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THE FIVE W'S AND ONE H

Pharmacy data collection under the CAA

(Consolidated Appropriations Act)

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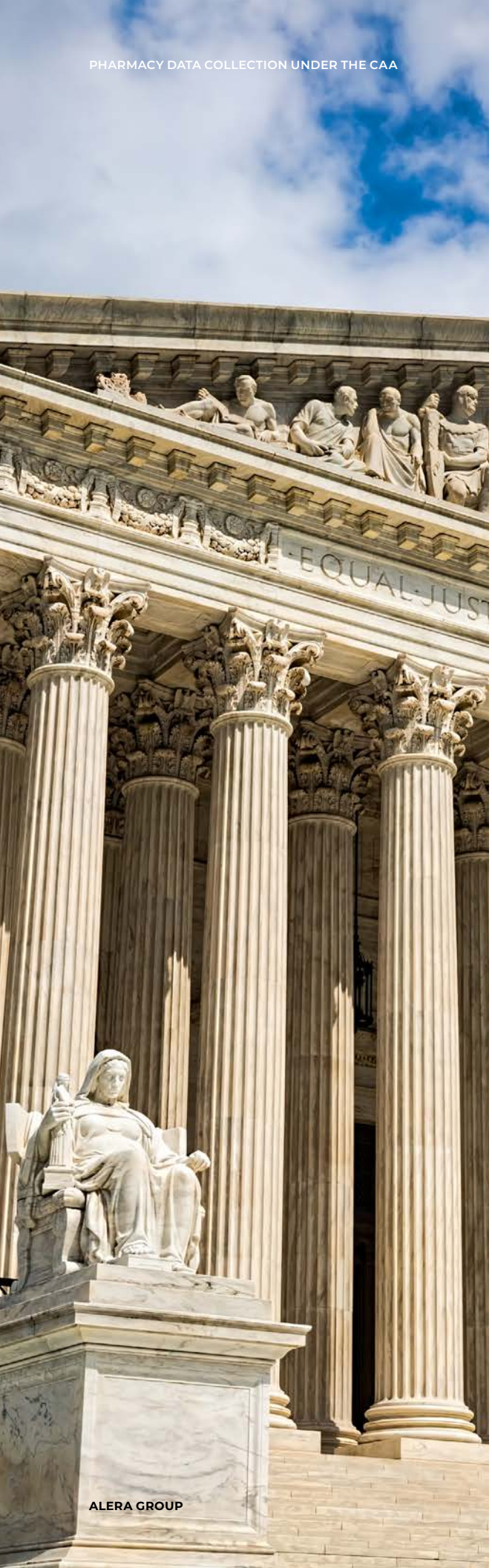

The Consolidated Appropriations Act of 2021 (CAA) added parallel complex pharmacy reporting requirements under the Internal Revenue Code (the Code), ERISA and the PHSA. This paper will deconstruct the pharmacy data collection (RxDC reporting, or "Section 204") reporting requirements. Importantly, most 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** (1.2025), **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 February 12, 2025.

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 that 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 in any calendar year beginning in 2020.

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 not billed on a claim;
- Retiree-only plans;
- Plans maintained outside the United States for the benefit of nonresident aliens;
- Church plans 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 HIOS (Health Insurance Oversight System) platform 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 the 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 no 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, 2025, for reference year 2024.

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 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 to avoid that issue during the initial reporting 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. In prior years, due to challenges in reporting, CMS allowed a reporting entity to aggregate, within a state and market segment, at a less granular level than the Reporting Entity that submitted D2. However, **starting with reporting for 2023 years, the data submitted in files D1 and D3 – D8 must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submitted the data in file D2 Spending by Category.**

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 those 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 monthly premium (or premium equivalent) by taking the total annual premium (or premium equivalents) paid by members during the reference year and dividing by 12. You should divide by 12 even if the coverage was not in effect for the entire calendar year.

Average monthly premium paid by employers: Report the average monthly premium (or premium equivalent) by taking the total annual premium (or premium equivalents) paid on behalf of members and dividing by 12. You should divide by 12 even if the coverage was not in effect for a member or members for the entire reference year.

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 for 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 that 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 EQUIVALENTS 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 no 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 remuneration 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 remuneration.
6. Describe the methods used to allocate Rx rebates, fees and other remuneration.
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 $184 per day for 2024.

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. Response time can vary from 24 hours to multiple weeks.

You can also sign up for a REGTAP account and attend informal webinars.

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About Alera Group

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*STATISTICS ACCURATE AS OF JANUARY 1, 2025.

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WPP-EB-5W1H-RXDCREPORTING-021425

HIOS Access Guide for RxDC Users

Description: The Centers for Medicare & Medicaid Services (CMS) Health Insurance Oversight System (HIOS) application's Prescription Drug Data Collection (RxDC) module provides a platform for users to submit their RxDC report. The term "RxDC report" refers to the data submission required under Section 204 of Division BB, Title II (Section 204) of the Consolidated Appropriations Act, 2021 (CAA).

To submit the RxDC report in HIOS, users must first register for a CMS Enterprise Portal account. **This guide provides instructions to create a CMS Enterprise Portal account, access the HIOS application, and obtain the RxDC Submitter user role in HIOS.**

Users: HIOS users include insurance companies, group health plans, state and local governmental plans, third-party administrators (TPAs), pharmacy benefit managers (PBMs), agents and brokers, and Federal Employee Health Benefit (FEHB) carriers.

Resources: This document is the first of two HIOS RxDC guides. After completing this guide's instructions and successfully accessing the CMS HIOS application and RxDC module, proceed to the second guide, the RxDC HIOS Module User Manual, for instructions on how to submit your RxDC report in the RxDC HIOS module. The RxDC HIOS Module User Manual is available on the CMS RxDC Home Page. The CMS RxDC Home Page contains other RxDC resources, such as the reporting instructions, data dictionaries, and reporting templates.

April 5, 2024

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Overview

The CMS HIOS application is used to register health insurance companies and products, obtain identification numbers, and report medical loss ratio and other company data. Additionally, HIOS is used for reporting by states and assister organizations for Patient Protection and Affordable Care Act (PPACA) grant activities. HIOS includes multiple consumer oversight modules. Group health plans, health insurance issuers offering group of individual or group coverage, and Federal Employee Health Benefit (FEHB) carriers use the CMS HIOS RxDC module to submit data on an annual basis.

To access HIOS RxDC, new users are required to create a CMS Enterprise Portal account. The CMS Enterprise Portal system includes user identity management, access control, authorization assistance workflow tools, and identity lifecycle management functions (e.g., forgot username, reset password, etc.).The system requires new users to register a multi-factor authentication (MFA) device for providing more than one form of identity.

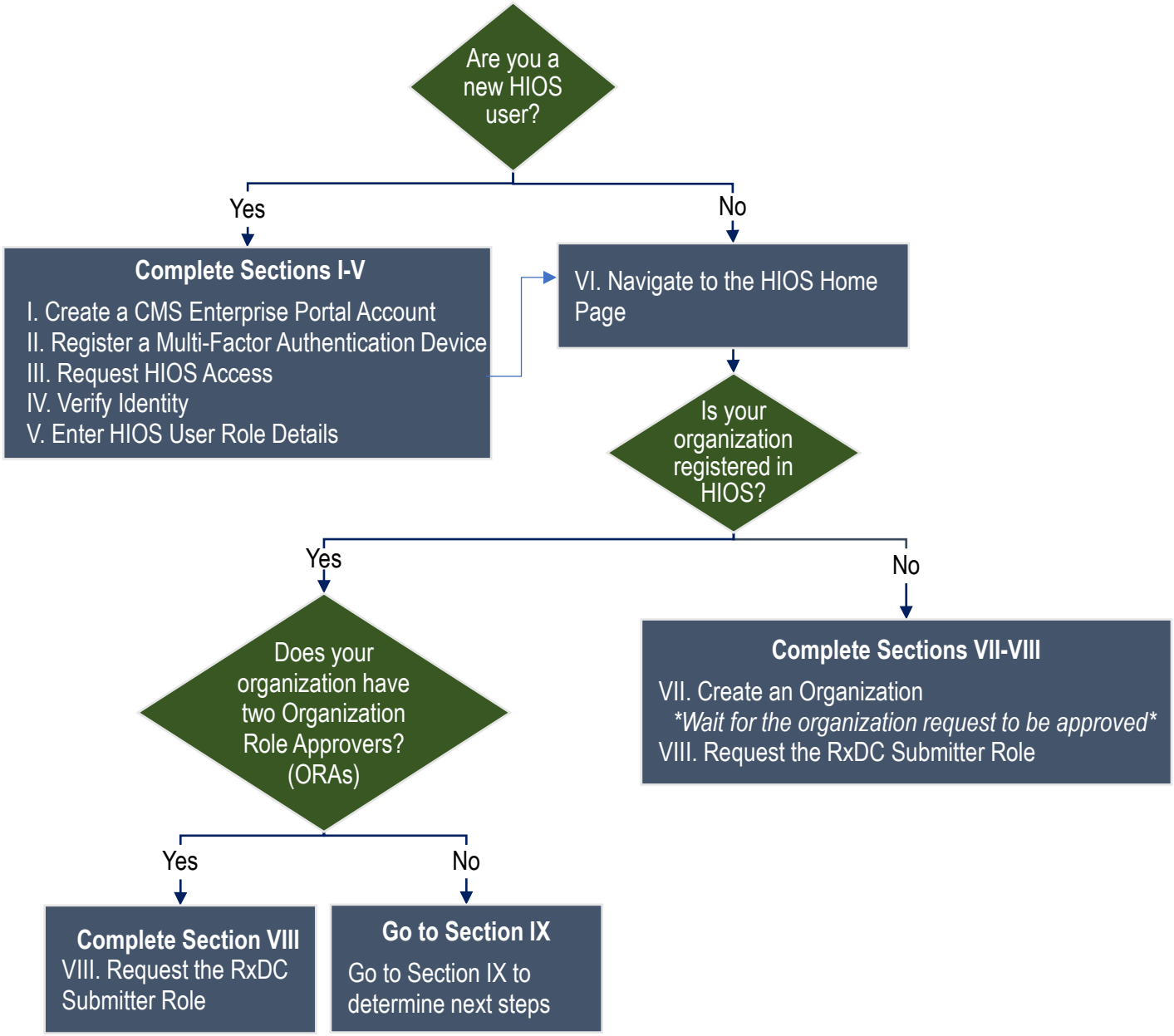
This guide provides instructions on how to register for a CMS Enterprise Portal account, request HIOS and RxDC roles, and access the HIOS application and RxDC module.

Before You Begin

Before you begin, please review the following helpful tips.

- It may take 1-2 weeks for your HIOS RxDC access requests to be approved.
- Use Google Chrome or Mozilla Firefox browsers to access HIOS. You may encounter errors if you use other browsers.
- Provide your work email address instead of a personal email address to expedite the process of obtaining a HIOS role.
- Obtain your organization's Federal Employer Identification Number (FEIN). You will need it to request a role or create a new HIOS organization.
- Determine if anyone from your organization has submitted data to any HIOS module in the past. If your organization has previously submitted data to HIOS, then DO NOT complete "Section VII. Create a HIOS Organization."
- Determine if anyone from your organization needs the Organization Role Approver (ORA) user role in HIOS. Some organizations are required to have two ORA users as a prerequisite to accessing the RxDC HIOS module. See "**Section IX. Request Organization Role Approver role**" for more information about the ORA requirements.
- Consult **Figure 1. HIOS RxDC Access Guide Sections**" to determine which sections of this guide are relevant to your situation.

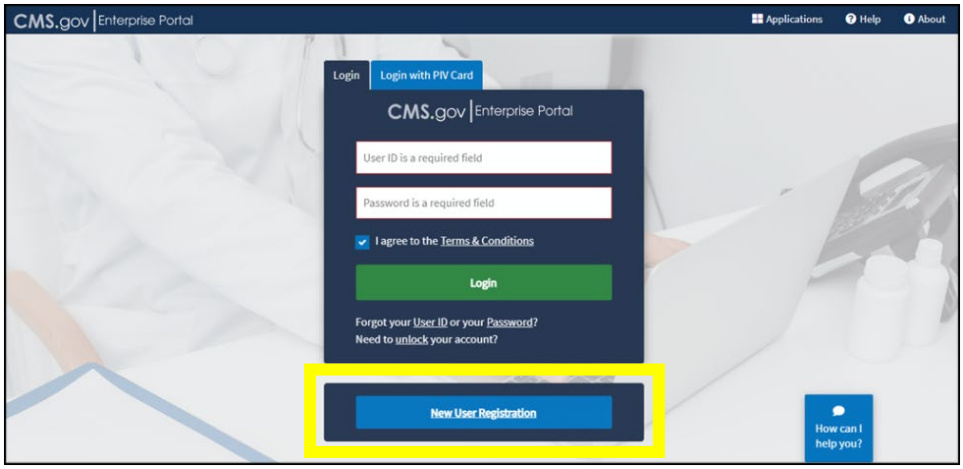
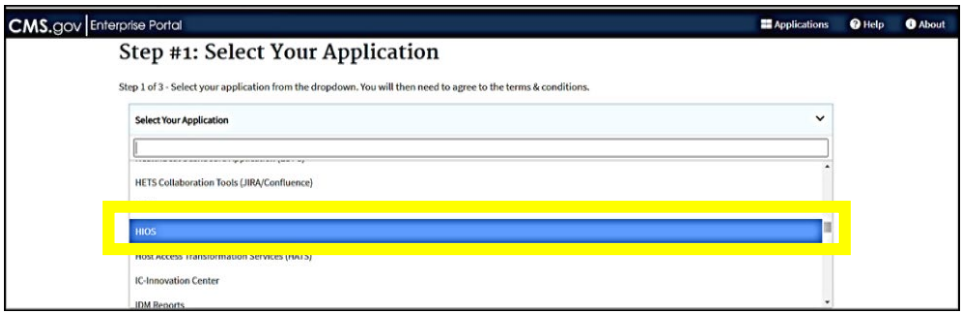
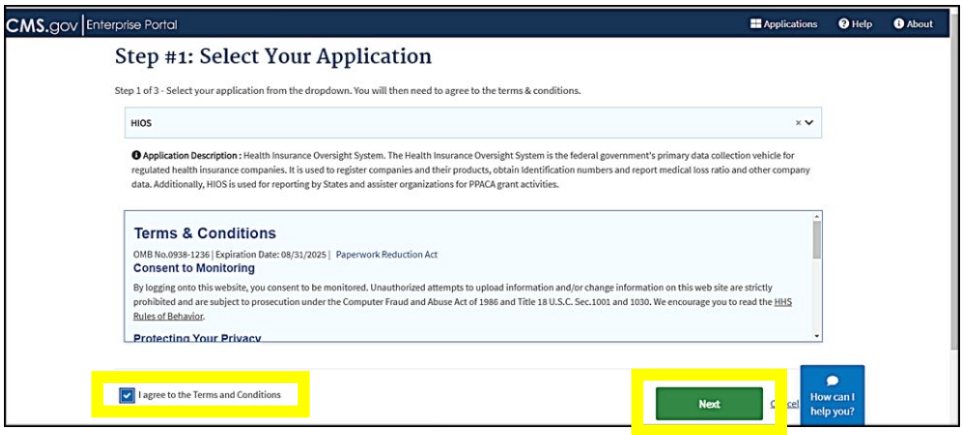
Figure 1: HIOS RxDC Access Guide Sections

