**2022**

Prescription Drug Data Collection (RxDC)

Presented by Benefit Comply

Prescription Drug Data Collection (RxDC)

- Welcome! We will begin at 3 p.m. Eastern

- There will be no sound until we begin the webinar. When we begin, you can listen to the audio portion through your computer speakers or by calling into the phone conference number provided in your confirmation email.

- You will be able to submit questions during the webinar by using the "Questions" or "Chat" box located on your webinar control panel.

- Slides can be printed from the webinar control panel – expand the "Handouts" section and click the file to download.
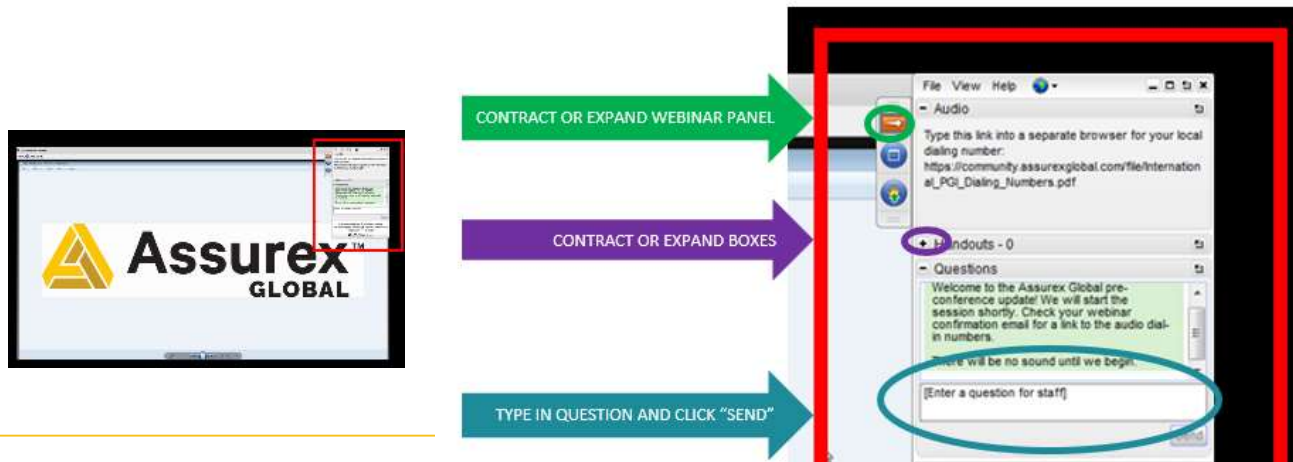
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Agenda

- Background
- Reporting Responsibility
- The Process
- Setting up an Employer HIOS Account
- Employers Submitting Data

Background

Prescription Drug Data Collection (RxDC) Background

- Why?
  - Section 204 of The Consolidated Appropriations Act, 2021 (CAA) requires insurance companies & employer-based health plans to annually submit information about prescription drugs and health care spending
  - Federal Government will issue annual report
  - Collects data on drug costs with the goal that the data can be used to help lower drug costs

Some Rx Cost Facts

- Spending growth on drugs was largely due to growth in spending per prescription, and to a lesser extent by increased utilization.
- Drug spending is heavily driven by a relatively small number of high-cost products.
- The majority (80%) of prescriptions that Americans fill are for generic drugs, but brand name drugs accounted for 80% of prescription drug spending
- The top 10% of drugs by price make up fewer than 1% of all prescriptions, but account for 15% of retail spending.

Trends in Prescription Drug Spending, 2016-2021. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2022.

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Prescription Drug Data Collection (RxDC) Background

- When?
  - Reporting Due by December 27, 2022 for Rx data for calendar year 2020 and 2021
    - Requirement was first scheduled to go into effect 12/27/2021 for 2020 data – but was delayed to 12/27/2022 (for 2020 and 2021 data)
  - Reporting then required annually by June 1 beginning 6/1/2023 (for 2022 data)
- Other Details
  - Required for all group health plans, but not for account-based plans (e.g., Health FSA or HRAs) or excepted benefits (e.g., limited-scope dental or vision)
  - Plans that may need to be included in reporting (more guidance is expected…)
    - Telemedicine
    - On-site clinics
    - Stand-alone specialty drug benefits

Prescription Drug Data Collection (RxDC) Background

- What?
  - Reporting for employer plans consists of 9 required data files (and possibly some narrative files explaining some of the data and assumptions) to be submitted electronically to the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS)
    - Data is submitted through the HHS Health Insurance Oversight System (HIOS) Portal
      - HIOS is used to collect health insurance data from insurance companies, states, and employers related to a number of different federal requirements
      - Self-insured employers may have already set up a HIOS account to apply for the Health Plan Identifier (HPID) number back in 2014

Important Note
The requirement is only a data collection requirement – it has nothing to do with the employer plan benefit structure (co-pays, deductibles, etc., what drugs are covered by the plan, etc.)

