# **RxDC** Reporting

Wednesday, March 27, 2024

11 a.m. (PT) / 12 p.m. (MT) 1 p.m. (CT) / 2 p.m. (ET)







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# Agenda

- Prescription Drug Data Collection (RxDC) Reporting:
  - Background & Overview
  - Deadlines
  - Applicability
  - Content and Process
    - $\,\circ\,$  Completing the P2 and D1
  - Action Items
- PCORI Fees
  - Who, When, How?
  - What Is a Health Plan?
  - How Much Is the PCORI Fee?
  - Covered Lives: Count Methods
- Resources & Questions





### RxDC Reporting







- The Law: On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) (CAA) was enacted. Section 204 of Title II of Division BB of the CAA added parallel provisions to ERISA, the IRC, and the PHS Act; enforced by DOL, HHS, and Treasury (the "Departments")
  - **Prescription Drug Data Collection (RxDC) Reporting:** The law requires <u>both</u> employer-sponsored group health plans <u>and</u> health insurance issuers offering group or individual health coverage to annually submit to the Departments certain information about prescription drug and health care spending; reported through CMS' HIOS system
- The Regulations: Prescription Drug and Health Care Spending Interim Final Rules (IFR) with Request for Comment were issued in 2021
  - CMS has also issued instructions, templates, and FAQs Updated in 2024!
- **The Results:** Reports are submitted to CMS, and CMS will then publish findings about prescription drug pricing trends and the impact of prescription drug rebates on patient out-of-pocket costs



#### Overview

- What information do insurance companies and employers submit to CMS?
  - The CAA requires insurance companies and employer-based health plans to submit information about:
    - $\,\circ\,$  Spending on prescription drugs and health care services
    - $\,\circ\,$  Prescription drugs that account for the most spending
    - $\,\circ\,$  Drugs that are prescribed most frequently
    - Prescription drug rebates from drug manufacturers
    - $\,\circ\,$  Premiums and cost-sharing that patients pay



- How will this information be used?
  - The data submitted by insurance companies and employer-based health plans will help 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
     Promote transparency in prescription drug pricing





#### Deadline! June 1!

- Prescription Drug Data Collection (RxDC) Reporting: Initial Deadlines: This mandate required plans and issuers to report for the 2020 and 2021 calendar years by December 27, 2022 (later extended to January 31, 2023), and for the 2022 calendar year by June 1, 2023
- What are the next reporting deadlines?
  - Important! <u>All</u> plans and issuers must report for the 2023 calendar year by <u>June 1, 2024</u>
    - $\circ$  Question: June 1 is a Saturday. Do we have until June 3?
  - Important! This reporting must be done every year by <u>June 1</u> mark your compliance calendars accordingly
- Note: Data is reported on a calendar year "reference year" basis



### Who Must Report?

- Health insurance issuers offering group health coverage are required to report (individual coverage, too)
- **Employer-sponsored group health plans** are required to report, including:
  - Fully insured and self-funded plans (level funded plans are self-funded plans)
  - Large group and small group plans
  - Grandfathered and non-grandfathered plans
  - Non-federal governmental plans, such as plans sponsored by state and local governments
  - Church plans that are subject to the Internal Revenue Code
- Who does <u>not</u> have to report? Stand-alone dental and vision plans and excepted benefits (see next slide)



# Applicability

#### **Required to Report**

- Health insurance issuers offering group market coverage
- Fully-insured and self-funded group health plans, including:
  - Non-federal governmental plans, such as plans sponsored by state and local governments
  - Church plans that are subject to the Internal Revenue Code
  - Federal Employees Health Benefits (FEHB) plans
- Health insurance issuers offering individual market coverage, including:
  - Student health plans
  - Plans sold through the Exchanges
  - Plans sold outside of the Exchanges
  - Individual coverage issued through an association

#### **Not Required to Report**

- Account-based plans, such as health reimbursement arrangements
- Excepted benefits, including but not limited to:
  - Limited-scope standalone **dental and vision** plans
  - Short-term, limited-duration insurance
  - Hospital or other fixed indemnity insurance
  - Disease-specific insurance
- Medicare Advantage and Part D plans
- Medicaid plans
- State children's health insurance program plans
- Basic Health Program plans
- Retiree-only plans
- Plans maintained outside of the U.S. primarily for the benefit of persons substantially all of whom are nonresident aliens