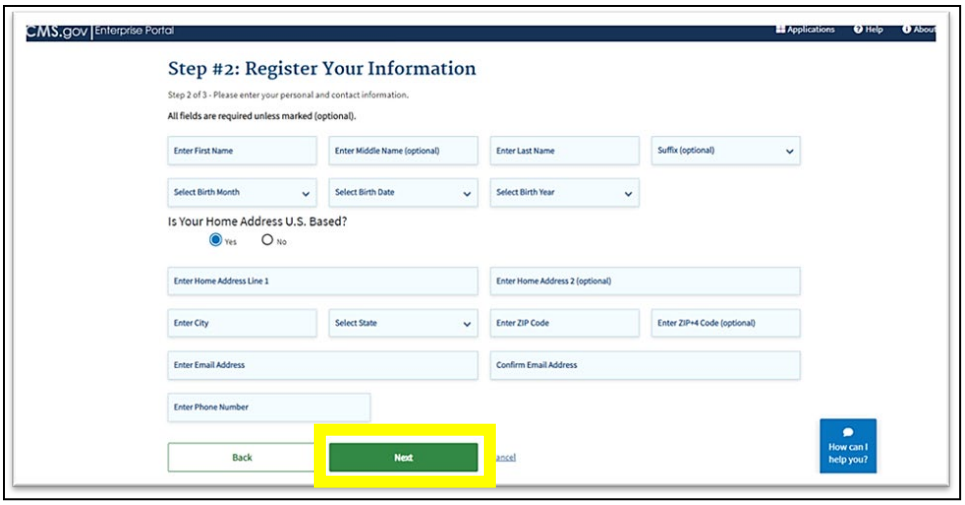
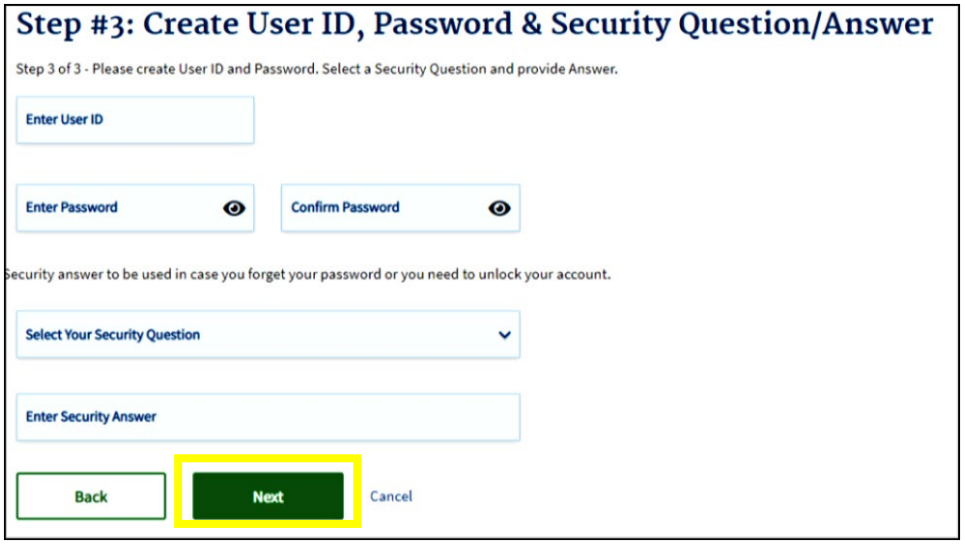
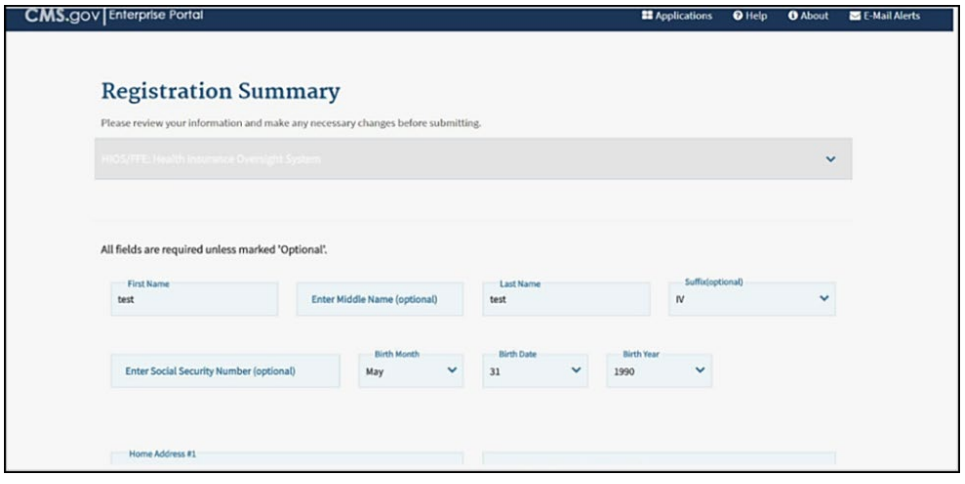


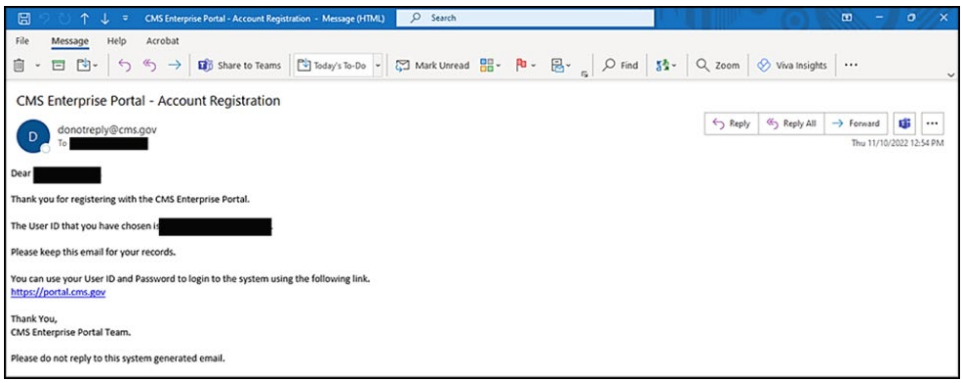
I. Create a CMS Enterprise Portal Account (New HIOS User)

A new HIOS user's first step is to create a CMS Enterprise Portal account. The table below describes steps for a new HIOS user to create a CMS Enterprise Portal account.

- If you are a new HIOS user, then you need to complete this document's "**Section I. Create a CMS Enterprise Portal Account**" through "**Section V. Enter Role Details**."
- If you are an approved HIOS user, then you can skip to this document's "**Section VI. Navigate to HIOS Home Page**."

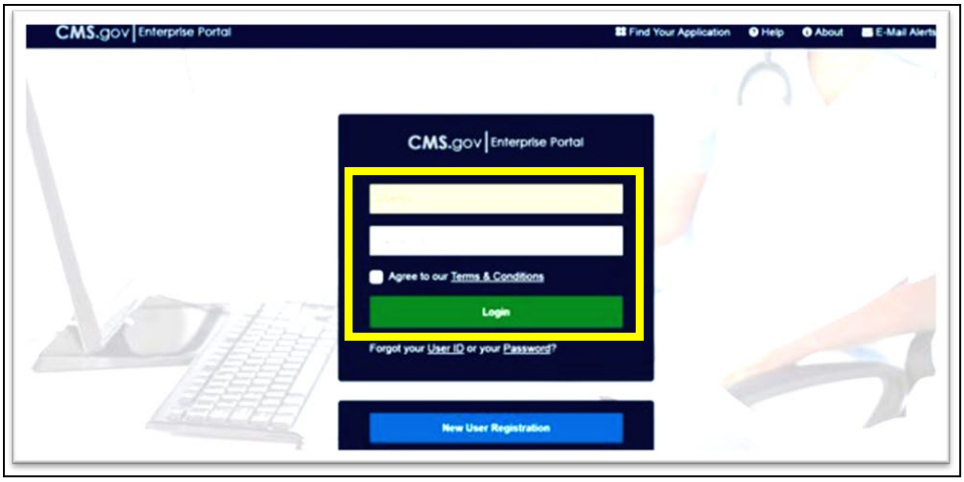
User Step	Screen Capture
[I-A] Using Google Chrome or Mozilla Firefox, open a new browser webpage and go to the CMS Enterprise Portal at https://portal.cms.gov. [Note: HIOS is only compatible with Google Chrome and Mozilla Firefox.] [I-B] Select "**New User Registration**."	
[I-C] On the "**Step #1: Select Your Application**" page, under "**Step 1 of 3**" and "**Select Your Application**," expand the drop-down list of applications and select "**HIOS**."	
[I-D] Read the "**Terms & Conditions**," select the checkmark for "**I agree to the Terms and Conditions**," and select "**Next**."	

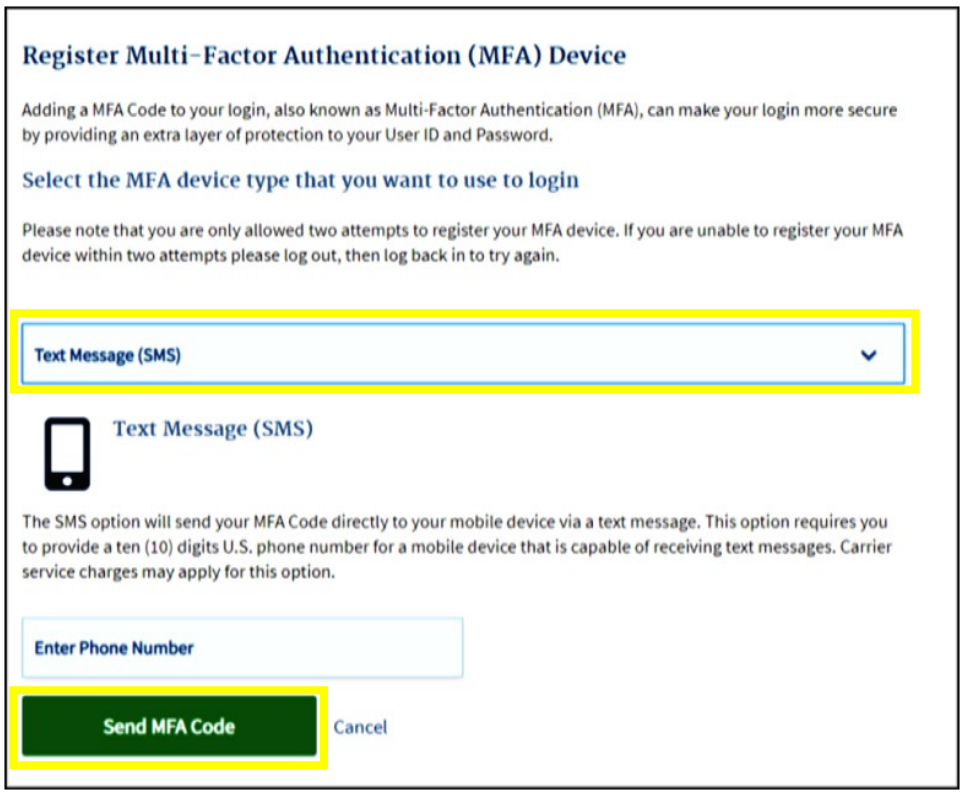
User Step	Screen Capture
[I-E] On the "**Step #2: Register Your Information**" page, under "**Step 2 of 3**," complete the form with your personal information and select "**Next**." [Note: Enter your work email address to speed up the approval process when you later request the RxDC Submitter role in HIOS. If you use your personal email address, your role request may be denied.]	
[I-F] On the "**Step #3: Create User ID, Password & Security Question/Answer**" page, under "**Step 3 of 3**," complete your user ID and password and select "**Next**."	
[I-G] Review your "**Registration Summary**" information, ensure all data fields are correct, and select "**Submit User**."	

User Step	Screen Capture
[I-H] You will receive an email from "donotreply@cms.gov" with subject "CMS Enterprise Portal – Account Registration" acknowledging successful registration. This email will contain your CMS Enterprise Portal User ID necessary for the next section to register a multi-factor authentication (MFA) device.	

