ALERAGROUP

THE FIVE W'S AND ONE H

Pharmacy data collection under the CAA

(Consolidated Appropriations Act)

Published March 2023

The Consolidated Appropriations Act of 2021 (CAA) added parallel complex pharmacy reporting requirements under the Internal Revenue Code (the Code), ERISA and the PHSA. This paper will deconstruct the pharmacy data collection (RxDC reporting, or "Section 204") reporting requirements. Importantly, the vast majority of employers who sponsor a group health plan will likely have some level of responsibility and should pay close attention to communications from their carriers, third-party administrators (TPAs) and/or pharmacy benefit managers (PBMs) with specific action items and due dates.

Here we will examine the Why, Who, What, Where, When, and How of the RxDC, as well as provide some other common questions that employers have.

At the end of this document, we include the CMS Enterprise Portal and RxDC Quick Reference Guide to assist in setting up the different accounts, including a new organization, that are required to submit information through the HIOS system.

Helpful tip:

Download and open the CMS RxDC Reporting Instructions (3.2023) the RxDC Templates and the RxDC Data Dictionary. Refer to these as you read the rest of the guide.

Other helpful resources include the HIOS Manuals and the regularly updated FAQs. For detailed instructions on setting up an account with CMS, download the RxDC HIOS Access Guide.

CMS may update its instructions, manuals and/or FAQs from time to time. Please understand that the information we have is current as of April 1, 2023.

Why?

Why is RxDC reporting required?

The data collected is statutorily required under the CAA, 2021. The statutory provisions and the promulgating regulations include more than just reporting on pharmacy drug information. They also require plan-level information, including the plan year and number of covered lives, premium equivalents, breaking out the medical claims costs, administrative costs, Administrative Services Only (ASO) and other TPA fees, and stop-loss premiums, and spending on medical claims, including total cost sharing and the amounts not applied to deductibles or out-of-pocket maximums (OOPM) for hospital, primary care, specialty care, and other medical care and services.

The idea is that RxDC reporting will increase medical and pharmacy transparency. Within 18 months of the first submission, the Department of Labor will post the findings on its website, including reimbursements under group health plans, prescription drug pricing trends and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated in such a way as no drug or plan-specific information will be made public.

Thereafter, each year's data will be compiled and findings about pricing trends and the impact of rebates on out-of-pocket costs will be available and updated every six (6) months.

Why is RxDC reporting based on the calendar year when the plan is a non-calendar-year plan?

The tri-agencies (the Department of Labor, Department of Health and Human Services, and the Treasury) explain that collecting pharmacy data for the preceding calendar year better accounts for the timing of when new drugs — both generic and prescription — become available. Accordingly, the annual deadline is not dependent on the plan or policy year.

Who must report the information?

In general, RxDC reporting applies to all private and public group health plans and health insurance issuers, including grandfathered and grandmothered plans that have sponsored such a plan during 2020, 2021 and/or beyond. Some plans are excluded, and they include:

- Account-based plans, such as health reimbursement arrangements (HRAs), flexible spending accounts (FSAs), and health savings accounts (HSAs);

- Excepted benefits, such as stand-alone dental and/or vision plans, many employee assistance plans (EAPs), point solutions such as onsite clinics, hospital or fixed indemnity insurance, disease-specific insurance and short-term limited duration insurance;

- Wellness services that are not billed on a claim;

- Retiree-only plans;

- Plans maintained outside of the United States for the benefit of nonresident aliens;

- Church plans that are not subject to the Code;

- CHIP (Children's Health Insurance Program), Medicaid, Medicare Advantage and Part D plans.

Plans that are not exempt and therefore must report include:

- Fully insured group health plans;

- Self-funded and level-funded group health plans (level-funded plans are instructed to report as a self-funded plan);

- Church plans;

- Non-federal governmental plans (such as plans sponsored by state or local governments, townships and municipalities);

- Group health plans that do not have pharmacy benefits (unless the plan is specifically exempt, it must file and complete a narrative response; Files D3-D8 do not have to be completed in this case);

- Plans that cover US territories;

- Plans that were fully insured and terminated because the company went out of business.

Reporting Entity or Entities

The parties submitting RxDC information (plans, issuers, carriers or vendors they hire) to the tri-agencies through the platform HIOS (Health Insurance Oversight System) are called *Reporting Entities*. As a starting point, plans' Reporting Entities can be summarized based on the funding source(s) during the *reference year*.

A "reference year" is the entire 12-month calendar year from January to December and includes claims paid or received through March 31 of the calendar year following the reference year. For non-calendar-year plans, include those claims incurred during the reference year and paid or received through March 31 of the calendar year following the reference year.

Reporting Entities including employers are permitted to work with vendors to assist in the filing (although the liability remains with the reporting entity). CMS has cautioned that some vendors (as well as some carriers or PBMs) are asking employers to complete an RxDC survey to assist the entity with completing the required forms. Some of these surveys might define things differently from CMS, order things differently or have their own formatting rules. CMS cannot assist with completing these surveys, and any questions should be directed to the organization sending the survey.

Fully insured group health plans:

For each reference year, the carrier is the Reporting Entity for the months in which the employer was fully insured.

Self-insured or level-funded group health plans:

For each reference year, the employer-plan sponsor is the party responsible and liable for failure to comply with RxDC reporting for the months in which it was self-insured.

Reporting Entities may include employers as sponsors of the plan, TPAs, PBMs, outside vendors or some combination thereof.

CMS suggests that plan sponsors get confirmation from their Reporting Entity(ies). Employers should retain this information for six (6) years.

If a non-calendar-year plan changes funding source at renewal, which is in the middle of a reference year, it will only report the information for the months it was self-insured/level-funded. The carrier reports the information for the months in which the plan was fully insured.

Only the Reporting Entity has knowledge of the data it submits. Once a data file is submitted, it cannot be accessed. Moreover, there is not a mechanism for notifying employers when or if their data has been submitted in part or in its entirety. Only the employer serving as its Reporting Entity or one that utilizes a vendor that provides granular information and confirmation will know what was reported when.

When must the information be reported?

The initial filing deadline was twice delayed, making January 31, 2023, the final deadline for reference years 2020 and 2021 RxDC reporting. Subsequent filings are due June 1 of the year immediately following the year being reported, e.g. June 1, 2023, for reference year 2022.

Keep in mind that Reporting Entities will place deadlines on employers in advance of June 1 each year. It is important to read the communications from TPAs, PBMs, carriers and other vendors informing employers of the different actions and deadlines those entities will or will not take on behalf of past and current clients. Employers that miss a deadline might be forced to file on their own or incur additional expenses from engaging with a new vendor. Alera Group is not able to serve as a Reporting Entity for clients.

What must be included?

RxDC reporting for group health plans includes one plan list (P2), a total of eight data files (D1-D8) and a narrative response addressing seven specific items requested by the tri-agencies pertaining to the "reference year," which is the calendar year for all plans. As noted above, there may be more than one Reporting Entity submitting information. The submission is considered complete if all the required files are submitted regardless of the Reporting Entity(ies). An entity cannot upload two versions of the same data file type or two versions of the narrative response in the same submission.

Plan lists – P2

As we go through the next sections, it will be helpful to **open the RxDC Data Dictionary and the P2 Group Health Plan List Excel file.**

P2 identifies the plan(s) included in each submission. If an employer is submitting data files or a narrative response, it MUST submit a P2 file.

Determining an employer's reporting compliance across multiple reporting entities

The plan list (P2) is the file that reconciles each plan sponsor's submissions across multiple Reporting Entities using column K – Plan Sponsor EIN – and columns R through Y, referring to each of the eight (8) data files.

Of all the complexities in RxDC reporting, determining if a plan has submitted all eight data files seems straightforwardly simple.

K	R	S	T	U	V	W	X	Y
Plan Sponsor EIN	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)

One reporting entity

There are four common scenarios in which a plan will have all its data submitted with one Reporting Entity. They are:

1. If a plan is fully insured the entire calendar year;
2. If a plan sponsor is its own Reporting Entity;
3. If a plan sponsor outsources to a single vendor submitting on its behalf;
4. If a plan sponsor has an integrated plan in which medical, pharmacy and stop-loss are all under one TPA and the TPA submits on the employer's behalf.

In these scenarios, the same row will have the plan sponsor's EIN, column K, and a "1" in columns R-Y. This indicates that the Reporting Entity filing P2 is submitting the data files (D1-D8) and narrative response tied to that employer's EIN.

K	R	S	T	U	V	W	X	Y
Plan Sponsor EIN	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)
012345678	1	1	1	1	1	1	1	1

Multiple reporting entities

There are many scenarios in which an employer will have multiple Reporting Entities during a single reference year. Here are some common scenarios:

- Employer has a non-calendar plan year and moved from fully insured to self-/level-funded or vice versa at renewal;

- Employer had a non-calendar plan year and changed administrator(s) at renewal;

- Employer had an ASO arrangement during the reference year and used different PBMs, behavioral health, and/or stop-loss carriers to manage the plan;

- Employer had a pharmacy carve-out or utilized a non-integrated PBM apart from its TPA;

- Employer had a specialty pharmacy benefit apart from the general PBM;

- Employer had a TPA and/or a PBM and/or a stop-loss carrier who is unwilling or unable to complete RxDC reporting on the employer's behalf.

A plan, issuer or carrier can allow multiple reporting entities to submit on its behalf. For example, a self-funded group health plan may contract with a TPA to submit the Spending by Category data file (D2) and separately contract with a PBM to submit the Top 50 Most Costly Drugs file (D4). The submission for a plan, issuer or carrier is considered complete if CMS receives all required files, regardless of who submits the files.

Here's an example of an employer who had an ASO as the Reporting Entity for D1 — premiums (including stop-loss) and life years; the TPA is the Reporting Entity for D2 — medical claims data; and the PBM is the Reporting Entity for D3-D8 — pharmacy data.

EMPLOYER'S P2

Capturing the TPA and PBM, and indicating that this filing includes on D1, premiums, lives, and ASO fees:

K	N	P	R	S	T	U	V	W	X	Y
Plan Sponsor EIN	TPA Name	PBM Name	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)
012345678	TPA	PBM	1	0	0	0	0	0	0	0

TPA'S P2

Capturing employer's information and only reporting on the medical claims information:

K	N	P	R	S	T	U	V	W	X	Y
Plan Sponsor EIN	TPA Name	PBM Name	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)
012345678	TPA	PBM	0	1	0	0	0	0	0	0

PBM'S P2

Capturing employer's information and reporting all the pharmacy data:

K	N	P	R	S	T	U	V	W	X	Y
Plan Sponsor EIN	TPA Name	PBM Name	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)
012345678	TPA	PBM	0	0	1	1	1	1	1	1

You can see how CMS will be able to reconcile utilizing plan lists and determining whether an EIN has its data accounted across all eight data files reported.

The instructions initially required that only one Reporting Entity can submit the same data file on behalf of the same plan. This means that employers who changed their PBM and/or TPA mid-year have to coordinate and encourage cooperation amongst two competitors involving sensitive information.

Updated instructions have changed that following relief during the initial reporting cycle; if a plan, issuer or carrier changes vendors during the reference year (such as changing a TPA or PBM), it's acceptable for the previous vendor to report the data from the period prior to the change and for the new vendor to report the data from the period beginning on the date the change was effective. Alternatively, the previous vendor may provide the data to the new vendor, and the new vendor would report the entire year of data.