#### What Must Be Reported?



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
Plan year end date
Members as of 12/31 of the reference year
Plan sponsor name and EIN
Issuer name and EIN
PBM name and EIN
Included in D1 - D8



Files

Data

D1-D8

- 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



Narrative

- 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
- Impact of prescription drug rebates
- Other relevant information



### Issuer Surveys or RFIs

- What has to be filed? For each employer-sponsored group health plan:
  - P2 plan list
  - D1-D8 data files
  - Narrative Response
- Fully Insured Plans: Issuer may agree to file for the employer if so, employer obligation is satisfied
  - But, the issuer might not have all the necessary information, so the issuer will send the employer a survey or RFI
  - If the employer does not complete the survey or RFI on time, the employer will have to complete the filings with CMS to provide the missing information this is time consuming!
  - Important! Fill Out the Survey or RFI!
  - For more information on carrier compliance: <u>Prescription Drug Reporting | Warner Pacific</u>



# Employer Responsibilities

- Fully Insured: <u>Both</u> the employer-sponsored group health plan <u>and</u> the issuer are legally obligated to report
  - The employer, as plan sponsor of its group health plan, may enter into a written agreement with the issuer to report all the required data
  - If the issuer does not file one or more files or files incomplete data the plan sponsor (employer) must file
    - Example: Issuer will file P2, D1-D8, and Narrative, but needs employer to complete a survey.
       Employer must complete survey accurately, or employer must file P2 and D1
- Self-Funded: The plan sponsor (employer) must file or outsource to one or more third parties
  - The employer must enter into a written agreement with the third parties
  - If the third parties fail to perform, the plan sponsor remains legally liable
    - Example: Employer files P2 & D1; TPA files P2, D1 & D2; PBM files P2, D3-D8 & Narrative



#### What Data Is Required From Employers In the Surveys?

- To Complete the P2 Data File, Employers May Be Asked to Provide:
  - Identifying information such as plan name; plan number(s); plan sponsor; plan sponsor EIN; and issuer, TPA, and PBM names and EINs;
  - Beginning and end dates of the plan year that ended on/before the last day of the reference year;
  - Number of participants and beneficiaries ("members") covered on the last day of reference year; and
  - Each state in which the plan or coverage is offered
- To Complete the D1 Data File, Employers May Also Be Asked to Provide:
  - Premium amounts, including—
    - Average monthly premium amount paid by employers and other plan sponsors on behalf of participants and beneficiaries;
    - Average monthly premium amount paid by participants and beneficiaries; and
    - Total annual premium amount and the total number of **life-years**.
  - Life-Years: The total number of members covered on a given day of each month of the reference year, divided by 12



# Completing the Forms: Key Definitions

- What is a Member? The term "member" means a person who has health coverage. For example, enrollees, dependents, participants, and beneficiaries are all considered members. Retirees and COBRA participants, including their dependents, also are considered members if they are covered by a plan that is <u>not</u> a retiree-only plan.
- **Reference Year:** Calendar year (2023)
- Market Segment:
  - Fully Insured: Small group market, large group market (use MLR reporting size)
  - Self-Funded: SF small employer plans (50 and under), SF large employer plans (over 50)
- Carve-Out: A benefit carve-out is a benefit administered, offered, or insured by an entity that is
  different than the entity that administers, offers, or insures the majority of the plan's other benefits.
  - **Examples**: Pharmacy only, medical only (do not use if plan does not offer Rx), behavioral health only, fertility only, specialty drugs only, hospital only, other.
  - New for 2023! Must report carve-outs (P2 Column C)



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If the employer did not complete the carrier survey on time and must submit missing premium data to CMS, the employer will have to file a D1 data file with a P2 — in that event, enter "1" in column "R" and "0" in "S"-"Y."