II. Register a Multi-Factor Authentication Device (New HIOS User)

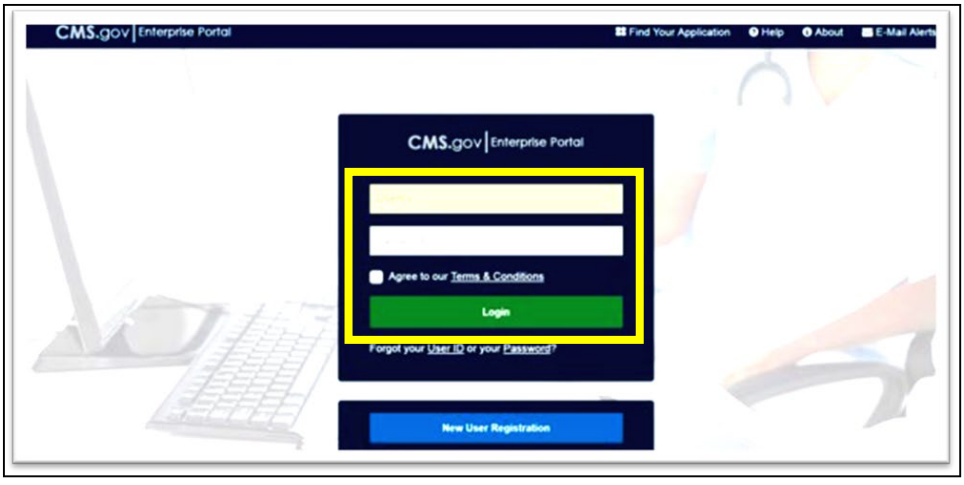
The CMS Enterprise Portal requires all users to register a multi-factor authentication (MFA) device. A new HIOS user's second step is to register your MFA device. The table below describes steps for a new HIOS user to register a preferred MFA device.

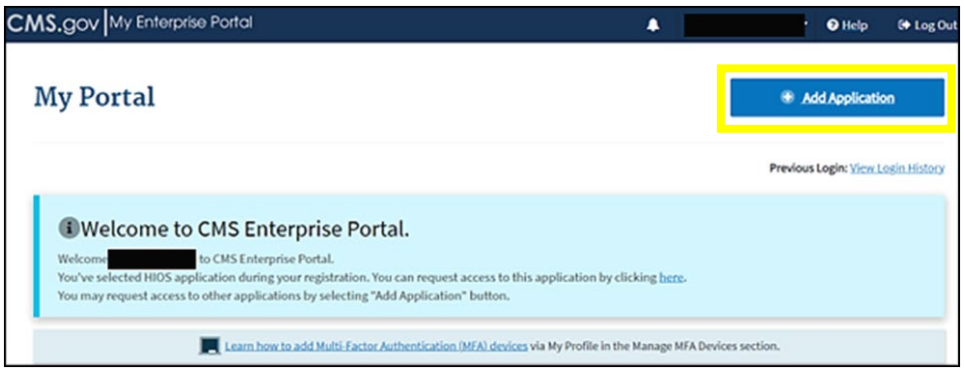
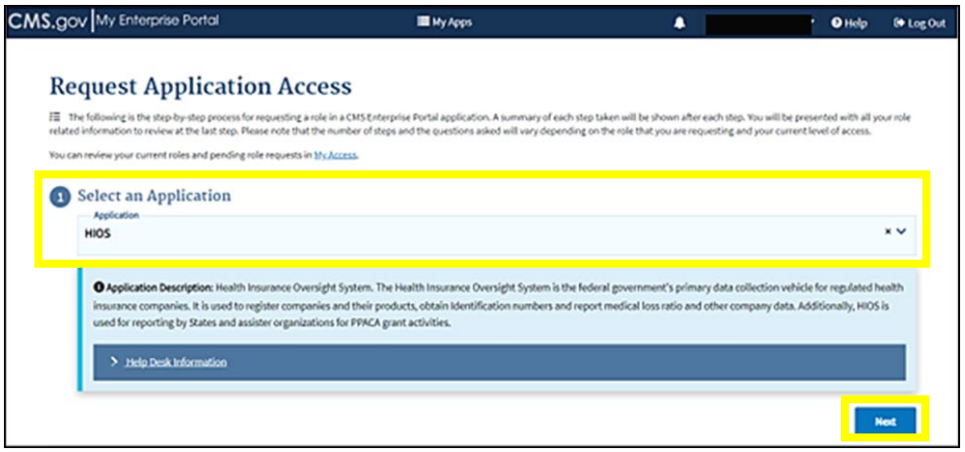
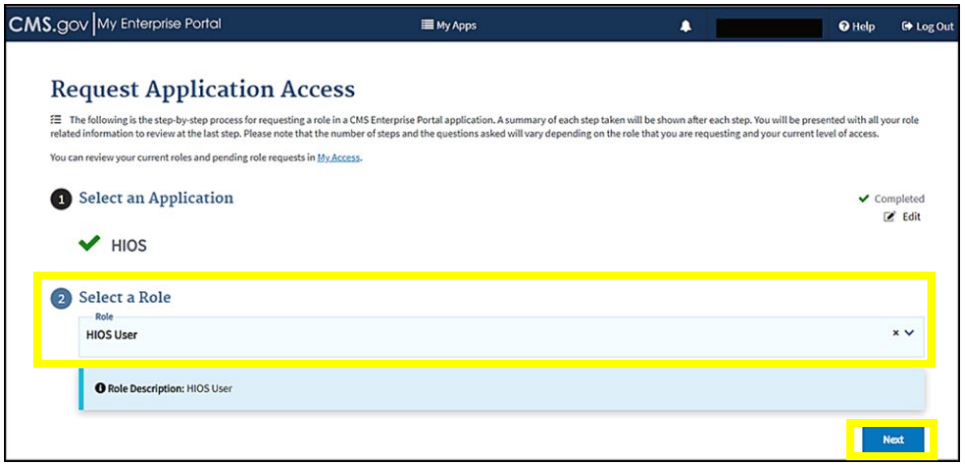
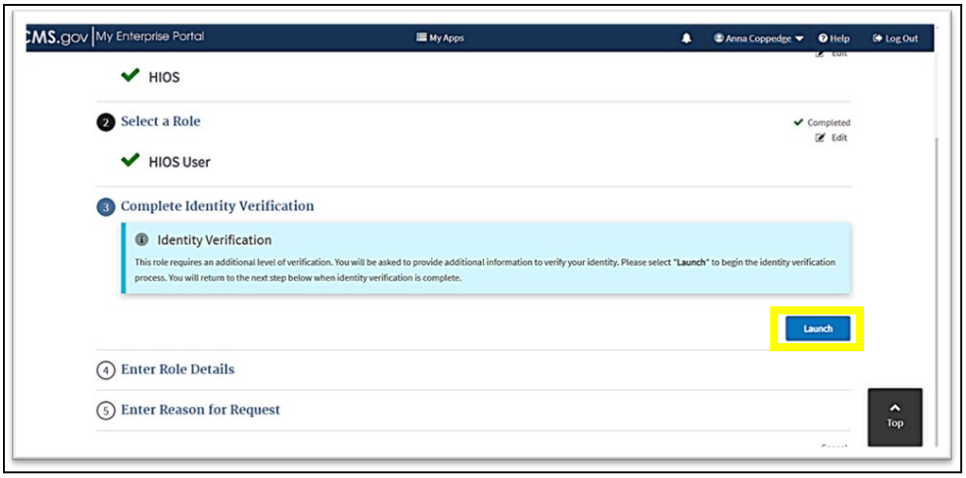
User Step	Screen Capture
[II-A] After receiving the email with your CMS Enterprise Portal User ID, using Google Chrome or Mozilla Firefox, open a new browser webpage and go to the CMS Enterprise Portal at https://portal.cms.gov. Enter your CMS Enterprise Portal User ID and Password, select the checkmark for "**I agree to the Terms and Conditions**," and select "**Login**." [Note: HIOS is only compatible with Google Chrome and Mozilla Firefox.]	

User Step	Screen Capture
[II-B] First-time users may be prompted to register a multi-factor authentication (MFA) device. If so, on the "**Register Multi-Factor Authentication (MFA) Device**" page, under "**Select the MFA device type**," expand the drop-down list and select "**Text Message (SMS)**" or "**Email**." Enter your phone number or email address and select "**Send MFA Code**." [Note: The MFA code should be sent to your MFA device within a couple of minutes. The CMS Enterprise Portal User Guide provides further details about CMS Enterprise Portal MFA devices.]	

III. Request HIOS Access (New HIOS User)

The table below describes steps for a new HIOS user to request access to the CMS HIOS application.

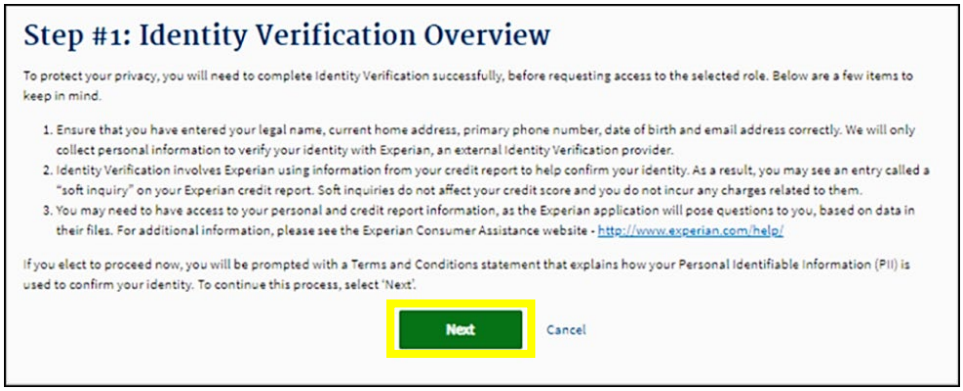
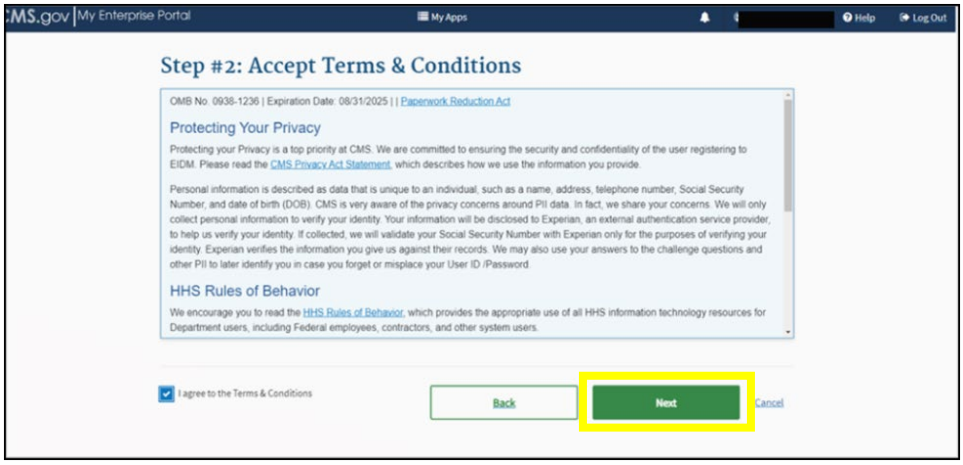
User Step	Screen Capture
[III-A] Using Google Chrome or Mozilla Firefox, open a new browser webpage and go to the CMS Enterprise Portal at https://portal.cms.gov. Enter your CMS Enterprise Portal User ID and Password, select the checkmark for "**I agree to the Terms & Conditions**," and select "**Login**." [Note: HIOS is only compatible with Google Chrome and Mozilla Firefox.]	

User Step	Screen Capture
[III-B] On the "**My Portal**" page, in the top right corner, select "**Add Application**."	
[III-C] On the "**Request Application Access**" page and under the first prompt "**Select an Application**," expand the drop-down list, select "**HIOS**," and select "**Next**."	
[III-D] Under the second prompt "**Select a Role**," expand the drop-down list, select "**HIOS User**," and select "**Next**."	
[III-E] Under the third prompt "**Complete Identity Verification**," select "**Launch**" to begin the identity verification process.	

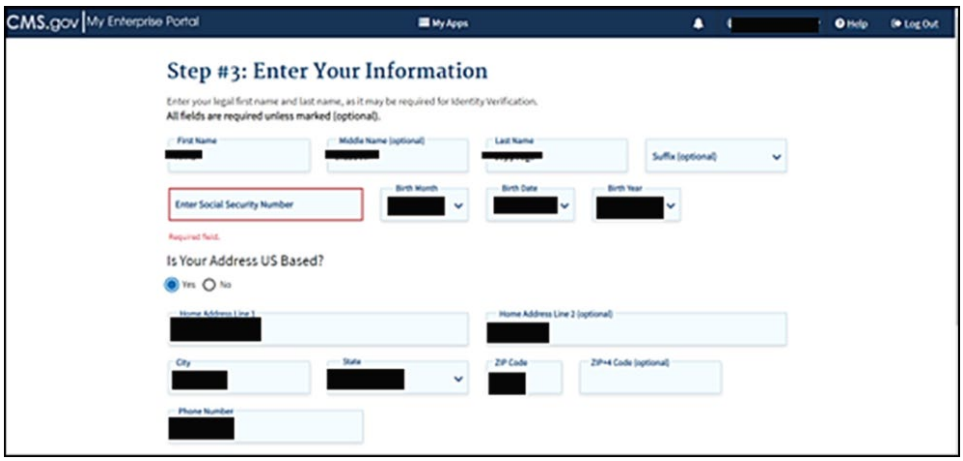
IV. Verify Identity (New HIOS User)

The identity verification process requires users to enter their Social Security Number (SSN). When you enter your SSN, it creates a "soft inquiry" on your credit report. Soft inquiries are visible only to you and no one else. Soft inquiries have no impact on your credit history or credit score. This document's "**Section X. Frequently Asked Questions**" provides additional guidance addressing the SSN requirement. [Note: The CMS identification verification process adheres to the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-63-3[1] titled "Digital Identity Guidelines."]

The table below describes steps for a new HIOS user to verify identity.

