



Medicare Part B Average Sales Price (ASP) Module

Certifier User Guide

Version 2.0

Date: May 18-August 29, 20256

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1. Purpose

The purpose of this user guide is to provide guidance and instructions to financial executives of drug manufacturing companies as they certify their federally required Medicare Part B drug Average Sales Price (ASP) data for the Centers for Medicare & Medicaid Services (CMS). CMS uses the Fee-for-Service Data Collection System (FFSDCS) to house various Fee-for-Service modules.

The ASP Data Collection System, referred to within this user guide as the ASP Module, is one of the modules under the FFSDCS system, and offers the following:

- Provides users with an online-based software application for automating the collection, editing, and processing of drug product pricing data drug manufacturers submit on a quarterly basis.
- Establishes a relationship between the manufacturers' reported data and the billing codes Medicare providers use to calculate a weighted average sales price for each billing code.
- Establishes prices for billing codes to determine payment limits of Part B drugs on certain Medicare claims.
- Eliminates data entry errors, data formatting errors, and incomplete submitted data, and greatly reduces the process cycle and resource time needed to provide the pricing to contractors through automation of the manually intensive processes.
- Accepts, stores, validates, and calculates drug pricing on Medicare Part B drug data received for the Center for Medicare Management (CMM) stakeholders.

Section 303 (b) and (c) of the [Medicare Modernization Act \(MMA\) of 2003](#) revised the payment methodology for the majority of Part B-covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs).

CMS applies the ASP methodology to the data drug manufacturers have submitted to the ASP Module. Per the MMA, ASP methodology determines the payment limit for these drugs. Local contractors calculate pricing for compounded drugs.

2. Logging in Using MFA

First time users must register and create an account in the [CMS Enterprise Portal](#). Refer to the Resource Library on the [Education and Outreach page](#) to view the ASP Module Registration User Guide for registration steps.

Once registration is complete, follow these steps to log into the Module as a Certifier using Multi-Factor Authentication (MFA):

1. Navigate to the [CMS Enterprise Portal](#) main page.

The ASP Module Login Page opens. Refer to [Figure 1](#) ~~Figure 1~~.

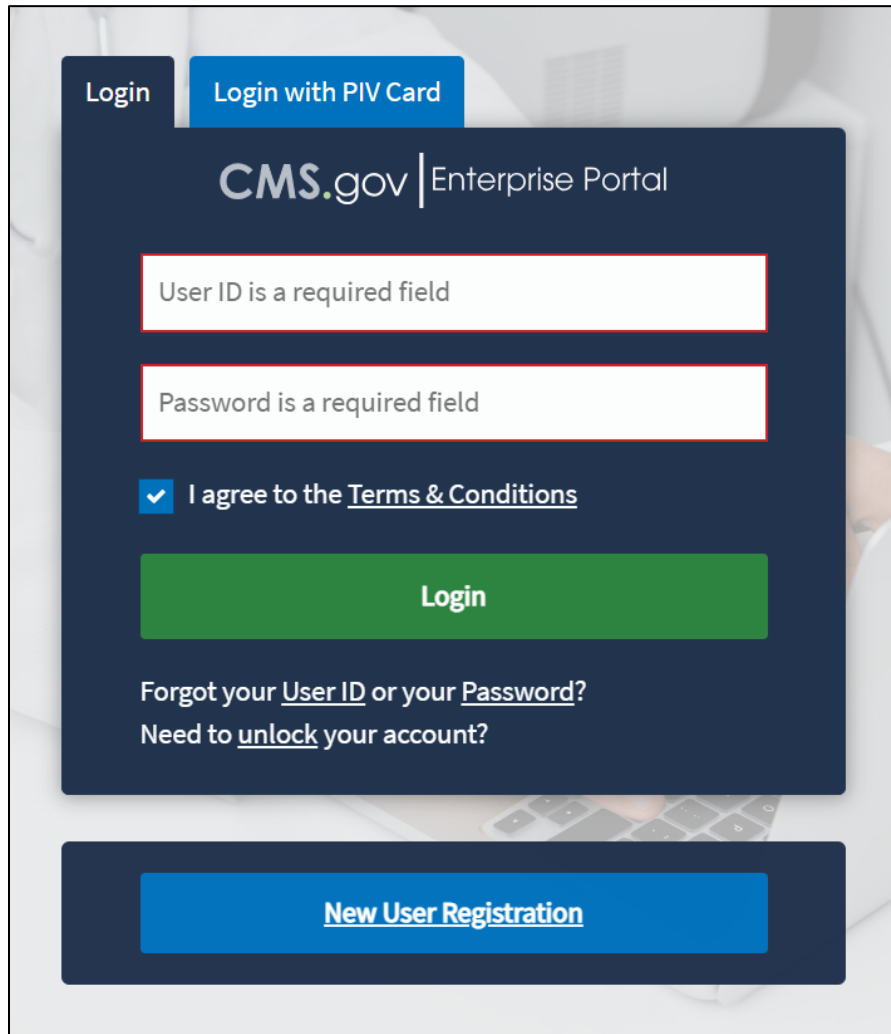


Figure 1: Logging in Using MFA - ASP Module Login

2. Enter your login information into the required **User ID** and **Password** fields.
3. Click the **Terms & Conditions** hyperlink and review the text in the pop-up window; close the window to move on to the next step.
4. Review the terms and conditions and select the **I agree to the Terms & Conditions** checkbox.

Note: By selecting this checkbox, you certify that you read and consent to monitoring while accessing and using the ASP Module. The terms and conditions link provides additional hyperlinks to the HHS Rules of Behavior and the CMS Privacy Act Statement.

5. Click **Login**.

Note: If you forget your user ID or password, click the **Forgot your User ID or your Password?** hyperlink under the **Login** button and follow the provided instructions. If you still cannot access your account and need to unlock it, click the **Need to unlock your account?** hyperlink under **Login** button.

The **Multi-Factor Authentication** page opens. Refer to [Figure 2](#).

