RxDC HIOS Module User Manual

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

Version 14

April 5, 2024

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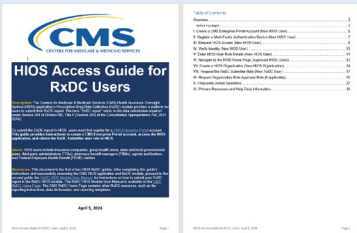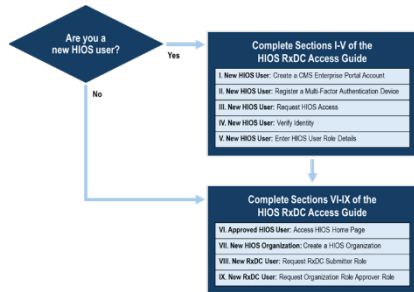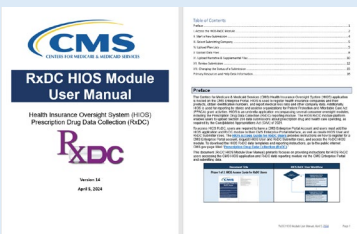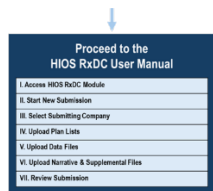
Preface

The Centers for Medicare & Medicaid Services (CMS) Health Insurance Oversight System (HIOS) application is hosted on the CMS Enterprise Portal. HIOS is used to register health insurance companies and their 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 is an umbrella application encompassing several consumer oversight modules, including the Prescription Drug Data Collection (RxDC) reporting module. The HIOS RxDC module platform enables users to upload Section 204 data submissions about prescription drug and health care spending, as required by the Consolidated Appropriations Act (CAA) of 2021.
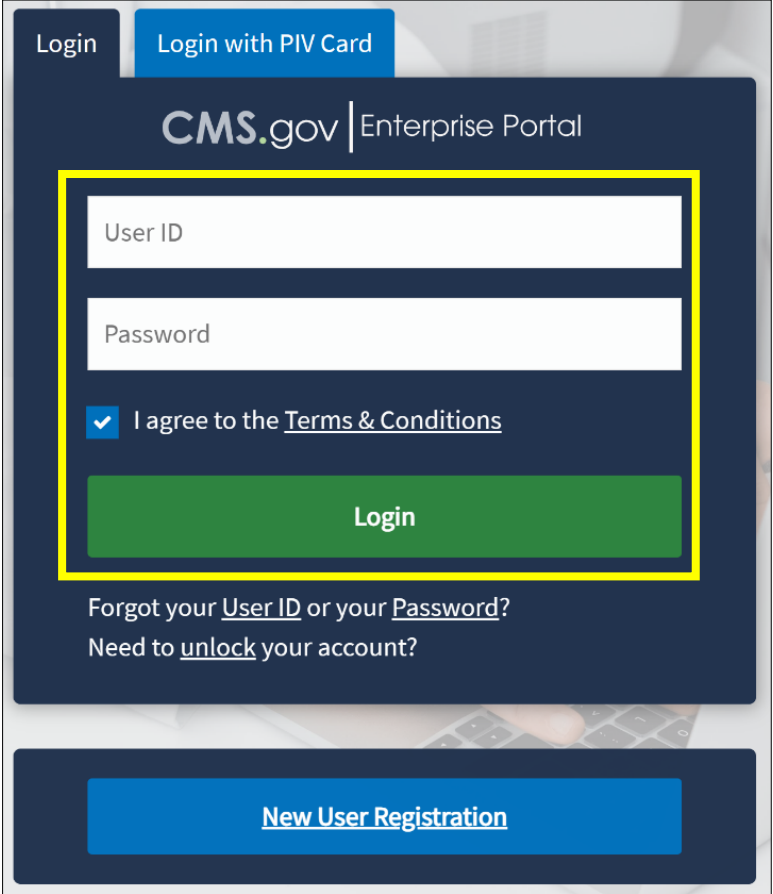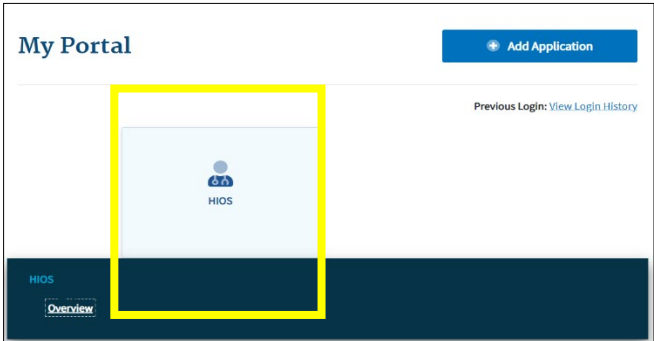
To access HIOS RxDC, users are required to have a CMS Enterprise Portal Account and users must add the HIOS application and RxDC module to their CMS Enterprise Portal interface, as well as create HIOS User and RxDC Submitter roles. The **HIOS Access Guide for RxDC Users** provides instructions on how to register for a CMS Enterprise Portal account, request HIOS User and RxDC Submitter roles, and access the RxDC HIOS module. To download the HIOS RxDC data templates and reporting instructions, go to the public internet CMS.gov page titled "**Prescription Drug Data Collection (RxDC)**."
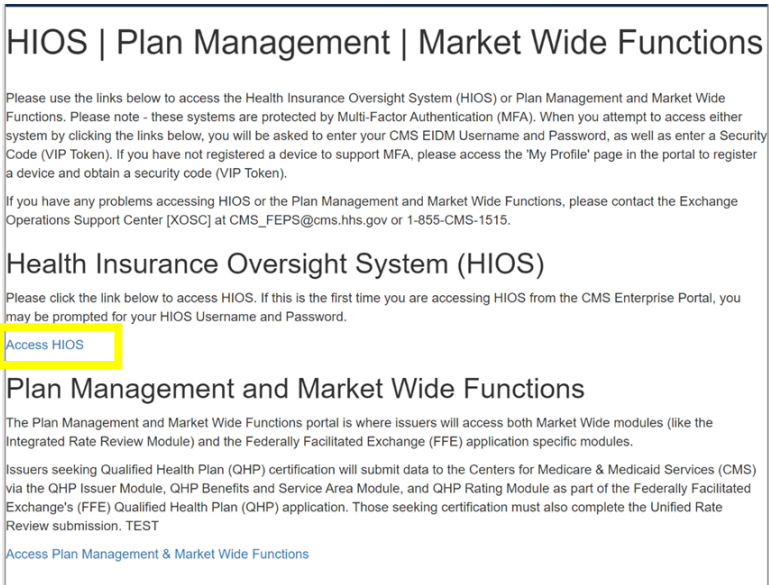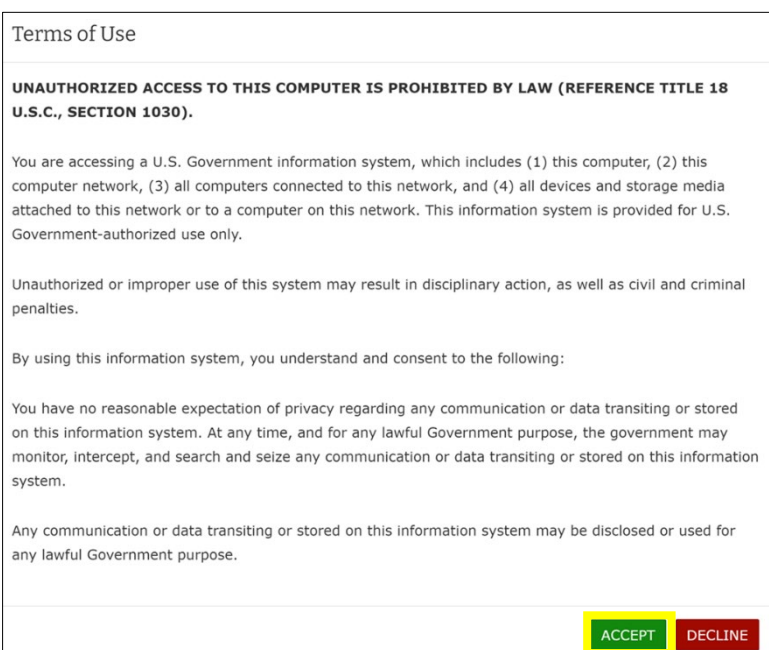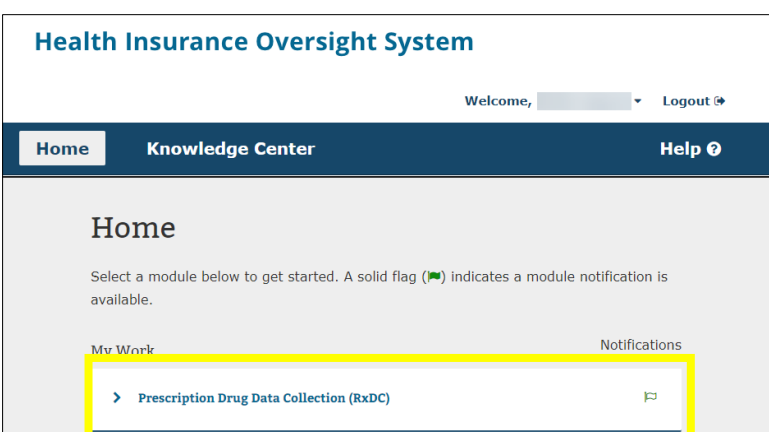
This document (RxDC HIOS Module User Manual) primarily focuses on providing instructions for HIOS RxDC users accessing the CMS HIOS application and RxDC data reporting module via the CMS Enterprise Portal and submitting data.
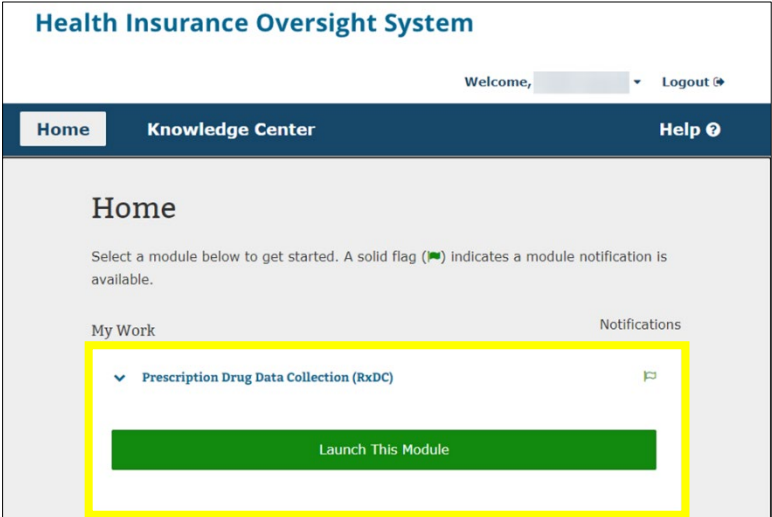
Document Title	HIOS RxDC User Workflow
Phase 1 of 2: HIOS Access Guide for RxDC Users	
Phase 2 of 2: RxDC HIOS Module User Manual	

