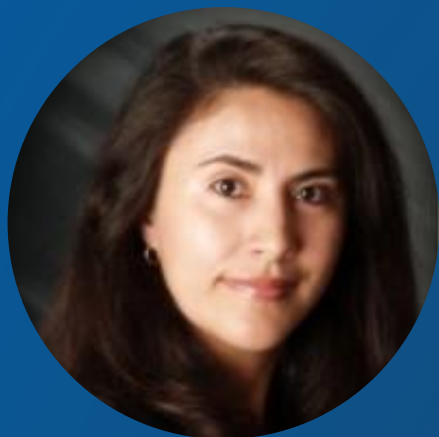




Risk & Insurance | Employee Benefits | Retirement & Private Wealth

Understanding Prescription Drug (RxDC) Reporting Under the Transparency Rules

2025 Overview and Reporting Guide For RxDC



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Agenda

1

Overview of RxDC Reporting

2

Completing Carrier, TPA and/or PBM Questionnaires

3

Creating a HIOS Account and Filing Reports

4

Next Steps

RxDC Reporting Overview

Who files and how to complete carrier, TPA or PBM questionnaires



Prescription Drug Reporting – RxDC Report Section 204

Overview

The Prescription Drug Data Collection (RxDC) reporting requirement was introduced by the 2021 Consolidated Appropriations Act (CAA). RxDC intends to collect information about prescription drugs, medical spend, and premiums paid by employers and covered participants to grant Congress and HHS greater insight on the cost of healthcare.

Plans subject to reporting

Grandfathered and non-grandfathered, self-insured, level funded, insured medical plans and MEC plans (even if MEC plans do not cover prescription plans), sponsored by employers of all sizes. Includes plans sponsored by private and public employers and church plans subject to IRC.

Plans exempt from reporting

Stand-alone and integrated HRAs, HSAs, ICHRAs, dental, vision, excepted benefit plans, health FSAs, retiree-only plans, and plans maintained outside of the U.S. for non-resident aliens.

Prescription Drug Reporting – RxDC Report Section 204

What plans report on

- P2 – Information about the plan, plan year, and plan information
- D1 – Plan enrollment, employer/employee cost-sharing information, TPA fees and stop-loss premiums
- D2 – Medical information
- D3 – Top 50 Most Frequently Dispensed Brand Drugs
- D4 – Top 50 Most Costly Drugs
- D5 – Top 50 Drugs by Spending Increase
- D7 – Rx Rebates by Therapeutic Class
- D8 – Rx Rebates for the Top 25 Drugs

Filing requirements based on plan offering

- P2 is required for all employer-based group health plans that are not FEHB plans (identifies plan and must be filed with every report submitted to CMS)
- D1-D8 reports are required for plans with medical and pharmacy benefits
- D1 and D2 are required for plans with only medical benefits (exclude pharmacy coverage)
- D1 and D3-D8 are required for plans with pharmacy benefits only
- Narrative is required for all plans

Prescription Drug Reporting – RxDC Report Section 204

How are RxDC reports filed

- Returns must be filed via the HIOS website: <https://portal.cms.gov/portal/>. Paper filings will not be accepted.
- Employers who are required to report on one or more areas must register in HIOS or may consider contracting with a third-party entity to comply with their reporting requirements.

RxDC Reporting Deadline June 1, 2025

Plans report for the 2024 calendar year, even if the medical plan is not a calendar year plan.

- Note that if an employer sponsors more than one plan (different ERISA plan number or plan ID if the plan does not use Plan number) the plans must be filed as an aggregate submission.
- Different entities can report for different benefits or services provided by a group health plan, however information reported must pertain to the 2024 calendar year only.
 - TPA can complete P2, D1 and D2 reports and narrative
 - PBM can report on P2, D3-D8 reports and narrative

Prescription Drug Reporting – RxDC Report Section 204

Parties Responsible for RxDC Reporting

Plan Type	Responsible Party	What They File
Insured medical plan	<ul style="list-style-type: none"> Insurance carrier 	<ul style="list-style-type: none"> P2, D1-D8 and narrative
	<ul style="list-style-type: none"> Employer 	<ul style="list-style-type: none"> Must complete carrier survey/questionnaire to provide information to file P2 (plan information) and D1 (employer/employee contribution information for 2024). If an employer fails to complete questionnaire on a timely basis, the employer will be responsible for filing missing information with CMS.
Level-funded medical plan and integrated self-insured medical plan (TPA and PBM are related entities)	<ul style="list-style-type: none"> Employer 	<ul style="list-style-type: none"> Must complete TPA or PBM survey/questionnaire to provide information to file P2 (plan information) and D1 (employer/employee contribution information for 2024). If an employer fails to complete questionnaire on a timely basis, the employer will be responsible for filing missing information with CMS.
	<ul style="list-style-type: none"> TPA and PBM (if same vendor is used or vendors are integrated) 	<ul style="list-style-type: none"> TPA- P2, D1-D8 and narrative
Self-insured medical plan (unintegrated, RX is carved out)	<ul style="list-style-type: none"> Employer 	<ul style="list-style-type: none"> May be required to file P2, D1-D8 and narrative if TPA and PBM will not assist. If TPA and PBM will assist with filing, the employer must complete questionnaire. Failure to complete questionnaire results in employer assuming reporting responsibilities for missing information.
	<ul style="list-style-type: none"> TPA 	<ul style="list-style-type: none"> P2, D1, D2 and narrative
	<ul style="list-style-type: none"> PBM 	<ul style="list-style-type: none"> P2, D3-D8 and narrative

Prescription Drug Reporting – RxDC Report Section 204

What happens if there was a change in PBM or TPA during 2024 or the funding medium (e.g., insured to self-insured) changed? Who reports on behalf of the plan?

- Partial submissions are allowed for the months the PBM and TPA were in service for separate parts of the calendar year (e.g., a fully-insured carrier would report only for the months in service, e.g., January-July data, and the subsequent self-insured plan should only report August-December data).

Important

- If the carrier, TPA, or PBM have informed you that they will be filing RxDC reports on your behalf, confirm what information you must provide to the carrier, TPA and/or PBM.
- If you are required to complete a survey or questionnaire, make sure that you satisfy the carrier, TPA, or PBM's deadline, as failure to meet the deadline you will be required to file with CMS the information that is missing.

Information Medical Carriers, TPAs and PBMs will ask for

If your TPA, ASO, or PBM sent you a letter informing you that they will not be filing P2, D1, D2 or any other reports (D3-D8 and the narrative), you will have to file the reports directly with CMS or engage another third-party to submit reports for you.

The HIOS registration process can take up to two weeks to complete, please make sure you have ample time to register and submit reports.



Completing Questionnaires



Information medical carriers, TPAs, and PBMs will ask for

Fully insured plans

The insurance carrier may send a survey or questionnaire to collect information about the plan, such as plan numbers, name of the plan, percentage or premium paid by the employer or members and the total premiums paid for 2024.