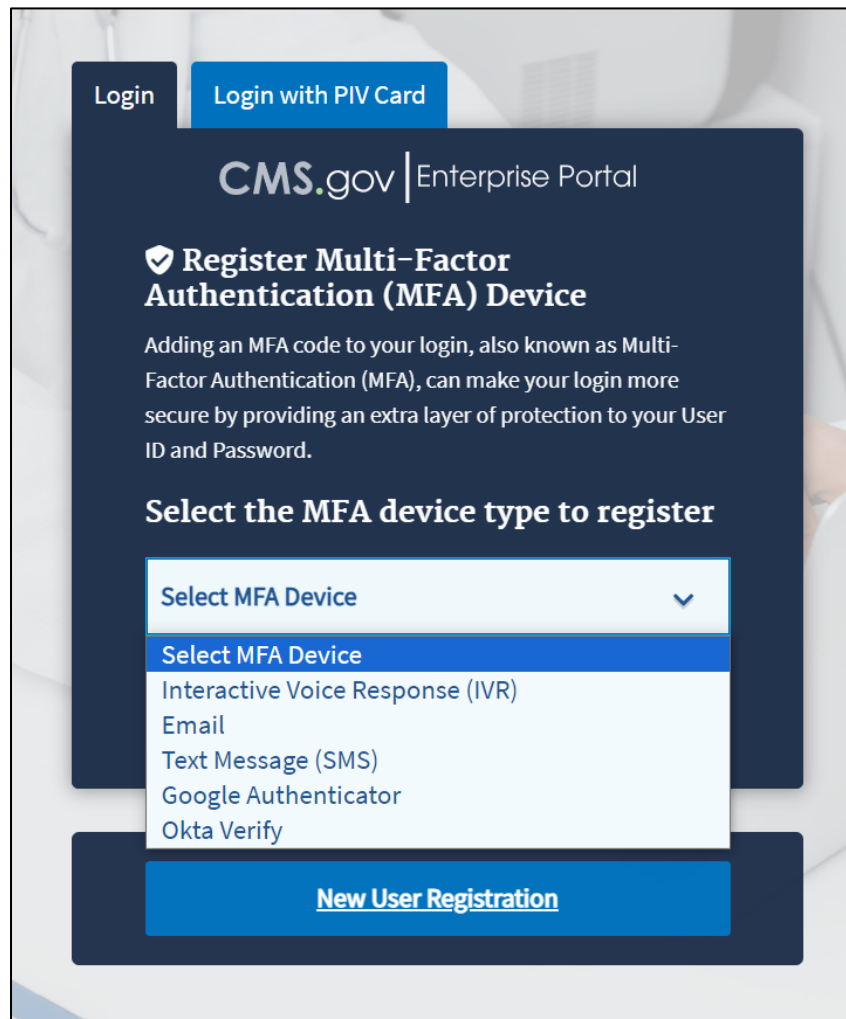
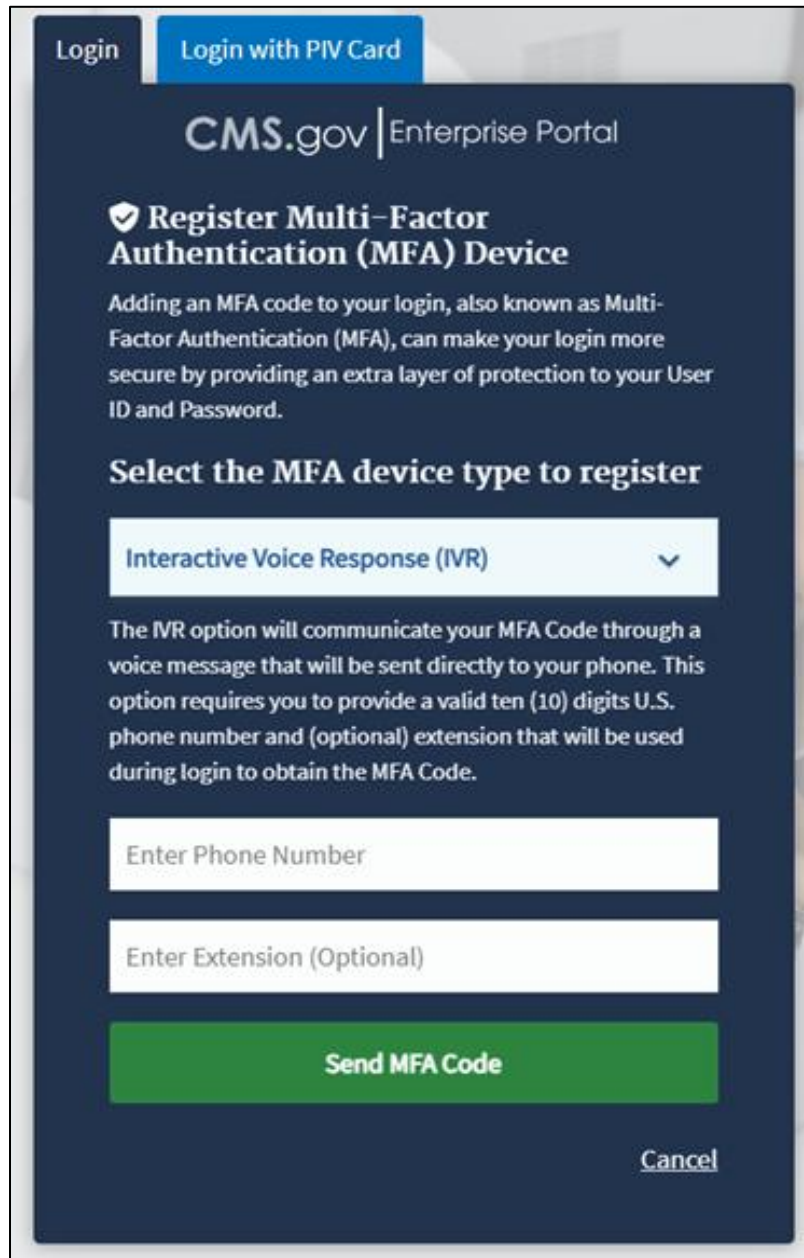


Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down

To ensure the security of high value data submitted to the ASP Module, you must authenticate your identity using an MFA process. The first time you attempt to log in, you must choose an authentication method. Users have various authentication options, including Interactive Voice Response (IVR), Email, Text Message (Short Message Service (SMS)), Google Authenticator and Okta Verify.

6. Click the **Select MFA Device** drop-down menu; select your preferred MFA device type from the list. Refer to [Figure 3](#). Whenever you log back into the Module through this process, your preferred method of MFA reloads automatically.

Note: [Figure 3](#) demonstrates MFA registration using IVR as the selected option.



The screenshot shows the 'Register Multi-Factor Authentication (MFA) Device' page on the CMS.gov Enterprise Portal. At the top, there are two tabs: 'Login' and 'Login with PIV Card'. The main heading is 'Register Multi-Factor Authentication (MFA) Device'. Below this, there is a paragraph explaining that adding an MFA code makes login more secure. The next section is 'Select the MFA device type to register', which features a dropdown menu currently set to 'Interactive Voice Response (IVR)'. Below the dropdown, there is a paragraph explaining that the IVR option sends a voice message to the user's phone and requires a valid ten-digit U.S. phone number and an optional extension. There are two input fields: 'Enter Phone Number' and 'Enter Extension (Optional)'. At the bottom, there is a large green button labeled 'Send MFA Code' and a smaller 'Cancel' link.

Figure 3: Logging in Using MFA - Multi-Factor Authentication - (IVR) Example

7. Enter your phone number in the **Phone Number** field; enter your extension in the **Extension** field, if necessary.
8. Click the **Send MFA Code** button to receive a six-digit code via your chosen contact method.

- Record and enter the six-digit code you received into the **Enter MFA Code** field. Refer to [Figure 4](#).

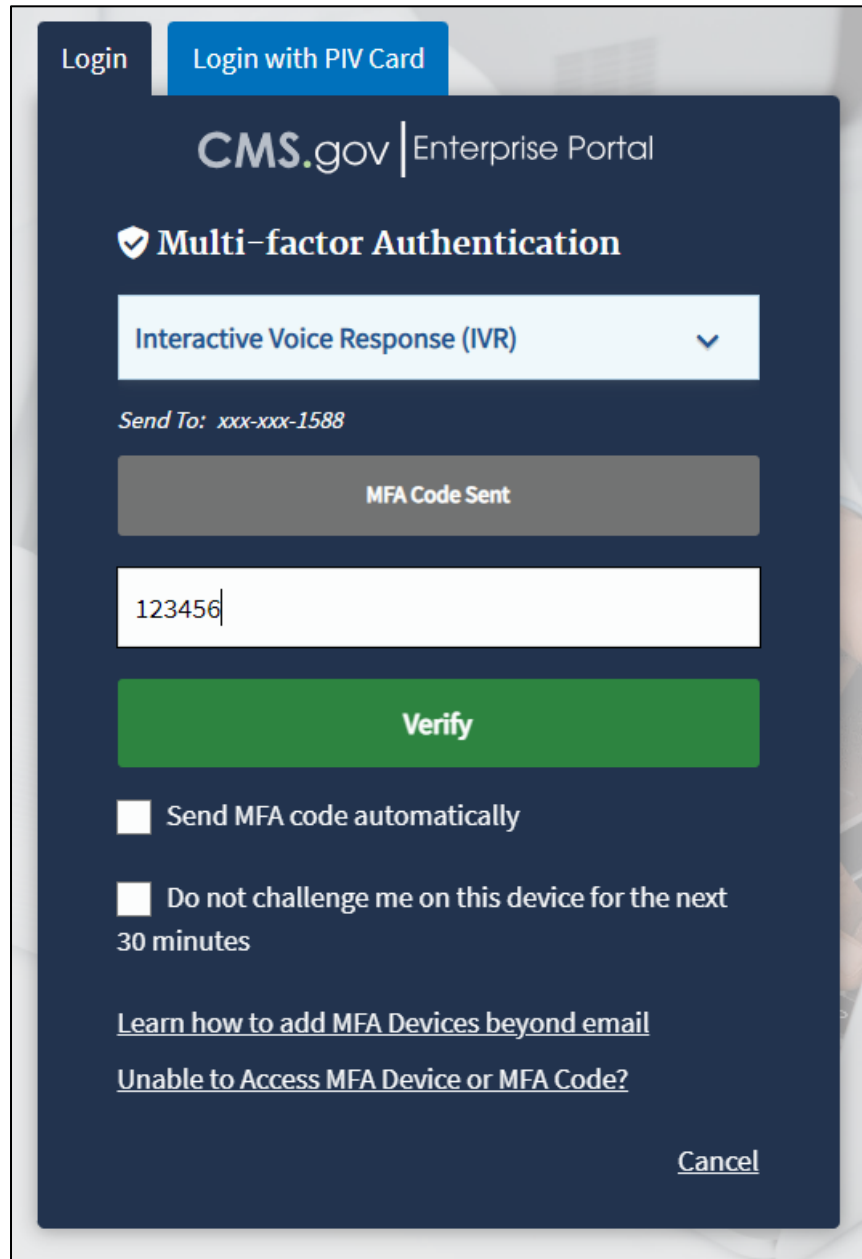


Figure 4 shows the Multi-factor Authentication (MFA) verification screen on the CMS.gov Enterprise Portal. The screen is titled "Multi-factor Authentication" and features a dropdown menu for "Interactive Voice Response (IVR)". Below this, it displays "Send To: xxx-xxx-1588" and a "MFA Code Sent" button. A text input field contains the code "123456". A prominent green "Verify" button is located below the code field. At the bottom, there are two checkboxes: "Send MFA code automatically" and "Do not challenge me on this device for the next 30 minutes". There are also two hyperlinks: "Learn how to add MFA Devices beyond email" and "Unable to Access MFA Device or MFA Code?". A "Cancel" link is positioned at the bottom right.

Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

- Check the **Send MFA code automatically** and **Do not challenge me on this device for the next 30 minutes** checkboxes depending on your preference.

Note: If you need help, click the **Learn how to add MFA Devices beyond email** and **Unable to Access MFA Devices or MFA Code?** hyperlinks.

- Click the **Verify** button to confirm your identity and enter the ASP Module.

The **My Portal** landing page opens. Refer to [Figure 5](#).



Figure 5: My Portal Landing Page

Note: Other CMS applications you have access to may display on the **My Portal** landing page.

- Click the **Fee For Service Data Collection System (FFSDCS)** box.

A Fee for Service Data Collection System (FFSDCS) drop-down menu opens. Refer to [Figure 6](#).

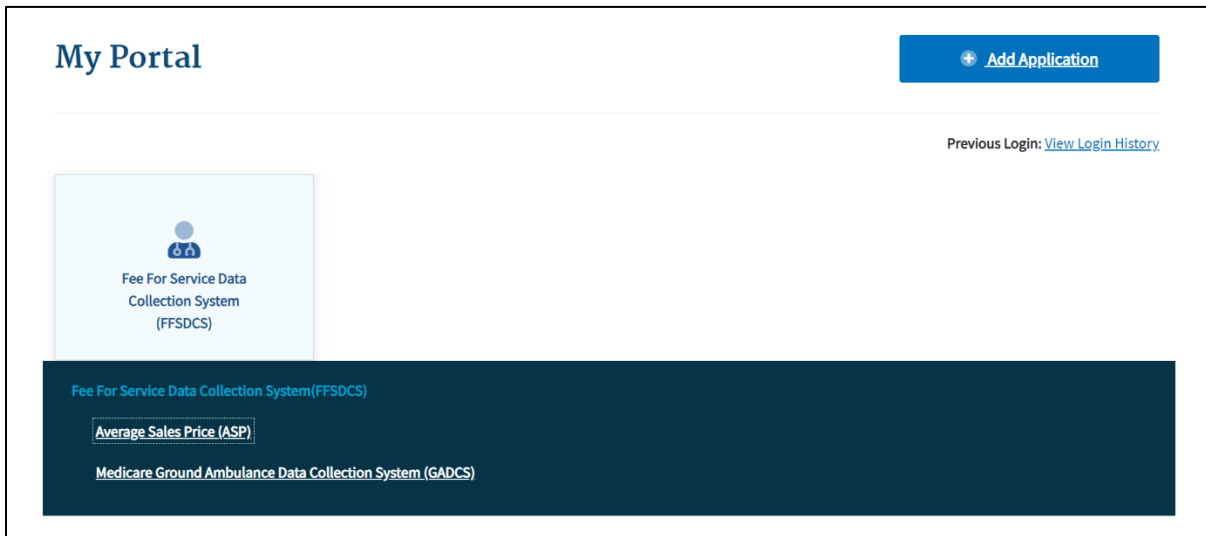


Figure 6: My Portal Landing Page - FFSDCS Drop-down

- Click the **Average Sales Price (ASP)** hyperlink.

A full-page statement displays, titled **ASP Data for Drugs and Biologics Covered Under Medicare Part B**. The statement details recent statutory requirements stated in the Social Security Act (the Act), and the [Consolidated Appropriations Act \(CAA\)](#), 2021. These requirements hold that manufacturers must report their ASP data to CMS

with precision on a quarterly basis without errors or miscalculations. Refer to [Figure 7](#).

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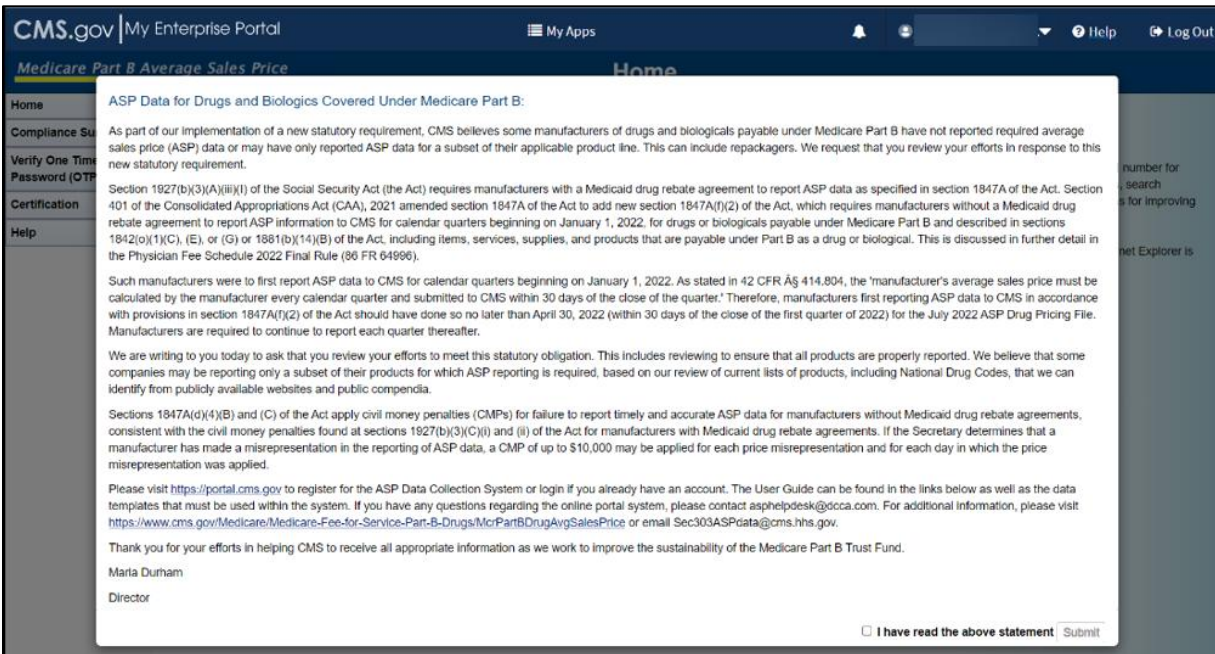
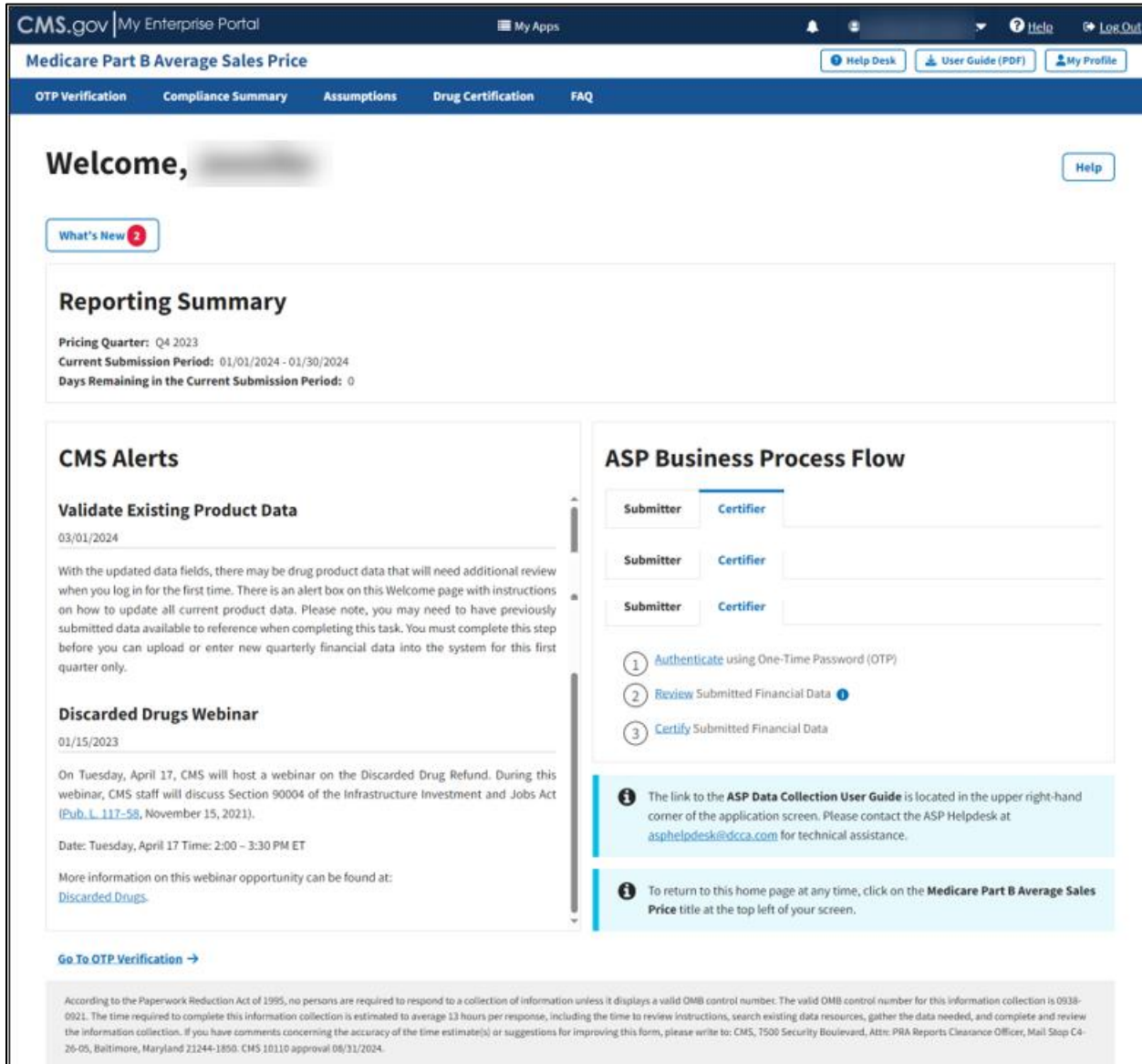