Providing basic plan information

P2 outlines plan-level information, such as the plan year, number of individuals who have coverage on the last day of the reference year (December 31) and states in which "coverage is offered."

Remember, if an employer is submitting any information as a Reporting Entity, it must file a P2. Alternatively, an employer may be asked by another party to respond to information requests for a Reporting Entity's "master" P2 file.

The Excel templates use red, yellow, blue and green in Row 1. CMS noted that the colors are merely to help the user's eyes differentiate between columns. Nothing is to be inferred from the color of a particular column. In fact, when the spreadsheets are saved as CSV files as required for submission, the colors disappear.

Here are some helpful tips for completing the P2 data points properly based on the guidance given to date.

WIDGETCO EXAMPLE

WidgetCo has approximately 150 employees working and living throughout Oklahoma and Texas. It offers a self-insured group health plan operating on a fiscal year. During the 2020 renewal, WidgetCo moved TPAs but kept the same PBM. Here is how WidgetCo reports for P2.

A	B	C	D
Group Health Plan Name	Group Health Plan Number	HIOS Plan ID	Form 5500 Plan Number
WidgetCo Employee Benefits Plan	501		501
WidgetCo Employee Benefits Plan	501		501
Enter the plan name as it appears on the Form 5500, if applicable, or as it appears on the certificate of coverage. If the name includes a comma, enclose the name within quotation marks or remove the comma. Do not use slashes.	Enter a plan number. Examples include the client number, Form 5500 plan number (e.g. 501), or some other alpha, numeric, or alphanumeric number.	LEAVE BLANK. This field is for carriers when they report fully insured plans.	If applicable, enter the 3-digit ERISA plan number reported on Form 5500. LEAVE BLANK if a plan does not have a Form 5500 Plan Number.

If an employer is the single Reporting Entity, it can choose to provide information at the plan option level (e.g. HDHP, PPO, Buy-Up) or combine all medical plan options into one group health plan. It may be easier to report at the plan option level.

E	F	G	H	I
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**
National	SF large employer plans	07/01/2019	06/30/2020	0
National	SF large employer plans	07/01/2020	06/30/2021	361
Use 2-alpha state code. Separate multiple states with a semicolon.	SF large employer plans OR SF small employer plans. An employer is small if it has 50 or fewer employees and large if it has more than 50 employees.	MM/DD/YYYY	MM/DD/YYYY	Total belly buttons
		If a plan has a non-calendar plan year, the plan will occupy two rows. The number of participants enrolled in coverage on the last day of the reference year is "0" because the first row does not include December 31, 2020. It only goes up to June 30, 2020. The second row's dates include the last day of the reference year. Accordingly, the number of belly buttons on December 31, 2020, is reported in column I.		

"States in which coverage is offered" means what, exactly? For purposes of RxDC reporting, a plan is considered "offered" in a state if a person living or working in that state would be eligible to obtain coverage under the plan. Self-funded plans may enter "National" if a person living or working in any state would be eligible to obtain coverage under the plan. "States in which the plan is offered" in the plan lists (P2, P3) is not the same thing as "Aggregation State" in the aggregate data files (D1 – D8).

J	K	L	M	N	O	P	Q
Plan Sponsor EIN	**Plan Sponsor EIN**	**Issuer Name**	**Issuer EIN**	**TPA Name**	**TPA EIN**	**PBM Name**	**PBM EIM**
WidgetCo LLC	012345678			TPA Old	123456789	PBM Same	987654321
		LEAVE BLANK. This is only for Fully Insured Plans.					

Data files and aggregation

All eight data files include a state as a data point. The column name was changed by CMS following the first reporting deadline, but the purpose was not: Column C is now labeled "aggregation state." For self-insured plans, column C is the state in which the plan sponsor has its principal place of business. For fully insured plans, the aggregation state is generally where the policy was issued. Additional instructions are available for employers struggling to determine the aggregation state.

If a TPA is the reporting entity, the data from the different plan sponsors will be aggregated within each state and market segment. PBMs aggregate the data based on issuer or TPA within the market segment and state. However, due to challenges in reporting, CMS will allow a reporting entity to aggregate, within a state and market segment, at a less granular level than the Reporting Entity that submitted D2. For example, within a state and market segment, a PBM submitting D3–D8 may aggregate to the issuer or TPA level even if an entity submitting D2 aggregates at the plan sponsor level.

Data file – D1

The reference year's premium equivalents, stop-loss premium, and ASO and TPA fees paid are reported in D1. Additionally, the average monthly premiums paid by members and that paid by employers as well as life-years (the average number of members throughout the reference year) are reported in D1.

The columns include:

- Average monthly premium paid by members
- Average monthly premium paid by employers
- Earned premium (fully insured)
- Premium equivalents (self-funded)
- Admin. fees paid
- Stop-loss fees paid

For reference years 2020 and 2021, Reporting Entities can leave blank the monthly premiums paid by members (column E) and that paid by employers (column F). However, the relief is temporary and applicable only to the initial filing. Accordingly, coordination between the Reporting Entity and the employer as plan sponsor must happen on some level, beginning in Spring 2023.

Average monthly premium paid by members: Calculate the average using actual spending by members during the reference year and not based on the premium rates charged to the member. Calculate the average based on the calendar year, even if the plan year is not the calendar year.

Average monthly premium paid by employers: Report the average monthly premium PMPM paid by employers or other plan sponsors on behalf of members. Calculate the average using actual spending by employers and not based on average premium rates. For self-funded plans, the total premium paid by employers is total premium equivalents (total plan cost) minus the premium paid by members.

Earned premium means all money paid by a member, policyholder, subscriber and/or plan sponsor as a condition of the member receiving coverage. Earned premium includes any fees or other contributions associated with the health plan.

Premium equivalents: For self-funded plans and other arrangements that do not rely exclusively or primarily on premiums, report the total annual premium equivalent amounts representing the total cost of providing and maintaining coverage or all members. Include claims costs, administrative costs (including ASO and TPA fees), stop-loss premium, network access fees/PPO fees, payments made under capitation contracts. Remove stop-loss reimbursements and prescription drug rebates received by the plan.

CMS recommends employers use a chart like the one below to assist in the premium calculation, and then calculate the premiums:

Average Monthly Premium Paid by Members = Total B divided by Total A

Average Monthly Premium Paid by Employers = Total C divided by Total A

MONTH	MEMBER COUNT (INCLUDING DEPENDENTS AND MEMBERS WHO PAY ZERO PREMIUM)	TOTAL PREMIUM OR PREMIUM EQUIVALENT PAID BY MEMBERS	TOTAL PREMIUM (OR PREMIUM EQUIVALENTS) PAID BY EMPLOYERS
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			
Total	Total A	Total B	Total C

For premium equivalents, COBRA rates should not be used although the same types of costs are used to calculate COBRA premiums. The total dollar amount paid for a reference year should be used rather than the amounts used to set the COBRA rates.

Data File – D2

This data file D2 — medical claims spending by category — makes RxDC reporting more than just pharmacy reporting. Rather, a breakdown of total spend, total cost sharing, and total amounts not applied to the deductible or out-of-pocket maximum is reported across four categories: hospital, primary care, specialty care, and other medical costs and services. An optional breakout of known medical benefit drugs and estimated medical benefit drugs is requested but not required.

Data Files – D3-D8

A plan sponsor's PBM will have the information necessary to complete D3-D8, assuming there is not a specialty pharmacy arrangement or another design feature impacting pharmacy collection. These files include information on the top 50 most prescribed brand drugs, the top 50 most expensive drugs, total pharmacy spend, and the amount in rebates, fees and other remuneration.

Refer to the RxDC Templates to view the following.

- D3 Top 50 Most Frequent Brand Drugs
- D4 Top 50 Most Costly Drugs
- D5 Top 50 Drugs by Spending Increase
- D6 Rx Total Spending, Amounts not Applied to Deductible/OOPM, Spread Amounts, Service Fees
- D7 Rx Rebates by Therapeutic Class
- D8 Rx Rebates for the Top 25 Drugs

Narrative response

Each plan must have one narrative response for compliant RxDC reporting. The open-ended requests are as follows:

1. When stating the market segment, describe the method for determining the number of employees.

2. Describe how net payments from federal or state reinsurance and cost-sharing reduction programs are accounted, if applicable.

3. If the CMS crosswalk is missing an NDC for a drug that was covered under the pharmacy benefit, provide the name and therapeutic class.

4. Explain the circumstances and describe the method used to determine the estimated portion of bundled or alternative payment arrangements (or other non-fee-for-service amounts) that can be attributed to drugs covered under a medical benefit.

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

6. Describe the methods used to allocate Rx rebates, fees and other renumeration.

7. Describe the impact of prescription drug rebates on premium and cost sharing.

> Remember, the Market Segment is either "SF large employer plans" or "SF small employer plans." An employer is small if it has 50 or fewer employees and large if it has more than 50 employees.
>
> Suggested response, as provided in the instructions on page 15: We used the FTE method under 4980H ALE determination for the employer mandate.

Optional supplemental documents

Up to thirty (30) documents can be submitted. Possible supplementation includes a listing of the participating employers in the particular plan.

Where are submissions made?

Submissions occur through the RxDC module in the Health Insurance Oversight System (HIOS) via the CMS Enterprise Portal.

See the appendix for instructions for registering for a CMS Identity Management (IDM) account, registering in HIOS and requesting a submitter role.

How?

How is this enforced?

One mechanism of enforcement is the same provision in the Code as failures of other group health plan requirements (COBRA, HIPAA, Market Reforms and now Balance Billing and RxDC) — IRC 4980D. Additionally, failing to furnish the DOL any requested information relating to the benefit plan results in $110 (indexed) per day — up to $171 per day for 2022.

How can we get more help?

Contact the REGTAP help desk at 1.855.267.1515 or CMS_FEPS@cms.hhs.gov and include "RxDC" in the body of the email for faster service. The responses are delayed about six (6) weeks.

You can also sign up for a REGTAP account and attend informal webinars if you happen to be available upon a moment's notice.

About Alera Group

Alera Group is an independent, financial services firm with more than $1 billion in annual revenue, offering comprehensive property and casualty insurance, employee benefits, wealth and retirement plan solutions to clients nationwide. By working collaboratively across specialties and geographies, Alera Group's team of more than 4,100 professionals in more than 180 locations provides creative, competitive services that help ensure a client's business and personal success. For more information, visit **aleragroup.com** or follow us on **LinkedIn**.

SOCIAL MEDIA

Prescription Drug Data Collection (RxDC)
Health Insurance Oversight System (HIOS)
Access Guide

Purpose: This guide is for group health plans, non-federal governmental plans, third-party administrators (TPAs), pharmacy benefit managers (PBMs), insurance companies (issuers), Federal Employee Health Benefit (FEHB) carriers, and other third-party vendors who want to submit data in the Prescription Drug Data Collection (RxDC) module in the Health Insurance Oversight System (HIOS).

Help Desk: If you need help setting up your account, contact the HIOS Help Desk at 1-855-267-1515 or email CMS_FEPS@cms.hhs.gov. Include "RxDC HIOS question" in the body of your email for faster service.

Resources: For instructions on how to use the RxDC HIOS module after you have access, consult the RxDC HIOS Module User Manual. To download the RxDC data templates and reporting instructions, go to the RxDC Homepage on the Center for Medicare & Medicaid (CMS) website.