#### P2 Group Health Plan List

А	В	С	D	E	F	G	Н	I
Group Health Plan Name	Group Health Plan Number	[N/A]	Form 5500 Plan Number (Not Required)	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
Jane's Furniture Health					Small group			
and Welfare Plan	5798X			DC;VA;MD	market	01/01/2022	12/31/2022	24
					SF large employer			
Acme Corp PPO	4H2359801-01		501	National	plans	07/01/2021	06/30/2022	0
					SF large employer			
Acme Corp PPO	4H2359801-01		501	National	plans	07/01/2022	06/30/2023	517
	Group Health Plan Name Jane's Furniture Health and Welfare Plan Acme Corp PPO	Group Health Plan Name     Group Health Plan Number       Jane's Furniture Health and Welfare Plan     5798X       Acme Corp PPO     4H2359801-01	Group Health Plan Name       Group Health Plan Number       [N/A]         Jane's Furniture Health and Welfare Plan       5798X         Acme Corp PPO       4H2359801-01	Group Health Plan NameGroup Health Plan Number[N/A]Form 5500 Plan Number (Not Required)Jane's Furniture Health and Welfare Plan5798X	Group Health Plan Name       Group Health Plan Number       [N/A]       Form 5500 Plan Number (Not Required)       States in which the plan is offered         Jane's Furniture Health and Welfare Plan       5798X       DC;VA;MD         Acme Corp PPO       4H2359801-01       501       National	Group Health Plan NameGroup Health Plan Number[N/A]Form 5500 Plan Number (Not Required)States in which the plan is offeredMarket SegmentJane's Furniture Health and Welfare Plan5798X	Group Health Plan NameGroup Health Plan Number[N/A]Form 5500 Plan Number (Not Required)States in which the plan is offeredMarket SegmentPlan Year Beginning DateJane's Furniture Health and Welfare Plan5798X	Group Health Plan NameGroup Health Plan Number[N/A]Form 5500 Plan Number (Not Required)States in which the plan is offeredMarket SegmentPlan Year Beginning DatePlan Year End DateJane's Furniture Health and Welfare Plan5798XSmall group market01/01/202212/31/2022Acme Corp PPO4H2359801-01501NationalSF large employer plans07/01/202106/30/2022

	J	К	L	M	N	0	P	Q
1	Plan Sponsor Name	Plan Sponsor EIN (9 digit EIN without a dash)	Issuer Name	Issuer EIN	TPA Name	TPA EIN	PBM Name	PBM EIN
	Jane's		Your insurance					
2	Furniture Store	123456789	company's name	*****			Your PBM's name	*****
3	ACME Corp	012345678			Your TPA's Name	#######################################	Your PBM's name	*****
4	ACME Corp	012345678			Your TPA's Name	*****	Your PBM's name	*****
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	1	Included in D1 Premium and Life Years? (1= Yes; 0 = No)	Included in D2 Spending by Category? (1=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)
	2	1	0	0	0	0	o	0	0
	3	1	o	0	o	0	o	o	0
ble	4	1	0	0	0	0	o	0	0
	5								

**CMS** Sample

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#### **D1** Company Name and EIN: Columns A - B

	А	В	С	D	E	F	G	Н	I	J	К
1	Issuer or TPA Name (or plan sponsor or vendor name)	Issuer or TPA EIN (or plan sponsor or other vendor name)	State		<b>.</b> ,	Average Monthly Premium Paid by Employers		Earned Premium (for fully insured plans)	· · ·	ASO/TPA Administrative Fees Paid (included in the Premium Equivalents field)	Paid (included in the Premium
2	Jane's Furniture Store	123456789	VA	small group market	\$165.00	\$200.00	23.4567347	\$ 8,561.71			
3	ACME Corp	012345678	DE	SF large employer plans	\$57.90	\$350.56	535.94826		\$ 218,913.43	\$ 17,513.07	\$ 4,378.27

Column A is now "Company Name" the title has changed, but the purpose is the same

What if the employer only must report average monthly premium (columns E & F), because another reporting entity will report the data in the other columns? Complete columns A-D and E and F; the other columns may be left blank.