Figure 7: ASP Data for Drugs and Biologics Under Medicare Part B

14. Read the statement; select the **I have read the above statement** checkbox and click **Submit**.

The Medicare Part B Average Sales Price homepage opens. Refer to [Figure 8](#).

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Medicare Part B Average Sales Price

Help Desk | User Guide (PDF) | My Profile

OTP Verification | Compliance Summary | Assumptions | Drug Certification | FAQ

Welcome, [User Name] Help

What's New 2

Reporting Summary

Pricing Quarter: Q4 2023
 Current Submission Period: 01/01/2024 - 01/30/2024
 Days Remaining in the Current Submission Period: 0

CMS Alerts

Validate Existing Product Data
 03/01/2024

With the updated data fields, there may be drug product data that will need additional review when you log in for the first time. There is an alert box on this Welcome page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the system for this first quarter only.

Discarded Drugs Webinar
 01/15/2023

On Tuesday, April 17, CMS will host a webinar on the Discarded Drug Refund. During this webinar, CMS staff will discuss Section 90004 of the Infrastructure Investment and Jobs Act ([Pub. L. 117-58](#), November 15, 2021).

Date: Tuesday, April 17 Time: 2:00 – 3:30 PM ET

More information on this webinar opportunity can be found at: [Discarded Drugs](#).

[Go To OTP Verification](#) →

ASP Business Process Flow

Submitter | **Certifier**

Submitter | Certifier

Submitter | Certifier

- 1 Authenticate using One-Time Password (OTP)
- 2 Review Submitted Financial Data 1
- 3 Certify Submitted Financial Data

i The link to the **ASP Data Collection User Guide** is located in the upper right-hand corner of the application screen. Please contact the ASP Helpdesk at asphelpdesk@dcca.com for technical assistance.

i To return to this home page at any time, click on the **Medicare Part B Average Sales Price** title at the top left of your screen.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0021. The time required to complete this information collection is estimated to average 13 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. CMS 10110 approval 08/31/2024.

Figure 8: Medicare Part B Average Sales Price Homepage

3. ASP Homepage Menu Tabs

The following sections describe the functionality of each menu tab on the ASP homepage, including **OTP Verification**, **Compliance Summary**, **Assumptions**, and **Drug Certification**.

3.1 One Time Password (OTP) Verification

Once the Submitter has completed and submitted product data, the Submitter must share the one-time password (OTP) with the Certifier to establish a relationship within the system. Note the following about OTPs:

- This step only occurs once as long as the people in both roles remain the same.
- A new OTP should only be generated if the person in either role changes.
- An OTP is valid for seven days. After seven days, the Submitter must generate a new OTP.
- Once the Submitter generates and provides the OTP to the Certifier, the Certifier must verify the OTP to continue.
- If the OTP is misplaced or lost, the Certifier must contact the Submitter to generate another OTP.

Follow these steps to verify the OTP:

1. From the Medicare Part B Average Sales Price homepage, click the **OTP Verification** tab.

The OTP Verification page opens. Refer to [Figure 9](#).

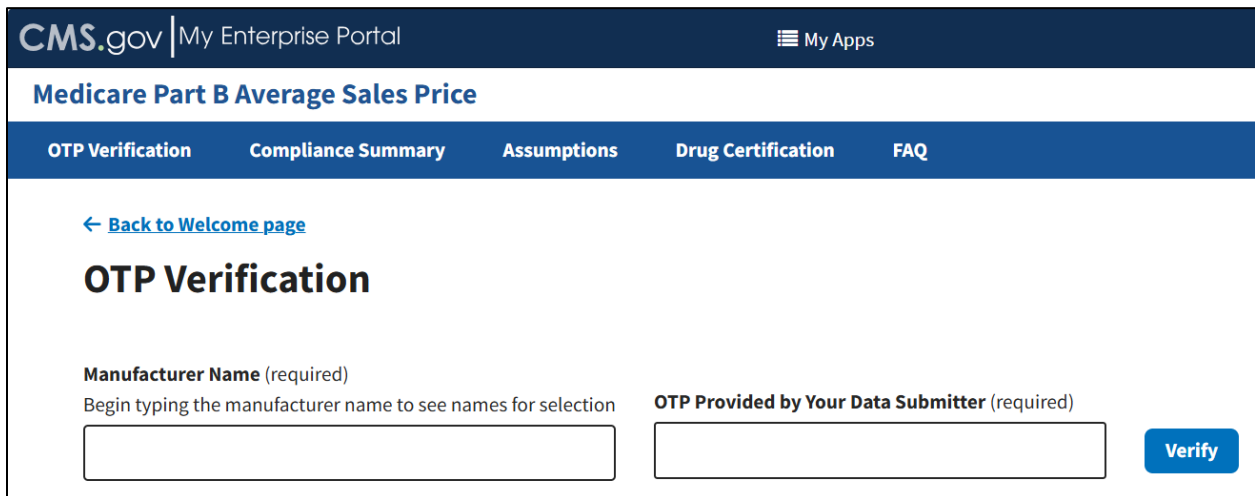
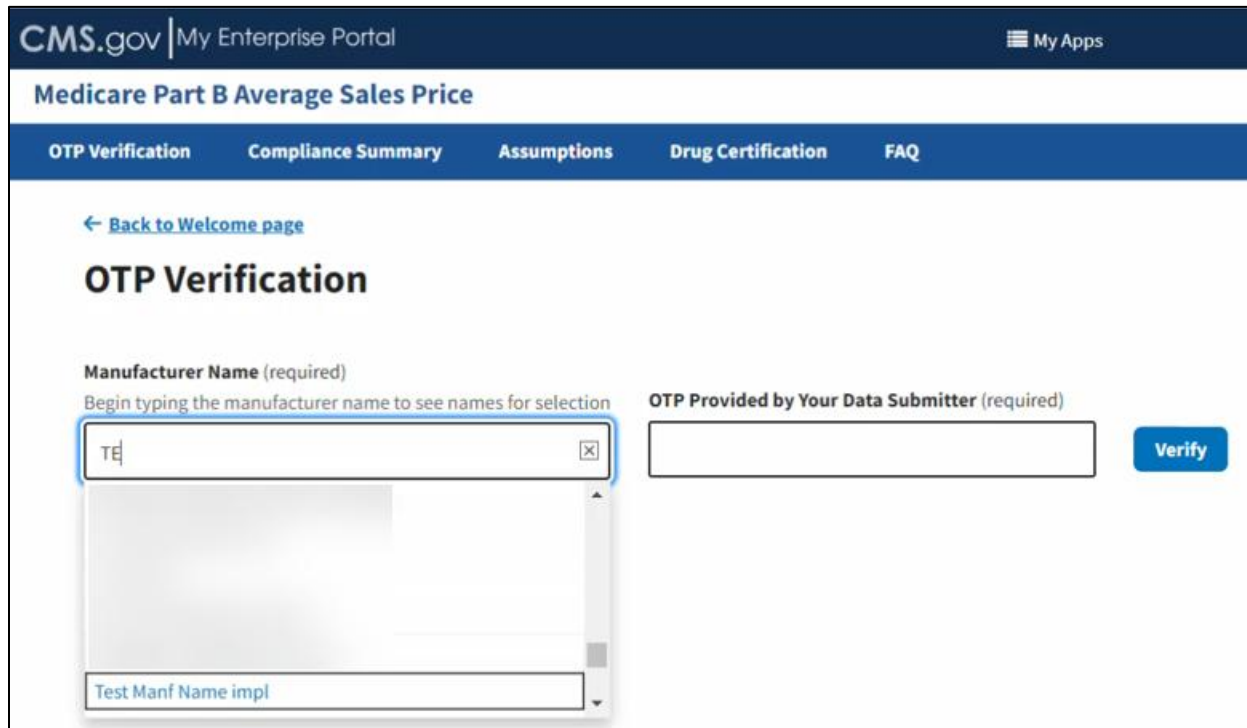