Important information before starting the registration process.

It is important that you skip certain sections of the HIOS registration process. They are not applicable to RxDC organizations and users.

- **DO NOT** "Add an Issuer" when creating and managing organizations. (Figure 1 and Figure 4)
- **DO NOT** "Add a relationship" when creating and managing organizations. (Figure 1 and Figure 5)
- **DO NOT** select "Company" or "Other" as the organization's primary function.[1] (Figure 2)
    - **DO** select **Non-Federal Governmental Health Plan** for non-federal governmental health plans (such as school districts and state and local governments).
    - **DO** select **Non-Insurance Company** for group health plans, TPAs, PBMs, and third-party vendors.
- **DO NOT** enter information in the "Third party administrator (TPA) information" section when entering organization details, even if you are a TPA. (Figure 3)
- **DO** select **"Organization with FEIN"** when requesting a role. Don't select "HIOS Issuer ID" or "Organization without FEIN." (Figure 6)
- **DO** enter your company's Employee Identification Number (EIN) when you request a role. Do not enter the EIN of your client. Similarly, you do not need to create an organization in HIOS for your client; only for your own company.

Note: The identity verification process for getting a secure HIOS account can take up to two weeks. To expedite the process, use your work email address instead of your personal email address when creating your account.

Note: If anybody at your company has submitted data in any HIOS module in the past, then your company is already registered in HIOS. You do not need to create an organization.

Note: Go to Section 6 if you already have a HIOS account, your company is registered in HIOS, and the only thing you need to do is request the RxDC submitter role.

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[1] The "Company" option is for insurance companies only. Insurance companies are already registered in HIOS and RxDC users will not need to create organizations.

Figure 1: Do Not Use "Add an Issuer" or "Add a Relationship" on the Manage Organization Page

Figure 2: Select "Non-Insurance Company" as the Organization's Primary Function

Figure 3: Do Not Enter TPA Information (even if you are a TPA)

Figure 4: Do Not "Add an Issuer"

Figure 5: Do Not "Add a Relationship"

Figure 6: Select "Organization with FEIN" on the Request a Role Page

Table of Contents

1   Create a CMS Enterprise Portal Account (For New Users)

Important Information

▪ Users that are not registered in HIOS need to create an Enterprise Portal account by completing sections 1-5.

▪ If you are an existing HIOS user with a CMS Enterprise Portal Account, skip to section 6.

To create a CMS Enterprise Portal Account:

1. Go to the CMS Enterprise Portal at https://portal.cms.gov.

   • HIOS is **only compatible** with Google Chrome and Mozilla Firefox.

2. Select **New User Registration** at the bottom of the screen. (Figure 7)

Figure 7: CMS Enterprise Portal New User Registration
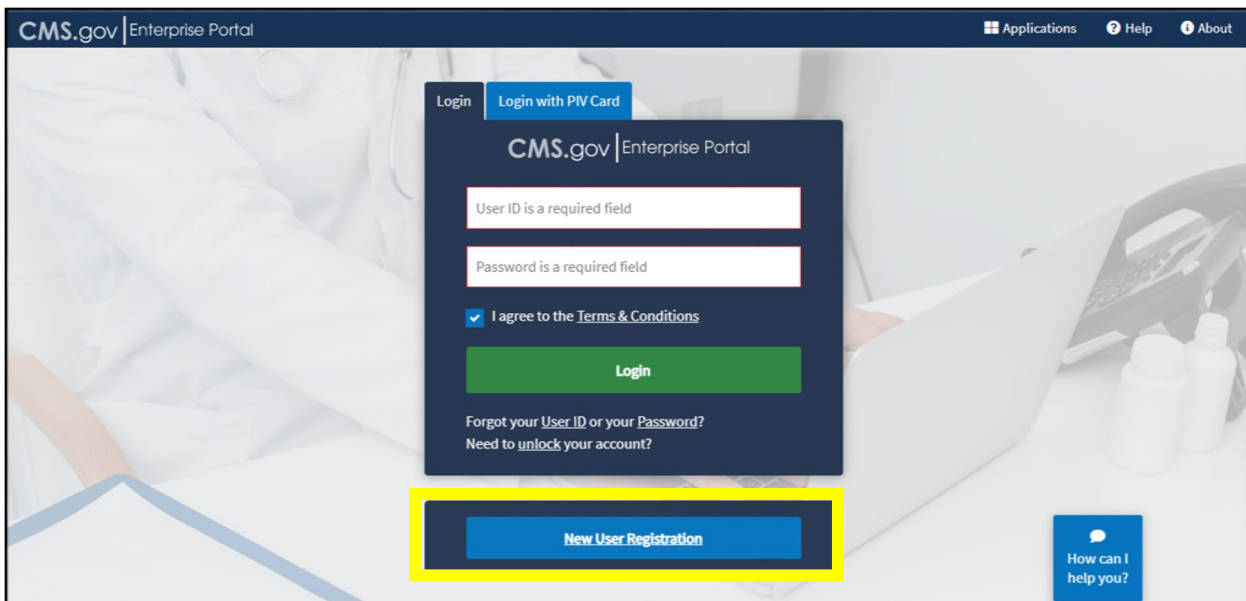
3. Step #1: Select Your Application - Select **HIOS** from the drop-down menu on. (Figure 8)

Figure 8: Select HIOS Application
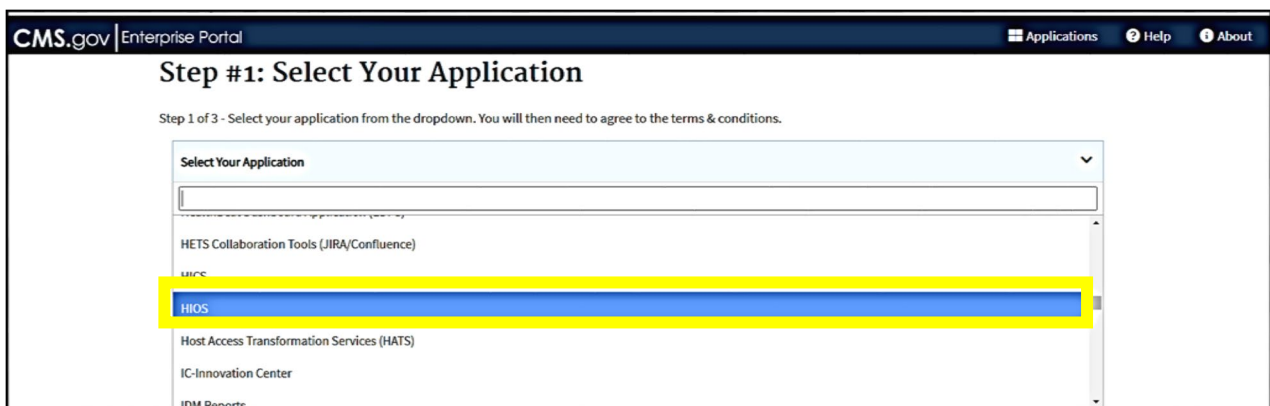
4. Select **I agree to the Terms and Conditions** check box, then select Next. (Figure 9)

Figure 9: Agree to Terms & Conditions

5. Step #2: Register Your Information – **Complete the form** with your personal information and select **Next**. (Figure 10)

   ▪ You may enter either your personal email address or your work email address. If you enter your work email address, it may speed up the approval process when you later request the RxDC Submitter role in HIOS.

Figure 10: Register Your Information

6. Step #3: Create User ID, Password & Security Question/Answer- **Complete the user information** and select **Next**. (Figure 11)

7. Review the Registration Summary Page and **ensure the information is correct**. Select **Submit User**. (Figure 12)
   - An email will be sent from donotreply@cms.gov acknowledging successful registration. This email will contain your Identity Management System (IDM) **User ID** necessary for Multi-Factor Authentication. (Figure 13)

Figure 12: Registration Summary

Figure 13: Account Registration Email
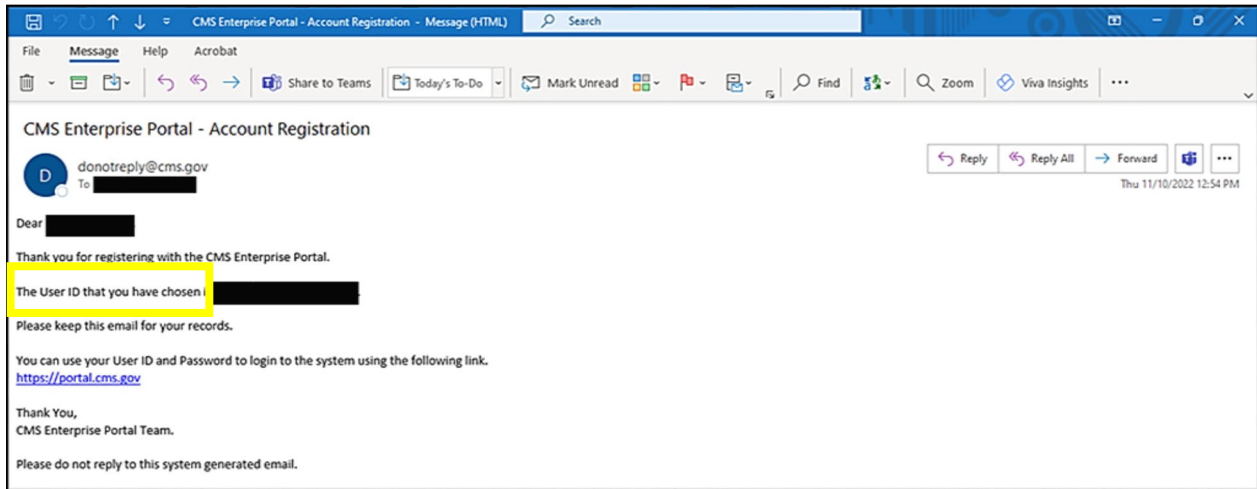
2   Register a Multi-Factor Authentication Device (For New Users)

1. After you receive the email with your User ID, return to the CMS Enterprise Portal at https://portal.cms.gov/ and login with your User ID and password. (Figure 14)

Figure 14: CMS Enterprise Portal Login Page
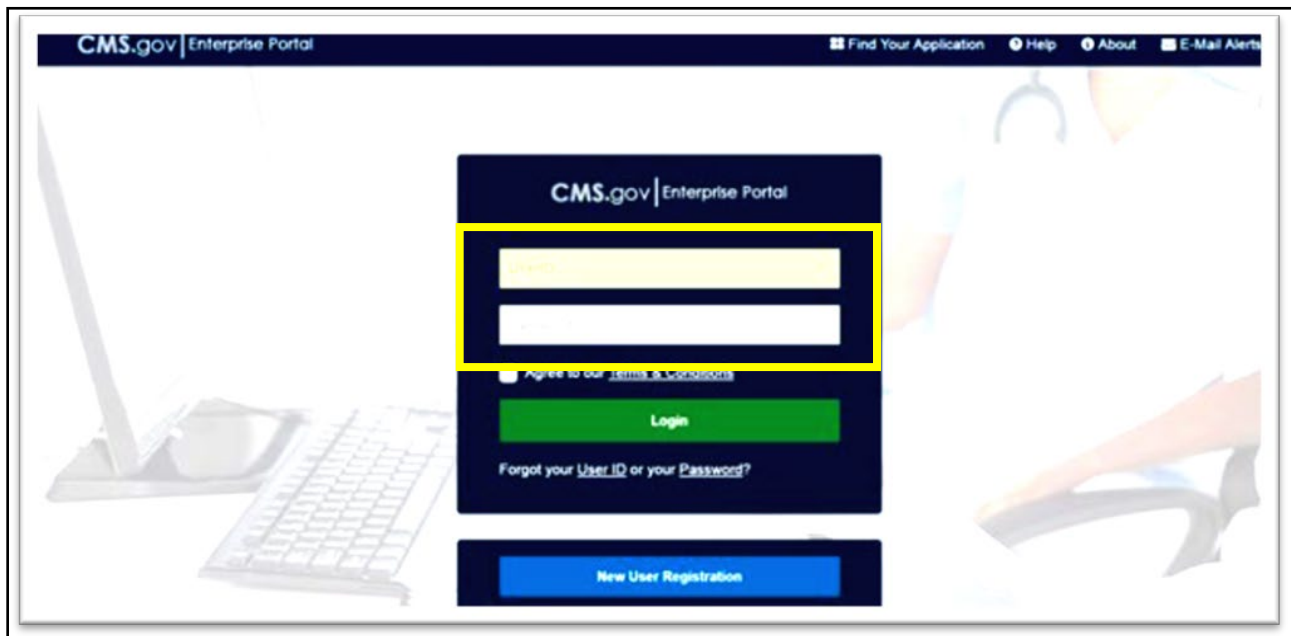
2. First-time users will be prompted to register a multi-factor authentication (MFA) device. Select either Text Message (SMS) or Email from the drop-down menu. **Enter your phone number or email address and select Send MFA Code**. (Figure 15)

    - The code should be sent to your device within a couple of minutes.
    - For further details about setting up your MFA device, consult the Enterprise Portal User Guide.