- This information is required to file P2 and D1 reports on your behalf.
- If you fail to provide the required information to the carrier, it is likely that you will be required to report this information to CMS via the HIOS portal, unless you contract with a third-party vendor to file on your behalf.

Level-funded and self-funded plans

Your TPA or PBM may send a questionnaire requesting plan information, in addition to total percentage of premiums paid by members vs. the employer. In addition, the TPA may request total TPA fees paid, and total stop-loss premiums paid by the plan.

- This information is required to file P2 and D1 reports on your behalf.
- If you fail to report the required information to the TPA or PBM, it is likely that you will be required to report this information to CMS via the HIOS portal, unless you contract with a third-party vendor to file on your behalf.

P2 Plan Information: Group Plan Information

Group Health Plan Name (Required)	Group Health Plan Number (Required)	Carve-Out Description	Form 5500 Plan Number (if known)
ABC Health & Welfare Plan	502		502

- **Group Health Plan Name:** Enter the plan’s legal name as it appears in plan documents, wrap SPDs, or Forms 5500.
- **Group Health Plan Number:** If the plan files Forms 5500, enter the plan number on the Form 5500. If not, enter any other unique plan ID number from your accounting system, employer EIN, or contract. Some insurance carriers may ask for a contract number or policy number instead. However, if reporting on HIOS use the ERISA plan number.
- **Form 5500 Number:** ERISA – subject plans with more than 100 participants covered at the beginning of a plan year file a Form 5500 with the Department of Labor. Enter the Plan Number found in the Form 5500.
 - If you aren’t sure if you have filed a Form 5500, visit <https://www.efast.dol.gov/5500Search/>.
 - If you don’t have a Form 5500 plan number, leave this column blank.

P2 Plan Year and Enrollment

Plan Year Beginning Date and Plan Year End Date: Enter the first day of the plan year. For calendar year plans enter 01/01/2024 for beginning and 12/31/2024 for Plan Year End Date. For Non-Calendar Year plans, use two rows as noted below.

Group Health Plan Name	Group Health Plan Number	Plan Year Beginning Date	Plan Year End Date	Members as of 12/31 of the reference year
Jane’s Furniture Health and Welfare Plan	501	07/01/2023	06/30/2024	0
Jane’s Furniture Health and Welfare Plan	501	07/01/2024	06/30/2025	27

Members as of the 12/31 of the Reference Year: Enter the number of members as of 12/31 of the reference year. You must enter a whole number without decimal places. If a plan year ended before 12/31 of the reference year, enter 0. A member is defined as employees, retirees, COBRA QBs, and any other individual covered under the plan, including their dependents (“belly-buttons”).

P2 Insured Plans, TPA and PBM Vendors

Plan Sponsor Name	Plan Sponsor EIN	Issuer Name	Issuer EIN	TPA Name	TPA EIN	PBM Name	PBM EIN
ABC Company	76-980768	ABC Insurance Company	569087960	BCD TPA	670098790	ABC PBM	670987689

Plan Sponsor Name & EIN	<ul style="list-style-type: none">In general, the plan sponsor is the employer, employer organization, association, or trust that sponsors the plan
Issuer Name and EIN	<ul style="list-style-type: none">Self-insured or level-funded and has stop-loss coverage, enter the stop-loss carrier’s name and EIN. If stop-loss coverage is not offered, leave the section blank
TPA Name & EIN	<ul style="list-style-type: none">Fully-insured plans: Leave it blankSelf-funded plans: Enter the information of your TPA or ASO Administrator and their EIN.
PBM Name & EIN	<ul style="list-style-type: none">Enter your PBM’s information. If you don’t have a PBM, leave it blank.

Prescription Drug Reporting (RxDC) – Completing D1 At-a-Glance

How to complete D1 Files

Average Monthly Premium Paid by Members Column E	Average Monthly Premium Paid by Employers Column F	Life Years Column G	Earned Premium Column H	Premium Equivalents (self-insured and level-funded plans) Column I	Admin Fees Paid (included in Premium Equivalents field) Column J	Stop Loss Premium Paid (included in Premium Equivalents field) Column K
Monthly Average <ul style="list-style-type: none"> Divide premium amounts (premium equivalents for self-insured plans) paid by members by 12. Divide by 12 even if the plan was not in effect for the full-12 months 	Monthly Average <ul style="list-style-type: none"> Divide annual premium amounts (premium equivalents for self-insured plans) paid by employer by 12. Divide by 12 even if the plan was not in effect for the full-12 months 	Annual Average <ul style="list-style-type: none"> To calculate member months: <ul style="list-style-type: none"> Count the number of members covered on a given day of each month of the reference year, and Add the number of members from to calculate total member months for the reference year. To calculate life-years: <ul style="list-style-type: none"> Divide member months by 12, and round the resulting number to the 8th decimal place. 	Annual Total (fully-insured plans) <ul style="list-style-type: none"> Earned premium means all premiums paid by a policyholder, and/or plan sponsor to a medical insurance carrier for the reporting year. 	Annual Total (self-funded plans ONLY) <ul style="list-style-type: none"> Premium equivalents may be reported on a cash basis or on a retrospective basis. May not use COBRA accrual rates. Include: <ul style="list-style-type: none"> Medical and pharmacy claims costs (you may use either paid claims or incurred claims) Administrative costs, including fees that self-funded plans paid to an ASO, TPA, PBM, or other entity administering a plan Stop-loss premiums Network access fees, such as preferred provider organization (PPO) fees Payments made under capitation contracts with providers for benefits covered under the plan Subtract: <ul style="list-style-type: none"> Stop-loss reimbursements Prescription drug rebates that were received and retained by the group health plan during the reference year, regardless of whether the payment is retrospective or prospective. 	Annual Total (self-funded plans ONLY) <ul style="list-style-type: none"> Report total annual administrative fees (such as claims processing fees) that self-funded plans paid to an ASO, TPA, PBM, or other entity administering a self-funded plan 	Annual Total (self-funded plans ONLY) <ul style="list-style-type: none"> Total annual stop-loss premium paid by the plan to the stop-loss insurer.