I. Access the HIOS RxDC Module

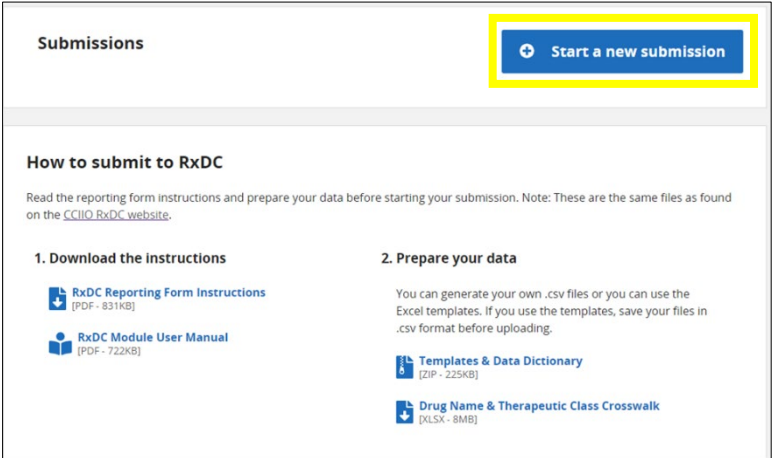The table below describes user steps for accessing the CMS Enterprise Portal, HIOS application, and RxDC module.

User Step	Screen Capture
[I-A] Using Google Chrome or Mozilla Firefox, open a new browser page and go to the **CMS Enterprise Portal Login Webpage**. Enter your CMS Enterprise Portal "**User ID**" and "**Password**," select checkmark for "**I agree to the Terms & Conditions**," and select "**Login**." [Note: HIOS is only compatible with Google Chrome and Mozilla Firefox.]	
[I-B] On the "**My Portal**" page, select **"HIOS"** and "**Overview**."	