Figure 15: Register a Multi-Factor Device

Register Multi-Factor Authentication (MFA) Device

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

Select the MFA device type that you want to use to login

Please note that you are only allowed two attempts to register your MFA device. If you are unable 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 MFA 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.

Enter Phone Number

Send MFA Code   Cancel

3   HIOS Access

1. After you create your CMS Enterprise Portal Account and set-up your MFA device, return to https://portal.cms.gov/. Upon login, you will see your My Portal homepage. Select "**Add Application**" in the upper right corner. (Figure 16)

Figure 16: My Portal Home Page – Add Application

CMS.gov | My Enterprise Portal   ❓ Help   ⮕ Log Out

My Portal   ⊕ Add Application

Previous Login: View Login History

ⓘ **Welcome to CMS Enterprise Portal.**

Welcome [   ] to CMS Enterprise Portal.
You've selected HIOS application during your registration. You can request access to this application by clicking here.
You may request access to other applications by selecting "Add Application" button.

🖥 Learn how to add Multi-Factor Authentication (MFA) devices via My Profile in the Manage MFA Devices section.

2. On the Request Application Access screen, select **HIOS** from the **Select an Application** drop-down, then select **Next**. (Figure 17)
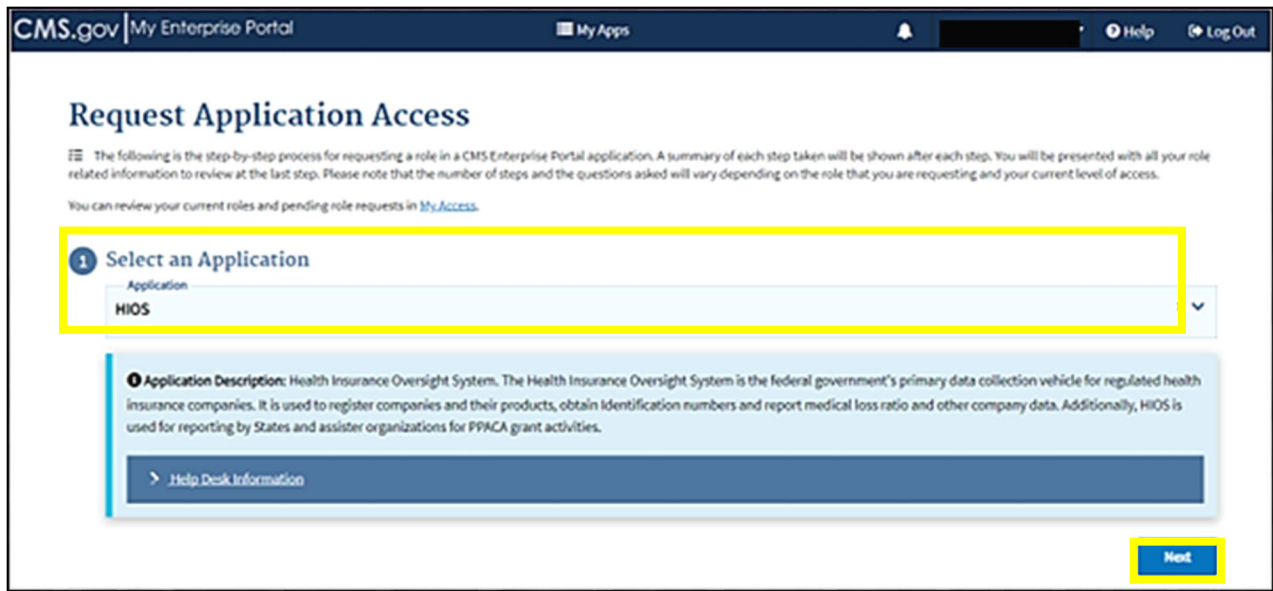
3. Select **HIOS User** in the **Select a Role** drop-down, then select **Next**. (Figure 18)

Figure 18: Select the HIOS User Role
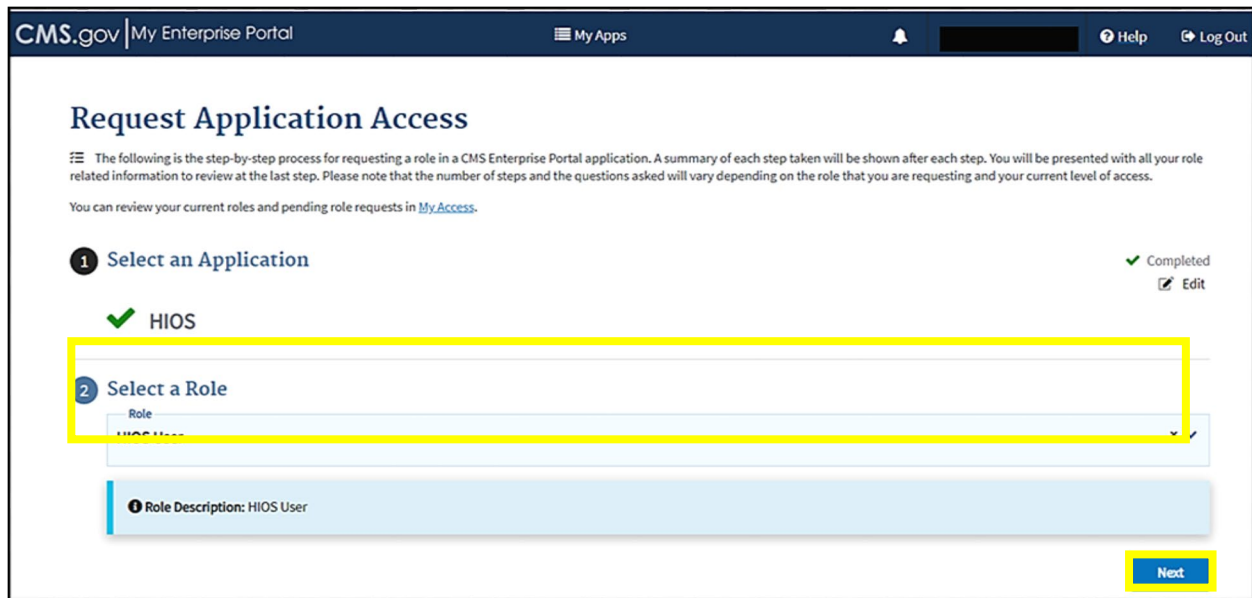
4. Select **Launch** to begin the process of completing identity verification. (Figure 19)

Figure 19: Begin Identity Verification
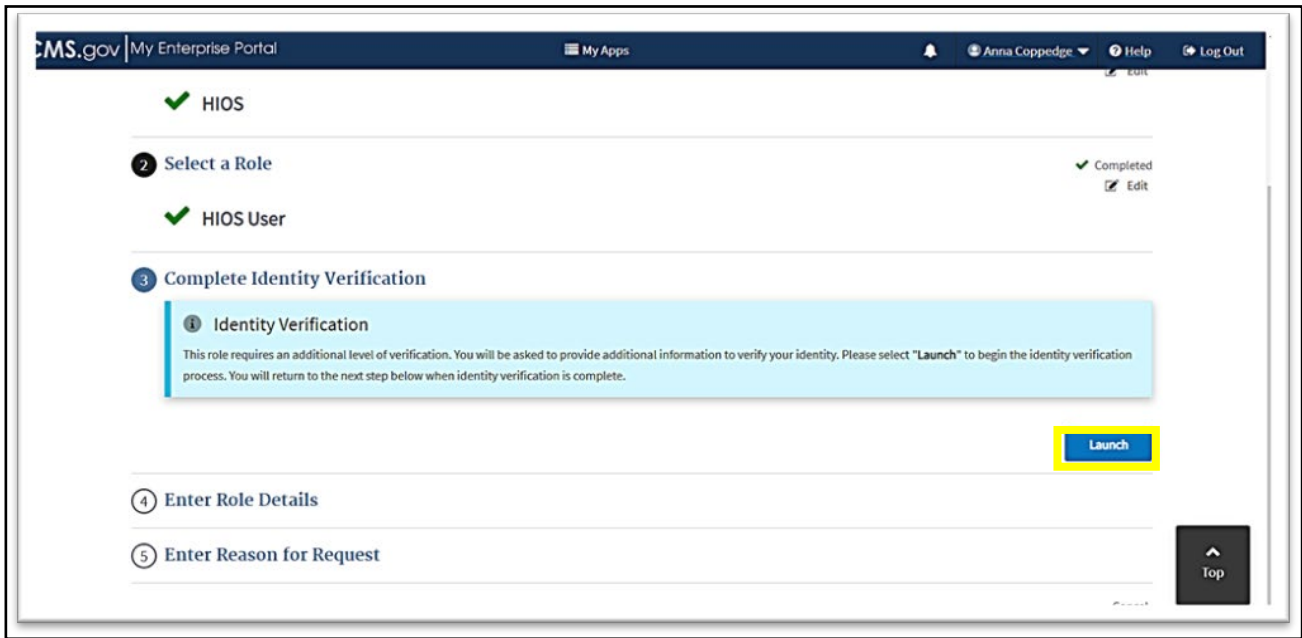
4 Identity Verification

The CMS identification verification process adheres to the guidelines in National Institutes of Standards and Technology Special Publication (NIST) 800-63-3.[2]