Figure 9: OTP Verification

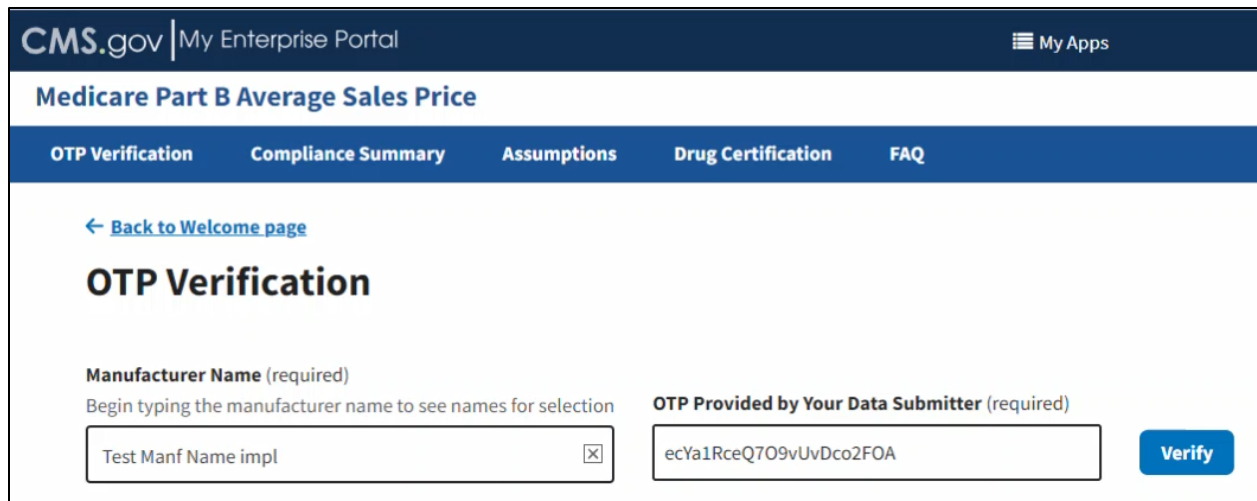
2. In the **Manufacturer Name (required)** field, begin typing the manufacturer name to narrow down names for selection; select the appropriate manufacturer name. Refer to [Figure 10](#).



The screenshot shows the 'Medicare Part B Average Sales Price' page on CMS.gov. The 'OTP Verification' tab is selected. The 'Manufacturer Name (required)' field contains 'TE' and has a dropdown menu open showing 'Test Manf Name impl'. The 'OTP Provided by Your Data Submitter (required)' field is empty. A 'Verify' button is visible on the right.

Figure 10: OTP Verification - Manufacturer Name

3. Enter the OTP code from the Submitter in the **OTP Provided by Your Data Submitter (required)** field. Refer to [Figure 11](#) ~~Figure 11~~.



The screenshot shows the same 'Medicare Part B Average Sales Price' page. The 'Manufacturer Name (required)' field now contains 'Test Manf Name impl'. The 'OTP Provided by Your Data Submitter (required)' field is filled with the code 'ecYa1RceQ709vUvDco2FOA'. The 'Verify' button is still present.

Figure 11: OTP Verification - OTP Provided by Your Data Submitter

4. Click **Verify** to confirm the OTP.
A message displaying confirming you have successfully verified the OTP. Refer to [Figure 12](#) ~~Figure 12~~.

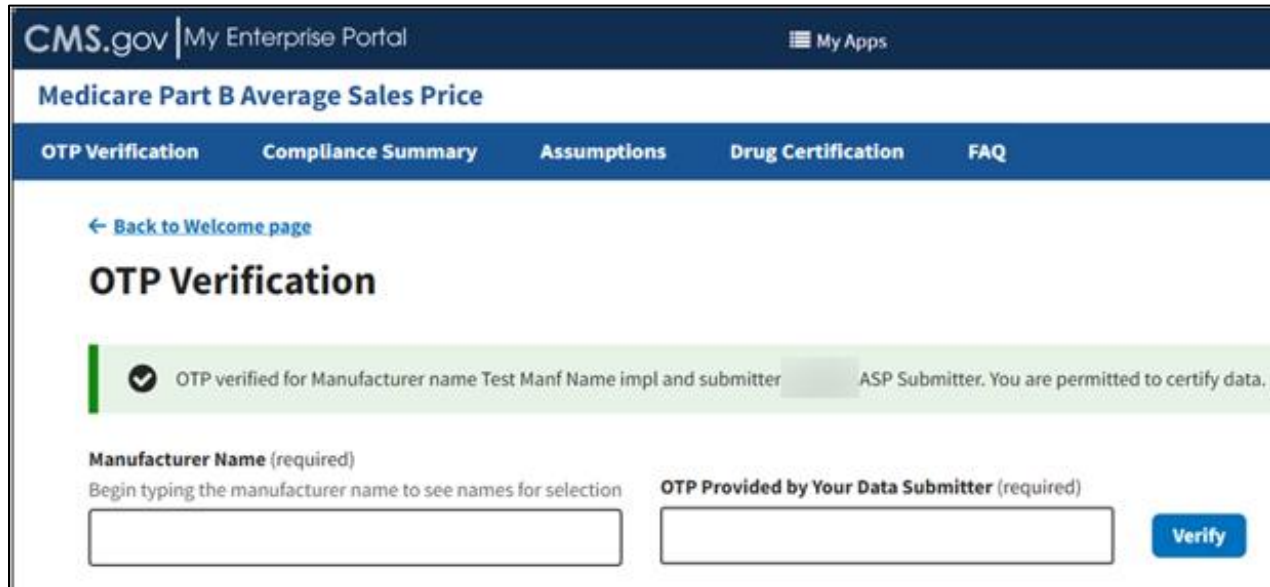


Figure 12: OTP Verification Successful

3.2 Compliance Summary

The features in the **Compliance Summary** section allow drug manufacturers to determine if their products meet the current submission reporting requirements.

The **Compliance Summary** consists of the following sections:

- **Missing:** Displays drug products that are missing financial data for the selected reporting period.
- **Pending:** Displays drug products that are both pending certification and pending restatement certification, combined under one tab.
- **Certified:** Displays previously certified drug products for the selected reporting period.

Note: Financial data will be suppressed for prior quarters.

- **New:** Displays drug products with a first marketing date in the same reporting period.
- **Off Cycle:** Displays drug products added on or after the first day of the submission window of the current quarter.
- **Expired:** Displays drug products that have an expired date of final lot sold which is prior to the reporting period selected. A drug product that expired in an earlier quarter will continue to show in subsequent quarters.

Follow these steps to navigate the **Compliance Summary** section:

1. From the Medicare Part B Average Sales Price homepage, click the **Compliance Summary** tab.

The **Compliance Summary** page opens. The page displays the status for each submitted drug product regarding the drug manufacturer's compliance for the selected reporting period. The page automatically defaults to the **Missing** tab. Refer to [Figure 13](#).

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Note: ~~Figure 13~~ shows an alert message under **Reporting Period** stating that there are drug products in need of attention.