CMS Sample

### Average Monthly Premium

- Average Monthly Premium Paid by Members (D1 Column E): Report the average monthly premium (or premium equivalents) paid by members. Calculate the average <u>using actual spending</u> by members during the reference year and <u>not</u> based on the premium rates charged to the member. Divide by 12. Divide by 12 even if the coverage was not in effect for the entire calendar year.
  - Include: Premium/premium equivalents paid by members for medical and Rx coverage; advanced premium tax credits (APTCs) in the individual and fully-insured small group markets; member payments for COBRA (including 2% administrative fee); spousal and tobacco surcharges
  - **Exclude:** Premium/premium equivalents paid by employers or other plan sponsors on behalf of members.



### Average Monthly Premium

- Average Monthly Premium Paid by Employers (D1 Column F): Report the average monthly premium paid by employers or other plan sponsors on behalf of members. Calculate the average using <u>actual spending</u> by employers and <u>not</u> based on average premium rates. Divide by 12. Divide by 12 even if the coverage was not in effect for a member or members for the entire calendar year.
  - Include: Premium/premium equivalents paid by employers and other plan sponsors on behalf of members (including dependents) for medical and pharmacy coverage; premium/premium equivalents paid by group trust, association, or MEWA plans if separate employers or other plan sponsors make premium contributions.
  - **Exclude:** Premium or premium equivalents paid by members





- Life-years (D1 Column G): Life-years are the average number of members throughout the year. To calculate life-years, you must first calculate member months.
- To calculate member months:
  - 1. Count the number of members covered on a given day (such as the 1st) of each month of reference year
  - 2. Add the number of members from Step 1 to calculate total member months for reference year
- To calculate life-years:
  - 1. Divide member months by 12
  - 2. Round the resulting number to the 8th decimal place
- If you are reporting for multiple plans, add the number of life-years for each plan and report the total amount for all plans.



#### Life-Years

Date	Members Covered by the Plan on the Given Date
January 1, 2023	882
February 1, 2023	872
March 1, 2023	884
April 1, 2023	921
May 1, 2023	924
June 1, 2023	923
July 1, 2023	925
August 1, 2023	916
September 1, 2023	907
October 1, 2023	906
November 1, 2023	902
December 1, 2023	869
Total Member Months	10,831
# of Life-Years (Total member months / 12)	902.58333333



- Aggregation: Entities reporting on behalf of multiple plans issuers or TPAs will aggregate data and report by market segment and state (D1-D8)
  - State for a fully insured plan is the place where the policy was issued
  - State for a self-funded plan is the employer's principal place of business
- Seven Market Segments:

Individual Market	Student Market
Fully-insured small group market (50 and under) (may differ in some states — use MLR categories)	Fully-insured large group market (over 50) (may differ in some states — use MLR categories)
Self-funded plans offered by small employers (50 and under)	Self-funded plans offered by large employers (over 50)
Federal Employees Health Benefits (FEHB) line of business	



#### What Else Do We Have to Submit? Narrative Response

- Narrative Response: In addition to the plan and data files (P and D), a Narrative Response is required. In it, describe the impact of prescription drug rebates on premium and cost sharing, and address other topics that may be described in places throughout the instructions
  - The Narrative Response file format must be Portable Document Format (.pdf) or Microsoft Word (.doc or .docx)
  - You can but do not have to submit additional information about your submission using PDF or Word documents
  - "It's not a problem if multiple reporting entities upload different narrative responses on behalf of the same plan, issuer, or carrier"
- Include, at a minimum, the following: Net payments from federal or state reinsurance or costsharing reduction programs, drugs missing from the CMS crosswalk, medical benefit drugs, prescription drug rebate descriptions, allocation methods for prescription drug rebates, and impact of prescription drug rebates. The Narrative Response may also used to describe certain methodologies chosen (for examples, see Instructions)



#### Submission Process

- Filing: Data is submitted to CMS through its Health Insurance and Oversight System (HIOS)
  - You must register in advance it can take 2 weeks or more to process the registration
  - They have a help desk and email address you can use if you have questions include "RxDC" in the body of the email (<u>CMS\_FEPS@cms.hhs.gov</u>) or call (855) 267-1515 (they prefer email)
- Resources: See slide at end of presentation