1. Step #1: Identity Verification Overview - After you select Launch, select **Next**. (Figure 20)

Figure 20: Step # 1 - Identity Verification Overview

---
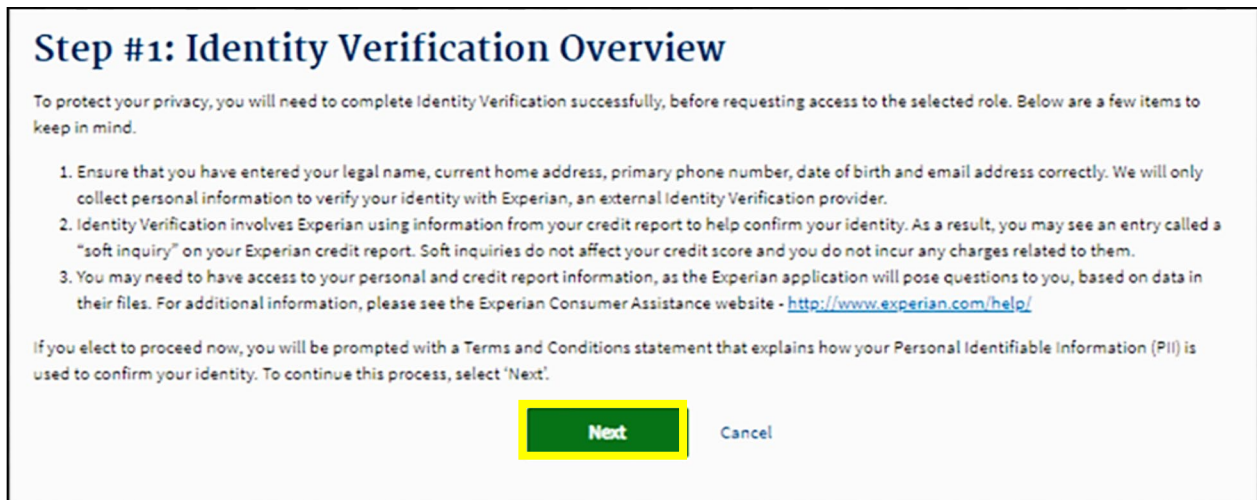
[2] NIST 800-63-3 is available at https://pages.nist.gov/800-63-3/.

2. Step #2: Accept Terms and Conditions - Check **I agree to Terms & Conditions** box and select **Next**. (Figure 21)

Figure 21: Step #2 - Accept Terms & Conditions

3. **Complete the form** to verify your identity and then select **Next**. (Figure 22)
   - The Social Security Number (SSN) is the primary piece of information that is required.[3]

Figure 22: Step #3 - Enter Your Information

4. Step #4: Verify Your Identity - Complete **the identity verification questions** and select **Next**. Select **Next** on the Confirmation screen. (Figure 23)
   - Examples of the identity verification questions include the dates you lived at an address, worked at a job, or opened a credit card.

---

[3] When you enter your SSN, Experian creates something called a soft inquiry. Soft inquiries are visible only to you and no one else. Soft inquiries have no impact on your credit report, history, or score.

- Entering this information will NOT impact your credit score.

Figure 23: Identity Verification Confirmation
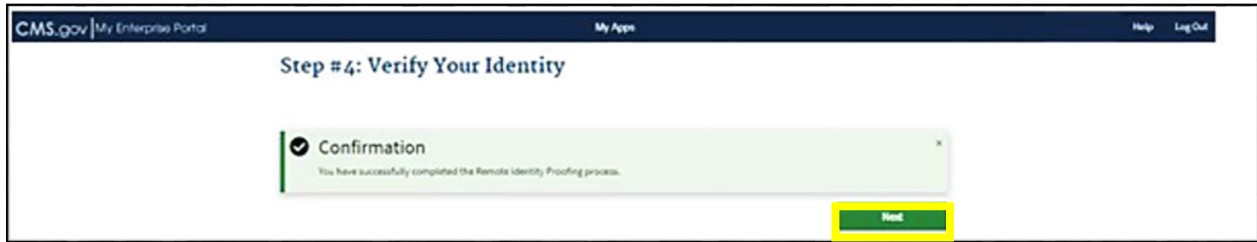
5 Enter Role Details

1. Upon completion of the identity verification, you will be returned to the Request Application Access screen. In the Enter Role Details section, **select Address location type** from the drop-down menu. (Figure 24)

Figure 24: Enter Role Details
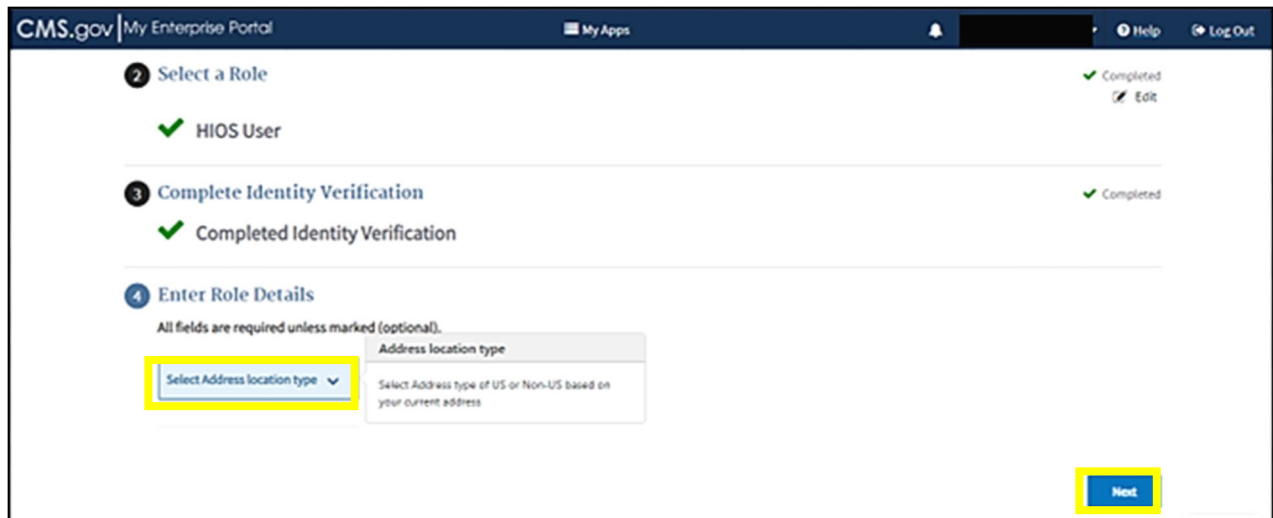
2. **Complete the form** and select **Next**. *(Figure 25)*

3. Fill-in the reason you need access within the **Enter Reason for Request box** and select **Submit**. (Figure 26)
   - For example, "I need to submit my data in the RxDC HIOS module."

Figure 26: Enter Reason for Request

4. When the pop-up confirmation message appears, select **OK**.

5. When the Request New Application Access Acknowledgement message appears, select **OK** again.

6 HIOS Home Page

Important Information
- Both new and existing HIOS users will follow the steps in this section to access HIOS once they have a CMS Enterprise Portal account.

To Access the HIOS Home Page:
1. After requesting the HIOS application, **log-out of CMS Enterprise Portal and then login again**. On the My Portal homepage, the HIOS application will display. Select **HIOS**, then select **Overview**. (Figure 27)

Figure 27: My Portal Page with HIOS Application

2. Select **Access HIOS**. (Figure 28)

Figure 28: Access HIOS Page
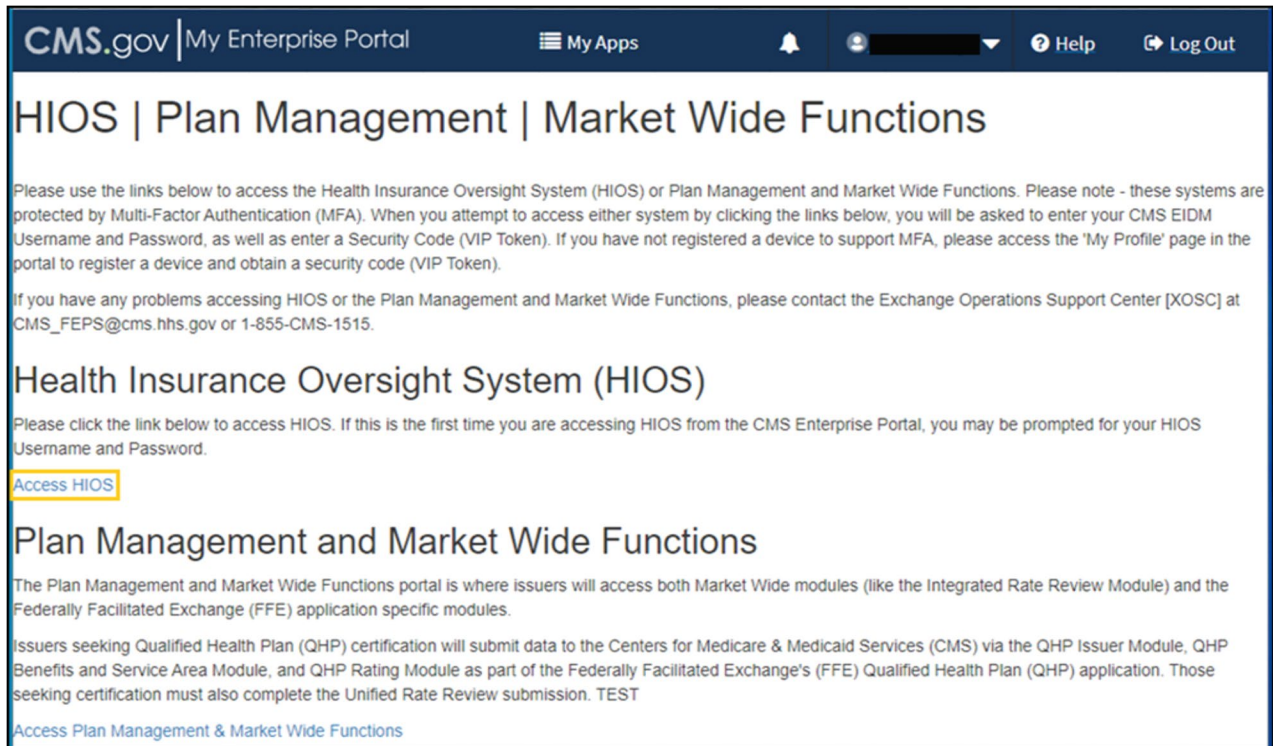
3. Read the Terms of Use and select **Accept**. (Figure 29)