User Step	Screen Capture
[I-C] On the HIOS page, select "**Access HIOS**."	**HIOS | Plan Management | Market Wide Functions** Please use the links below to access the Health Insurance Oversight System (HIOS) or Plan Management and Market Wide Functions. Please note - these systems are protected by Multi-Factor Authentication (MFA). When you attempt to access either system by clicking the links below, you will be asked to enter your CMS EIDM Username and Password, as well as enter a Security Code (VIP Token). If you have not registered a device to support MFA, please access the 'My Profile' page in the portal to register a device and obtain a security code (VIP Token). If you have any problems accessing HIOS or the Plan Management and Market Wide Functions, please contact the Exchange Operations Support Center [XOSC] at CMS_FEPS@cms.hhs.gov or 1-855-CMS-1515. **Health Insurance Oversight System (HIOS)** Please click the link below to access HIOS. If this is the first time you are accessing HIOS from the CMS Enterprise Portal, you may be prompted for your HIOS Username and Password. Access HIOS **Plan Management and Market Wide Functions** The Plan Management and Market Wide Functions portal is where issuers will access both Market Wide modules (like the Integrated Rate Review Module) and the Federally Facilitated Exchange (FFE) application specific modules. Issuers seeking Qualified Health Plan (QHP) certification will submit data to the Centers for Medicare & Medicaid Services (CMS) via the QHP Issuer Module, QHP Benefits and Service Area Module, and QHP Rating Module as part of the Federally Facilitated Exchange's (FFE) Qualified Health Plan (QHP) application. Those seeking certification must also complete the Unified Rate Review submission. TEST Access Plan Management & Market Wide Functions
[I-D] On the "**Terms of Use**" pop-up window, read the information and select "**Accept**."	Terms of Use **UNAUTHORIZED ACCESS TO THIS COMPUTER IS PROHIBITED BY LAW (REFERENCE TITLE 18 U.S.C., SECTION 1030).** You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following: You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose. ACCEPT DECLINE
[I-E] On the HIOS "**Home**" page, in the drop-down list, select "**Prescription Drug Data Collection (RxDC)**."	**Health Insurance Oversight System** Welcome, ▾ Logout ⟶ **Home** **Knowledge Center** **Help** ❓ Home Select a module below to get started. A solid flag (🏳) indicates a module notification is available. My Work Notifications ❯ **Prescription Drug Data Collection (RxDC)** 🏳

User Step	Screen Capture
[I-F] On the HIOS "**Home**" page, after selecting "Prescription Drug Data Collection (RxDC)," select "**Launch This Module**."	

II. Start a New Submission

The table below describes user steps for starting a new submission.

User Step	Screen Capture
[II-A] At the top right corner of the RxDC "**Submissions**" page, select "**Start a new submission**." [Note: If your organization has previously submitted data, you will see a list of submissions.]	

At the bottom of the "**Submissions**" page, there are links to the following resources:
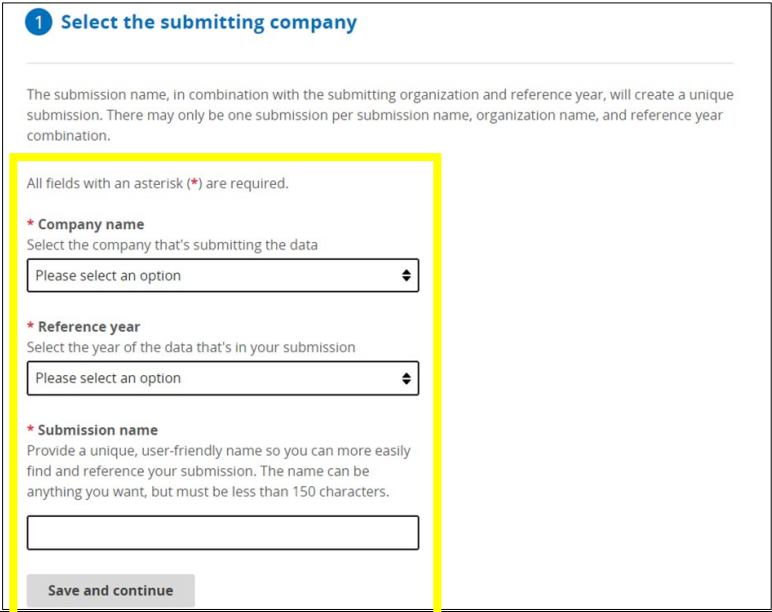
- RxDC Reporting Form Instructions [PDF]: The RxDC reporting form instructions describe the data elements and methods you must use to fill out your plan list and data files. The instructions also describe the information you must include in the narrative file.

- RxDC Module User Manual: The user manual provides instructions on how to create an RxDC submission in HIOS.
  [Note: This file link points to this document.]

- Templates & Data Dictionary [ZIP]: The zip file provides RxDC templates and data dictionary information.
  [Note: If you use the Excel templates, save your files as a "*.csv" file before uploading to RxDC. All uploads must be CSV files. Non-CSV file types will be rejected.]

- [Drug Name & Therapeutic Class Crosswalk [XLSX]](): The crosswalk provides RxDC drug and therapeutic class names that you must use to fill out data files D3, D4, D5, D7, and D8.

[Note: These documents are also available on the [CMS RxDC Home Page]().

III. Select Submitting Company

The table below describes user steps for selecting the submitting company.
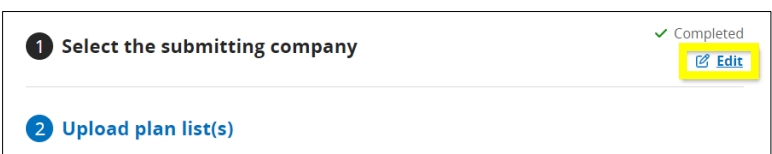
User Step	Screen Capture
[III-A] On the "**Select the submitting company**" page, in the first drop-down list, select the "**Company name**" of the reporting entity that is submitting the data. [Note: Examples of reporting entities include issuers, TPAs, PBMs, group health plans, state and local governmental plans, FEHB carriers, or other type of entity that is reporting data on behalf of a group health plan or issuer.] [III-B] In the second drop-down list, select the "**Reference year**" of the data in the submission (e.g., 2020, 2021, 2022, 2023). [III-C] In the third prompt "**Submission name**" text box, provide a name for your submission. [III-D] After completing the three prompts, select "**Save and continue**."	**1 Select the submitting company** The submission name, in combination with the submitting organization and reference year, will create a unique submission. There may only be one submission per submission name, organization name, and reference year combination. All fields with an asterisk (*) are required. * Company name Select the company that's submitting the data [Please select an option] * Reference year Select the year of the data that's in your submission [Please select an option] * Submission name Provide a unique, user-friendly name so you can more easily find and reference your submission. The name can be anything you want, but must be less than 150 characters. [Save and continue]