### Action Items: Written Agreement Requirement

- Fully Insured Plan: If your plan is fully insured, the plan satisfies the reporting mandate if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement
  - Then, if the issuer fails to provide the information, <u>the issuer</u>, but not the plan, violates the reporting requirement
- Self-Funded Plan: If your plan is self-funded, the plan may satisfy the mandate if the plan enters into a written agreement under which another party (such as a TPA, ASO, or PBM) will provide the information
  - But, if the third party fails to provide the information, the <u>plan</u> violates the reporting requirement
- Form of Written Agreement: Not defined
- Liability Protection: Particularly for self-funded plans, review the full agreement to ensure it provides the protections the plan and employer need



#### **PCORI Fees**



- The Patient-Centered Outcomes Research Institute (PCORI) fees fund the Patient-Centered Outcomes Research Institute
- The Institute funds "comparative clinical effectiveness research (CER), which compares two or more medical treatments, services, or health practices to help patients and other stakeholders make better informed decisions"



## PCORI Fee: Who, When, How?

- Who must comply? The PCORI fee applies to issuers with policy years ending after September 30, 2012, and before October 1, 2029, and applicable self-insured employer-sponsored health plans with plan years ending after September 30, 2012, and before October 1, 2029
  - Employers of all sizes with self-funded plans must comply (including level funded plans)
  - Nonprofits, and state and local government plans must comply
  - Grandfathered and non-grandfathered plans must comply
  - Employers with fully insured plans do <u>not</u> have to comply
- When do self-funded plans have to comply? July 31
  - If July 31 falls on a weekend or holiday, file the next business day
- How do self-funded plans comply? Complete and file with the IRS a Form 720, along with payment



Form <b>720</b> (Rev. March 2024) Department of the Treasury Internal Revenue Service	See the Ins	ral Excise Tax Return tructions for Form 720. or instructions and the latest information.		OMB No. 1545-0023
Check here if:	Name	Quarter ending	F	OR IRS USE ONLY
<ul> <li>Final return</li> <li>Address change</li> </ul>	Number, street, and room or suite no. (If you have a P.O. box, see the instructions.)	Employer identification number	T F	

Part I	Patient-Centered Outcomes Research Fee (see	(a) Avg. number of lives covered	(b) Rate for				
RS No.	instructions)	(see inst.)	avg. covered life	(c) Fee (see instructions)		Tax	IRS No.
	Specified health insurance policies						
	(a) With a policy year ending before October 1, 2022		\$2.79		1		]
	(b) With a policy year ending on or after October 1, 2022, and before October 1, 2023		\$3.00				
133	Applicable self-insured health plans				}		133
	(c) With a plan year ending before October 1, 2022		\$2.79				]
	(d) With a plan year ending on or after October 1, 2022,		<b>A</b> 2 2 2				
	and before October 1, 2023		\$3.00		,		



# What Is a Health Plan?

- Which common types of health coverage or arrangements qualify as health plans for purposes of PCORI compliance?
  - Major medical
  - Retiree-only
  - COBRA coverage
  - State and local government plans
  - Health reimbursement arrangements and health FSAs (sometimes)
- Which common types of health coverage or arrangements do <u>not</u> qualify?
  - Stand-alone dental and vision
  - Coverage for employees working outside the U.S.
  - Medicare, Medicaid, CHIP, military health plans, certain Indian Tribal government plans
  - HSAs, hospital indemnity, specified illness, accident-only, STD, LTD, on-site clinics
  - EAPs (sometimes)



## How Much Is the PCORI Fee?

- How much is the PCORI fee? It adjusts annually:
  - For policy years and plan years that end on or after October 1, 2023, and before October 1, 2024, the PCORI fee is \$3.22 per covered life
  - For policy years and plan years that end on or after October 1, 2022, and before October 1, 2023, the PCORI fee is \$3.00 per covered life
  - **Example**: If your plan ending in 2023 ended on December 31, the PCORI rate is \$3.22; however, if your plan year ending in 2023 ended on September 30, the PCORI rate is \$3.00
- How is the PCORI fee calculated? By multiplying the fee amount by the average number of the plan's covered lives (covered employees, dependents, COBRA-qualified beneficiaries, and retirees)
- What method does a self-funded employer use to count the average number of lives? One of the following:
  - Actual count method, snapshot methods, or Form 5500 method