Figure 29: HIOS Terms of Use
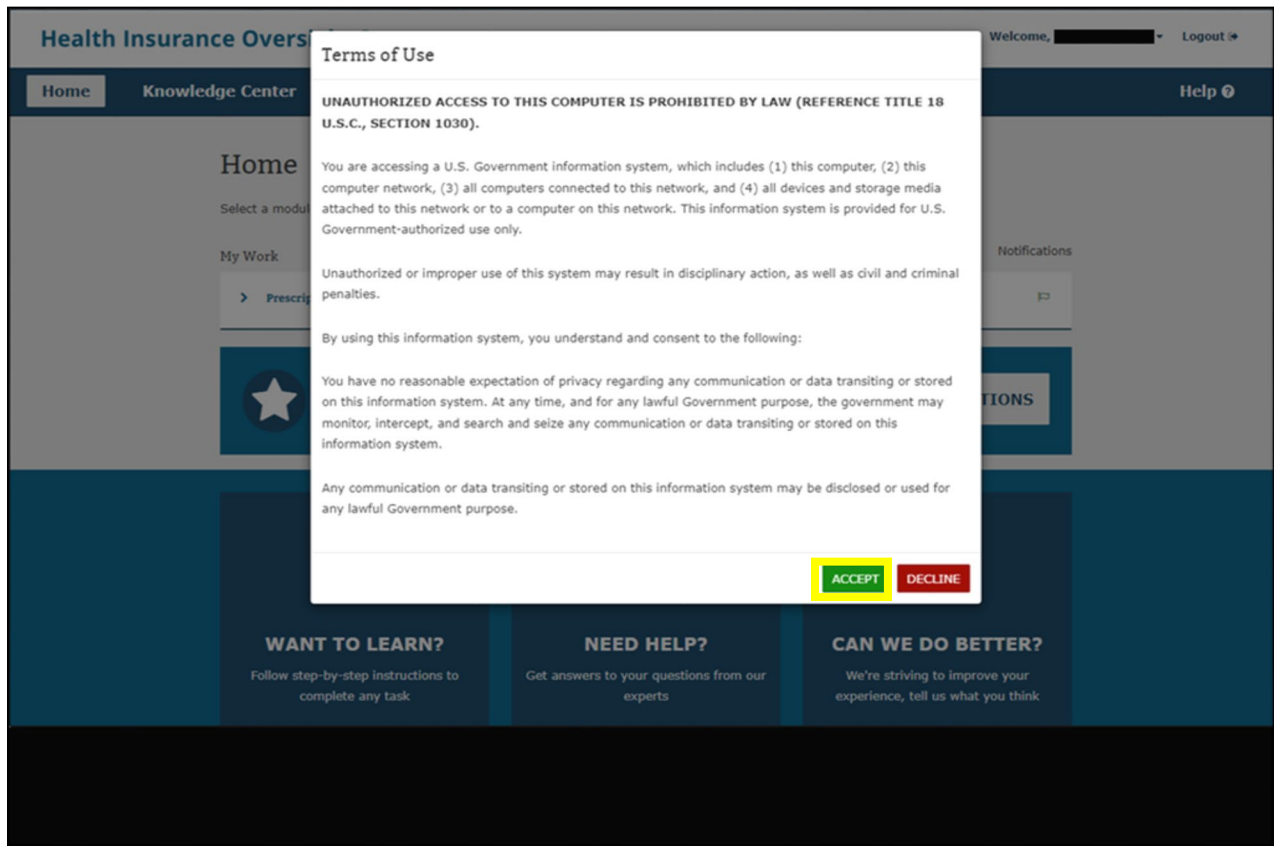
7 RxDC Submitter Role

Note: If your organization does not exist in HIOS, skip to section 9 to create the organization. Once your organization has been created and approved in HIOS, come back to this section to request the RxDC submitter role.

To request the RxDC Submitter role:
1. If you are a new HIOS user, select the **Request A Role** button on the page. (Figure 30)
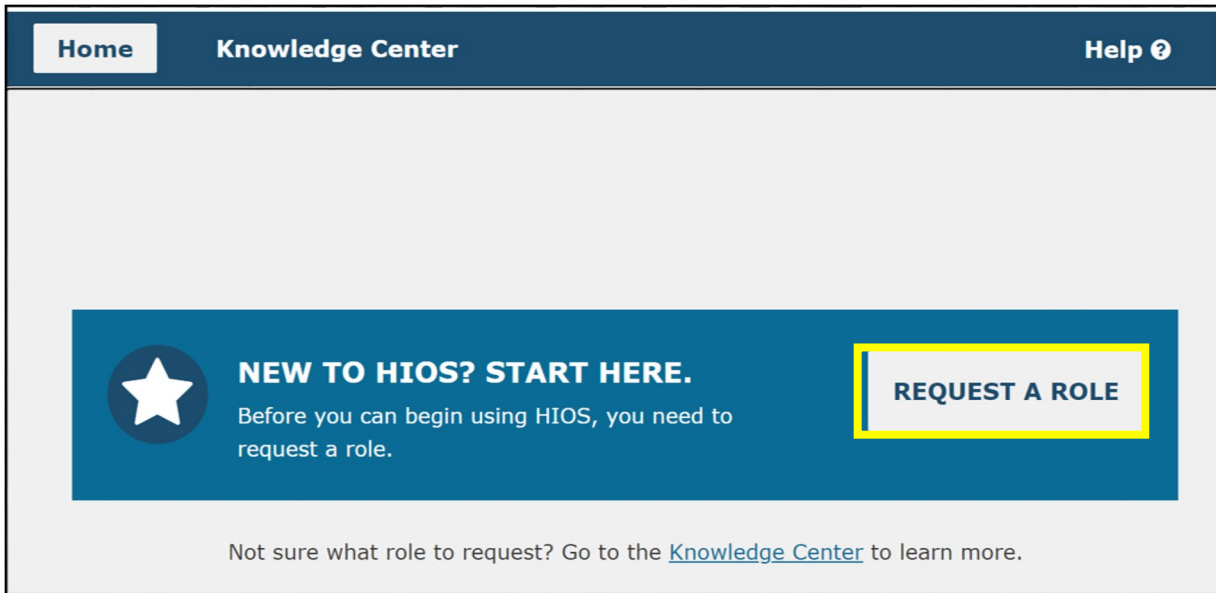
2. If you are an existing HIOS user but do not have access to the RxDC module, select the **Welcome** drop-down at the top of the page and then select **Request A Role**. (Figure 31)

Figure 31: Request a Role Drop-Down
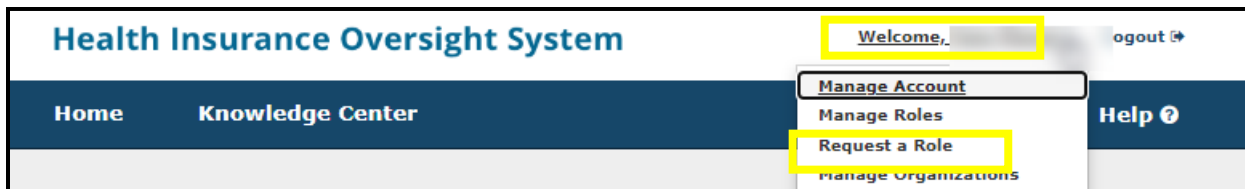
3. Select **Prescription Drug Data Collection (RxDC)** and select **Next**. (Figure 32)

Figure 32: Request a Role - Select a Module

4. Select **Next**. (Figure 33)

5. Under Add association, select **Organization with FEIN**. (Figure 34)
   - **DO NOT** select HIOS Issuer ID or Organization without FEIN.

Figure 34: Add Association

6. Within the Search for Association box, enter **YOUR company's EIN** and select **Search**. (Figure 35)
   - **NOTE:** If you are submitting on behalf of a client, enter your own company's EIN, not your client's EIN.

7. Select your company from the results and select **Next**. (Figure 36)
    *   **NOTE:** If your company is not already registered in HIOS, you will receive the message "The organization does not exist." select **"Create an Organization"** and then skip to the instructions in **Section 9** below. After the organization has been approved, come back section 7 to request the role.
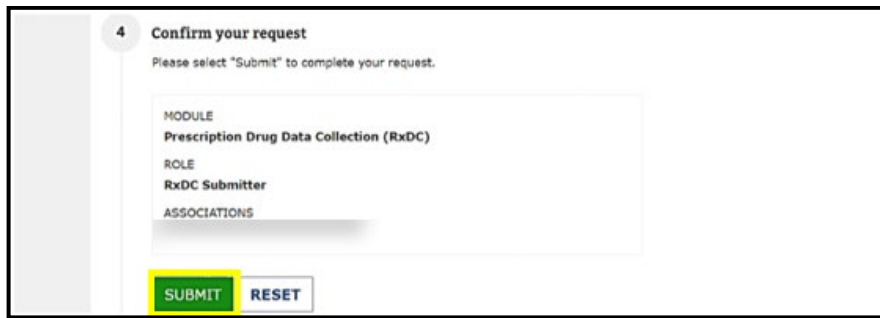
Figure 36: Association Search Results

8. Review the information in the Confirm your request section and select **Submit**. (Figure 37)
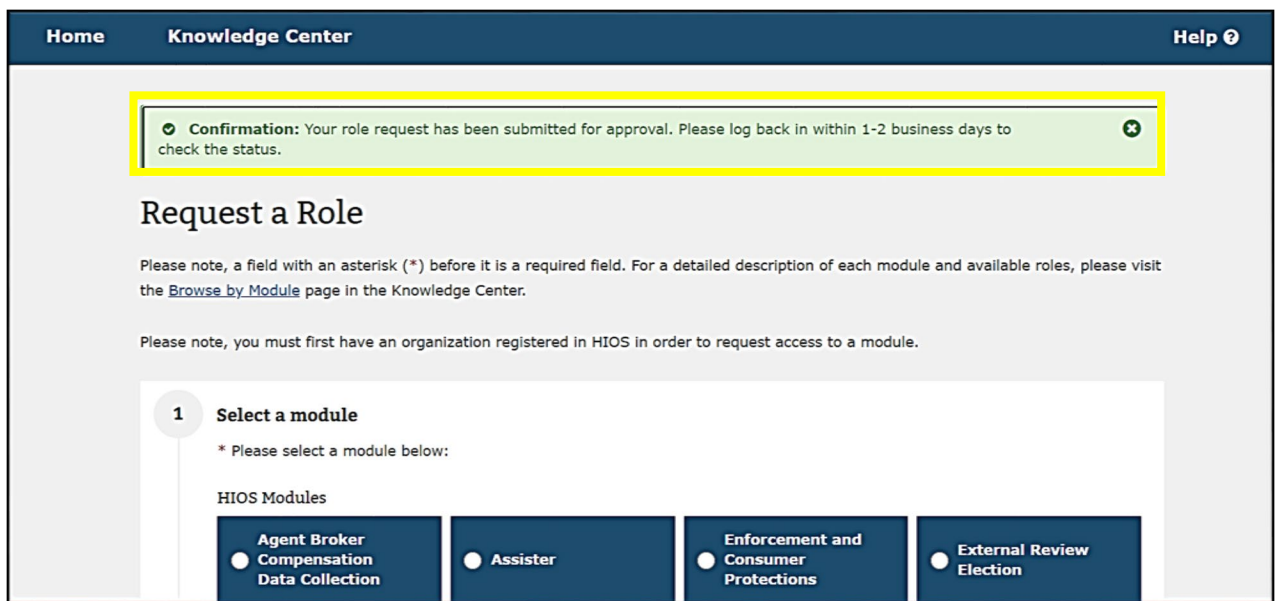   *   If the information is not correct, return to the step where the incorrect information was entered and make the necessary correction.