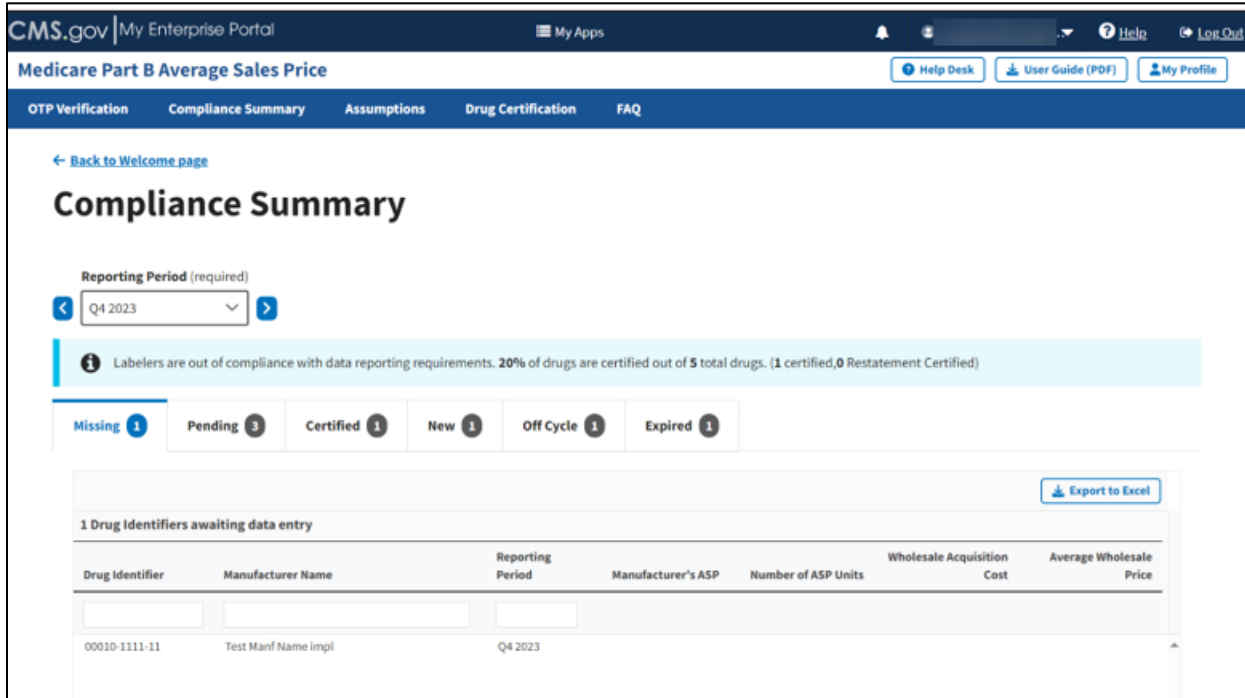


Figure 13: Compliance Summary

Note: Click the **Reporting Period** (required) tab in the top left to scroll through previous quarters. Use the drop-down to navigate to a previous quarter starting with the most recent, or the next quarter.

3.2.1 Missing

Follow these steps to review your data in the **Missing** tab of the **Compliance Summary**:

1. Under **Drug Identifiers waiting for data entry**, review and identify the missing financial information to address with the Submitter.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price** fields.

Note: Click the **Export to Excel** button to download all products under the **Missing** tab.

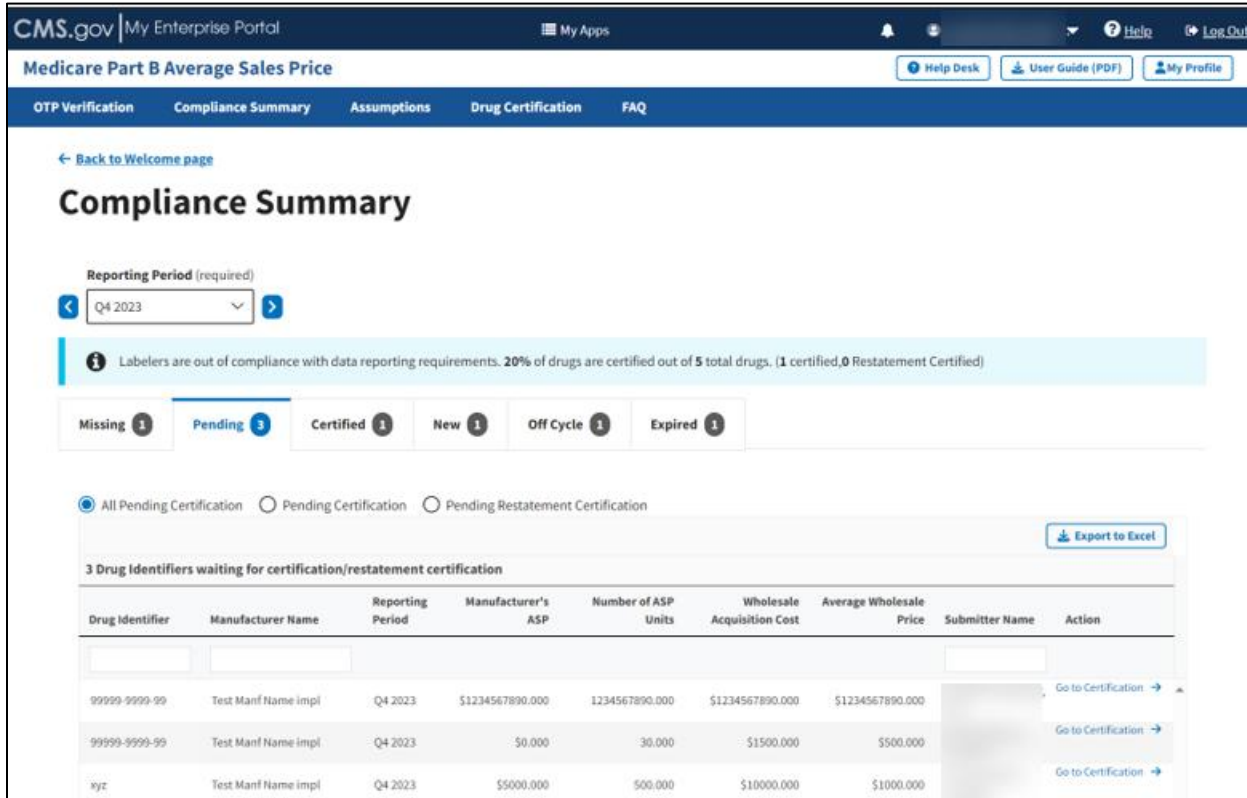
2. Inform the Submitter of any missing financial information to ensure the inclusion of all data collected in the Module.
3. Click the **Pending** tab to move on to the next page.

3.2.2 Pending

Follow these steps to review the **Pending** tab of the **Compliance Summary**:

1. From the default Compliance Summary page, click the **Pending** tab.

The **Pending** page displays. Refer to [Figure 14](#)[Figure 14](#).



Compliance Summary

Reporting Period (required): Q4 2023

Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)

Missing 1 Pending 3 Certified 1 New 1 Off Cycle 1 Expired 1

All Pending Certification Pending Certification Pending Restatement Certification

3 Drug Identifiers waiting for certification/restatement certification

| Drug Identifier | Manufacturer Name | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price | Submitter Name | Action |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|----------------|-----------------------|
| 99999-9999-99 | Test Manf Name impl | Q4 2023 | \$1234567890.000 | 1234567890.000 | \$1234567890.000 | \$1234567890.000 | | Go to Certification → |
| 99999-9999-99 | Test Manf Name impl | Q4 2023 | \$0.000 | 30.000 | \$1500.000 | \$500.000 | | Go to Certification → |
| xyz | Test Manf Name impl | Q4 2023 | \$5000.000 | 500.000 | \$10000.000 | \$1000.000 | | Go to Certification → |