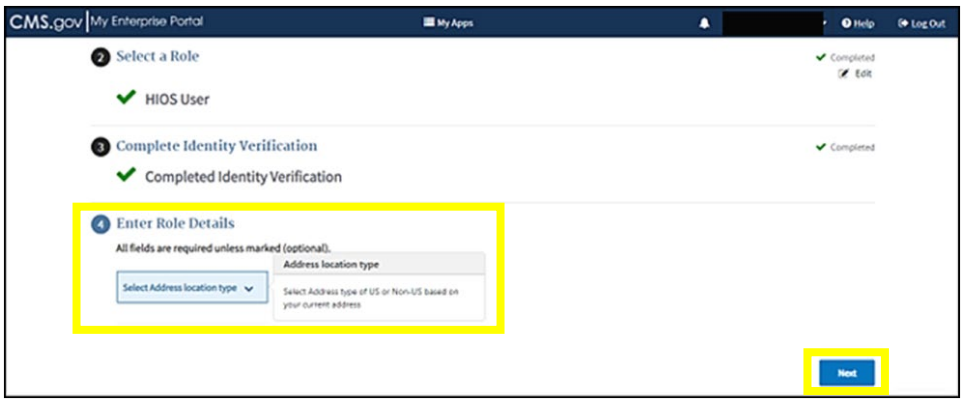
User Step	Screen Capture
[IV-A] On the "**Step #1: Identity Verification Overview**" page, read the information and select "**Next**."	
[IV-B] On the "**Step #2: Accept Terms & Conditions**" page, read the information, select the checkmark for "**I agree to the Terms & Conditions**," and select "**Next**."	

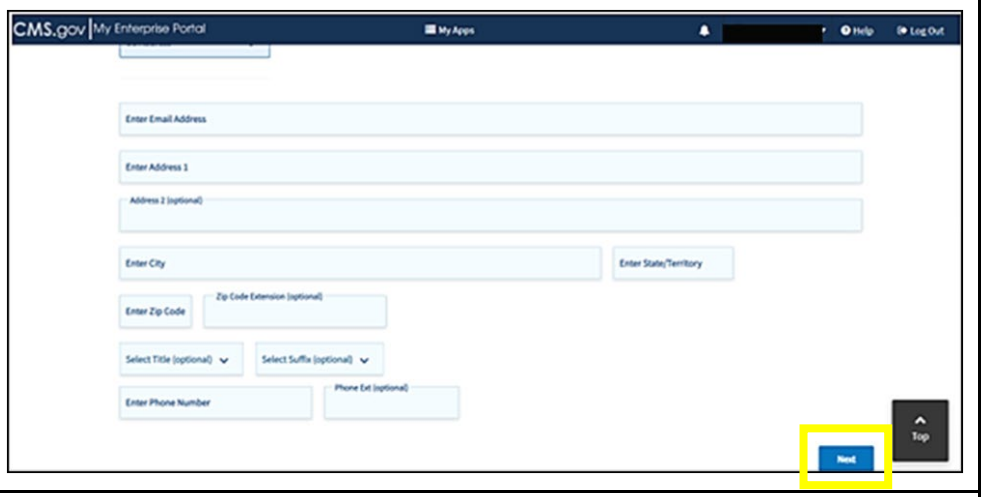
[1] NIST SP 800-63-3. "Digital Identity Guidelines." June 2017 (includes updates as of March 2, 2020). Available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-3.pdf.

User Step	Screen Capture
[IV-C] On the "**Step #3: Enter Your Information**" page, complete the form to verify your identity and select "**Next**." [Note: Your Social Security Number (SSN) is required. This document's "**Section X. Frequently Asked Questions**" provides additional guidance addressing the SSN requirement.]	
[IV-D] On the "**Step #4: Verify Your Identity**" page, complete the identity verification questions and select "**Next**." [Note: Examples of the identity verification questions include the dates you lived at an address, worked at a job, or opened a credit card. Entering this information will not impact your credit score.]	

V. Enter HIOS User Role Details (New HIOS User)

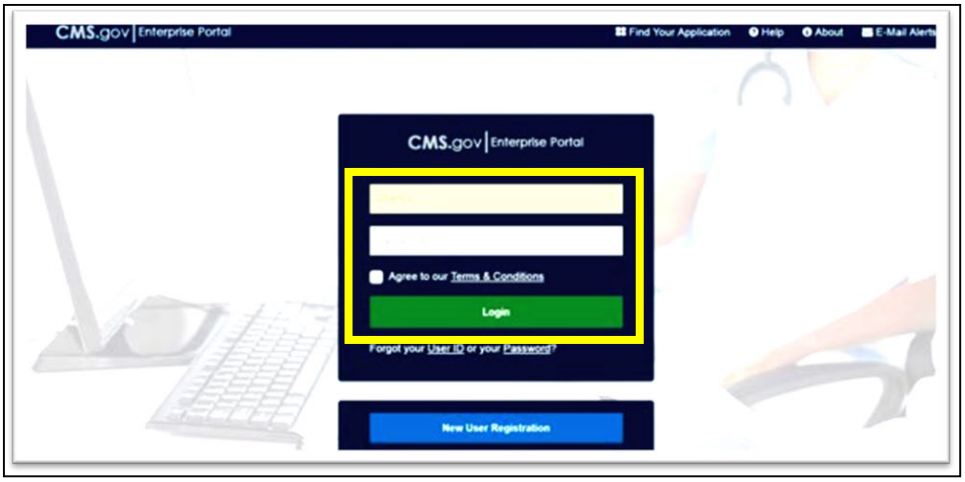
The table below describes steps for a new HIOS user to enter HIOS user role details.

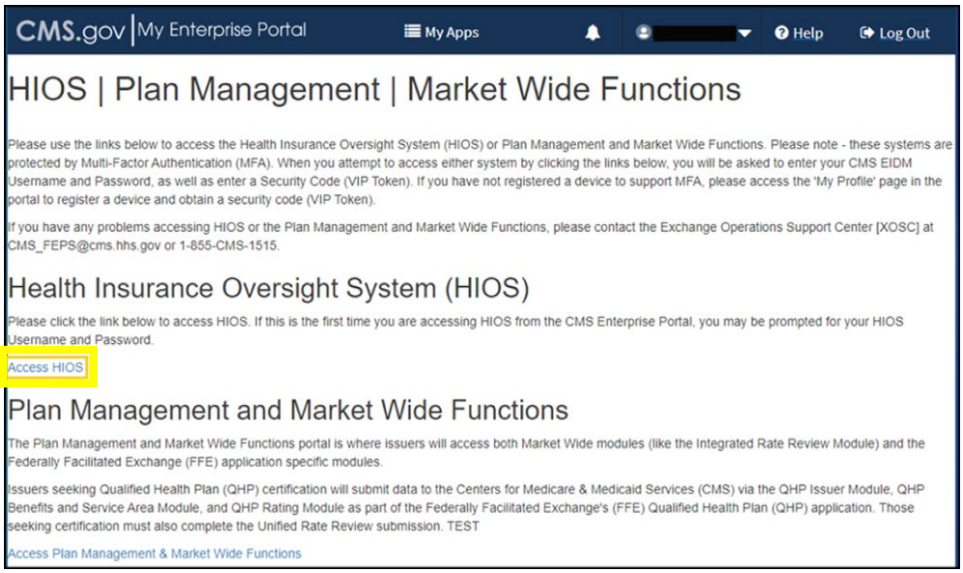
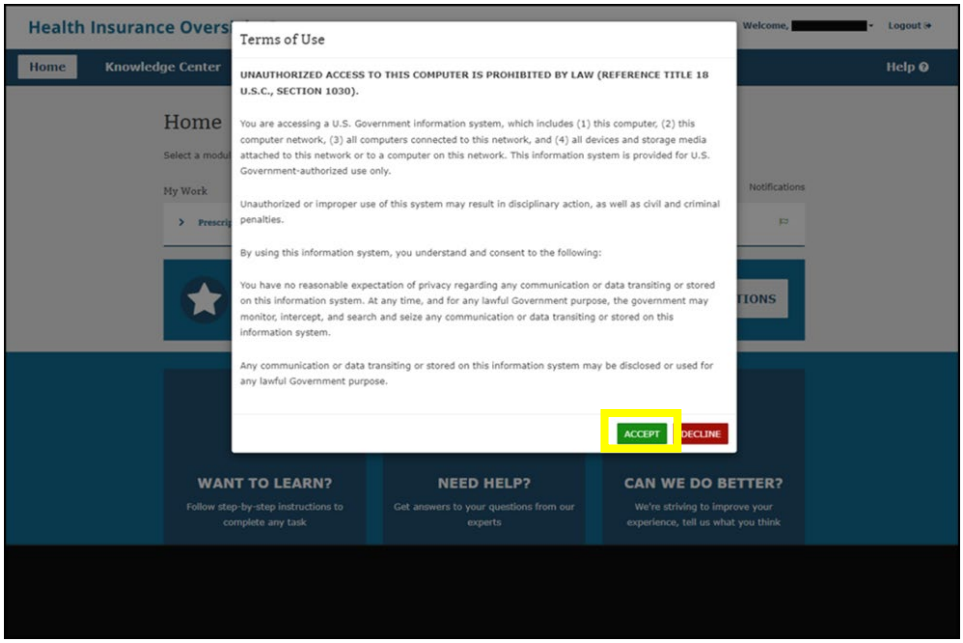
User Step	Screen Capture
[V-A] Upon completion of the identity verification in the previous section, you will be returned to the "**Request Application Access**" page. Under the 4th prompt "**Enter Role Details**," expand the drop-down list, select "**Address location type**," and select "**Next**."	

User Step	Screen Capture
[V-B] Complete the form and select "**Next**." Please use the same work email address entered above.	
[V-C] Under the 5th prompt "**Enter Reason for Request**," add your justification statement for the reason you need access and select "**Submit**." [Note: For example, "I need to submit data in the HIOS RxDC module."] [V-D] For the prompt "**Confirmation**," select "**OK**." [V-E] For the prompt "**Request New Application Access Acknowledgement**," select "**OK**."	

VI. Navigate to the HIOS Home Page (Approved HIOS Users)

The table below describes steps for approved HIOS users to access the HIOS application.

User Step	Screen Capture
[VI-A] Using Google Chrome or Mozilla Firefox, open a new browser webpage and go to the CMS Enterprise Portal at https://portal.cms.gov. Enter your CMS Enterprise Portal User ID and Password, select the checkmark for "**I agree to the Terms & Conditions**," and select "**Login**." [Note: HIOS is only compatible with Google Chrome and Mozilla Firefox.]	

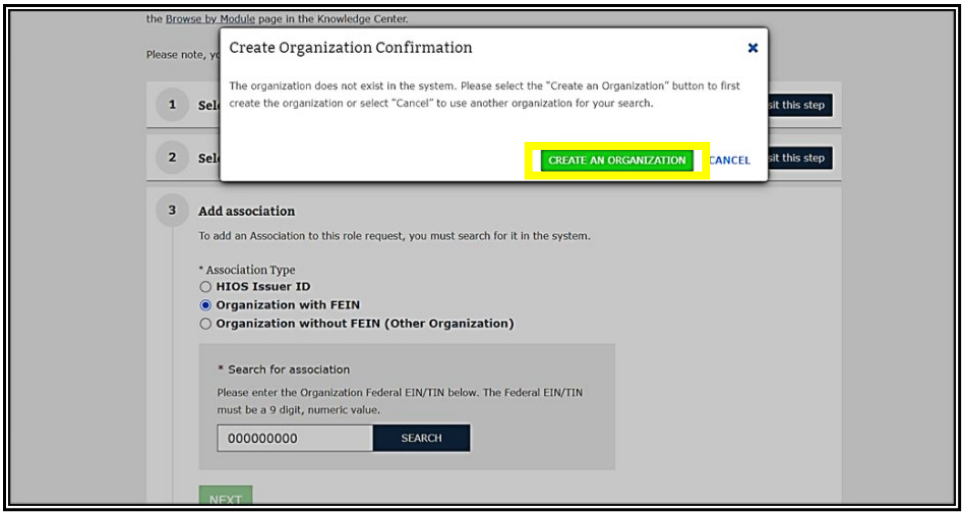
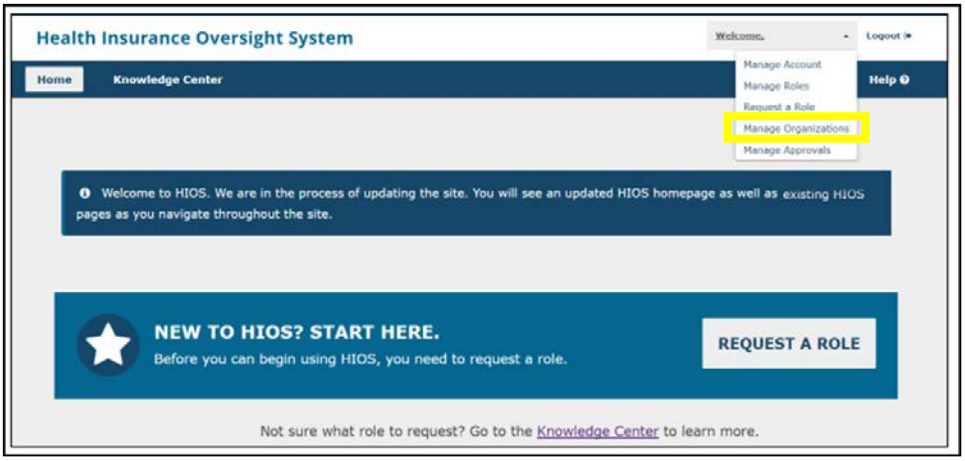
User Step	Screen Capture
[VI-B] On the "**My Portal**" page, select **"HIOS**" and select "**Overview**."	
[VI-C] On the "**HIOS**" page, select "**Access HIOS**."	
[VI-D] On the "**Terms of Use**" page, read the information and select "**Accept**."	