9. After you select Submit, a confirmation box will show noting that your role request has been submitted for approval. (Figure 38)

Figure 38: Role Request Confirmation

10. 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**. (Figure 39)

Figure 39: Launch the RxDC Module
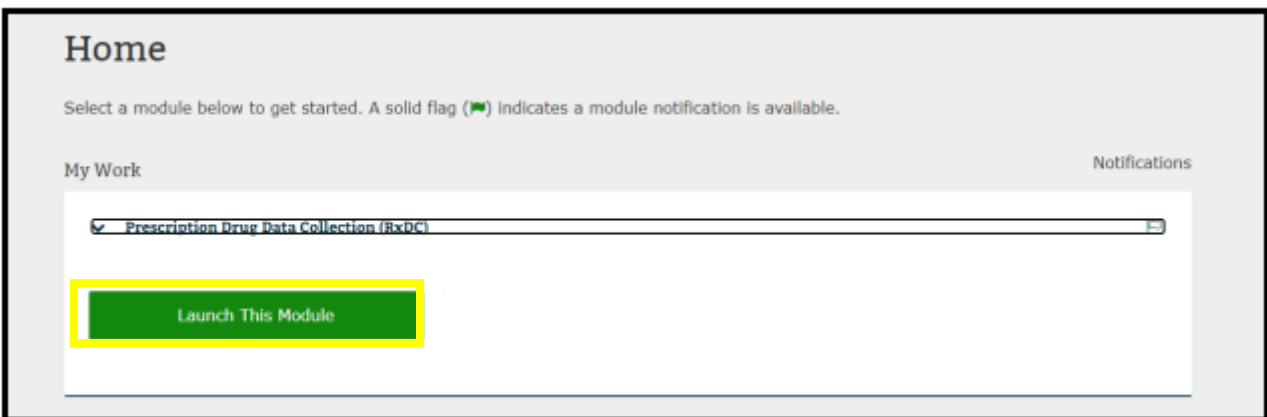
Note: The RxDC HIOS Module User Manual has instructions on how to submit your data in the RxDC HIOS Module.

8 Organization Role Approver (ORA) Roles

The Organization Role Approver (ORA) is a representative of a HIOS Organization that is responsible for viewing, approving, and/or denying pending role requests for their company/organization. The ORA role allows an organization to control who can view or submit data for their organization.

- Organizations that use a HIOS module other than the RxDC module must have two ORAs. Those organizations must have a primary ORA and a backup ORA because users cannot approve their own role requests.
- If your organization already has a primary ORA and a backup ORA, you do not need to delete or request an ORA role.
- For additional information on the Organization Role Approver (ORA) role, please refer to the FAQ section of this document.

Does every organization need a Primary and Backup ORA to access RxDC?

No. If you work for an organization, such as a group health plan, that **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 role. If your organization fits the description above and does not have any ORAs, CMS can approve requests for the RxDC Submitter role.

- CMS can only approve RxDC role requests if your organization has ZERO ORAs. If you already requested the ORA role, you need to remove the existing ORA role from your account before CMS can approve your RxDC Submitter role request. To remove the role from your account, select the 'Welcome' drop-down at the top of the page and select 'Manage Roles' page. Next, select 'View' on the role request you need to remove. Then you will have the option to delete the role. You also need to delete any pending RxDC submitter role requests and re-submit that request after the ORA role has been removed from your account.

If you need an ORA role, follow the steps below.

1. Follow the same general steps that are in Section 7. Select the **Welcome** drop-down and then select **Request A Role**. (Figure 40)

Figure 40: Request a Role Drop-Down

2. On the "Select a Module" step, select the **HIOS Portal** module and select **Next**. (Figure 41)

3. On the "Select a Role" step, select the **Organization Role Approver** role. Select **Organization Role Approver (ORA)** role type and then select either **Primary ORA** or **Backup ORA** and select **Next**. (Figure 42)

Figure 42: Request a Role - Select a Role

4. Under Add association, select **Organization with FEIN**. (Figure 43)
   - **DO NOT select** HIOS Issuer ID.

Figure 43: Add Association

5. Within the Search for Association box, enter **YOUR company's EIN** and select **Search**. (Figure 44)
   - If you are submitting on behalf of a client, enter your own company's EIN, not your client's EIN.
   - Do not create an organization in HIOS for your client. You should only register your own company.

Figure 44: Search for Association

Request a Role

Please note, a field with an asterisk (*) before it is a required field. For a detailed description of each module and available roles, please visit the Browse by Module page in the Knowledge Center.

Please note, you must first have an organization registered in HIOS in order to request access to a module.

1	**Select a module**	HIOS Portal	Revisit this step
2	**Select a role**	Organization Role Approver, Organization Role Approver (ORA), Primary ORA	Revisit this step

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**

    * Search for association

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

    [   ] SEARCH

NEXT

6. **Select your company** from the results and select **Next**. (Figure 45)
   - **NOTE:** If your company is not already registered in HIOS, you will receive the message "The organization does not exist..." select **"Create an Organization"** and then skip to the instructions in **Section 9** below. After the organization has been approved, you will need to revisit section 7 to request the role.

Figure 45: Association Search Results

7. Review the information in the Confirm your request section, select the **checkbox,** and select **Submit**. (Figure 46)
    *   If the information is not correct, return to the step where the incorrect information was entered and make the necessary correction.

Figure 46: Confirm Your Request

Figure 46: Confirm Your Request

8. After you select Submit, a confirmation box will show noting that your role request has been submitted for approval. (Figure 47)
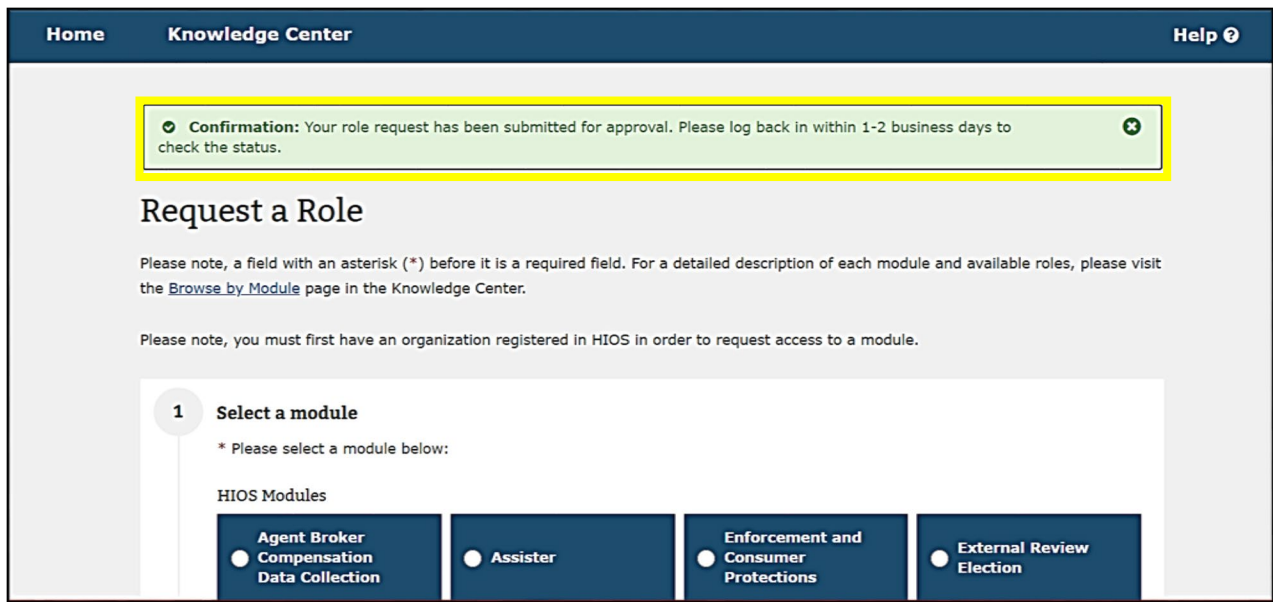
9 Create an Organization

Important Information

- If your organization does not currently exist in HIOS, please complete this section to register your organization in HIOS.
- You may skip this section if your organization already exists in HIOS. (Note - If your company has previously submitted data within HIOS, then your organization is already registered within HIOS.)
- If you are submitting on behalf of a client, do not create an organization in HIOS for your client. Only create an organization in HIOS for your own company.

To create a new organization in HIOS:

1. If your organization does not currently exist in HIOS, you will receive a message "The organization does not exist…" when attempting to Add association during the role request process. Select **Create an Organization.** (Figure 48)
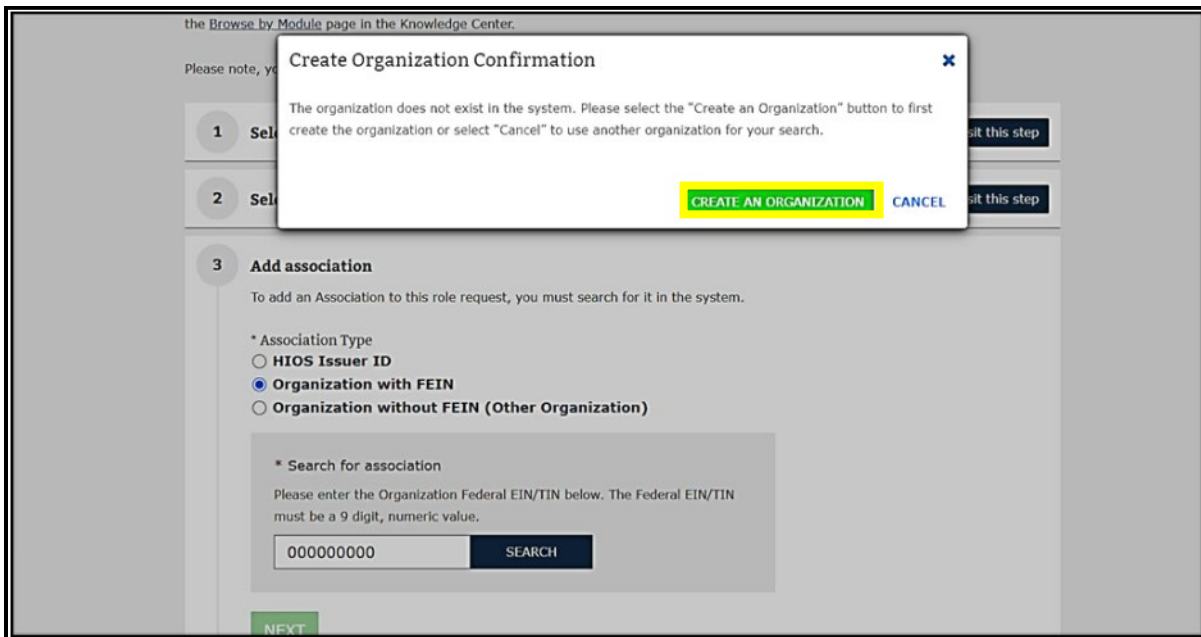
Alternatively, you can create an organization directly from the HIOS home page by selecting **Manage Organizations** from the Welcome drop-down (Figure 49). Either action will take you to the 'Create an Organization' page when you can then complete the steps to register your organization in HIOS.