IV. Upload Plan Lists
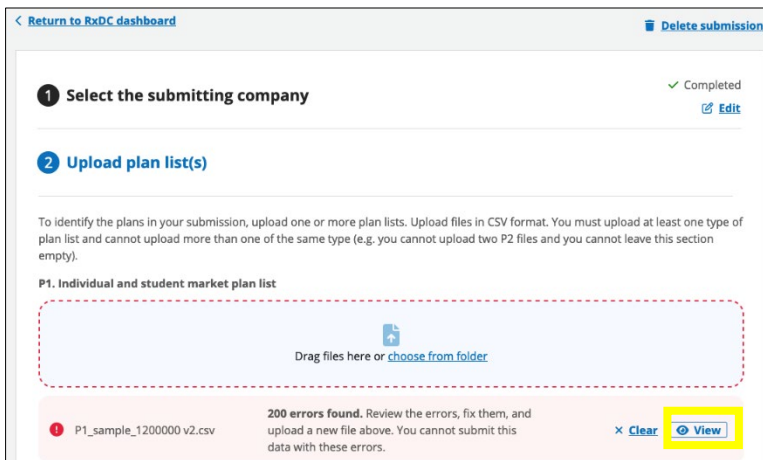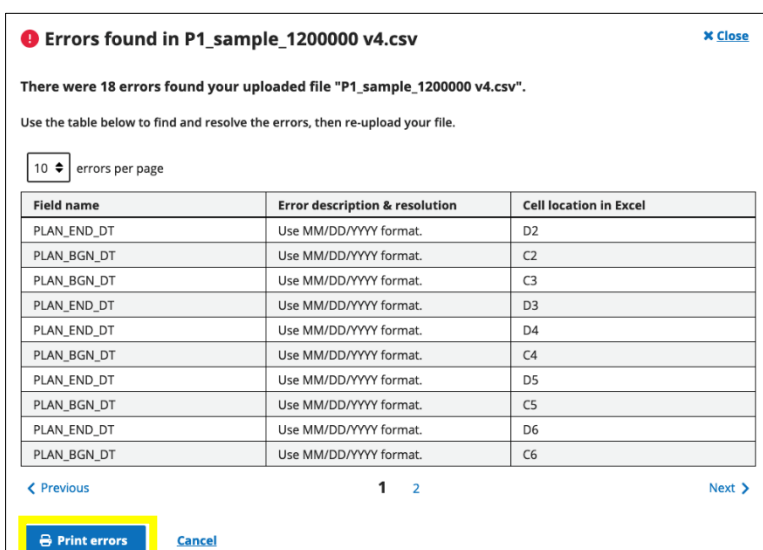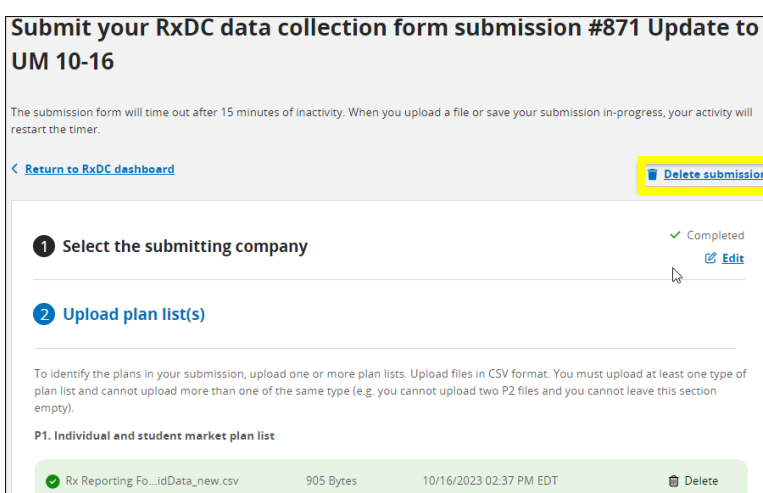
On the "Upload Plan Lists" page, users have options to upload three types of plan lists.
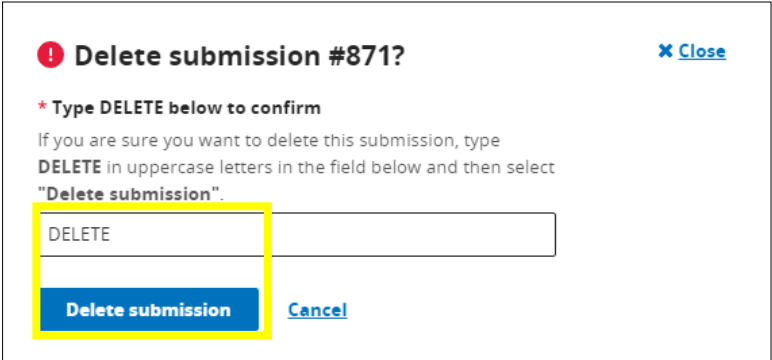
- P1: Individual/Student Market Plan List
- P2: Group Health Plan List
- P3: Federal Employees Health Benefits (FEHB) Plan List

For each type of plan list, users upload information regarding the plans for which data are being provided. At least one of the plan data files is required for submission to continue to the next section. The submission form will time out after 15 minutes of inactivity. When users upload a file or save their submission in progress, the activity will restart the timer. The **RxDC Reporting Instructions** and **RxDC Data Validations** reference documents provide additional information addressing which files are required for RxDC submission. The table below describes user steps for uploading plan lists.