RxDC– The Employer Plan Files

- Plan Files and Data Files
    - ~~P1. Individual and student market plan list~~
    - P2. Group health plan list
    - ~~P3. FEHB plan list~~
    - D1. Premium and Life-Years
    - D2. Medical 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

Who has the data?

Carrier, TPA and/or Employer

Carrier, TPA, or PBM

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Prescription Drug Data Collection (RxDC) Background

- Reporting Includes:
  - Total Rx spending
  - 50 most common brand prescription drugs paid by the plan
  - 50 drugs with greatest cost increase
  - Claims paid for each of the 50 most costly drugs by total annual spending and the annual amount spent for each
  - Rebate Data
  - TPA and PBM fees
  - Total spending by the plan by types of cost (e.g., hospital, primary care, specialty care, prescription drugs)
  - More

Examples of Data Being Collected

	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
Bona Fide Service Fees				x		
Dollar Increase in Total Spending			x			
Drug Code	x	x				
Drug Name	x	x				
Frequency Rank	x	x				
Manufacturer Cost Sharing Assistance	x	x	x		x	x
Transfer of Fees & Other Remuneration from Mfg. to Plan/Issuer/Carrier					x	x
PBM Spread Amounts				x		
Prior Year Manufacturer Cost Sharing Assistance			x			
Rebate Rank						x
Rebates Passed to Member at POS					x	x
Rebates Retained by PBM					x	x
Rebates Retained by Plan/Issuer/Carrier					x	x
Rebates/Fees/Other Remuneration					x	
Restated Prior Year Rebates/Fees/Other				x		x
Spending Increase Rank			x			
Total Rebates/Fees/Other Remuneration				x	x	x

Reporting Responsibility

Reporting Responsibility

Most employers will rely on vendors to do some, or all, of the reporting – However – some self-insured employers may need to do some of the reporting themselves

- The organization submitting the data is referred to as the "Reporting Entity"
  - There may be multiple reporting entities for an employer's plan (TPA, PBM, Employer)
- Most vendors will be submitting aggregate files data that includes data for all of their employer clients – not plan specific employer plan data

