aggregation State	Market Segment	Spending Category	Total Spending	Total Cost Sharing	Amounts Not Applied to Deductible and/or Out- of-Pocket Maximum
Cigna	55-555555	AL	SF large employer plans	Hospital			
Cigna	55-555555	AL	SF large employer plans	Primary care			
Cigna	55-555555	AL	SF large employer plans	Specialty care			
Cigna	55-555555	AL	SF large employer plans	Other medical costs and services			
Cigna	55-555555	AL	SF large employer plans	Known medical benefit drugs		[Leave blank]	[Leave blank]
Cigna	55-555555	AL	SF large employer plans	Estimated medical benefit drugs		[Leave blank]	[Leave blank]

See pages 37-44 of the CMS
Prescription Drug Data
Collection (RxDC) Reporting
Instructions for detailed
instructions on what to include
and exclude in the final three
columns of the D2 Data File

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 - Rx Totals

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D3-D8 Data Files

	Company Name	Company EIN	Aggregation State	Market Segment	Drug Name	Drug Code	Frequency 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
L													

The first four columns will be the same in Data Files D3-D8

D3: Top 50 Most Frequent Brand Drugs

Drug Name	Drug Code	Frequency 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

- ► CMS indicates which drugs are brand name in the RxDC Drug Name and Therapeutic Class Crosswalk File.
- ► Rank the drugs according to number of paid claims (only for Rxs filled during the reference year), sorted in descending order. Identify the 50 brand name drugs with the highest number of paid claims. A rank of 1 means the drug is the most frequently prescribed.
- ► When you complete the D3 table, there will be 50 rows for your state, market segment, and TPA name/EIN combination.

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 - Rx Totals

D7 – Rebates by Therapeutic Class



D4: Top 50 Most Costly Drugs

Drug Name	Drug Code	Cost 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

- Same as the D3 Data File, except:
 - Not limited to brand name drugs; and
 - Ranking/reporting based on cost rather than frequency of prescription.
- Rank the drugs according to total spending, net of prescription drug rebates, fees, and other remuneration.

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 - Top 50 Most Frequent Brand

D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



D5: Top 50 Drugs by Spending Increase

Drug Name	Drug Code	Spending Increase 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

Prior Year Number of Paid Claims	Prior Year Number of Members with a Paid Claim	Prior Year Number of Dosage Units	Prior Year Total Spending	Prior Year Total Cost Sharing	Prior Year Manufacturer Cost-Sharing Assistance	Dollar Increase in Total Spending

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

D4 - Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



D8: Rebates for Top 25 Drugs

Drug Name	Drug Code	Rebate Rank	Number of Paid Claims	Number of Members with a Paid Claim	Number of Dosage Units	Total Spending	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/ Other Remuneration from Pharmacy to Plan/Issuer/Carrier	Total Rebates/ Fees/Other Remuneration	Restated Prior Year Rebates/Fees/Other Remuneration

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

D2 – Spending by Category

D3 – Top 50 Most Frequent Brand

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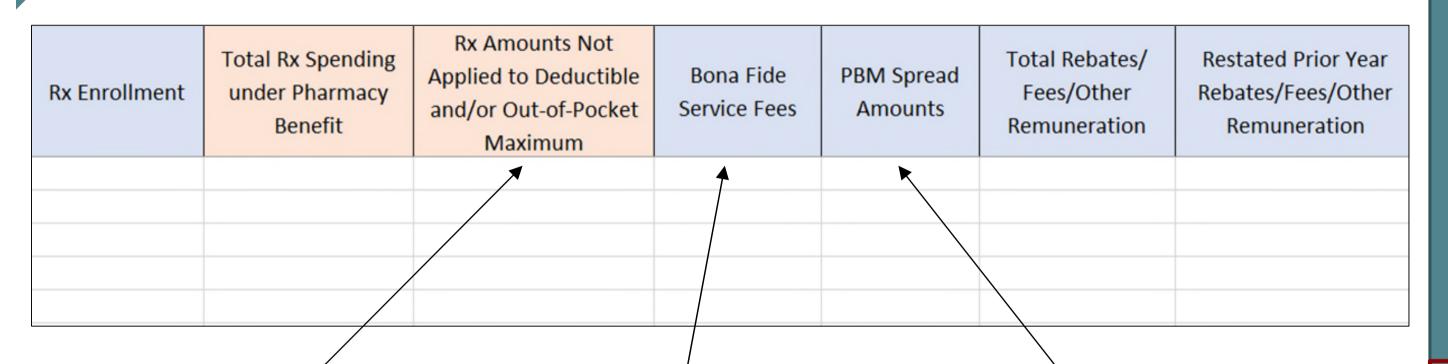
D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



D6: Rx Totals



Billed amounts that were (1) not applied to a member's deductible or out-of-pocket max, (2) not paid by the plan, and (3) not included in Rx Total Spending.