User Step	Screen Capture
Note: You may return to previously completed steps by selecting the 'Edit' button that appears once a step has been successfully completed.	**1 Select the submitting company** ✓ Completed ⟐ Edit **2 Upload plan list(s)**

User Step	Screen Capture
[IV-A] On the "**Upload plan lists**" page, submit plan list CSV files by dragging the files into the light blue shaded box or selecting the link "**choose from folder**" to browse files. [Note: The RxDC Reporting Instructions and RxDC Data Validations reference documents provide additional information addressing plan list file requirements.] [Note: Large files may take up to 8 minutes to upload.]	
[IV-B] Once a plan list CSV file has been uploaded, the system will process the data and indicate whether the upload was successful. Successfully uploaded files will be displayed with a green checkmark icon followed by the file name, file size, date, and time.	
[IV-C] If an upload was successful but you want to upload a different document, select "**Delete**" to remove the file and then upload the new file.	
[IV-D] If the file contains errors, then an error message will be displayed with a red error icon followed by the file name and error description. Select "**Clear**" and make corrections in the file to resolve the error. Upload the new file. [Note: Additional options include selecting "**Return to RxDC dashboard**" to go back to the RxDC dashboard or select "**Delete submission**" to delete your submission.] [Note: The **RxDC Reporting Instructions** and **RxDC Data Validations** reference document provide additional information addressing errors.]	

User Step	Screen Capture
[IV-E] If there are multiple errors in the file, select "**View**" to see a summary table of errors listing the field name, error description, and cell location. [Note: The RxDC Reporting Instructions and RxDC Data Validations reference documents provide additional information addressing errors.]	< Return to RxDC dashboard 🗑 **Delete submission** ① **Select the submitting company** ✓ Completed ✎ Edit ② **Upload plan list(s)** To identify the plans in your submission, upload one or more plan lists. Upload files in CSV format. You must upload at least one type of plan list and cannot upload more than one of the same type (e.g. you cannot upload two P2 files and you cannot leave this section empty). **P1. Individual and student market plan list** Drag files here or choose from folder ❗ P1_sample_1200000 v2.csv **200 errors found.** Review the errors, fix them, and upload a new file above. You cannot submit this data with these errors. ✕ Clear 👁 **View**
[IV-F] Below the error summary table, select "**Print errors**" to print the error details.	❗ **Errors found in P1_sample_1200000 v4.csv** ✕ Close **There were 18 errors found your uploaded file "P1_sample_1200000 v4.csv".** Use the table below to find and resolve the errors, then re-upload your file. 10 ⬍ errors per page | Field name	Error description & resolution	Cell location in Excel
---	---	---
PLAN_END_DT	Use MM/DD/YYYY format.	D2
PLAN_BGN_DT	Use MM/DD/YYYY format.	C2
PLAN_BGN_DT	Use MM/DD/YYYY format.	C3
PLAN_END_DT	Use MM/DD/YYYY format.	D3
PLAN_END_DT	Use MM/DD/YYYY format.	D4
PLAN_BGN_DT	Use MM/DD/YYYY format.	C4
PLAN_END_DT	Use MM/DD/YYYY format.	D5
PLAN_BGN_DT	Use MM/DD/YYYY format.	C5
PLAN_END_DT	Use MM/DD/YYYY format.	D6
PLAN_BGN_DT	Use MM/DD/YYYY format.	C6	 ‹ Previous **1** 2 Next › 🖨 **Print errors** Cancel
[IV-G] After uploading at least one plan file, select "**Save and continue**." [Note: If at any time during the submission process you need to leave the RxDC module, then select "**Save and exit**" to save your submission in its current state and resume at another time.]	**Save and continue** **Save and exit**
[IV-H] After you select "**Save and continue**", the prompt "**Delete submission**" will become available so that you can delete the submission if you want to. [Note: By selecting the prompt "**Delete submission**," a notification will appear with instructions on how to continue with deleting the in-progress submission.]	**Submit your RxDC data collection form submission #871 Update to UM 10-16** The submission form will time out after 15 minutes of inactivity. When you upload a file or save your submission in-progress, your activity will restart the timer. < **Return to RxDC dashboard** 🗑 **Delete submission** ① **Select the submitting company** ✓ Completed ✎ Edit ② **Upload plan list(s)** To identify the plans in your submission, upload one or more plan lists. Upload files in CSV format. You must upload at least one type of plan list and cannot upload more than one of the same type (e.g. you cannot upload two P2 files and you cannot leave this section empty). **P1. Individual and student market plan list** ✓ Rx Reporting Fo...idData_new.csv 905 Bytes 10/16/2023 02:37 PM EDT 🗑 Delete

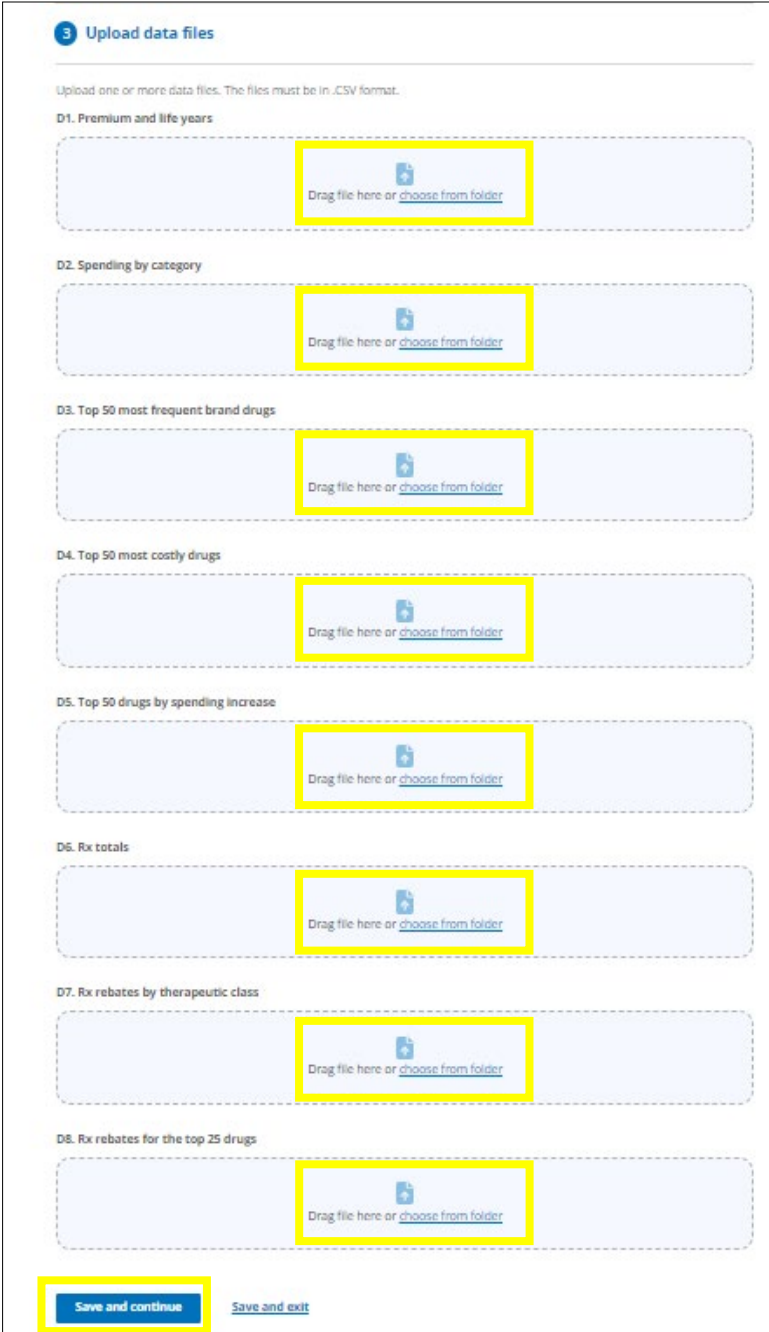| User Step	Screen Capture
[IV-I] In the "**Delete submission**" pop-up window, if you wish to delete your submission and start over, type "DELETE" in all uppercase letters in the text box and select "**Delete submission**." Once deleted, you will be returned to the RxDC dashboard page.	ⓘ Delete submission #871? ✖ Close * Type DELETE below to confirm If you are sure you want to delete this submission, type **DELETE** in uppercase letters in the field below and then select "**Delete submission**". [DELETE] **Delete submission** Cancel