Prescription Drug Reporting (RxDC) – Completing D1 - Insured Plans

How to complete the medical carrier questionnaire

2024 Annual Premiums Paid to Medical Carrier	Average Monthly Premium Paid by Members	Where is this information found?	Which plans does an employer report for?
<ul style="list-style-type: none"> ○ Add all medical premiums paid to the carrier during calendar year 2024. ○ Include premiums paid to medical carrier for all plans offered by the carrier for the 2024 calendar year (e.g. HMO, PPO and EPO), unless carrier states that each plan must be reported for separately. ○ Must report plans offered during 2024, even if the plan(s) were not offered during all of 2024. 	<p>Monthly Average</p> <ul style="list-style-type: none"> ○ Identify annual premium amounts paid by members covered under the plan(s) during calendar year 2024. ○ Include all premiums paid by employees, dependents, COBRA QB (include 2% administrative fee), retirees and tobacco and spousal surcharges. ○ Divide total premiums paid by members by 12. Divide by 12 even if the plan was not in effect for the full-12 months in 2024. <p>* Note that some carriers may request you report a percentage vs. a dollar amount. Follow the instructions provided by the carrier in completing the survey.</p>	<ul style="list-style-type: none"> ○ Insurance carrier or accounting software ○ Payroll/HRIS system- Contributions paid by members for calendar year 2024. 	<ul style="list-style-type: none"> ○ Insured medical plans offered by the carrier sending the questionnaire during 2024 that are reported under the same plan number (if an ERISA plan) or treated as a single plan if the employer is exempt from ERISA. ○ Do not include HRA or HSA contributions made by the employer ○ If the employer offered more than one carrier, employer may have to complete the survey for each carrier. ○ Aggregate the premiums paid in 2024 for each plan sponsored by the employer through the carrier

Prescription Drug Reporting (RxDC) – Completing D1 Self-Insured or Level Funded Plans

How to complete the TPA questionnaire

How to calculate Premium Equivalents for level-funded and self-insured medical plans	Average Monthly Premium Paid by Employers	Where is this information found?	Which plans does an employer report for?
<p>Annual Total (self-funded plans)</p> <ul style="list-style-type: none"> Premium equivalents may be reported on a cash basis or on a retrospective basis. May not use COBRA accrual rates. Include: <ul style="list-style-type: none"> Medical and pharmacy claims costs (you may use either paid claims or incurred claims) Administrative costs, including fees that self-funded plans paid to an ASO, TPA, PBM, or other entity administering a plan Stop-loss premiums Network access fees, such as preferred provider organization (PPO) fees Payments made under capitation contracts with providers for benefits covered under the plan Subtract: <ul style="list-style-type: none"> Stop-loss reimbursements Prescription drug rebates that were received and retained by the group health plan during the reference year, regardless of whether the payment is retrospective or prospective 	<p>Monthly Average</p> <ul style="list-style-type: none"> Identify total premium equivalents for the 2024 calendar year. Subtract the amount paid by members for 2024 from the total premium equivalents. The resulting amount is the employer contribution. Divide 2024 premium equivalent amounts paid by employer by 12. Divide by 12 even if the plan was not in effect for the full-12 months 	<ul style="list-style-type: none"> TPA can provide total claims paid for calendar year 2024 and potentially RX information and stop-loss reimbursements. If Rx is carved out, PBM can provide claims and prescription drug rebate information. Total stop-loss premiums paid can be obtained from client's HRIS/accounting system or from the TPA or stop-loss carrier. Payroll/HRIS system-Contributions paid by members for calendar year 2024. 	<ul style="list-style-type: none"> Self-insured medical plans and prescription drug plans offered by the employer during 2024 Do not include HRA or HSA contributions made by the employer Aggregate all claims and fixed costs for 2024 for all plans offered under the same plan number.

D1 Calculating Life Years

Life Years
902.58
789.86

Life Years is the average number of members throughout the year.

- Count the number of members covered on a given day of each month of the reference year, and add them to get total annual member months
- Divide by 12

Date	Members covered by the plan on the given date
January 1, 2024	882
February 1, 2024	872
March 1, 2024	884
April 1, 2024	921
May 1, 2024	924
June 1, 2024	923
July 1, 2024	925
August 1, 2024	916
September 1, 2024	907
October 1, 2024	906
November 1, 2024	902
December 1, 2024	869
Total Member Months	10,831
# of Life-Years (Total member months / 12)	902.58333333

D1 Premium Equivalents (Columns J–K)

Administrative Fees Paid

\$250,560

included in the Premium Equivalents field

- Report total annual administrative fees (such as claims processing fees) that self-funded plans paid to an ASO, TPA, or other entity administering a self-funded plan. This amount should also be included in Premium Equivalents.

Stop-loss premium paid

\$185,000

included in the Premium Equivalents field

- Report the total annual stop-loss premium paid by the plan to the stop-loss insurer. This amount should also be included in Premium Equivalents. Leave this section blank if the self-funded plan does not have stop-loss insurance coverage.

Next Steps

1

Confirm which report(s) your insurance carrier, TPA and/or PBM will file on your behalf and if you must complete a survey/questionnaire and the deadline to submit the survey/questionnaire. Submit the carrier, TPA, or PBM questionnaire.

2

If you are required to report on one or more of the RxDC reports, refer to Section 3 of this presentation to learn how to Register on HIOS.

3

Gather the necessary information to complete and file RxDC reports from your vendors.

4

Once the registration process is complete and you have the reports to file, file reports on HIOS.

Health Insurance Oversight System (HIOS) New Users

For New Users Registering Tool



Steps for Registration – HIOS User & Submitter

If First Time Using HIOS Must Register and Create Enterprise Portal Account

New Users HIOS Registration

- CMS HIOS Registration will require multiple steps
- CMS Application registration to access the Enterprise Portal
→ registration within the portal to access the HIOS system.
 - Personal Information of the user registering in HIOS to submit RxDC reporting information
 - **Reporting entity only needs one individual for reporting and submitting RxDC Organizational Role Approver (ORA)**
 - If an organization is only registering for the purpose of RxDC reporting in HIOS, it ONLY needs one person to access to the RxDC module and DOES NOT need access to any other module in HIOS, you do not need to request the Organization Role Approver (ORA) role.

○ Registration Process includes:

- Account Creation
- Registering Devices | Multi Factor Authentication (MFA)
- Identity Verification
- Creating Organizations | Assign Organization Functions (must be done before Requesting a Role)
- Requesting Roles within HIOS
- Proceed to upload files and submit them

Creating New HIOS Account

Getting Started on HIOS First Time User

New Users:

1. Navigate to the CMS Enterprise Portal ([CMS Enterprise Portal](#)) and select **New User Registration** at the bottom of the page.
2. Choose Your **Application page** and select your application from the drop-down list (select **HIOS**).
3. Review and **accept** the Terms & Conditions before selecting Next to continue with the registration process.

CMS.gov | Enterprise Portal

Applications Help About

Step #1: Select Your Application

Step 1 of 3 - Select your application from the dropdown. You will then need to agree to the terms & conditions.

Select Your Application

- HETS Collaboration Tools (JIRA/Confluence)
- HIOS**
- Host Access Transformation Services (HATS)
- IC-Innovation Center
- IDM Reports

Login Login with PIV Card

CMS.gov | Enterprise Portal

User ID

Password

☐ I agree to the [Terms & Conditions](#)

Login

Forgot your [User ID](#) or your [Password](#)?
Need to [unlock](#) your account?