Employer Responsibility By Type of Plans Offered

- Employer Type 1 – Fully-Insured
  - Health Plan is fully-insured and all Rx claims are paid by the carrier
    - Subgroup A – In most cases the employer can rely on the carrier to submit all required reports
    - Subgroup B – A small number of carriers will file most of the data but are telling the employer to file the D1 file (Premium & Life Years) and accompanying P2 file
- Employer Type 2 – Self-Insured With Integrated Vendor
  - Health plan is self-funded – employer uses TPA and its affiliated PBM to handle prescription drugs – medical and Rx claims data are paid by integrated vendor
    - Subgroup A – In many cases, the employer will be able to rely on the TPA to submit all required reports
    - Subgroup B –Some TPAs will file most of the substantive files (e.g. D2- D8) but expect the employer to file one or more files
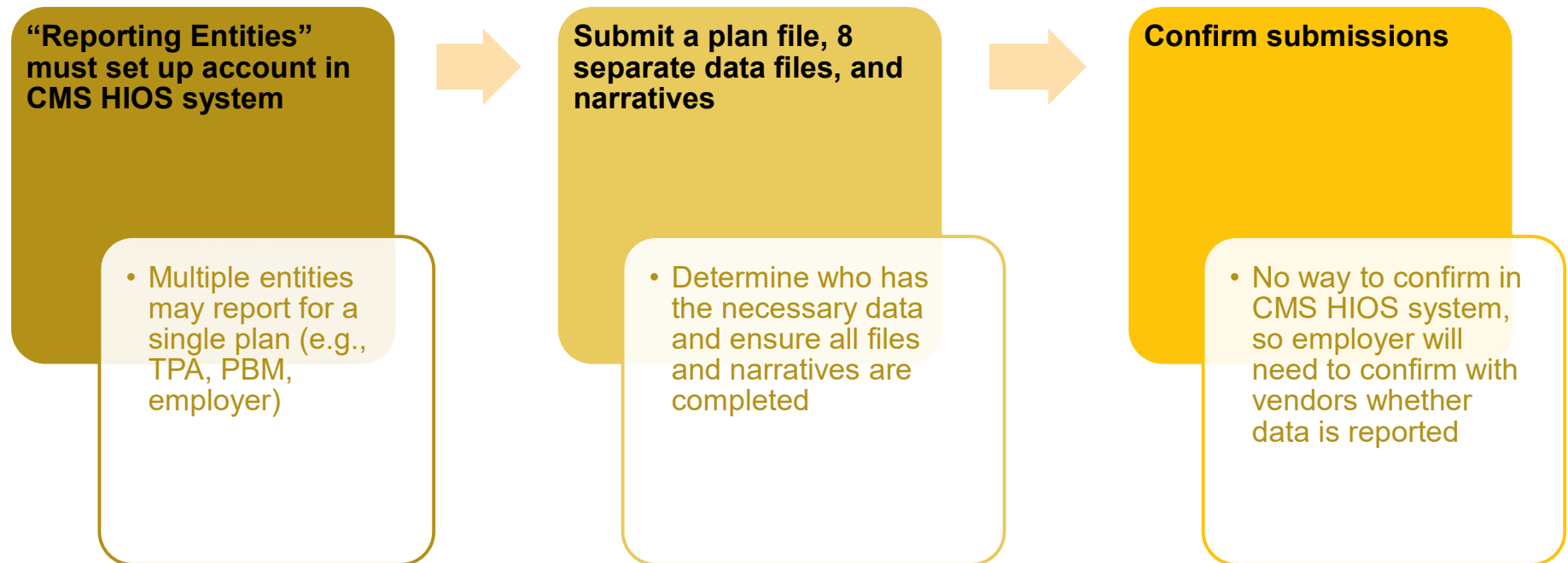   - Most commonly the D1 file (Premium & Life Years) and accompanying P2 file

Employer Responsibility By Type of Plans Offered

- Employer Type 3 – Self-Insured with Separate, Multiple, or Carve-out Vendors
  - Health plan is self-funded but has one or more vendors who handle drug claims separate from the medical TPA (e.g. TPA with a carve-out PBM, integrated TPA/PBM but separate specialty drug program, etc.)
    - The employer will need to work with the TPA and each drug vendor separately to complete the filing
    - Communicate with each vendor to make sure that vendor is submitting the reports that vendor is responsible for
      - A common scenario would be the TPA submits the D1 and D2 files and the PBM submits the D3-D8 files
      - The vendors may also require the employer to submit certain files itself, e.g. the D1 file and accompanying P2 file

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The Process

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RxDC – The Process

"Reporting Entities" must set up account in CMS HIOS system

- Multiple entities may report for a single plan (e.g., TPA, PBM, employer)

Submit a plan file, 8 separate data files, and narratives

- Determine who has the necessary data and ensure all files and narratives are completed

Confirm submissions

- No way to confirm in CMS HIOS system, so employer will need to confirm with vendors whether data is reported

Prescription Drug Data Collection (RxDC) Background

- Step 1 – Identify how much of the reporting will be done by vendor

- Step 2 – If employer needs to submit any of the data set up an employer HIOS account

- Step 3 – Collect 2020 and 2021 data to complete necessary files and upload to HIOS by December 27, 2022

- Step 4 – Repeat process for 2022 data due by June 1, 2023

Common Employer Filing Scenarios

- In many cases the TPA is filing the D1 & D2 and the PBM is filing the D3-D8 files
- We are hearing from some vendors that the Carrier, TPA, and/or PBM are submitting all files except D1
  - Employer must submit a D1 and P2 File
- Multiple Vendors submitting the same file for a plan
  - In cases where multiple vendors are submitting the same files for one employer plan, one of the vendors is supposed to submit a P2 file that lists all vendors reporting on that plan
    - We are seeing vendors request "other vendor" data from the employer

Setting Up a HIOS Account

Setting Up Your HIOS Account

- Setting up Your HIOS Account
  - There are several steps that need to be completed for a new user to gain access to the HIOS system to upload RxDC files
- Resources
  - HIOS Portal User Manual - https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HIOS-Portal-User-Manual.pdf
  - A Quick Reference Guide outlining the steps for new users to register for a CMS EIDM account and request access to HIOS - https://regtap.cms.gov/uploads/library/HIOS-Portal-RxDC-Quick-Guide-09-06-2022.pdf

> **TIP:** CMS has set up a help desk to assist with this process which can be reached at 1-855-267-1515 or CMS_FEPS@cms.hhs.gov .