V. Upload Data Files

Users may upload up to eight separate data files.

- D1. Premium & Life Years

- D2. Spending by Category

- D3. Top 50 Most Frequent Brand Drugs

- D4. Top 50 Most Costly Drugs

- D5. Top 50 Drugs by Spending Increase

- D6. Rx Totals

- D7. Rx Rebates by Therapeutic Class

- D8. Rx Rebates for Top 25 Drugs

The **RxDC Reporting Instructions** provide additional information addressing which files are required for submitting RxDC data. The table below describes user steps for uploading data files.
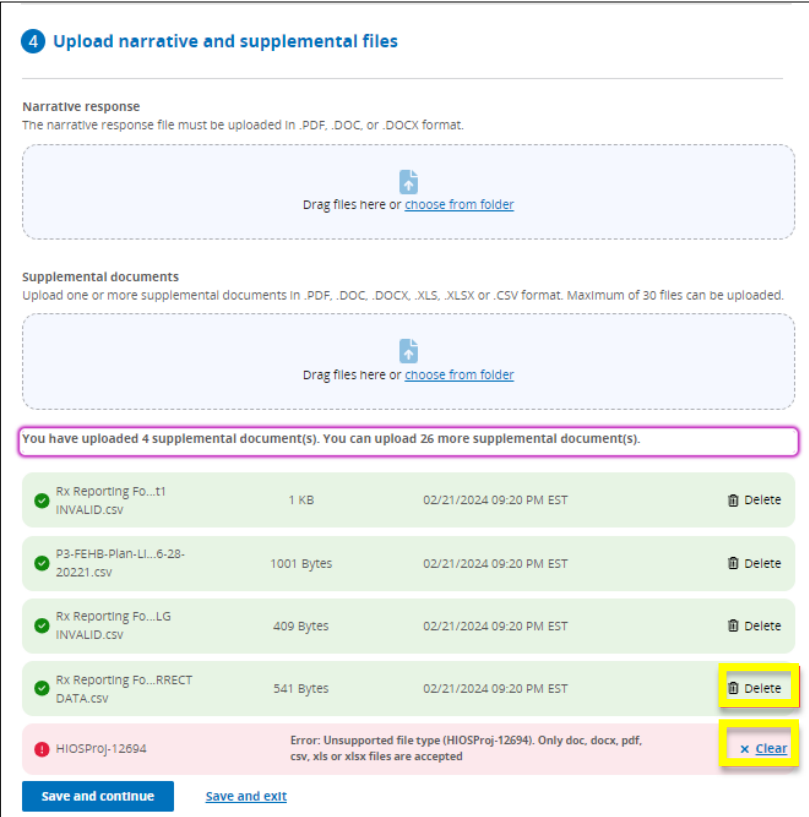
User Step	Screen Capture
[V-A] On the "**Upload data files**" page, drag and drop one or more files into the blue shaded boxes or select the link "**choose from folder**" to upload data files. [Note: The RxDC Reporting Instructions and RxDC Data Validations reference documents provide additional information addressing data file requirements.] [Note: You must save your files as the "*.csv" format before you upload them. Only CSV files will be accepted.] [Note: Large files may take up to 8 minutes to upload.] [V-B] Select "**Save and continue**."	③ Upload data files Upload one or more data files. The files must be in .CSV format. D1. Premium and life years Drag file here or choose from folder D2. Spending by category Drag file here or choose from folder D3. Top 50 most frequent brand drugs Drag file here or choose from folder D4. Top 50 most costly drugs Drag file here or choose from folder D5. Top 50 drugs by spending increase Drag file here or choose from folder D6. Rx totals Drag file here or choose from folder D7. Rx rebates by therapeutic class Drag file here or choose from folder D8. Rx rebates for the top 25 drugs Drag file here or choose from folder Save and continue Save and exit
[V-C] When you navigate away from an active, in-progress submission, a "Warning" notification pops up. This alert notifies you that, by leaving the page, you may lose unsaved work. If you want to leave the page with unsaved work, then select "**Yes**." If you do not want to leave the page, then select "**No**."	⚠ Warning ✖ Close Your work isn't saved. Do you want to proceed? Yes No