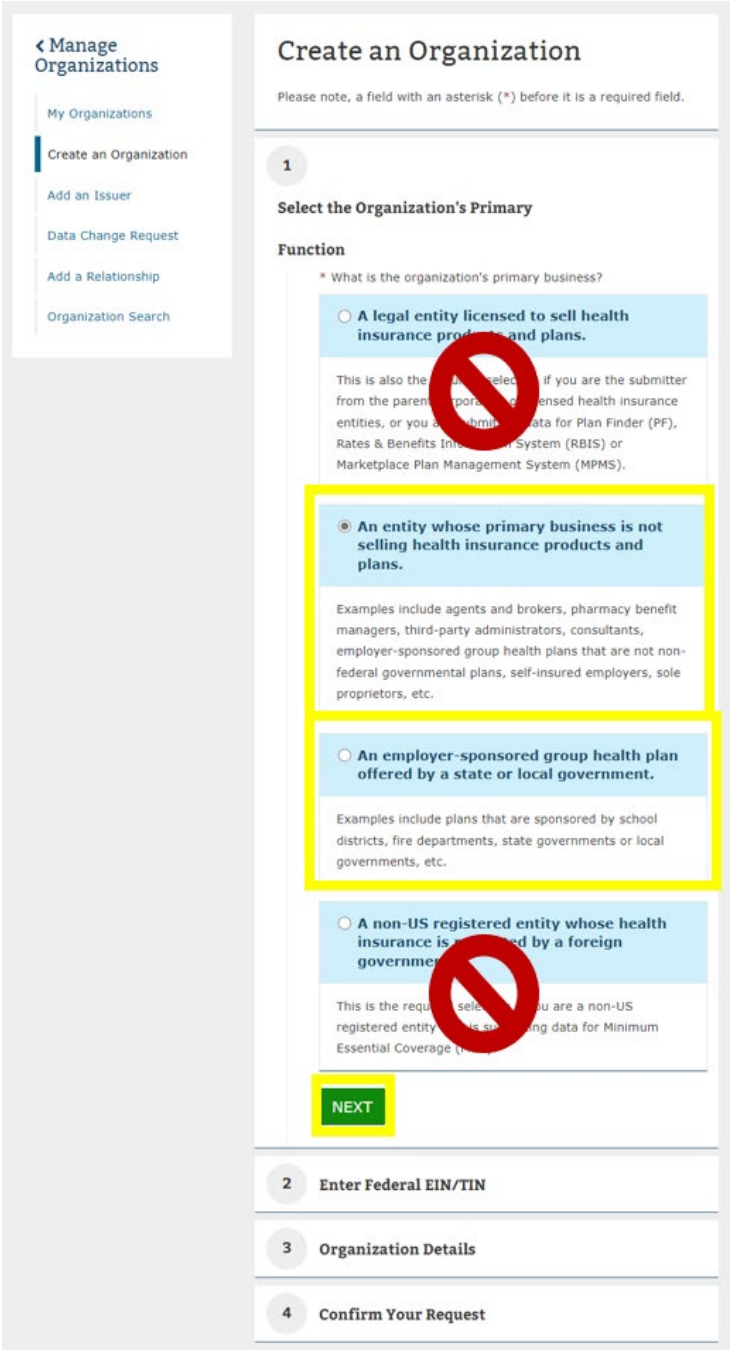
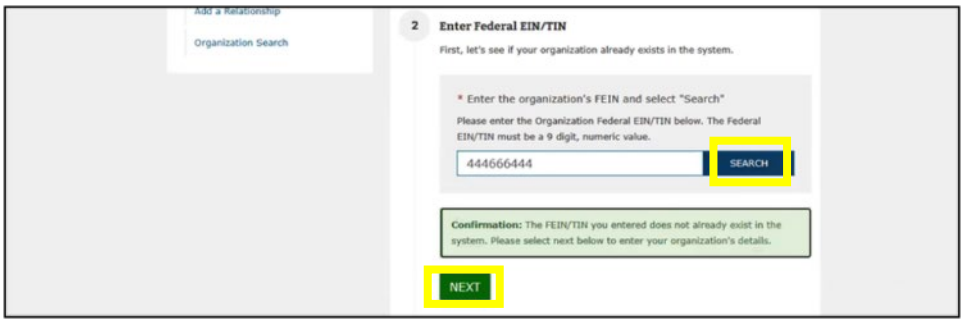
VII. Create a HIOS Organization (New HIOS Organization)

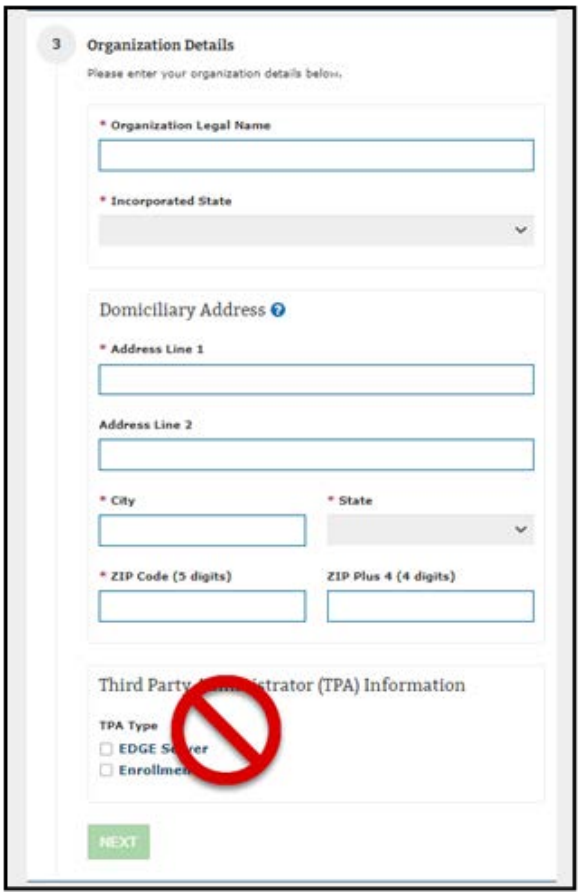
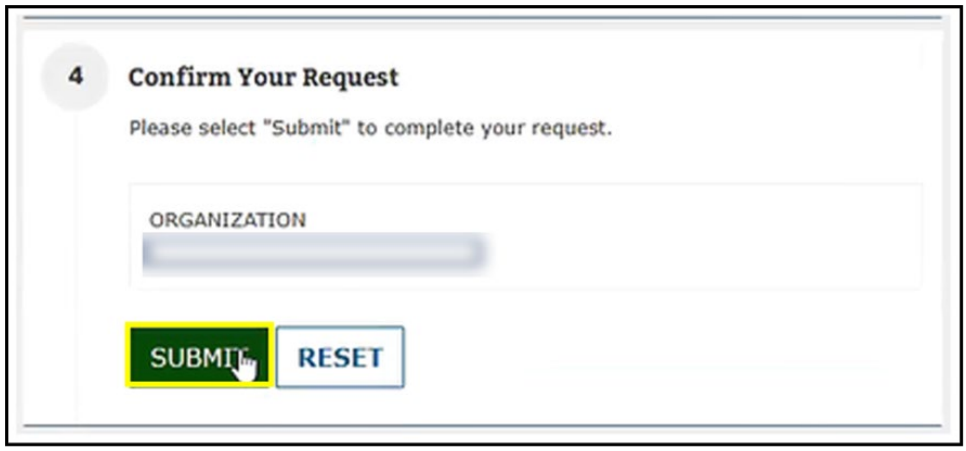
The following bullets address different scenarios for creating a new HIOS organization.

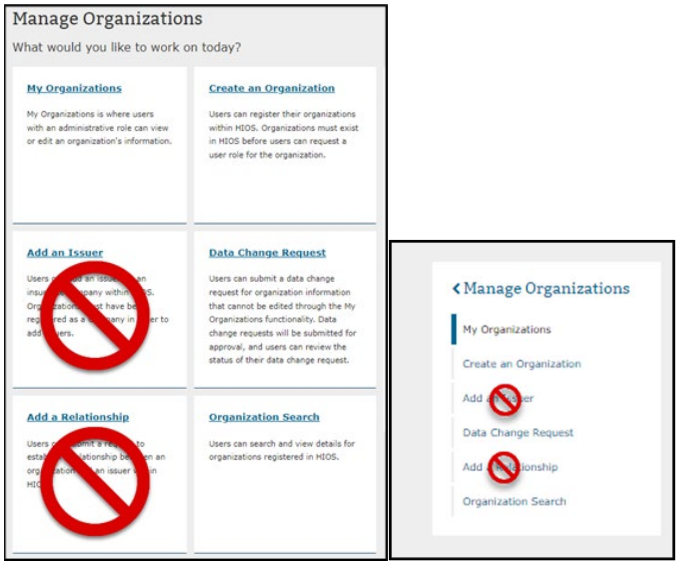
- ***If your organization does not currently exist in HIOS***, then complete this document's "**Section VII. Create a HIOS Organization**" to register your organization in HIOS.
- ***If your organization already exists in HIOS,*** then **DO NOT** complete this document's "**Section VII. Create a HIOS Organization**" and go to "Section IX. Request Organization Role Approver Role" and see Figure 2. ORA Decision Chart. [Note: If your company has previously submitted data in any HIOS module, then your organization is already registered in HIOS.]
- ***If you are submitting on behalf of a client,*** then **DO NOT** create an organization in HIOS for your client. [Note: Only create an organization in HIOS for your own company. The HIOS Team rejects requests to create organizations if the user's email extension does not correspond with the name of the user's organization.] This document's "**Section X. Frequently Asked Questions**" provides additional guidance addressing submitting on behalf of a client.

The table below describes the steps for creating a new HIOS organization.

User Step	Screen Capture
[VII-A] If your organization does not currently exist in HIOS, you will receive a message, "The organization does not exist…," when attempting to add an association during the role request process. Select "**Create an Organization**."	
[VII-B] Alternatively, you can create an organization directly from the HIOS home page by selecting the "**Welcome**" drop-down list and "**Manage Organizations**." Either the previous step or this step takes you to the "**Create an Organization**" page for you to complete the next steps to register your organization in HIOS.	

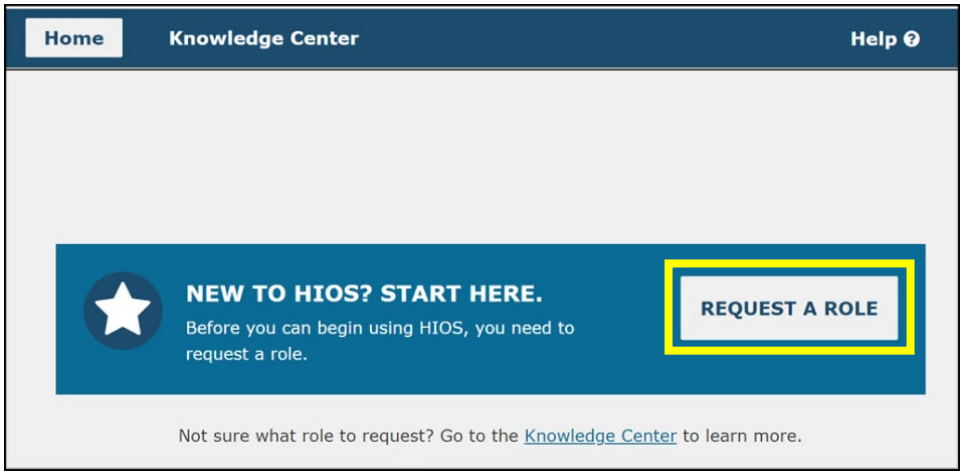
User Step	Screen Capture
[VII-C] Under "**Manage Organizations**," select "**Create an Organization**." On the "**Create an Organization**" page, under the 1st prompt "**Select the Organization's Primary Function**," select the type of your organization and select "**Next**." If your organization is a group health plan (non-governmental), TPA, PBM, or third-party vendor (such as an agent or broker)," then select the 2nd option "**An entity whose primary business is not selling health insurance products and plans**." If your organization is governmental health plan, such as a school district, state, or local government, then select the 3rd option "**An employer-sponsored group health plan offered by a state or local government**." **DO NOT** select the 1st option "**A legal entity licensed to sell health insurance products and plans**." [Note: This option is for insurance companies only. Insurance companies are already registered in HIOS.] **DO NOT** select the 4th option "**A non-US registered entity whose health insurance is regulated by a foreign government**." [Note: This type of organization is not utilized in the RxDC module.]	
[VII-D] Under the 2nd prompt "**Enter Federal EIN/TIN**," type your organization's FEIN 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**."	