New User Registration

Registering New HIOS Account

- Follow steps under **Register Your Information**: requires personal information to generate your User ID and Password to request use of the CMS Application.
 - Personal information Company Email Address and Company Mailing Address
 - If using Personal email or personal mailing address the request for registration may be denied. Use company address' (as this will speed up approval process for access)
 - Create User ID, Password & Security Question/Answer” page, it will state under “Step 3 of 3,” complete your user ID and password and select “Next.”
 - Review “Registration Summary” information, ensure all data fields are correct, and select “Submit User.”
 - An email from **donotreply@cms.gov** subject **“CMS Enterprise Portal – Account Registration”** acknowledging registration will be sent, along with User ID.
- Once received Account Registration email, log in to continue registration process.

HIOS Register Phone, Computer, or E-mail (MFA) Device

Next: Register/Manage Multi-factor Authentication MFA Device

- After you log back into [CMS Enterprise Portal](#), **first time users** will be requested to register a multi-factor authentication (MFA) device.
- Select either Text Message (SMS) or Email from the drop-down menu.
- Enter your phone number or email address and **select Send MFA Code**.
 - The code should be sent to the device within a couple of minutes.
 - Once received, enter verification code to device
- Once the code is entered the device will show in the portal as a new device.

The image displays three screenshots from the CMS Enterprise Portal illustrating the MFA registration process. The top screenshot, titled 'Register Multi-Factor Authentication (MFA) Device', shows a user selecting 'Text Message (SMS)' from a dropdown menu. Below this, there is a text input field for the phone number and a green 'Send MFA Code' button. The middle screenshot shows the 'Text Message (SMS)' selection confirmed, with a 'Re-send Security Code' button and a 'Code' input field containing '291836'. The bottom screenshot shows the 'My Profile' page with a table of registered MFA devices. A blue arrow points from the 'Send MFA Code' button in the first screenshot to the 'Register a device' button in the bottom screenshot, indicating the flow of the process.

Register Multi-Factor Authentication (MFA) Device

Adding a MFA Code to your login, also known as Multi-Factor Authentication, by providing an extra layer of protection to your User ID and Password.

Select the MFA device type that you want to use to log in.

Please note that you are only allowed two attempts to register your MFA device within two attempts please log out, then log back in to try again.

Text Message (SMS)

Text Message (SMS)

The SMS option will send your Security Code directly to your mobile device via a text message. This option requires you to provide a ten (10) digits U.S. phone number for a mobile device that is capable of receiving text messages. Carrier service charges may apply for this option.

The security code has been sent to your MFA device. If you are having trouble, we can resend the security code in 30 seconds.

Re-send Security Code

Code: 291836

Enter Phone Number

Send MFA Code Cancel

Add Device Cancel

My Profile

Manage Multi-Factor Authentication (MFA) Devices

Device Type	Identifier	Status	Actions
Email		Active	View Details
Text Message (SMS)		Active	View Details

Register a device

Creating New HIOS Account

My Portal Page | Add Applications | Roles | Identity Verification

1. Sign into <https://portal.cms.gov> with your User ID and Password and agree to the terms and conditions.
2. On the My Portal page, select **Add Application** or select Here.
3. Under '**Select an Application**', choose HIOS.
4. In the drop-down under 'Select a Role', select HIOS User and then select **Launch**

The image displays two screenshots of the CMS.gov My Enterprise Portal. The top screenshot shows the 'My Portal' page with the 'Add Application' button highlighted in a yellow box. The bottom screenshot shows the 'Select an Application' page with 'HIOS' selected, 'Select a Role' dropdown set to 'HIOS User', and the 'Launch' button highlighted in a yellow box. A blue arrow points from the 'Launch' button in the bottom screenshot to the text 'Launch Identity Verification'.

Launch Identity Verification

Creating New HIOS User Account

Identity Verification & Confirmation

1

Step #1: Identity Verification Overview

To protect your privacy, you will need to complete Identity Verification successfully, before requesting access to the selected role. Below are a few items to keep in mind.

1. Ensure that you have entered your legal name, current home address, primary phone number, date of birth and email address correctly. We will only collect personal information to verify your identity with Experian, an external Identity Verification provider.
2. Identity Verification involves Experian using information from your credit report to help confirm your identity. As a result, you may see an entry called a "soft inquiry" on your Experian credit report. Soft inquiries do not affect your credit score and you do not incur any charges related to them.
3. You may need to have access to your personal and credit report information, as the Experian application will pose questions to you, based on data in their files. For additional information, please see the Experian Consumer Assistance website - <http://www.experian.com/help/>

If you elect to proceed now, you will be prompted with a Terms and Conditions statement that explains how your Personal Identifiable Information (PII) is used to confirm your identity. To continue this process, select 'Next'.

Next

Cancel

3

Step #2: Accept Terms & Conditions

OMB No. 0938-1236 | Expiration Date: 04/30/2017 | (OMB Re-Certification Pending) | [Paperwork Reduction Act](#)

Protecting Your Privacy

Protecting your Privacy is a top priority at CMS. We are committed to ensuring the security and confidentiality of the user registering to EIDM. Please read the [CMS Privacy Act Statement](#), which describes how we use the information you provide.

Personal information is described as data that is unique to an individual, such as a name, address, telephone number, Social Security Number, and date of birth (DOB). CMS is very aware of the privacy concerns around PII data. In fact, we share your concerns. We will only collect personal information to verify your identity. Your information will be disclosed to Experian, an external authentication service provider, to help us verify your identity. If collected, we will validate your Social Security Number with Experian only for the purposes of verifying your identity. Experian verifies the information you give us against their records. We may also use your answers to the challenge questions and other PII to later identify you in case you forget or misplace your User ID /Password.

HHS Rules of Behavior

We encourage you to read the [HHS Rules of Behavior](#), which provides the appropriate use of all HHS information technology resources for Department users, including Federal employees, contractors, and other system users.

I have read the HHS Rules of Behavior for Divisional User Accounts, and I agree to the HHS Rules of Behavior. HHS DoB document number: HHS_OCI_2013

☒ I agree to the Terms & Conditions

Back

Next

Cancel

2

CMS.gov | My Enterprise Portal

Step #3: Enter Your Information

Enter your legal first name and last name, as it may be required for Identity Verification. All fields are required unless marked (optional).

First Name Middle Name (optional) Last Name Suffix (optional)

Enter Social Security Number Birth Month Birth Date Birth Year

Required field:

Is Your Address US Based?
☒ Yes ☐ No

Home Address Line 1 Home Address Line 2 (optional)

City State ZIP Code ZIP+4 Code (optional)

Phone Number

4

Step #4: Verify Your Identity

Confirmation

You have successfully completed the Remote Identity Proofing process.