Figure 49: Manage Organizations
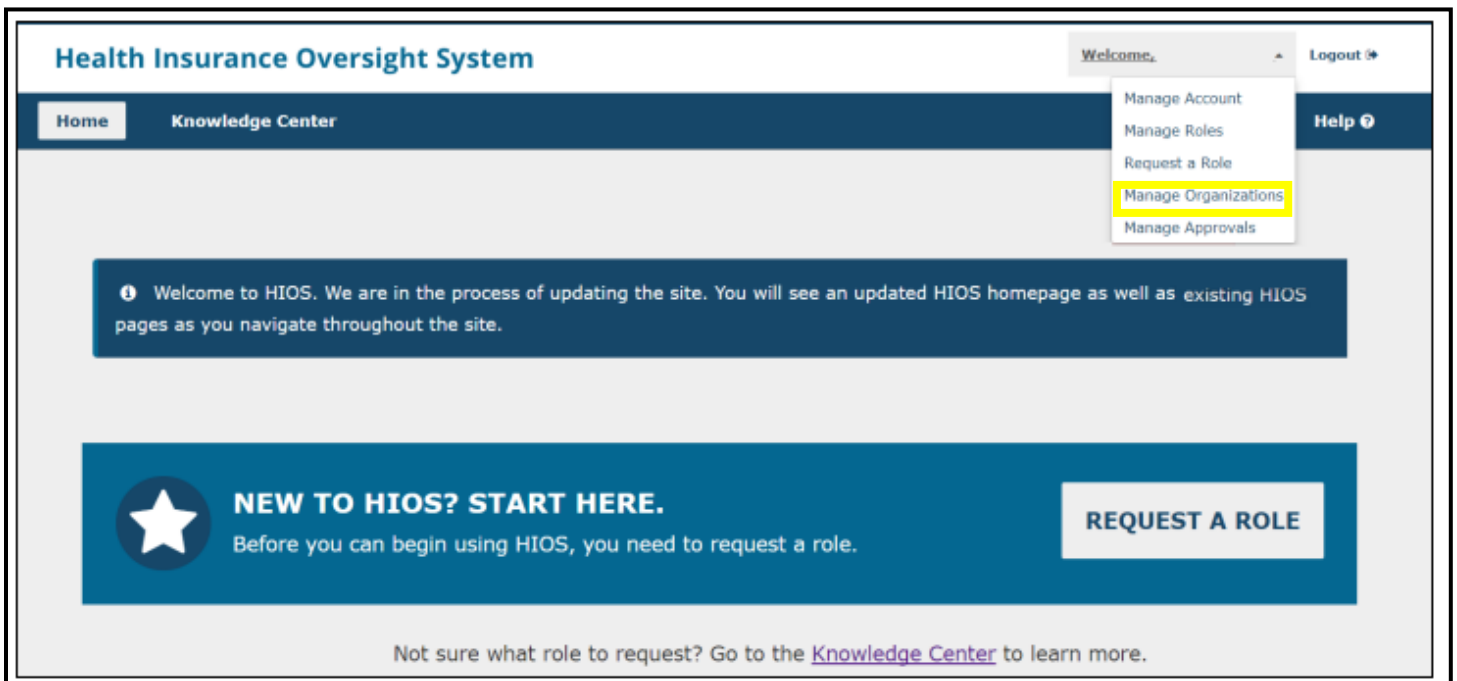
2. On the Create an Organization page, **Select the Organization's Primary Function** according to the instructions below. After selecting your organization's primary function, select **NEXT**. (Figure 50)
   - Non-federal governmental health plans (such as school districts and state and local governments) should select **Non-Federal Governmental Health Plans**.
   - TPAs, PBMs, third-party vendors, and other group health plans, should select **Non-Insurance Company**.
   - Do **NOT** select Other Organization as your Organization's Primary Function. This organization type is not utilized in the RxDC module.

Figure 50: Select the Organization's Primary Function
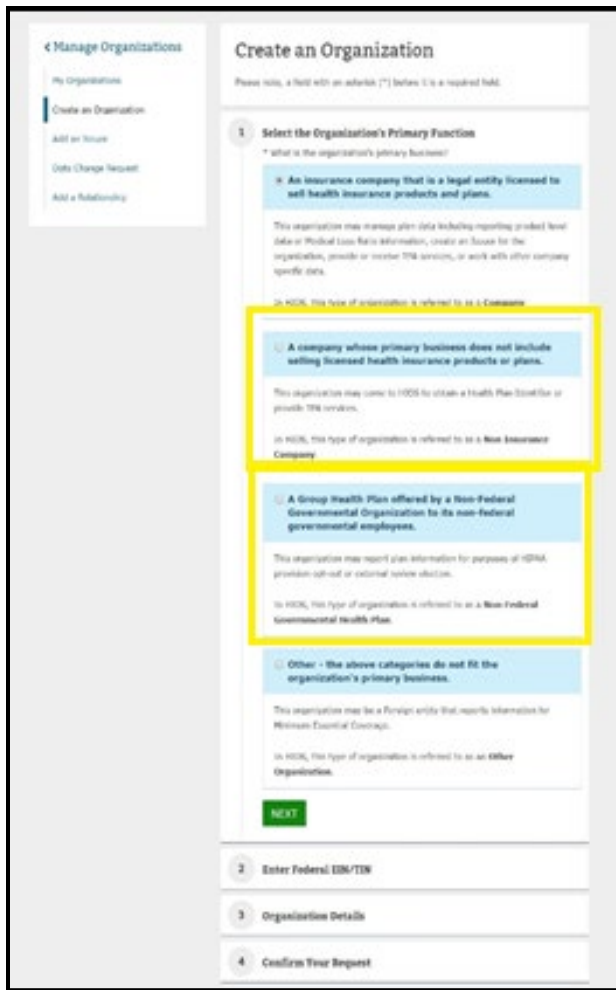
- **Note:** On the Manage Organizations menu bar, **DO NOT** "Add an Issuer" and **DO NOT** "Add a Relationship" (Figure 51)

Figure 51: Manage Organizations – Sections to Skip
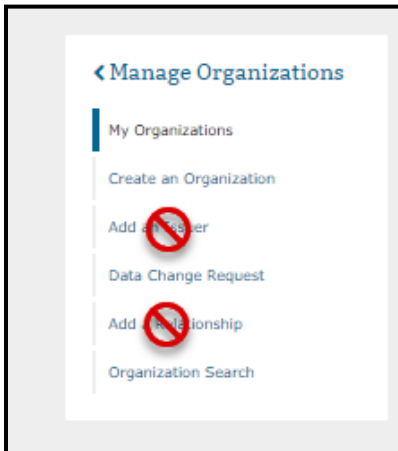
3. After selecting your organization's primary function, select **NEXT**. (Figure 52)

Figure 52: Finalize Selection

4. Enter **your company's EIN** in the search box and select **Search**. If the number is not in the system, a confirmation message will appear, stating that the number does not already exist in the system. Select **Next**. (Figure 53)

Figure 53: Create an Organization: Enter Federal EIN/TIN

5. **Scroll down** to Organization Details and complete the form for your organization. (Figure 54)

- **Note:** The Third-Party Administrator (TPA) information section is not applicable to the RxDC module. **All organizations, including TPAs, should skip this section** and select **Next**. (Figure 55)

6. Review the organization's information and scroll down to the Confirm Your Request section and select **Submit**. (Figure 56)
    - You may revisit any previous steps to make changes prior to confirming your request.

- 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.

Figure 56: Confirm Your Request

10 Help Desk Information

Contact the CMS help desk at CMS_FEPS@cms.hhs.gov or 1-855-267-1515 if you have questions about setting up your account. For faster service, send your question by email and include "RxDC HIOS Question" in the body of the email with a brief description of the issue.

11 Frequently Asked Questions

The below table has a list of frequently asked questions.

Questions	Answers
Why do I have to provide my SSN?	Establishing confidence in a person's identity is a critical starting point for conducting online business with CMS. CMS identification verification processes must adhere to the guidelines as issued by the National Institutes of Standards and Technology Special Publication (NIST) 800-63-3.
	To meet assurance level two or above (LOA2/3) for remote users over an open network, NIST requires verification of identifying materials and information. CMS contracts with a remote identity proofing (RIDP) vendor to meet the NIST standard.
	Users must provide their SSN as part of the RIDP. The RIPD vendor creates an aggregate risk score which summarizes the vendor's confidence in the user's identity. The vendor creates something called a soft inquiry on your credit report. Soft inquiries are only visible to you and no one else. Soft inquiries have no impact on your credit report, history, or score.
How long does it take for an organization to be approved/denied?	Normally, it takes 1-2 business days. During periods of high volume, it may take significantly longer.

Questions	Answers
How long does it take for a role request to be approved/denied?	Normally, it takes 1-2 business days. During periods of high volume, it may take significantly longer.
How do I access the HIOS Module?	To access HIOS, visit https://portal.cms.gov. Users will need to complete the registration for the CMS IDM account through the CMS Enterprise Portal prior to requesting access to HIOS.
Where do I request roles and access to HIOS modules?	Module access and role requests are done via the Request a Role function on the HIOS Home Page. To submit a request, users select the Request a Role link from the Welcome drop-down menu, the HIOS module(s), and role(s) applicable to the module(s).
Why can't I find the role(s) needed on the Request Role page?	Some roles for HIOS modules have restricted access. These will not display on the user interface. Users will need CMS approval before certain roles can be granted.
How do I know when my role request has been approved?	The user will be notified via email when the role request has been approved.
What type of Organizations are required to have an Organization Role Approver (ORA)?	Any organization with two or more employees registered in HIOS is required to have two ORAs. There needs to be a primary ORA and a back-up ORA.
Do I need to request an ORA role if I am a sole proprietor or a group health plan with only one user registered for HIOS?	No. Organizations with only one registered user in HIOS do not need ORAs to access the RxDC module. In this situation, the Help Desk will approve your pending role requests. After you have requested the RxDC submitter role, please email the CMS Help Desk at CMS_FEPS@cms.hhs.gov and request that the HIOS Technical Team approve your RxDC Submitter Role Request.
My organization is a sole proprietor or a group health plan with only one user registered for HIOS and I already requested the ORA role. What should I do now?	You will need to remove the existing Organization Role Approver (ORA) role from your account. To remove the role from your account, select 'Welcome' and then navigate to the 'Manage Roles' page and then select 'View' on the role request you need removed. Then you will have the option to delete the role. You will also need to delete any pending RxDC submitter roles and re-submit that request after the ORA role request has been removed from your account.
How do I know if my company already has an ORA?	If your company has a Company Administrator in HIOS, the Company Administrator can see whether there is an ORA by viewing the roles of all HIOS users at the company.
	If your company doesn't have a Company Administrator, or you don't know who the Company Administrator is, you may email the CMS help desk CMS_FEPS@cms.hhs.gov to find out if your company has an ORA.
The ORA has left our company, what should I do now?	Someone else from the company will need to assume the role of the Organization Role Approver (ORA). They will need to come into HIOS and request the Organization Role Approver (ORA) role.
Which roles are required to submit data to RxDC?	You need the RxDC submitter role to submit RxDC data.
How do I delete an approved role from my account?	Select 'Welcome' and then navigate to the 'Manage Roles' page and then select 'View' on the role request you need removed. Then you will have the option to delete the role.

Questions	Answers
How can I delete an RxDC submitter who is no longer with the company?	Your ORA can delete the user's role. If your company doesn't have an ORA, you may request deactivation of the user's account by emailing CMS_FEPS@cms.hhs.gov or calling 1-855-267-1515.
Does the ORA need to have their own/separate CMS logon from the RxDC Submitter?	No, a user can have both roles at the same time.
Will a I receive an email if my role request has been denied?	No. An email will not be generated if the role request was denied. You can navigate to the 'Manage Roles' page to determine if your role request is still pending or approved. The denied role requests will be removed from this view.
I received an email stating my org was approved but I don't see it under "My Organizations".	You will need to request a role for that organization. Roles are not automatically assigned with the creation of the org. Orgs will only appear on the 'My Organization' page if you are assigned the 'Company Administrator' role within the HIOS Portal module.
Who needs to register as a Third-Party Administrator (TPA)?	RxDC module users do **NOT** need to register their organization as a TPA. TPA registration is only for EDGE Server Management and Direct Enrollment Management for Qualified Health Plans.
My organization was denied, what should I do now?	Please verify the information that was submitted was correct and re-submit the request. If you believe the request was denied in error, then email to CMS_FEPS@cms.hhs.gov or call 1-855-267-1515