User Step	Screen Capture
[V-D] The number of errors found in a file will be displayed in a red shaded banner. Select "**View**" to see the error summary table. [Note: The RxDC Reporting Instructions and RxDC Data Validations reference documents provide additional information addressing errors.] [Note: This section's three steps (V-D, V-E, V-F) provide additional examples of uploading file errors to supplement the previous section's steps (IV-E, IV-F, IV-G).]	**D1. Premium and life years** Drag files here or choose from folder ⊗ Rx Reporting Form 2021-D... .csv **5 errors found.** Review the errors, fix them, and upload a new file above. You cannot submit this data with these errors. ✕ Clear 👁 View
[V-E] The error summary table lists the field names, error descriptions, and cell locations. Select "**Print errors**" to print the error details. Resolve each error in the data file and upload the new file.	⊗ **Errors found in INVALID Rx Reporting Form 2021-D1.csv** ✕ Close There were 5 errors found your uploaded file "INVALID Rx Reporting Form 2021-D1.csv". Use the table below to find and resolve the errors, then re-upload your file. 10 ⬍ errors per page | Field name	Error description & resolution	Cell location in Excel
---	---	---
Issuer or TPA EIN	This field is required.	B3
Life Years	Use numbers only.	G3
Issuer or TPA Name	This field is required.	A3
Market Segment	This field is required.	D3
State	This field is required.	C3	 🖨 **Print errors** **Cancel**
[V-F] After you select "**Print errors**" in the previous step above, a "**Print**" window will pop up. Select "**Print**" to print the error details.	⊗ **5 errors found in INVALID Rx Reporting Form 2021-D1.csv** There were 5 errors found your uploaded file "INVALID Rx Reporting Form 2021-D1.csv". Use the table below to find and resolve the errors, then re-upload your file. | Field name	Error description & resolution	Cell location in Excel
---	---	---
Issuer or TPA EIN	This field is required.	B3
Life Years	Use numbers only.	G3
Issuer or TPA Name	This field is required.	A3
Market Segment	This field is required.	D3
State	This field is required.	C3	 Print — 1 sheet of paper Destination: Microsoft Print to PDF Pages: All Layout: Portrait Color: Color More settings ⌄ **Print** Cancel

VI. Upload Narrative & Supplemental Files

The table below describes user steps for uploading narrative and supplemental files.
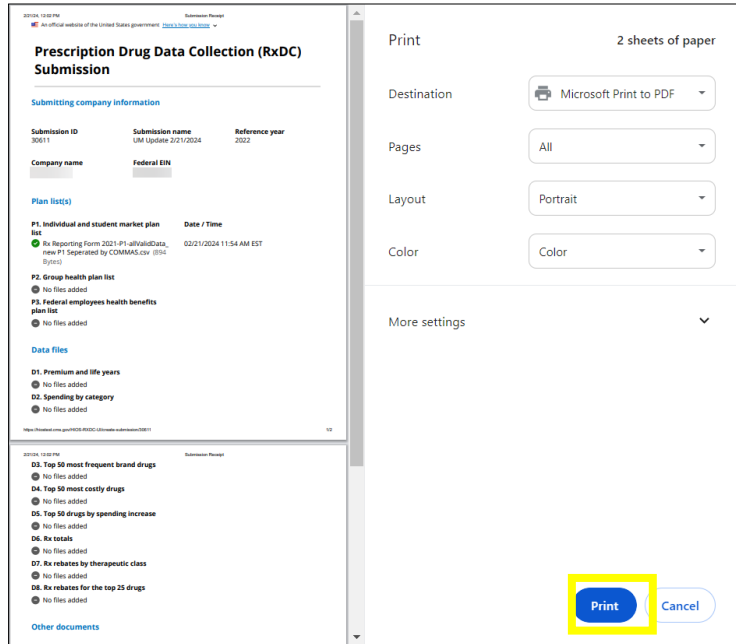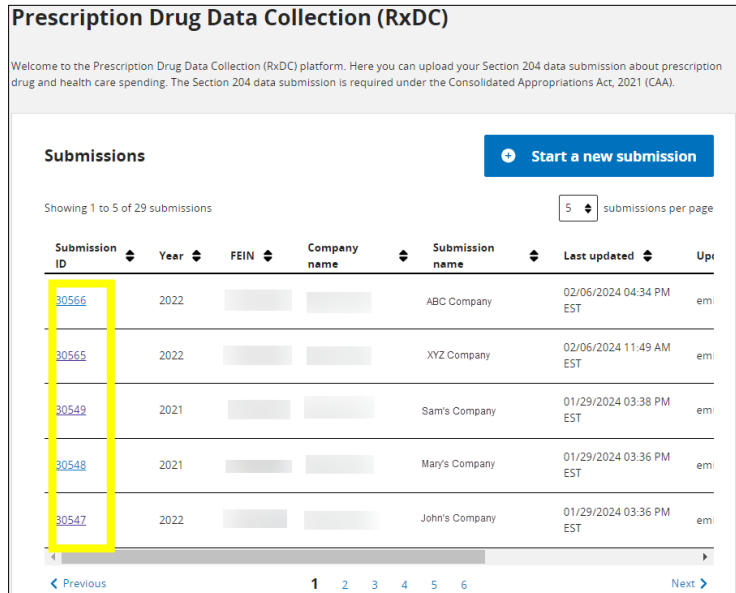
User Step	Screen Capture
[VI-A] On the "**Upload narrative and supplemental files**" page, upload your "**Narrative response**" (if applicable) and "**Supplemental documents**" (if applicable) and select "**Save and continue**." [Note: The RxDC module allows one narrative response file and up to 30 supplemental documents.]	
[VI-B] On the "**Upload narrative and supplemental files**" page, the system will display an indicator below the "**Supplemental file upload box**" that will indicate the number of files that has been uploaded, the number of files in progress, and the number of files remaining that can be uploaded.	

User Step	Screen Capture
[VI-C] On the "**Upload narrative and supplemental files**" page, you will have the ability to clear files that have been identified to have errors by selecting the "**Clear**" button. You will also have the ability to delete any unwanted files by selecting the "**Delete**" button on the corresponding uploaded file.	