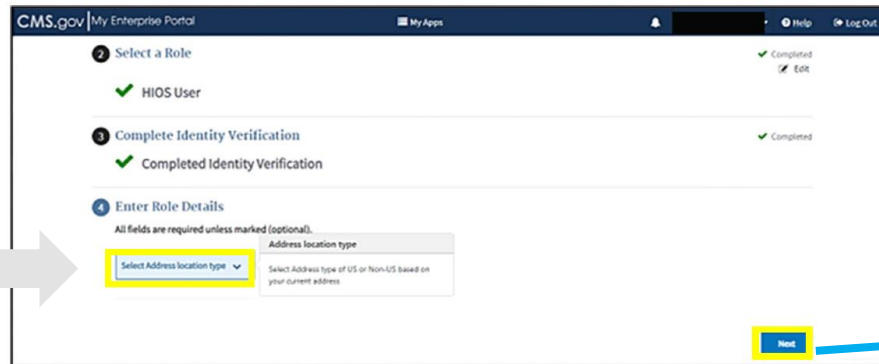
Next

The system requires user to enter their SSN.

- Once you complete the questions and answers on the Verify Identity screen, select the **Next** button. You will see an onscreen message confirming successful remote identity proofing.

Creating New HIOS User Account

HIOS Initial Setup



CMS.gov | My Enterprise Portal

2 Select a Role

- ✓ HIOS User

3 Complete Identity Verification

- ✓ Completed Identity Verification

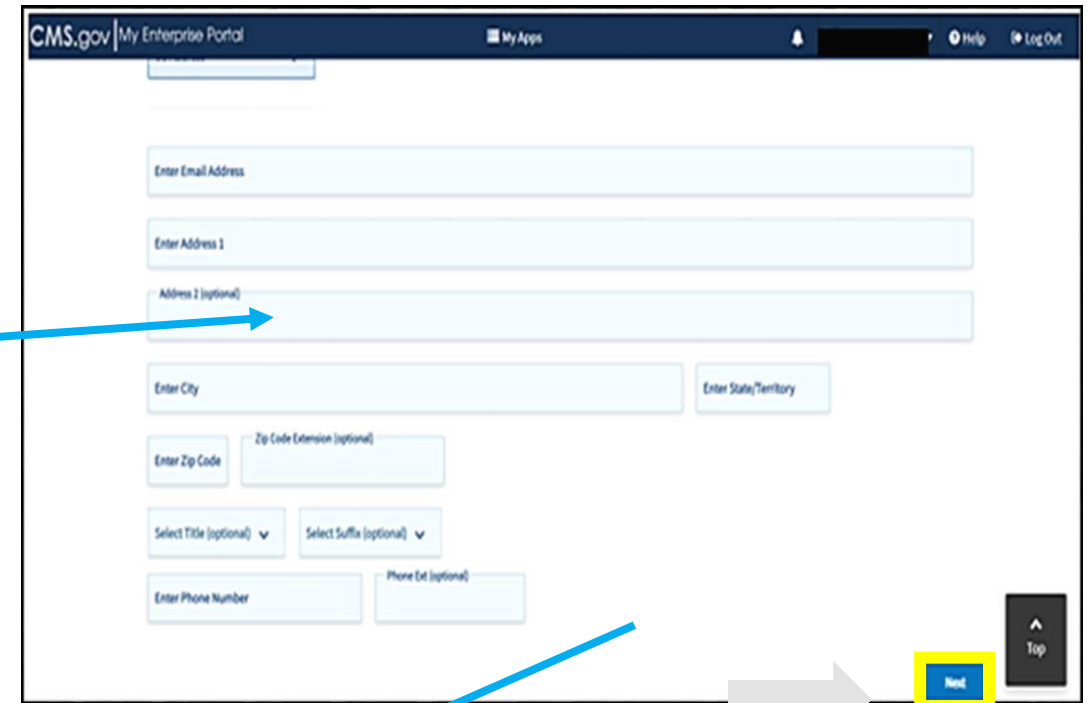
4 Enter Role Details

All fields are required unless marked (optional).

Select Address location type

Select Address type of US or Non-US based on your current address

Next



CMS.gov | My Enterprise Portal

My Apps

Enter Email Address

Enter Address 1

Address 2 (optional)

Enter City

Enter State/Territory

Enter Zip Code

Zip Code Extension (optional)

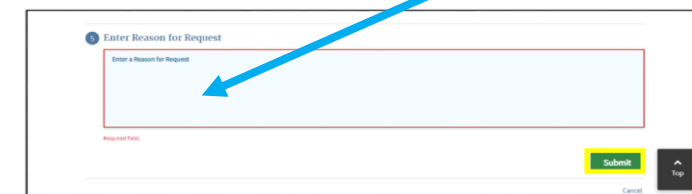
Select Title (optional)

Select Suffix (optional)

Enter Phone Number

Phone Ext (optional)

Next



Enter Reason for Request

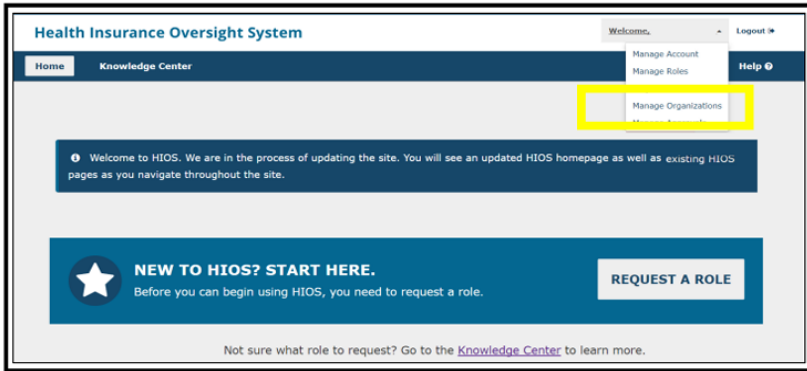
Enter a Reason for Request

Submit

- 5 After completing the Identity Verification process, it will take you back to the Request Application page. Select **Enter Role Details; select Address location type from the drop-down menu**, click on **Next**.
- 6 **Enter information, click next**
- 7 Fill in the reason you need access within the Enter Reason for Request box and select Submit.
 - For example, "I need to submit my data in the RxDC HIOS module."
 - Pop-up confirmation appears click OK**
 - Request New Application Access Acknowledgement message appears, select OK again.**

HIOS Registering New Organization Submitter Role

Adding Organization and Submitter Role



NOTE: New Users will not have any role **permissions**. *Manage Organizations* is for creating these organizations and roles. **Not all users will need to register an Organization.**

- Select **Manage Organizations** link on the HIOS Home Page to register Organizations.
- On the Manage Organizations page, select Create an Organization. You should only create an organization for your company.
- Users can register their Organizations within HIOS. Organizations must exist in HIOS before a user can request a role for the organization.
- It takes **1-2 business days for an organization to be approved**. After the organization has been approved, it will then be available for users to submit role requests.

Manage Organizations

Manage Organizations

What would you like to work on today?

My Organizations

My organizations is where users with an administrative role can view or edit an organization's information.

Create an Organization

Users can register their organizations within HIOS. Organizations must exist in HIOS before users can request a user role for the organization.

Administrator Roles

Certain functionality such as My Organizations or Data Change Requests require users to have at least one of the following administrator roles:

Company Administrator

Representative who is solely responsible for editing Company and associated issuer level data, including relationship information.