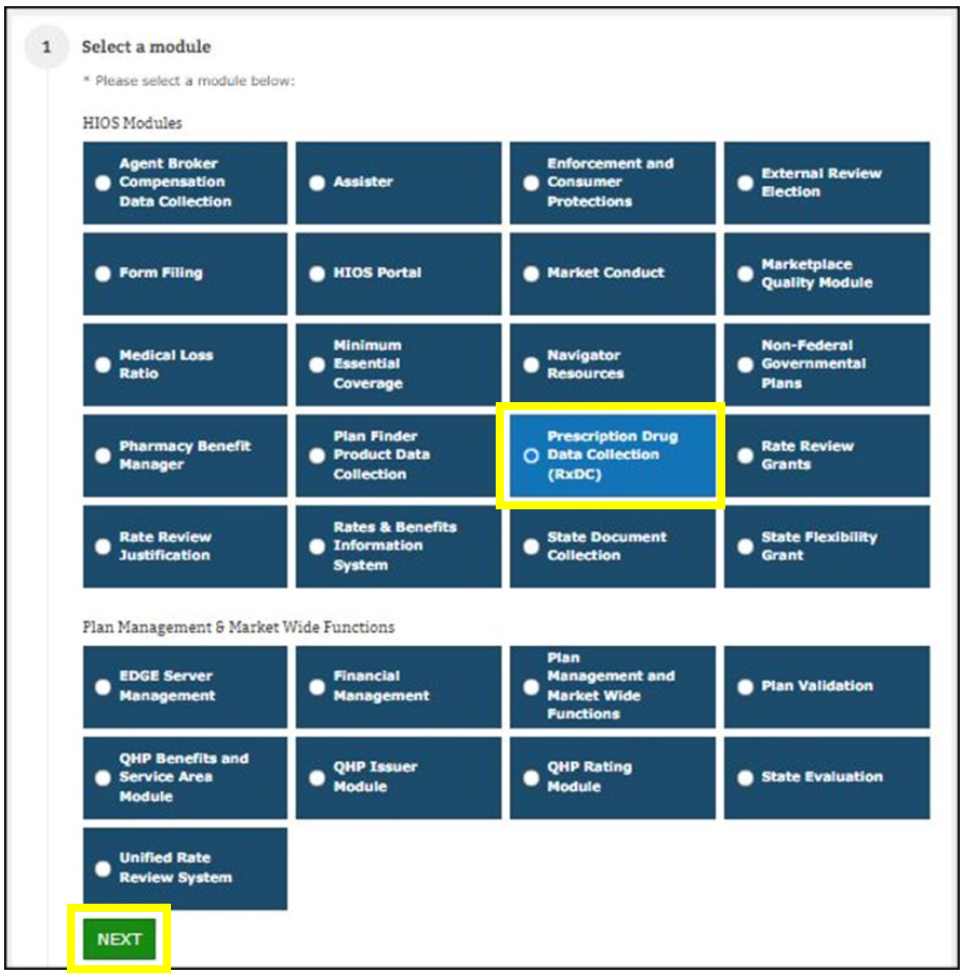
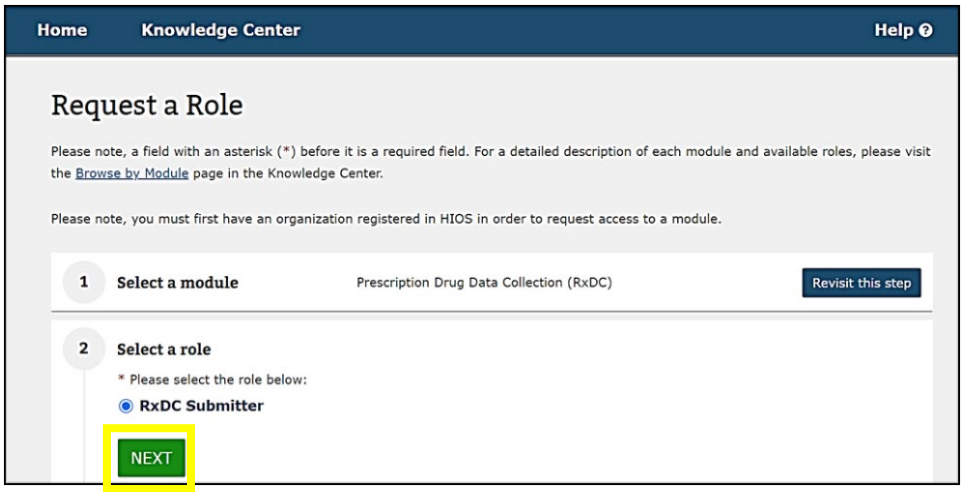
User Step	Screen Capture
[VII-E] Under the 3rd prompt "**Organization Details**," complete the form for your organization and select "**Next**." **DO NOT** complete "**Third Party Administrator (TPA) Information**." [Note: The TPA information is not applicable to the RxDC module. All organizations, including TPAs, should proceed to the next step below.]	
[VII-F] Under the 4th prompt "**Confirm Your Request**," select "**Submit**." [Note: You may revisit previous steps to make changes prior to confirming your request. Check back after 1-2 business days to see if your organization has been approved. After the organization has been approved, it will then be available for users to submit role requests.]	

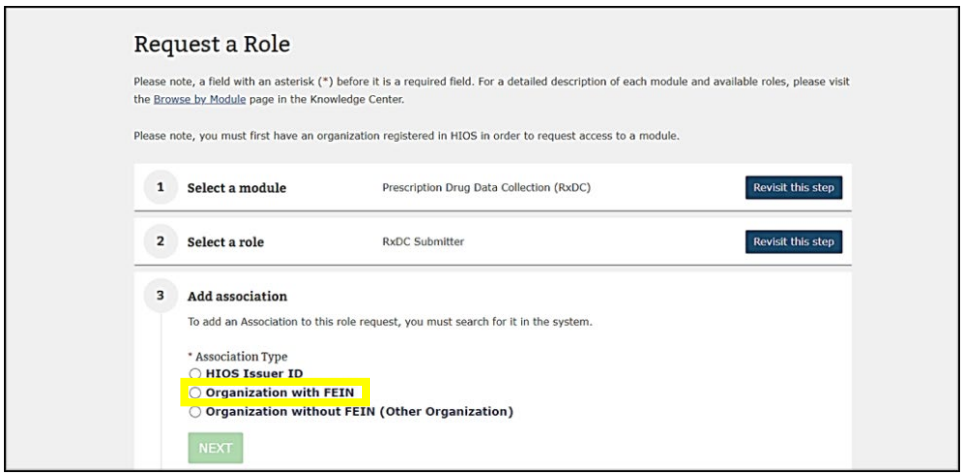
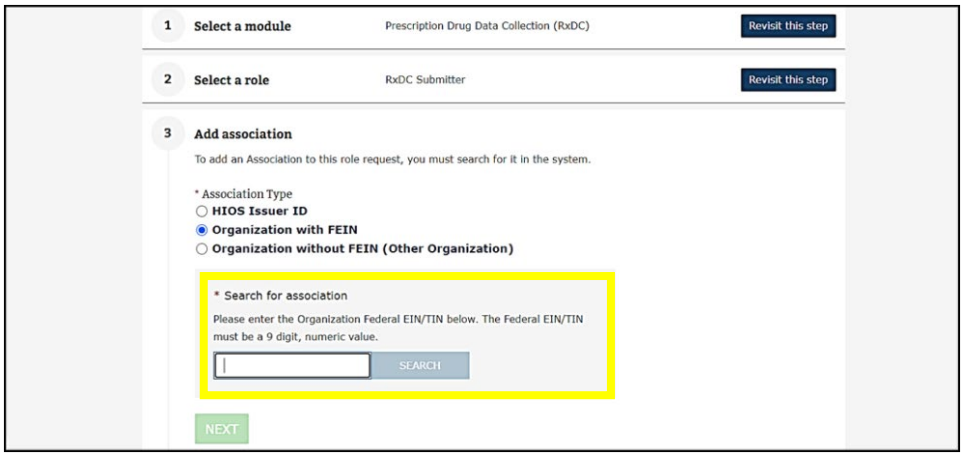
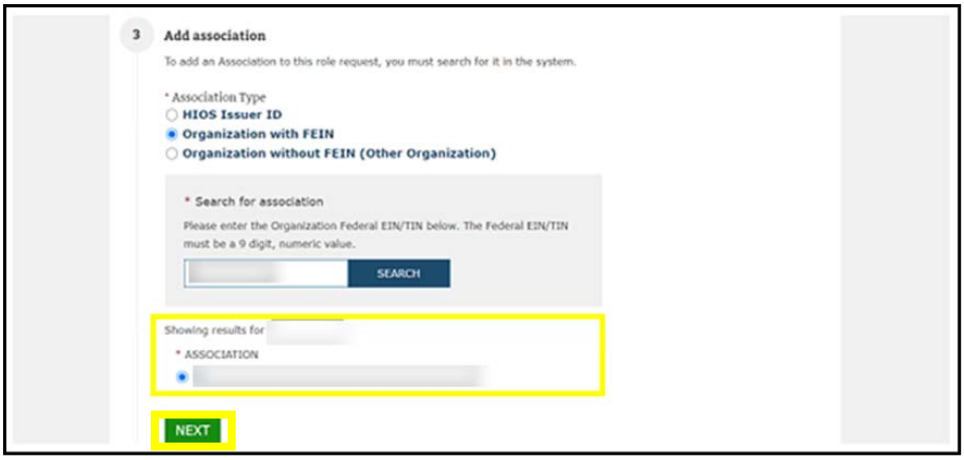
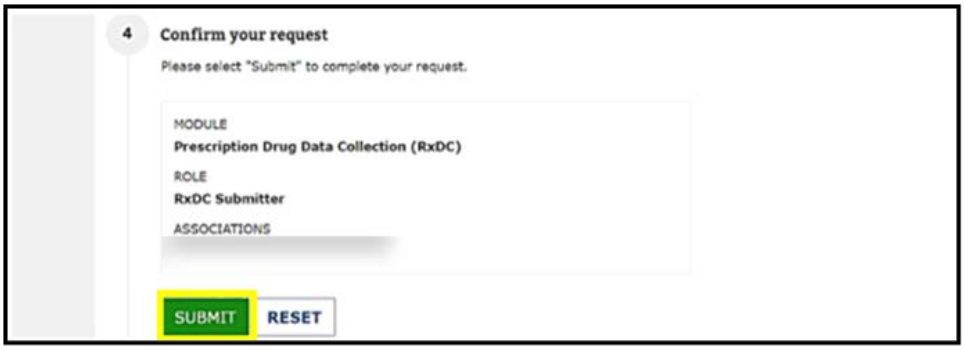
User Step	Screen Capture
[VII-G] Under "**Manage Organizations**," DO NOT select "**Add an Issuer**" and DO NOT select "**Add a Relationship**." [Note: These two options are not applicable to the RxDC module.]	

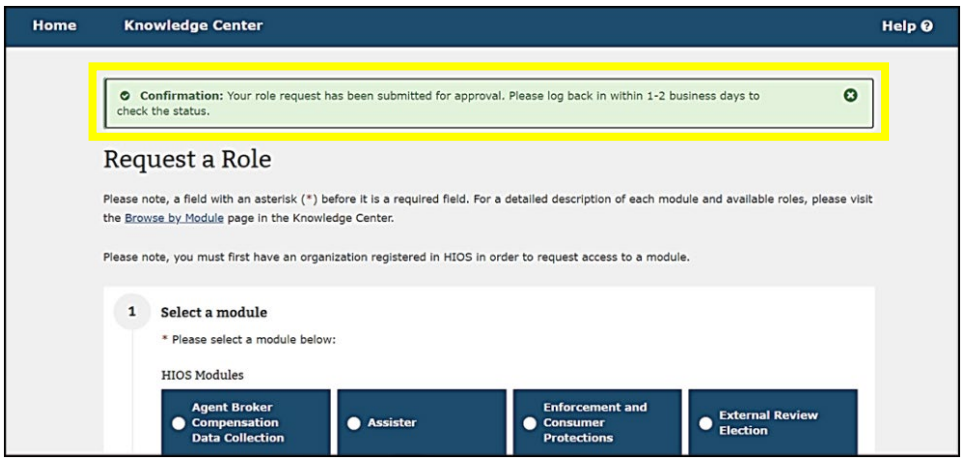
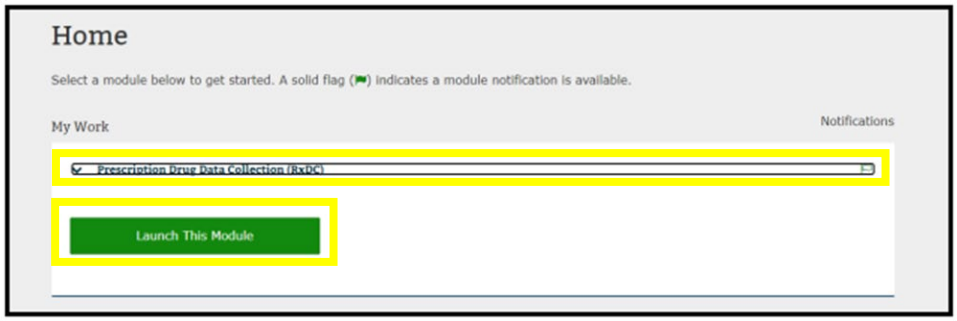
VIII. Request the RxDC Submitter Role (New RxDC User)

The table below describes a new RxDC user's steps for requesting the RxDC Submitter role.

User Step	Screen Capture
[VIII-A] Go to the **CMS Enterprise Portal** at https://portal.cms.gov and navigate to the HIOS homepage. (See Section VI above.) If you are a new HIOS user, then select "**Request A Role**."	
[VIII-B] If you are an existing HIOS user and do not have access to the RxDC module, then select the "**Welcome**" drop-down list at the top of the page and select "**Request a Role**."	

User Step	Screen Capture
[VIII-C] On the "**Request a Role**" page, under the 1st prompt "**Select a module**," select "**Prescription Drug Data Collection (RxDC)**" and select "**Next**."	
[VIII-D] On the "**Request a Role**" page, under the 2nd prompt "**Select a role**," select "**RxDC Submitter**" and select "**Next**."	