Export to Excel

Figure 14: Compliance Summary - All Pending Certification

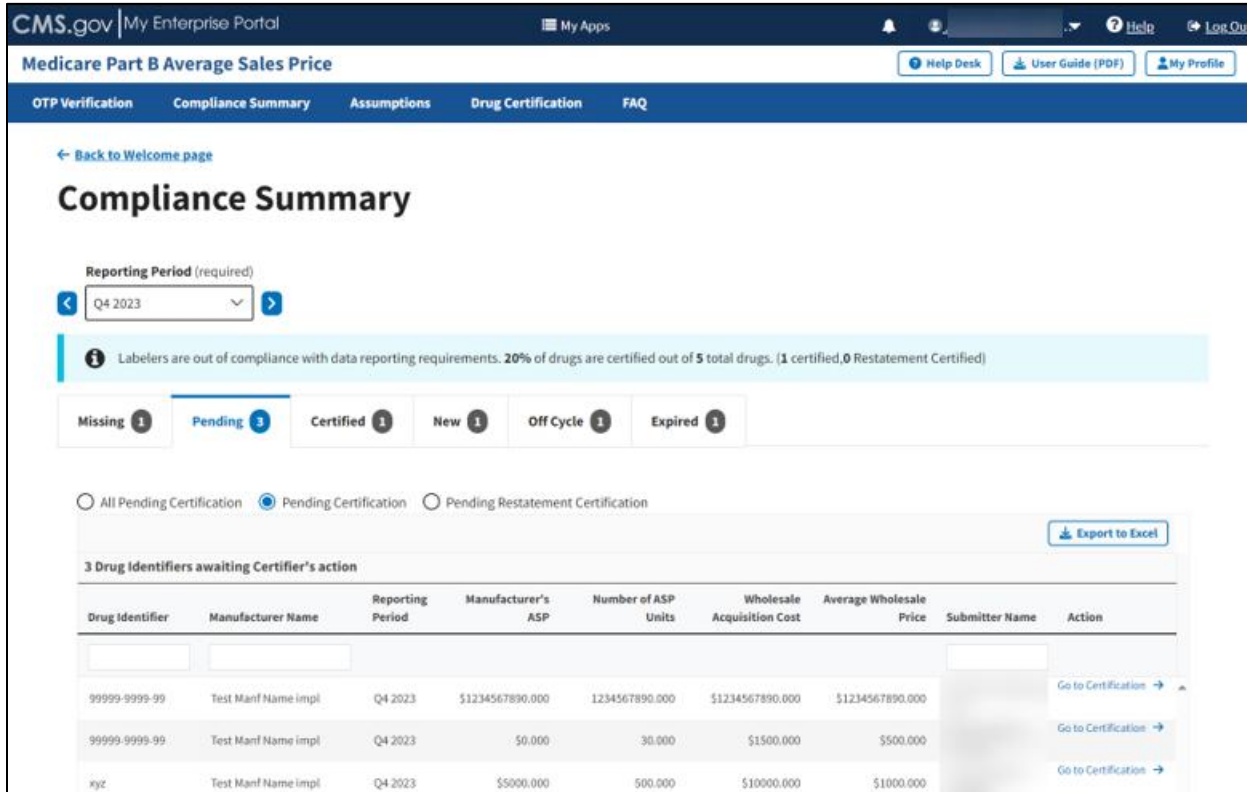
The Module automatically selects the **All Pending Certification** radio button, and the page displays the drug identifiers waiting for certification/restatement certification.

Note: Click the **Export to Excel** button to download all products under the **Pending** tab.

2. Review the drug information under **Drug Identifiers Waiting for Certification/Restatement Certification**.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.

3. Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to [Section 3.53.4 - Drug Certification](#).)
4. Click the **Pending Certification** radio button to filter only for drugs pending certification. Refer to [Figure 15](#).



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 Medicare Part B Average Sales Price | Help Desk | User Guide (PDF) | My Profile

Back to Welcome page
Compliance Summary

Reporting Period (required): Q4 2023

Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)

Missing 1 | **Pending 3** | Certified 1 | New 1 | Off Cycle 1 | Expired 1

All Pending Certification | Pending Certification | Pending Restatement Certification

3 Drug Identifiers awaiting Certifier's action | Export to Excel

| Drug Identifier | Manufacturer Name | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price | Submitter Name | Action |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|----------------|-----------------------|
| 99999-9999-99 | Test Manf Name impl | Q4 2023 | \$1234567890.000 | 1234567890.000 | \$1234567890.000 | \$1234567890.000 | | Go to Certification → |
| 99999-9999-99 | Test Manf Name impl | Q4 2023 | \$0.000 | 30.000 | \$1500.000 | \$500.000 | | Go to Certification → |
| xyz | Test Manf Name impl | Q4 2023 | \$5000.000 | 500.000 | \$10000.000 | \$1000.000 | | Go to Certification → |

Figure 15: Compliance Summary - Pending Certification

Note: Click the **Export to Excel** box to download all products under the **Pending** tab.

- Review the submitted drug information.
The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.
- Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to Section 3.53.4 - [Drug Certification](#).)
- Click the **Pending Restatement Certification** radio button to filter only for drugs that are pending restatement certification. Refer to [Figure 16](#).
- Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to Section 3.53.4 - [Drug Certification](#).)

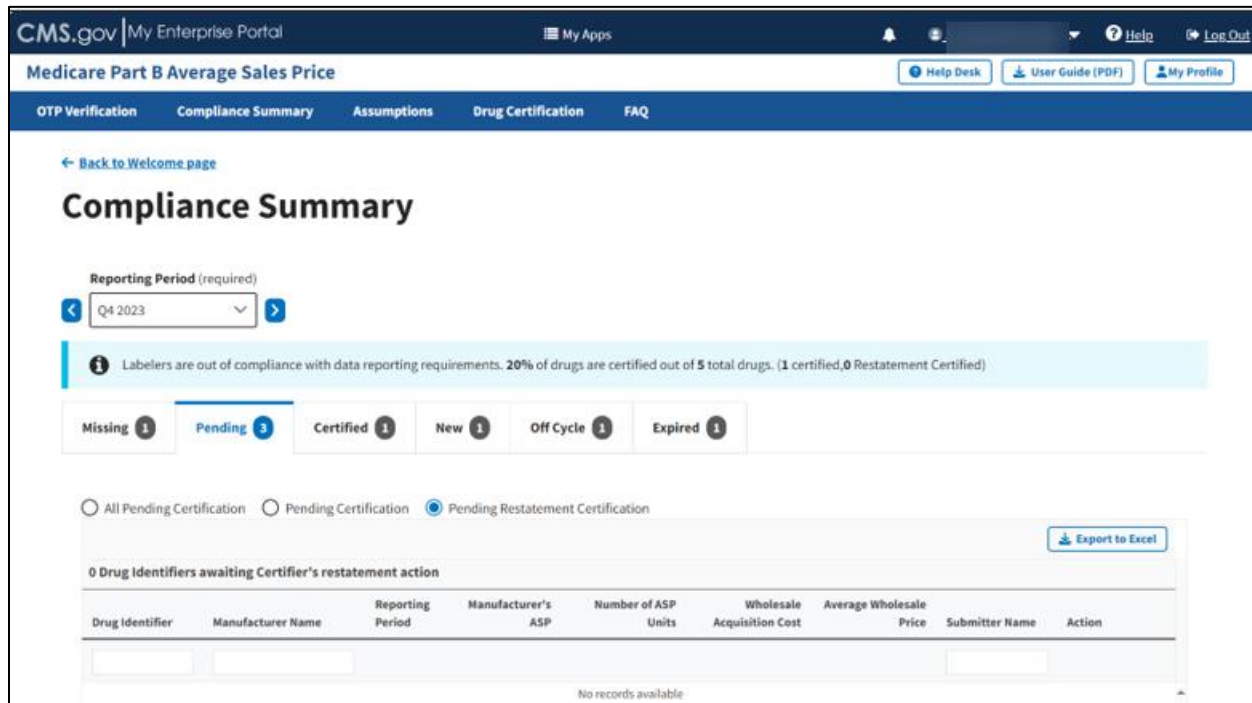


Figure 16: Compliance Summary - Pending Restatement Certification

Note: Click the **Export to Excel** box to download all products under the **Pending** tab.

9. Review the submitted drug information.
The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.
10. Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to [Section 3.53-4 - Drug Certification](#).)
11. Click the **Certified** tab to move on to the next page.

3.2.3 Certified

Follow these steps to review your data in the **Certified** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Certified** tab.
The **Certified** page displays. Refer to [Figure 17](#).