Issuer Administrator

Representative who can edit Issuer level data only, including relationship information.

Organization Administrator

Representative of a Non-Federal Governmental Plan or Other Organization who is responsible for editing their organization data.

Add an Issuer

Users can add an issuer for an insurance company within HIOS. Organizations must have been registered as a Company in order to add issuers.

Data Change Request

Users can submit a data change request for organization information that cannot be edited through the My Organizations functionality. Data change requests will be submitted for approval, and users can review the status of their data change request.

Add a Relationship

Users can submit a request to establish a relationship between an organization and an issuer within HIOS.

HIOS Registering New Organization

Register an Organization in HIOS *Continued*

- Organization's Primary Function. There are descriptions of each HIOS organization's primary business to help you decide which organization type to create.
 - All insured/self-insured or level funded Group Health Plans that are not sponsored by a public agency (of a state or subdivision city, county, etc.) should **select “A company whose primary business does not include selling licensed health insurance products or plans.”**
 - A Group Health Plan sponsored by Public agencies (county, city, school district etc.) should select **“A Group Health Plan offered a Non-Federal Governmental Organization to its non-federal governmental employees.”**
- Next enter the Federal EIN/TIN of the entity that sponsors the group health plan.
 - For ERISA subject plans, use EIN found on form 5500 if information has not changed. For Non-ERISA subject plans, use the EIN found in the plan contractual documentation.

1

Select the Organization's Primary Function

* What is the organization's primary business?

☒ **An insurance company that is a legal entity licensed to sell health insurance products and plans.**

This organization may manage plan data including reporting product level data or Medical Loss Ratio information, create an Issuer for the organization, provide or receive TPA services, or work with other company specific data.

In HIOS, this type of organization is referred to as a **Company**.

☐ **A company whose primary business does not include selling licensed health insurance products or plans.**

This organization may come to HIOS to obtain a Health Plan Identifier or provide TPA services.

In HIOS, this type of organization is referred to as a **Non Insurance Company**.

☐ **A Group Health Plan offered by a Non-Federal Governmental Organization to its non-federal governmental employees.**

This organization may report plan information for purposes of HIPAA provision opt-out or external review election.

In HIOS, this type of organization is referred to as a **Non-Federal Governmental Health Plan**.

HIOS Registering New Organization

Register an Organization in HIOS *Continued*

- If an organization does not exist, enter the organization's details:
 - Enter address of the entity that is sponsoring the group health plan.
 - **Leave the TPA section blank. ALL organizations, including TPAs, should skip this section.** Once you complete this step, submit application, and log out. You will receive an email confirming that the organization has been approved. You will have to log in to appoint roles.
- “Confirm the Organization” to process request clicking **Submit**.
- Review and/or edit, click “Revisit this step”

To view further details of Organization details, click [here](#)

Manage Organizations

3

Organization Details

Please enter your organization details below.

* Organization Legal Name

* Incorporated State

Domiciliary Address

Note: The Domiciliary Address is the address where the establishment is maintained or where the governing power of the enterprise is exercised.

* Address Line 1

Address Line 2

* City

* State

* ZIP Code (5 digits)

ZIP Plus 4 (4 digits)

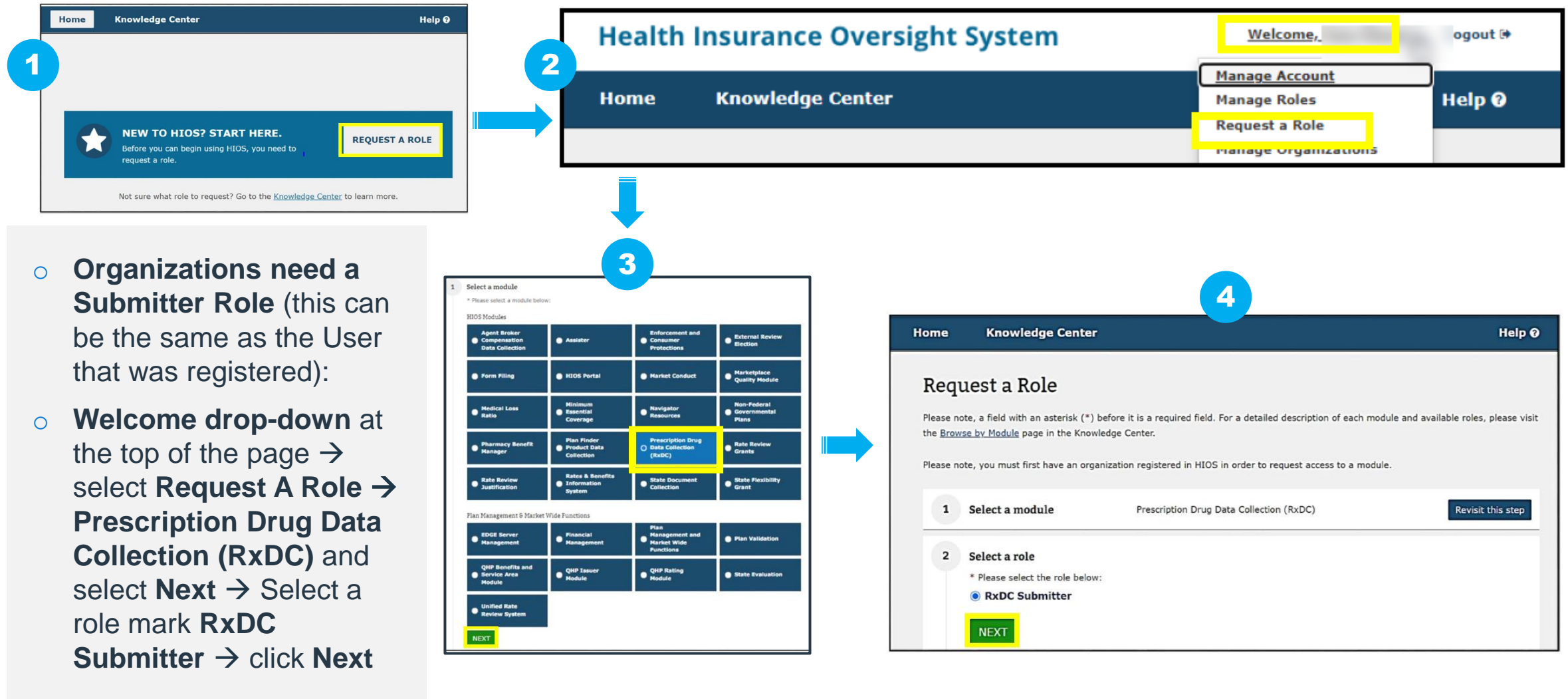
Third Party Administrator (TPA) Information

TPA Type

☒ EDGE Server

☐ Enrollment

HIOS Submitter Role Request



Requesting Roles for HIOS

Requesting Roles For HIOS Module(s)

Reminders

The Organization must exist in HIOS to complete a Role Request.