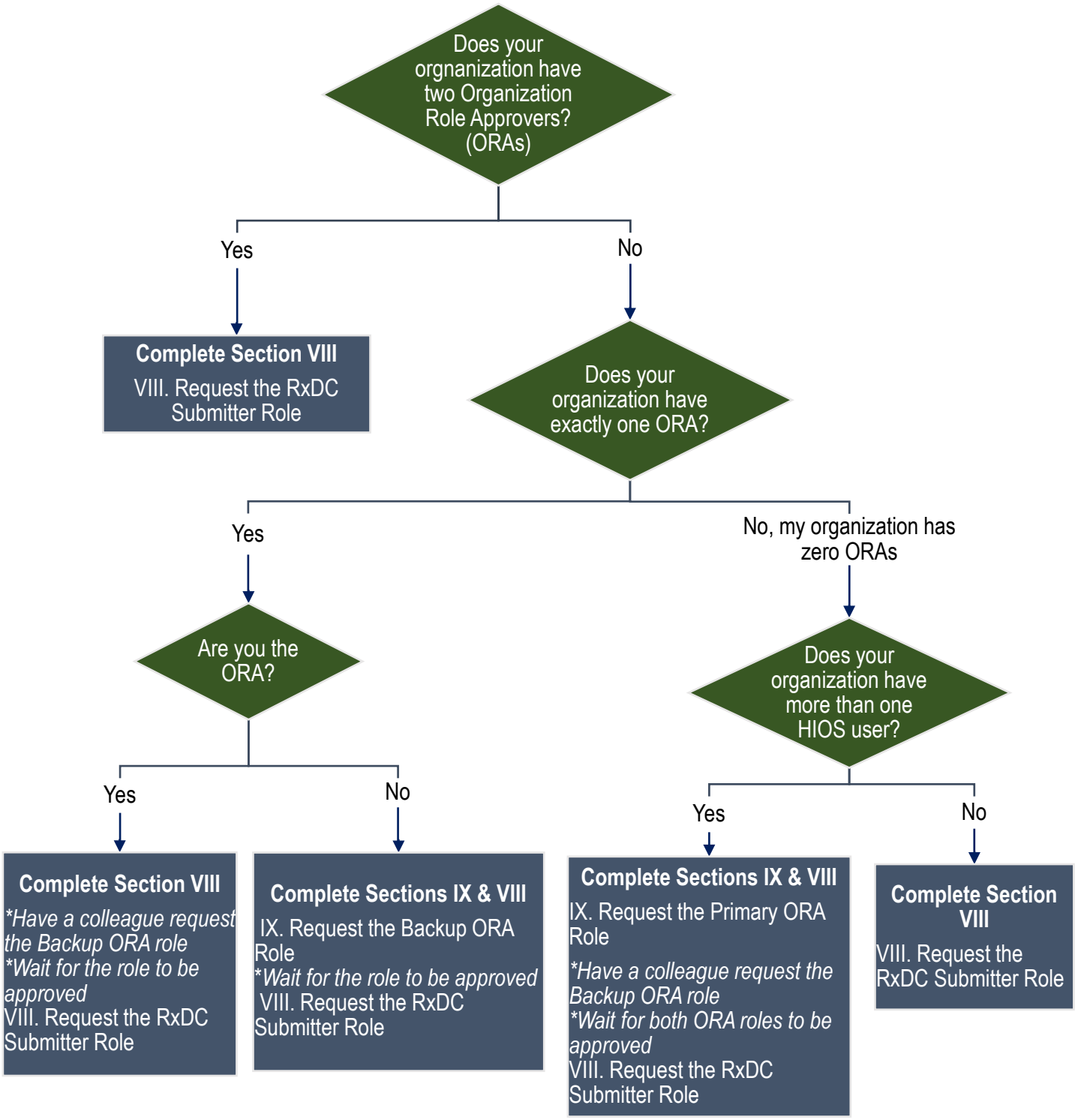
User Step	Screen Capture
[VIII-E] On the "**Request a Role**" page, under the 3rd prompt "**Add association**," select the second option "**Organization with FEIN**."	
[VIII-F] In the "**Search for association**" box, type your organization's FEIN and select "**Search**." [Note: If you are submitting on behalf of a client, enter your own organization's FEIN, not your client's organization FEIN.] HIOS will only approve a role request submitted for your own organization.	
[VIII-G] In the search results box under "**Association**," select your organization and select "**Next**." [Note: If your organization is not already registered in HIOS, you will receive a message stating, "the organization does not exist." Go to this document's previous "**Section VII. Create a HIOS Organization**."]	
[VIII-H] Under the 4th prompt "**Confirm your request**," review your information and select "**Submit**." [Note: If the information is incorrect, then return to the previous step where the incorrect information was entered and make the necessary correction.]	

User Step	Screen Capture
[VIII-I] After you submit, a confirmation box will indicate that your role request has been submitted for approval.	
[VIII-J] After your RxDC Submitter role request is approved, access the RxDC module from the HIOS home page. Select "**Prescription Drug Data Collection (RxDC)**" and select "**Launch This Module**." [Note: The RxDC HIOS Module User Manual provides instructions for submitting data in the HIOS RxDC module.]	

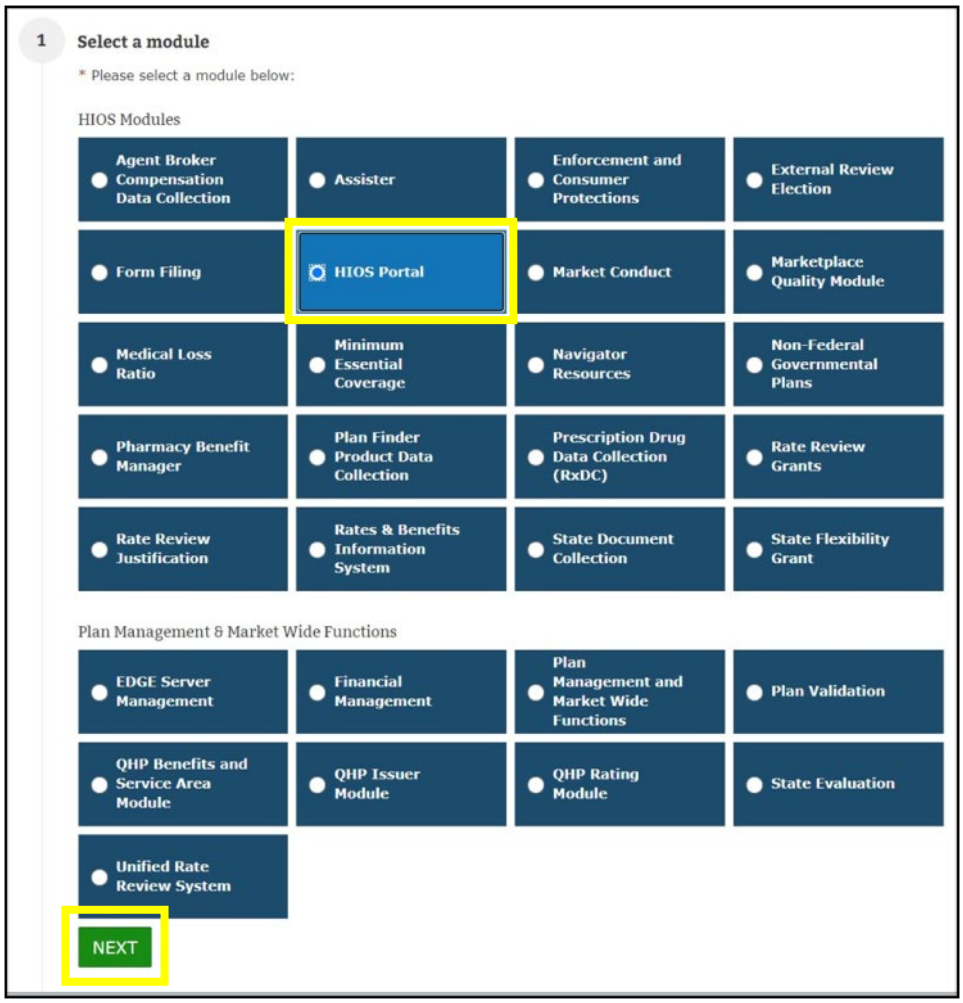
IX. Request Organization Role Approver Role (if applicable)

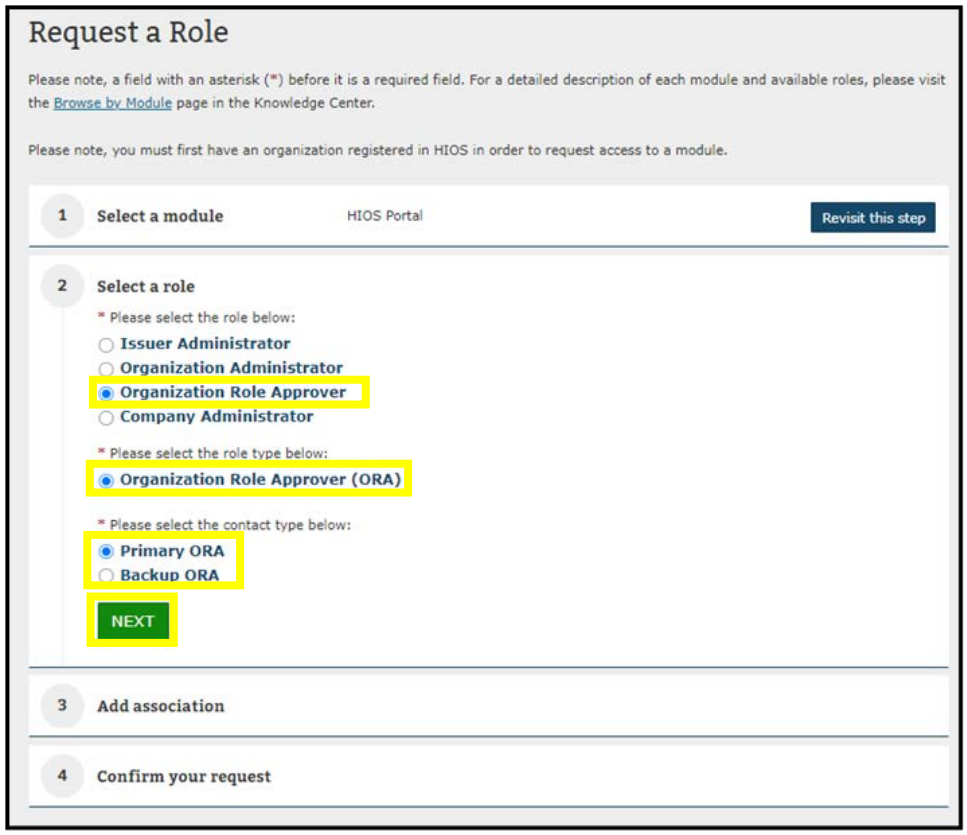
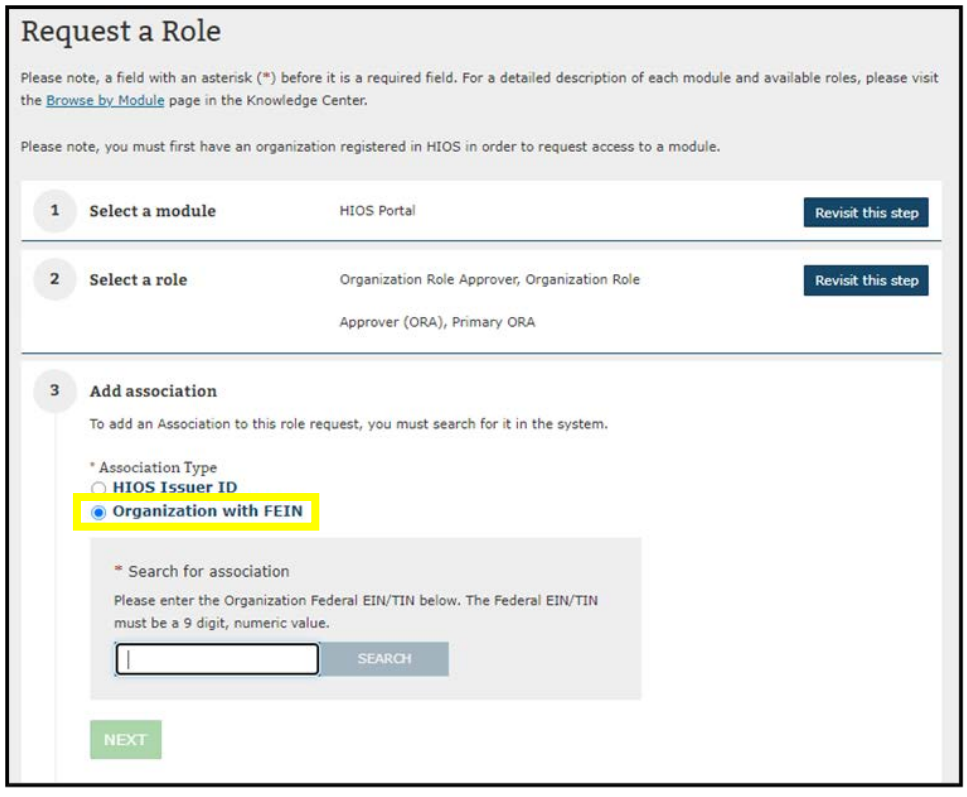
The Organization Role Approver (ORA) is a representative of a HIOS organization that is responsible for viewing, approving, and/or denying pending role requests for its own organization. The ORA role allows an organization to control who can view or submit data for their organization. Most organizations in HIOS must have two ORAs – a Primary ORA and a Backup ORA. However, if you are the only person at your company that needs a HIOS role, then your organization is not required to have ORAs. Figure 2 below depicts the decision-making criteria for navigating through the ORA role options. This document's "**Section X. Frequently Asked Questions**" provides additional guidance addressing the ORA role.