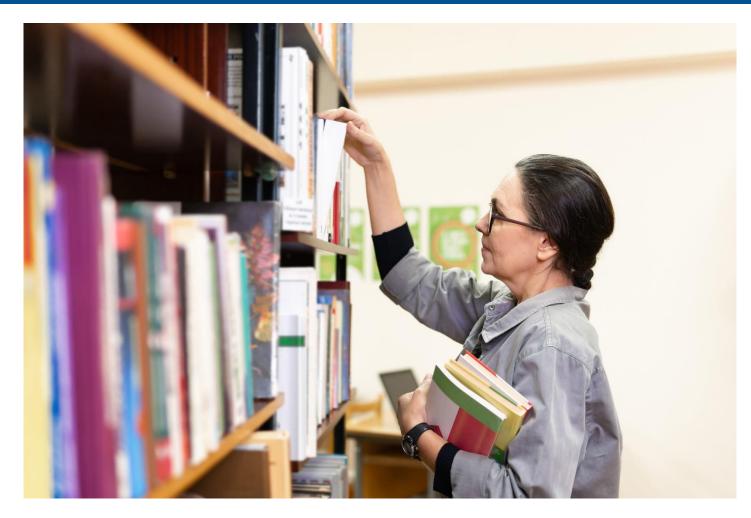


### Covered Lives: Count Methods

- Actual Count Method: Count the number of covered lives on each day of the plan year, add the daily totals together, and divide by the number of days in the plan year
- Snapshot Methods: To begin, choose one or more dates in each quarter of the plan year (the date in the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> quarter must be within 3 days of the date used in the 1<sup>st</sup> quarter)
  - **Snapshot Count Method**: Add the number of covered individuals on those dates and divide by the number of dates used.
    - Example Calendar Year Plan: On 1/4, 2,000 lives; 4/5, 2,100 lives; 7/5, 2,050 lives; 10/4, 2,050 lives. Total 8,200 (2,000, 2,100, 2,050, 2,050). 8,200 ÷ 4 = 2,050 lives
  - **Snapshot Factor Method:** Add, for the chosen dates, the number of participants with self-only coverage to the number of participants with other than self-only coverage multiplied by 2.35
- Form 5500 Method: If the plan offers only self-only coverage, add the number of participants on the first and last day of the plan year and divide by 2; if the plan also offers other than self-only coverage, add the number of participants on the first and last day of the plan year (do not divide by 2)
  - Cannot use if you file your Form 5500 later than July 31, including if you request an extension



#### Resources





#### PCORI

- IRS Resources:
  - Overview: <a href="https://www.irs.gov/newsroom/patient-centered-outcomes-research-institute-fee">https://www.irs.gov/newsroom/patient-centered-outcomes-research-institute-fee</a>
  - FAQs: <u>https://www.irs.gov/affordable-care-act/patient-centered-outcomes-research-trust-fund-fee-questions-and-answers</u>
  - Chart of Coverages: <u>https://www.irs.gov/newsroom/application-of-the-patient-centered-outcomes-research-trust-fund-fee-to-common-types-of-health-coverage-or-arrangements</u>
  - Form 720 & Instructions (Rev. March 2024)
- Patient-Centered Outcomes Research Institute (PCORI):
  - https://www.pcori.org/



# RxDC Reporting

- Prescription Drug Data Collection (RxDC):
  - Overview: <u>https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc</u>
  - RxDC reporting instructions (PDF); RxDC templates and data dictionary (ZIP) (D1-D8 templates); RxDC drug name and therapeutic class crosswalk (XLSX); RxDC data validations (XLSX)
  - Frequently Asked Questions (PDF)
  - Training Resource Directory (PDF); RxDC YouTube Playlist
- HIOS Manuals:
  - HIOS Portal RxDC Quick Reference Guide (PDF)
  - RxDC HIOS Module User Manual (PDF)



#### Questions?

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The information provided during this program does not constitute legal advice. In addition, this program only provides a summary of certain complex and always evolving laws and regulations. Attendees should consult their legal counsel for guidance on the application and implementation of the many federal and state laws that impact employee benefit plans and the workplace, including the topics discussed during this program.
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# **RxDC** Reporting