*Approval for Roles in HIOS occur **within 1-2 business days***

To appoint an RxDC submitter:

- 1. Select a module:** Select the Prescription Drug Data Collection (**RxDC**) to request the RxDC Submitter role (as shown in the image)
- 2. HIOS Role Submitter:** This may be the same individual serving in the user role, or a different individual within the company may be appointed to submit the RxDC report
- 3. Add Association:** Only if the Organization exists in HIOS can a search be done using the “Organization with FEIN” search option
- 4. Enter the FEIN** and click **Search**

HIOS Submitter Role Request

- If the **organization exists** in HIOS, the name will be displayed – Select your company and click **Next**.

NOTE: If your company is not already registered in HIOS, you will receive the message, “The organization does not exist.” If so, select “Create an Organization”. After the organization has been approved, follow these steps to request a role.

- Review the information in the Confirm your request section and select **Submit**.

3 Add association

To add an Association to this role request, you must search for it in the system.

* Association Type

- ☐ HIOS Issuer ID
- ☒ Organization with FEIN
- ☐ Organization without FEIN (Other Organization)

* Search for association

Please enter the Organization Federal EIN/TIN below. The Federal EIN/TIN must be a 9 digit, numeric value.

Showing results for

* ASSOCIATION

- ☒

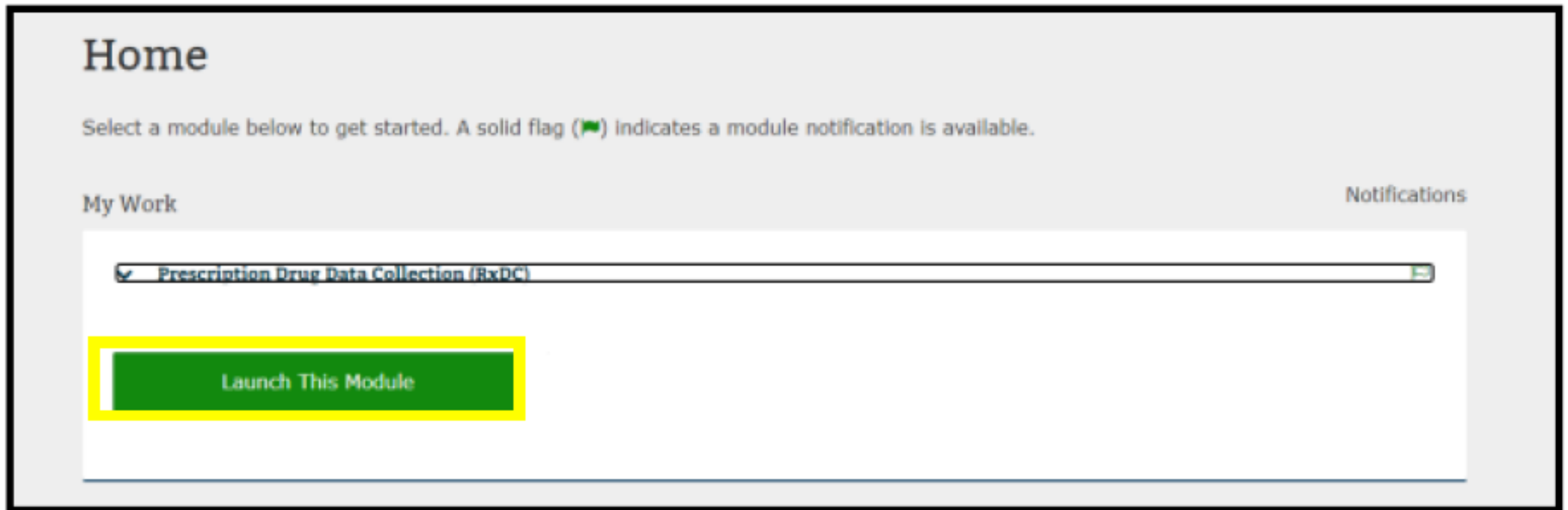
If the information is not correct, return to the step where the incorrect information was entered and make the necessary correction.

A confirmation box will show noting that your role request has been submitted for approval. After a role request for the RxDC submitter role has been approved, you will have access to the Prescription Drug Data Collection (RxDC) module on the HIOS Homepage. Reminder this may take 1-2 business days.

NOTE: If you want more than one role, you will need to use the **Request Role** functionality more than once. However, you should wait for the first role to be approved before requesting a second role. If only using HIOS for RxDC reporting, you do not need additional Roles.

Role Approved | Access to HIOS

After your RxDC Submitter role request is approved, access the RxDC module from your HIOS home page. Select **Prescription Drug Data Collection (RxDC)** and then select **Launch This Module** to begin reporting RxDC data. The [RxDC HIOS Module User Manual](#) has instructions on how to submit your data in the RxDC HIOS Module.



Next | Submit Reports in HIOS

You have confirmed that you are responsible for filing one or more RxDC reports in HIOS (refer to Module 1),

You have completed the HIOS registration process (refer to Section 2 on how to register), and

You have collected the necessary information to file the RxDC reports for your plan

Submit Reports in HIOS

Access the **HIOS RxDC Module**

- Once logged in on “My Portal” page, select “**HIOS**” and then “**Overview.**”
- Follow the prompts within the HIOS until you reach the “**HIOS home page**” scroll to “**My Work**” and select the “**Prescription Drug Data Collection (RxDC)**”
 - Select **Start a New Submission**
 - Select **Submitting Company** – The company name will be listed if the Organization was registered.
 - **Enter Reference Year** – Enter 2024 for reporting due June 1, 2025
 - **Upload Plan Lists** – P2: Group Health Plan List : Drag data files or choose to upload from saved folder
 - **Upload Data Files** – Upload the files which entity is reporting on D1-D8
 - **Upload Narrative and Supplemental Files** – Upload the narrative and supplemental files if applicable
 - **Submit to CMS**
 - **Review Submissions located on the HIOS Dashboard** – To see submitted RxDC reports or if saved for later report will indicate Pending

P2 Group Health Plan List

Plan List: P2 Group Health Plan

Included in D1 Premium and Life Years?	Included in D2 Spending by Category?	Included in D3 Top 50 Most Frequent Brand Drugs?	Included in D4 Top 50 Most Costly Drugs?	Included in D5 Top 50 Drugs by Spending Increase?	Included in D6 Rx Totals?	Included in D7 Rx Rebates by Therapeutic Class?	Included in D8 Rx Rebates for the Top 25 Drugs?
(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)	(1= Yes; 0 = No)



Included in D1 – D8 Location: P2 | Valid Values:

- 0 or 1 | Must not be blank
- Enter 1 if a plan’s data is included in the respective data file in your submission.
- Enter a 0 if the plan’s data is not included in the respective data file in your submission.

For example: If an employer is submitting D1 and D2 on behalf of a plan, the employer should enter 1 in “Included in D1” and “Included in D2” and enter 0 for “Included in D3” through “Included in D8.” CMS will use this information to reconcile submissions when more than one reporting entity is submitting on behalf of a plan.