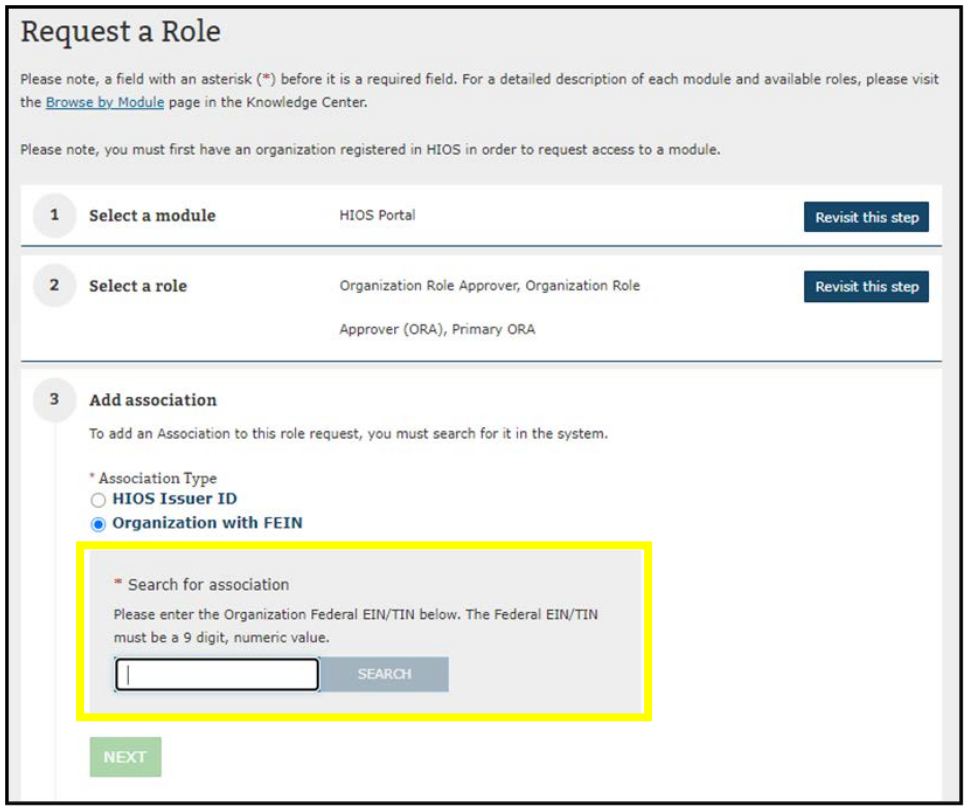
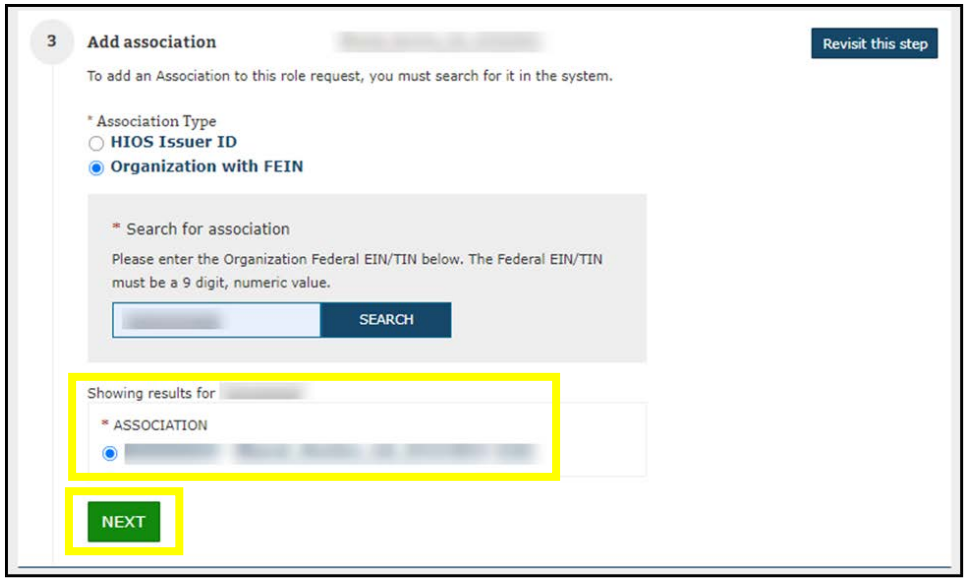
Figure 2: ORA Decision Chart

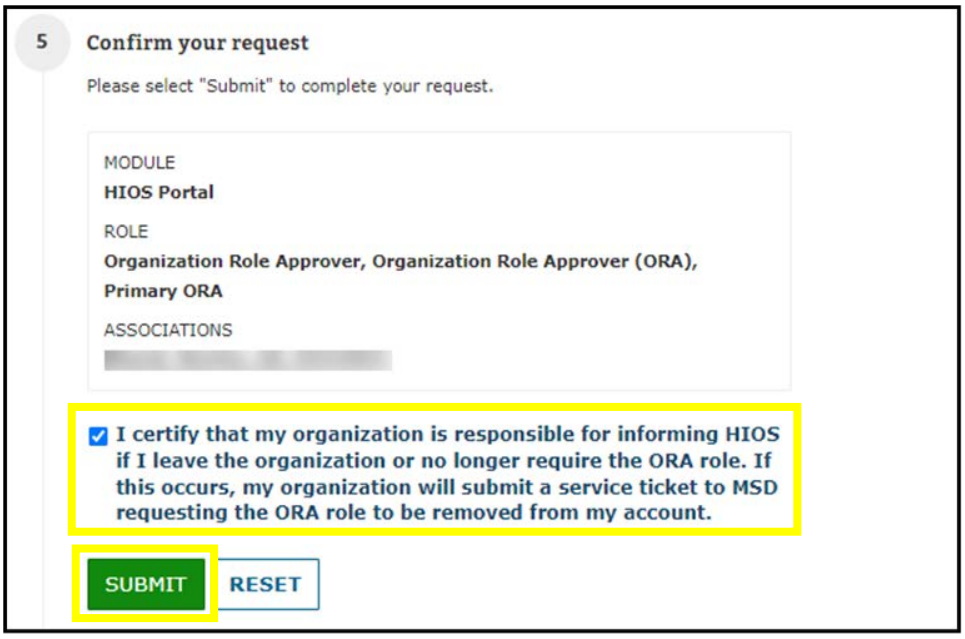
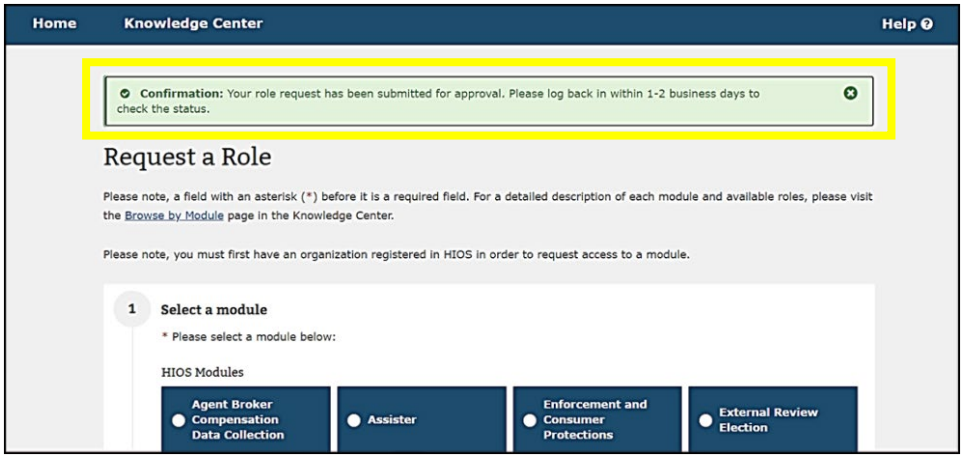


The table below describes the steps for requesting the ORA role.

User Step	Screen Capture
[IX-A] On the HIOS home page, select "**Welcome**" and select "**Request a Role**."	
[IX-B] On the "**Request a Role**" page, under the 1st prompt "**Select a module**," select "**HIOS Portal"** and select "**Next**."	

User Step	Screen Capture
[IX-C] On the "**Request a Role**" page, under the 2nd prompt "**Select a role,**" select "**Organization Role Approver,**" "**Organization Role Approver (ORA)**," select either "**Primary ORA**" or "**Backup ORA**," and select "**Next**."	
[IX-D] On the "**Request a Role**" page, under the 3rd prompt "**Add association**," select the second option "**Organization with FEIN**."	

User Step	Screen Capture
[IX-E] In the "**Search for association**" box, type your organization's FEIN and select "**Search**." [Note: If you are submitting on behalf of a client, enter your own organization's FEIN, not your client's organization FEIN.]	
[IX-F] In the search results box under "**Association**," select your organization and select "**Next**." [Note: If your organization is not already registered in HIOS, you will receive a message stating, "the organization does not exist." Go to this document's previous "**Section VII. Create a HIOS Organization**."]	

User Step	Screen Capture
[IX-G] Under the 4th prompt "Confirm your request," review your information and select the checkmark "**I certify…**," and select "**Submit**." [Note: If the information is incorrect, then return to the previous step where the incorrect information was entered and make the necessary correction.]	
[IX-H] After you submit, a confirmation box will indicate that your role request has been submitted for approval.	

X. Frequently Asked Questions

The table below provides FAQs and answers for additional guidance.

Questions	Answers
How do I contact the Help Desk?	Contact the Marketplace Service Desk (MSD) via Phone: 1-855-267-1515 or Email: CMS_FEPS@cms.hhs.gov. Include "HIOS RxDC Question" in the body of your email to expedite processing. You can typically expect a response within the same day and a full resolution within 1-2 weeks. During periods of high volume, response times may be significantly longer.

Questions	Answers
Why do I have to provide my Social Security Number (SSN)?	Establishing confidence in a person's identity is a critical starting point for conducting online business with CMS. The CMS identification verification process adheres to the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-63-3[2] titled "Digital Identity Guidelines." To meet levels of assurance 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 requirement. Users must provide their SSN as part of the RIDP process. The RIDP 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.
What if I don't have a work email address?	Email the Marketplace Service Desk at CMS_FEPS@cms.hhs.gov to inquire about next steps. [Note: Include "HIOS RxDC Question" in the body of your email to expedite service.]
How do I get to the RxDC Module home page to submit my data?	After your RxDC Submitter role is approved, consult the RxDC HIOS Module User Manual for instructions on submitting data in the RxDC Module
How long does it take for an organization request or a role request to be approved or denied?	Normally, it takes 1-2 business days. During periods of high volume, it may take significantly longer.
Who approves user role requests?	If your organization has two ORAs, one of the ORAs will approve/deny your request. If your organization doesn't have any ORAs and doesn't need ORAs, then CMS will approve/deny your request. See "**Section IX. Request Organization Role Approver role**" for more information about the ORA requirements
How do I know when my organization request has been approved or denied?	You will receive an email when the role request has been approved or denied.
How do I know when my role request has been approved or denied?	You will receive an email when the role request has been approved or denied. If you don't receive an email, you can also check in HIOS. Navigate to the page "Manage Roles" to determine if your role request is pending or approved. If you don't see your role request, it means that your role request was denied.
What type of organizations are required to have an Organization Role Approver (ORA)?	All organizations with two or more employees registered in HIOS are required to have two ORAs: (1) a Primary ORA and (2) a Backup ORA. See "**Section IX. Request Organization Role Approver role**" for more information about the ORA requirements.

[2] NIST SP 800-63-3. "Digital Identity Guidelines." June 2017 (includes updates as of March 2, 2020). Available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-3.pdf.

Questions	Answers
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, CMS can approve your role request. After you have requested the RxDC Submitter role, please send an email to CMS_FEPS@cms.hhs.gov and request approval of your RxDC Submitter role request. [Note: Include "HIOS RxDC Question" in the body of your email to expedite processing.]
My organization is a sole proprietor or a group health plan with only one user registered for HIOS. I already requested the ORA role. What should I do?	You will need to remove the existing ORA role from your account. To remove the role from your account, expand the "**Welcome**" drop-down list, select "**Manage Roles**," and select "**View Details**" on the role request you need removed. Then select "**Delete Role Request**". You will also need to delete any pending RxDC Submitter roles and resubmit that request after the ORA role request has been removed from your account.
How do I know if my organization already has an ORA?	If your organization 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 an organization. If your company doesn't have a Company Administrator, or you don't know who the Company Administrator is, email CMS_FEPS@cms.hhs.gov and ask about your organization's ORA. [Note: Include "HIOS RxDC Question" in the body of your email to expedite processing.]
The ORA is no longer with my organization. What should I do?	Someone else from your organization will need to assume the ORA role. They will need to access HIOS and request the ORA role.
Which roles are required to submit data to RxDC?	You need the RxDC Submitter role to submit RxDC data. Go to Section IX to determine if you also need the ORA role.
How do I delete an approved role from my account?	Expand the "**Welcome**" drop-down list, select "**Manage Roles**," and select "**View Details**" on the role request you need removed. Select the option to delete the role.
How can I delete an RxDC Submitter who is no longer with my organization?	Users with the Company Administrator role or the Organization Administrator role can delete users who are no longer with the organization. See the HIOS Portal User Manual for more information on the Company Administrator and Organization Administrator roles. The HIOS Portal User Manual is available at https://www.hhs.gov/guidance/document/hios-portal-user-manual, and more HIOS resources can be found on https://www.cms.gov/marketplace/resources/forms-reports-other. If your organization doesn't have a Company Administrator or Organization Administrator, email the Marketplace Service Desk at CMS_FEPS@cms.hhs.gov and request deactivation of the user's account.
Do ORAs need to have their own separate CMS login from the RxDC Submitter?	Each user must have a separate account and login; however, one user can have both roles at the same time.

Questions	Answers
Will I receive an email if my role request has been denied?	Yes, you will receive an email if your role request was denied. You can also check the status of your request in HIOS on the "Manage Roles" page. Approved and pending roles will display a status. Denied role requests will be removed from this view.
I received an email stating my organization was approved but I don't see it under "My Organizations."	You will need to request a role for your organization. Roles are not automatically assigned with the creation of an organization. Organizations will only appear on the page "**My Organization**" if you are assigned the Company Administrator role within HIOS.
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 request was denied. What should I do?	Verify your submitted information was correct and resubmit the request. If you believe the request was denied in error, email CMS_FEPS@cms.hhs.gov. [Note: Include "HIOS RxDC Question" in the body of your email to expedite processing.]
How do I submit RxDC data on behalf of my client?	HIOS will not approve a role request nor organization creation request for an organization that is not your organization. To submit RxDC data for other organizations, you must first request the RxDC Submitter role for your own organization, and then use your RxDC Submitter role to submit RxDC data for other organizations within the RxDC HIOS module. If you are submitting for multiple organizations, you can create a separate submission for each company and label each submission accordingly within the RxDC module. Alternatively, you can create one submission and list each organization in a separate row. You can also mix submitting separately for some organizations and aggregating multiple submissions for others.

XI. Primary Resources and Help Desk Information

CMS RxDC Home Page

The CMS RxDC Home Page contains all the documents you need to prepare and submit your RxDC report. You will also find a list of Frequently Asked Questions and links to training materials.

HIOS Portal User Manual

The HIOS Portal User Manual contains detailed instructions for all aspects of HIOS functionality and is applicable to all HIOS modules. The HIOS Portal User Manual is available at https://www.cms.gov/marketplace/resources/forms-reports-other.

Help Desk

If you still have questions after reading these instructions, contact the Marketplace Service Desk (MSD) at CMS_FEPS@cms.hhs.gov. Include "RxDC" in the body of the email to expedite processing. You can typically expect a response within the same day and a full resolution within 1-2 weeks. During periods of high volume, response times may be significantly longer. MSD is also available by phone at 1-855-267-1515 for questions about HIOS access and user role requests.

REGTAP

Sign up for RxDC emails and register for training webinars at https://regtap.cms.gov/rxdc.php.