VII. Review Submission

The table below describes user steps for reviewing submission.
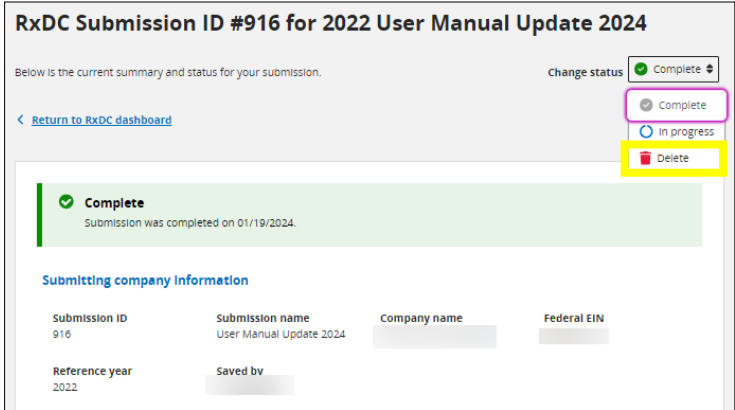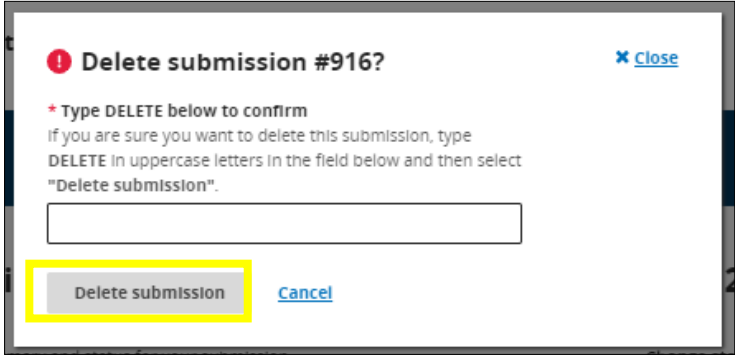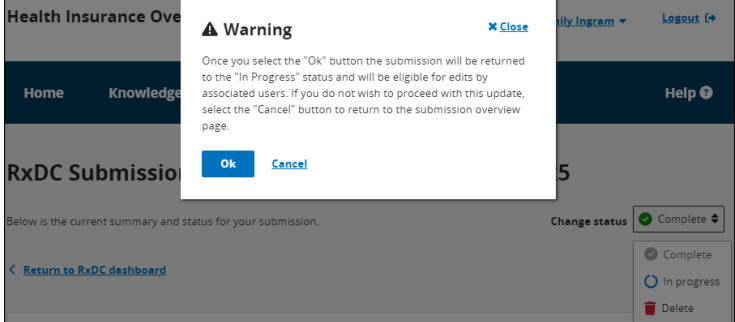
User Step	Screen Capture
[VII-A] The "**Review submission**" page provides an opportunity to review your submission content. The green checkmarks indicate which files were successfully uploaded. The "**No files added**" indicators show which types of files were not submitted. For any section that is incorrect or may require edits (e.g., organization information, uploaded files, other documents), select "**Edit**" in the blue shaded banners. After reviewing and confirming your submitted files, select "**Submit**." [Note: By selecting "**Submit**," you confirm that you have reviewed the files for accuracy and approve the submission.] [Note: If you later need to edit or delete your submission, you may do so by clicking on the submission ID on the RxDC dashboard.]	
[VII-B] The "**Submission successful**" confirmation message indicates that an email will be sent to the submitter. Write down the "**Submission ID**" for future reference and select "**Return to dashboard**" to navigate to the RxDC dashboard. Select "**Submission receipt**" to print a receipt.	

User Step	Screen Capture
[VII-C] After you select the prompt "**Submission receipt**" in the previous step above, a "**Print**" window pops up. Select "**Print**" to print the submission receipt.	
[VII-C] Once a submission has been started, the RxDC dashboard will display a table listing the in-progress and completed submissions. On this page, you may sort the items within the table or select the "**Submission ID**" of a submission to view or resume it. For resumed submissions, you will be returned to the last step in which the submissions were saved. For completed submissions, you will see a submission view page that will provide an overview of the submitted data.	

User Step	Screen Capture
[VII-D] If you want to view the files you previously uploaded, select the file links to download your submitted files.	

VIII. Changing the Status of a Submission

The table below describes user steps for changing the status of a submission.

User Step	Screen Capture
[VIII-A] After you select as submission ID on the RxDC dashboard, you will have the ability to change the status to "Delete" by selecting "**Delete**" from the dropdown.	**RxDC Submission ID #916 for 2022 User Manual Update 2024** Below is the current summary and status for your submission. Change status: Complete ▾ Complete / In progress / Delete ‹ Return to RxDC dashboard ✔ **Complete** Submission was completed on 01/19/2024. **Submitting company information** Submission ID: 916 — Submission name: User Manual Update 2024 — Company name — Federal EIN Reference year: 2022 — Saved by
[VIII-B] If you select "**Delete**" from the dropdown, you will be provided the option of deleting your submission by typing "**DELETE**" in all capital letters and selecting the "**Delete submission**" button. Once deleted, you will be returned to the RxDC dashboard.	ⓧ **Delete submission #916?** ✕ Close * Type DELETE below to confirm If you are sure you want to delete this submission, type DELETE in uppercase letters in the field below and then select "Delete submission". [ ] Delete submission Cancel
[VIII-C] Once the Submitter selects a completed submission from the RxDC dashboard, they will have the ability to change the status to "in progress" by selecting "**In progress**" from the dropdown. This action will change the status of the submission from "**Complete**" to "**In progress.**"	Health Insurance Ove… ⚠ **Warning** ✕ Close … Ingram ▾ Logout ⤴ Once you select the "Ok" button the submission will be returned to the "In Progress" status and will be eligible for edits by associated users. If you do not wish to proceed with this update, select the "Cancel" button to return to the submission overview page. Home Knowledge… Ok Cancel Help ⓘ **RxDC Submissio…** Below is the current summary and status for your submission. Change status: Complete ▾ ‹ Return to RxDC dashboard Complete / In progress / Delete

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Primary Resources and Help Desk Information

Listed below are CMS HIOS RxDC references provided on CMS.gov [Prescription Drug Data Collection (RxDC) [Webpage]](#).

CMS RxDC Home Page
The [CMS RxDC Home Page](#) contains all the documents you need to prepare and submit your RxDC report.

CMS HIOS RxDC Instructions
- [HIOS Access Guide for RxDC Users [PDF]](#)
- [RxDC HIOS Module User Manual [PDF]](#) [Note: This file link points to this document.]

RxDC Reporting Resources
- RxDC Reporting Instructions [PDF]
- RxDC Templates & Data Dictionary [ZIP]
- RxDC Drug Name & Therapeutic Class Crosswalk [XLSX]
- RxDC Data Validations [XLSX]
- Click Here to Submit Your RxDC Data in the CMS Enterprise Portal [Webpage]

Additional Resources
- RxDC Frequently Asked Questions (FAQs) [PDF]
- RxDC Training Materials [PDF]
- Consolidated Appropriations Act (CAA) of 2021 [PDF]
  ["DIVISION BB—PRIVATE HEALTH INSURANCE AND PUBLIC HEALTH PROVISIONS TITLE II—TRANSPARENCY Section 204. Reporting on pharmacy benefits and drug costs."]
- Federal Register Rule: Prescription Drug & Health Care Spending [Webpage]
- Federal Register, Volume 86, Number 223, 11/23/2021, Rules & Regulations, Pages 66662-66704 [PDF]

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 registration.

REGTAP
Sign up for emails, register for training webinars, and access additional training materials at https://regtap.cms.gov/rxdc.php.