Fees that a manufacturer pays to a PBM that: (1) represent FMV for a bona fide, itemized service performed on behalf of the manufacturer; and (2) are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Difference between the amount the plan, issuer, or carrier paid to the PBM and the amount the PBM paid to manufacturers, wholesalers, pharmacies, or other vendors.

Data Files

P2 – Group Health Plan List

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D2 – Spending by Category

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D4 – Top 50 Most Costly

D5 – Top 50 by Spending Increase

D6 - Rx Totals

D7 – Rebates by Therapeutic Class



D7: Rebates by Therapeutic Class

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 Pharmacy to Plan/Issuer/Carrier	Total Rebates/Fees/Other Remuneration	Restated Prior Year Rebates/Fees/Other Remuneration

Data Files

P2 – Group Health Plan List

D1 – Premium & Life Years

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D5 – Top 50 by Spending Increase

D6 – Rx Totals

D7 – Rebates by Therapeutic Class



Narrative Responses

- Must be submitted in PDF or DOC/DOCX file formats
- Only part of the reporting where multiple files could be submitted for the same plan, and multiple reporting entities could upload different narrative response files (covering different topics) for the same plan
- Narrative responses must address the following topics:
 - Employer size for self-funded plans
 - Net payments from federal or state reinsurance or costsharing reduction programs
 - Drugs missing from the CMS crosswalk
 - Medical benefit drugs (i.e., drugs covered under hospital/ medical benefits)
 - Rx rebate descriptions
 - Rx rebate allocation methods
 - > Impact of Rx rebates on plan premiums and OOP costs
- Departments have not provided templates



Transparency in Coverage (TiC) Regulations

Public Disclosures

- Non-grandfathered plans and insurers must disclose, through separate machine-readable files (MRFs) on a public website:
 - 1. Negotiated rates for all covered services and items between the plan/insurer and in-network providers
 - 2. Historical payments to, and billed charges from, out-ofnetwork providers for covered services and items
 - 3. Negotiated rates and historical net prices for all covered prescription drugs
- Does <u>not</u> apply to grandfathered plans, accountbased plans, excepted benefits, short-term limited duration insurance, or retiree-only plans



Transparency in Coverage (TiC) Regulations

Participant Disclosures

- ► Non-grandfathered health plans and insurers must provide to participants and beneficiaries certain personalized cost-sharing information and underlying negotiated rates for all covered services and items:
 - Estimated cost-sharing liability
 - Participant's accumulated amounts toward deductibles and OOPMs
 - In-network negotiated rates & out-of-network allowed amounts
 - > Items and services subject to bundled payment arrangements
 - Notice of prerequisites (e.g., prior authorization)
 - Disclaimer notice
- Must provide through an internet-based, self-service tool with search capabilities, or paper format, if requested



Transparency in Coverage (TiC) Regulations

Participant Disclosures

- ► DOL Model Notice: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/transparency-in-coverage-draft-model-disclosure
- Does <u>not</u> apply to grandfathered plans, account-based plans, excepted benefits, short-term limited duration insurance, or retiree-only plans
- ► Effective for plan years beginning on or after 1/1/2023 for 500 services and items selected by the Departments
- ► Effective for plan years beginning on or after 1/1/2024 for all services and items



Consolidated Appropriations Act, 2021 (CAA): Other Requirements for Group Health Plans

- No Surprises Act: Emergency Services
- Advanced ID Cards and EOBs
- Notices of Continuity of Care
- Price Comparison Tool and Updated Provider Directories
- Balance Billing Disclosures
- Gag Clause Prohibition and Attestation
- Broker-Consultant Disclosures
- Mental Health Parity and Addiction Equity Act: Comparative Analysis







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