Setting Up Your HIOS Account

1. Set Up CMS Security
   - Employers must set up CMS Enterprise Identity Management (EIDM) security controls before gaining access to HIOS

2. Set Up Your Access to HIOS
   - Go to the CMS Enterprise Portal (https://portal.cms.gov) and enter your credentials from the EIDM process you have completed - Select "Access HIOS"
   - Register an Organization in HIOS (for New Users).
   - Request HIOS Roles
     - Each organization must have at least TWO users assigned as the Organization Role Approver, because a user cannot approve their own pending role requests.

3. Go to Rx Data Collection in HIOS
   - After HIOS Role request is approved, log back into HIOS and select "Prescription Drug Data Collection (RxDC)" under HIOS Modules

Employers Submitting Data

Employer Filing

Reporting instructions and templates for each data file are available on the CMS RxDC website

https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

The Files

- The filing instructions show exactly how the data should be formatted for each data element

- Any time a reporting entity submits any data they must include P2 file with plan information

- There are narrative files that need to be submitted to explain information in some of the files – If all the employer is submitting is a D1 and P2 file then a narrative file is not necessary

The D1 Premium and Life Years File

Issuer or TPA Name
Issuer or TPA EIN
State (Enter one state where plan is located)
Market Segment ((FI Small Group, FI Large Group, SF small employer, SF large employer)
Average Monthly Premium Paid by Members Note 1
Average Monthly Premium Paid by Employers Note 1
Life Years
Earned Premium (Fully-insured plan)
Premium Equivalents (Self-insured plans)
ASO/TPA Fees Paid (included in the Premium Equivalents field)
Stop Loss Premium Paid (included in the Premium Equivalents field)

NOTE 1: Employer/Employee premiums do not have to be included if the reporting entity does not have the data for 2020 and 2021 data reported by 12/27/22. Employers should include if they are filing heir own D1 file. This will be required for 2022 data which will be reported by 06/01/23.

The P2 Group Health Plan List File

Group Health Plan Name
Group Health Plan Number (any internal identifying number – can be the 5500 plan number)
~~HIOS Plan ID~~ (Employers Ignore - Data for Health insurance carriers only)
Form 5500 Plan Number
States in which the plan offered
Market Segment (FI Small Group, FI Large Group, SF small employer plan, SF large employer plan)
Plan Year Beginning Date
Plan Year End Date
Members as of 12/31 of the reference (calendar) year
Plan Sponsor Name
Plan Sponsor EIN
Issuer Name (Fully-insured plans)
Issuer EIN (Fully-insured plans)
TPA Name (self-inured plans) (list all)
TPA EIN (self-inured plans) (list all)
PBM Name (list all)
PBM EIN (list all)
Included in D1 Premium and Life Years? **Employer will answer 1 (y) if also filing the D1 file**
~~Included in D2 Spending by Category? (1= Yes; 0 = No)~~ Note 1
~~6 additional fields regarding detailed D3-D8 files~~ Note 2

NOTE 1: Employers will not use this field unless they are submitting the D2 spending file. Most employers will rely on their TPA to submit this data

Note 2: Employers will not use the following fields unless they are submitting Rx spending data themselves. Most employers will rely on their TPA or PBM to submit this data

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Resources

- CMS Rx Reporting Page (Instructions & Templates)
    - https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection
- CMS FAQs
    - https://regtap.cms.gov/uploads/library/faq-tracker-20220922-5CR.pdf
- HIOS Portal User Manual
    - https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/HIOS-Portal-User-Manual.pdf
- HIOS Quick Reference Guide
    - https://regtap.cms.gov/uploads/library/HIOS-Portal-RxDC-Quick-Guide-09-06-2022.pdf

Summary

- We do not expect the requirement to be delayed again
- Work with vendors to figure out what they will submit and what employer may need to submit themselves
- Prepare to do it all over again in a few months for the June 1 deadline for 2022 data
- Enforcement
  - We expect regulatory agencies to take an educational approach to enforcement for at lease the first couple of reporting cycles…