Submitting Reports | Upload Files D1-D8

Upload Data File(s)

- In the Data Files section, you may upload up to eight separate files. **NOTE:** If the group needs to self-report, most likely they will only be filing the D1 report, however other reports can also be submitted if the TPA or PBM will not file on the plan's behalf.
 - **D1. Premium and Life Years**
 - D2. Spending by Category
 - D3. Top 50 Most Frequently Dispensed 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
- The specific data being requested within each of the files can be found within the RxDC Reporting Form Instructions on the RxDC Home Page. **Reminder:** The system will only accept CSV files.

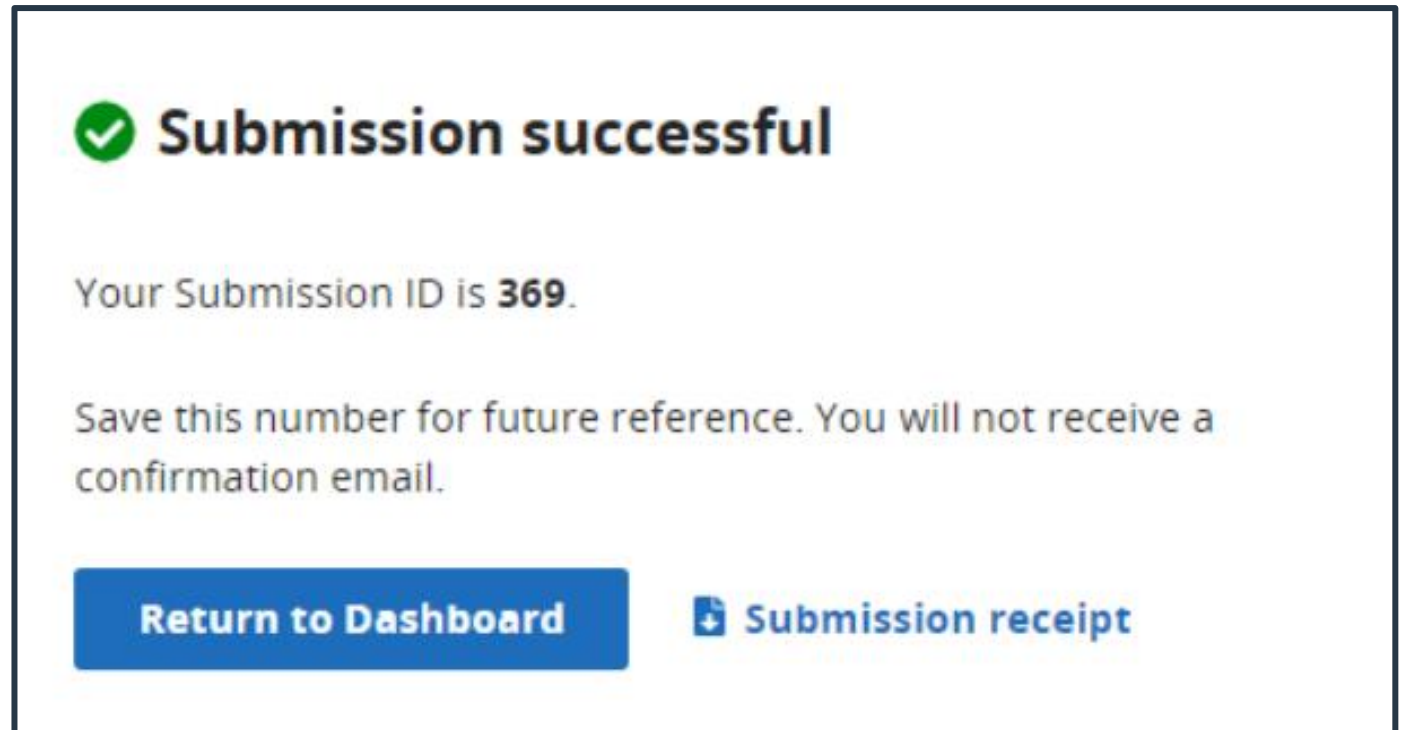
Assembling Your Narrative Response for the Module

Step 4: Upload Narrative and Supplemental Files

- Please note that most TPAs and PBMs are handling the narrative response. The narrative response will likely address the following topics:
 - Employer size
 - Net payments from federal or state reinsurance or cost-sharing reduction programs
 - Drugs missing from the CMS crosswalk
 - Prescription drug rebates included or excluded in the D1 Rx Totals
 - Medical benefit drugs and bundled/alternative payment arrangements
 - Allocation methods for prescription drug rebates
 - Impact of prescription drug rebates on premium and out-of-pocket costs

Submit Reports in HIOS

- If the submission was successful, you will receive a Submission successful alert. **Write down your submission ID number and take a screenshot of the confirmation message for your records. You will not receive a confirmation email.**
- After recording your submission ID number, select the 'Return to Dashboard' button to return to the RxDC Home Page, or select the 'Submission receipt' to prompt a printable version of the Submission successful page.



Next Steps & Resources



Next Steps: Key Takeaways for Employers

IMPORTANT

- Discuss with the insurance carrier, TPA, and PBM any shared responsibilities for filing reports; be sure to provide the vendor with a completed data survey by their given deadline if they will report on behalf of the Sponsor of the Group Health Plan.
- For any reporting that will not be completed by the carrier, TPA or PBM, be sure to gather and pre-populate within the [RxDC excel templates](#) for easier upload process.
- Remember that RxDC reports are due on **June 1st of each calendar** year for the prior reporting year.
- Retain copies of the information you filed and confirmation that your submission was accepted.
- Be sure to register and submit files early to meet the June 1st deadline.

HIOS System Access & Resources

HIOS System Access

- <https://portal.cms.gov/>

CMS Resources

- [RxDC reporting Instructions \(PDF\)](#)
- [RxDC templates and data dictionary \(ZIP\)](#)
- [Regulation](#)
- [Frequently Asked Questions \(PDF\)](#)

HIOS Online Manuals

- [HIOS Portal User Manual \(PDF\)](#)
- [HIOS Portal RxDC Quick Reference Guide \(PDF\)](#)
- [RxDC HIOS Module User Manual \(ZIP\)](#)
- [Prescription Drug Data Collection \(RxDC\) Training Materials](#)

REGTAP

If you want to receive an email when the RxDC resources are updated, create a Registration for Technical Assistance Portal (REGTAP) account at <https://regtap.cms.gov>. Select the checkbox "Please send me updates for the Consolidated Appropriations Act / No Surprises Act" in your account settings.

CMS Contact

- Phone Number: 1-855-267-1515
- Email Address: CMS_FEPS@cms.hhs.gov
- Hours of Operation: 9:00AM to 6:00PM ET, Monday - Friday
- [Prescription Drug Data Collection \(RxDC\) | CMS](#)

Thank you

For more information visit www.hubinternational.com