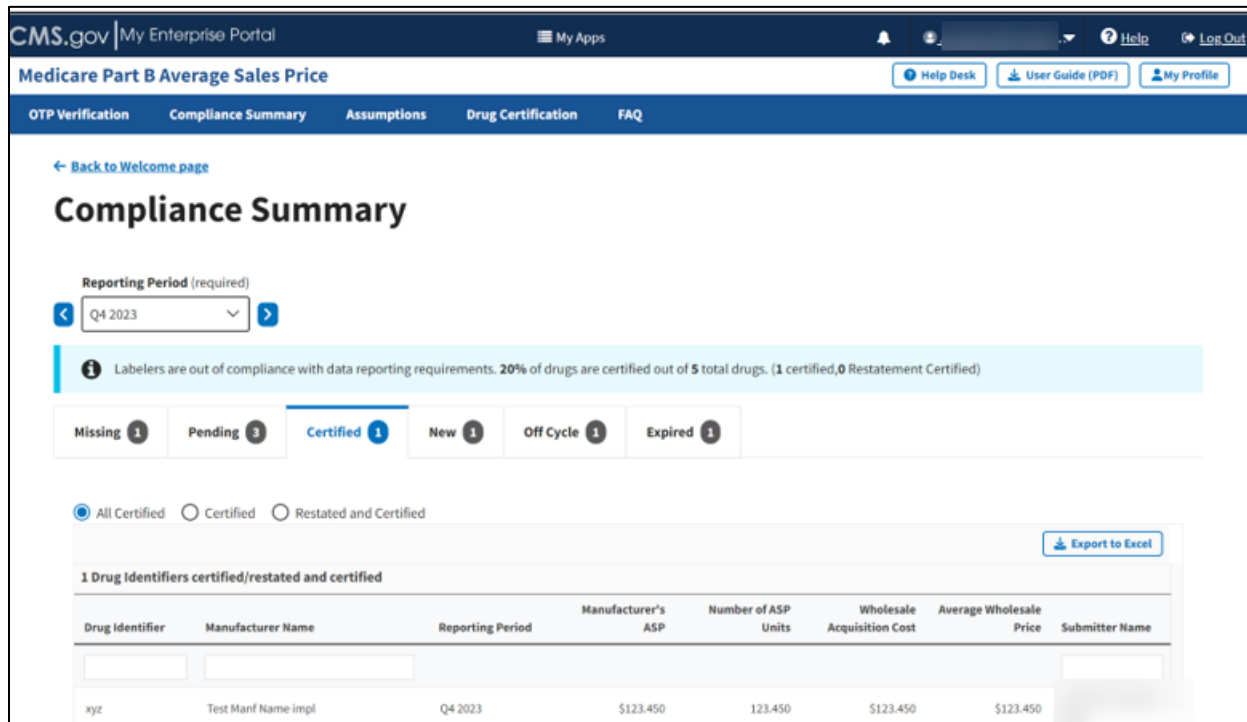


Figure 17: Compliance Summary - Certified

The Module automatically selects the **All Certified** radio button, and the page displays the certified/restated drug identifiers.

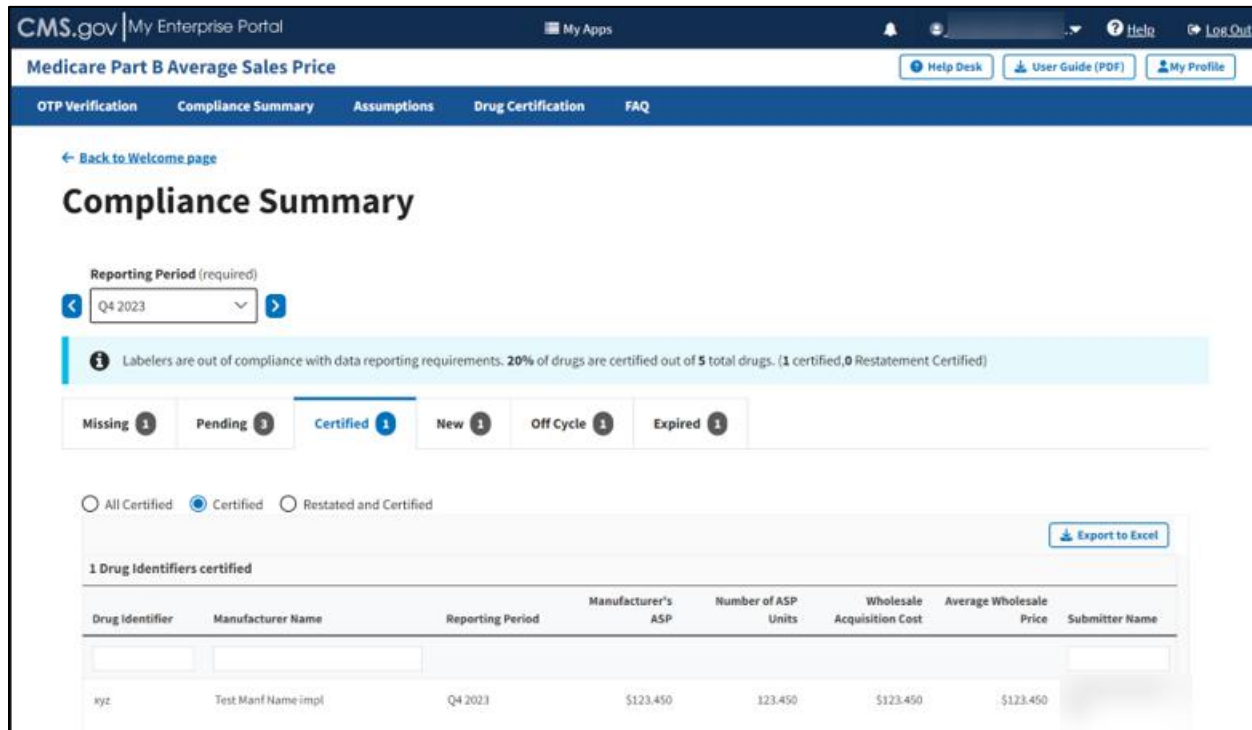
Note: Click the **Export to Excel** button to download all products under the **Certified** tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

3. Click the **Certified** radio button to filter only for certified drugs. Refer to [Figure 18](#).

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← Back to Welcome page

Compliance Summary

Reporting Period (required)
 Q4 2023

i Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)

Missing **1** Pending **3** **Certified 1** New **1** Off Cycle **1** Expired **1**

All Certified Certified Restated and Certified

1 Drug Identifiers certified

| Drug Identifier | Manufacturer Name | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price | Submitter Name |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|----------------|
| xyz | Test Manf Name impl | Q4 2023 | \$123.450 | 123.450 | \$123.450 | \$123.450 | |

Figure 18: Compliance Summary - Certified

Note: Click the **Export to Excel** button to download all products under the **Certified** tab.

- Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

- Click the **Restated and Certified** radio button to filter only for certified drugs that were restated. Refer to [Figure 19](#).

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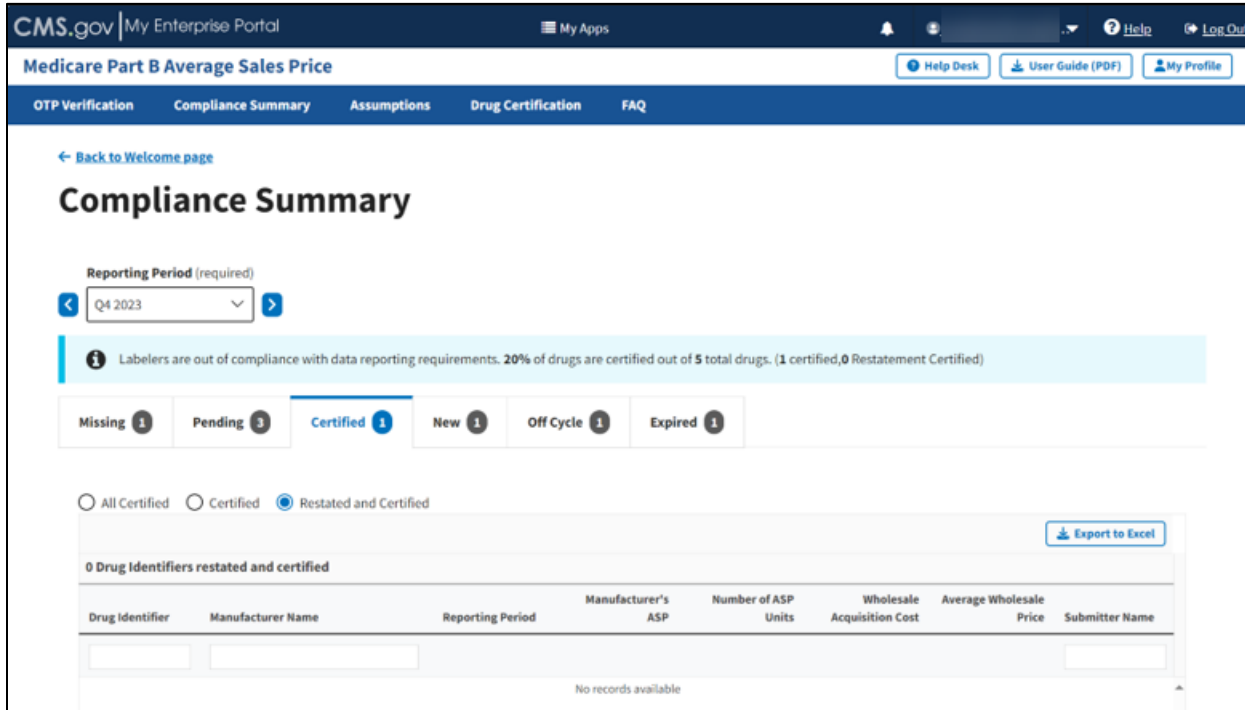


Figure 19: Compliance Summary - Restated and Certified

Note: Click the **Export to Excel** button to download all products under the **Certified** tab.

6. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

7. Click the **New** tab to move on to the next page.

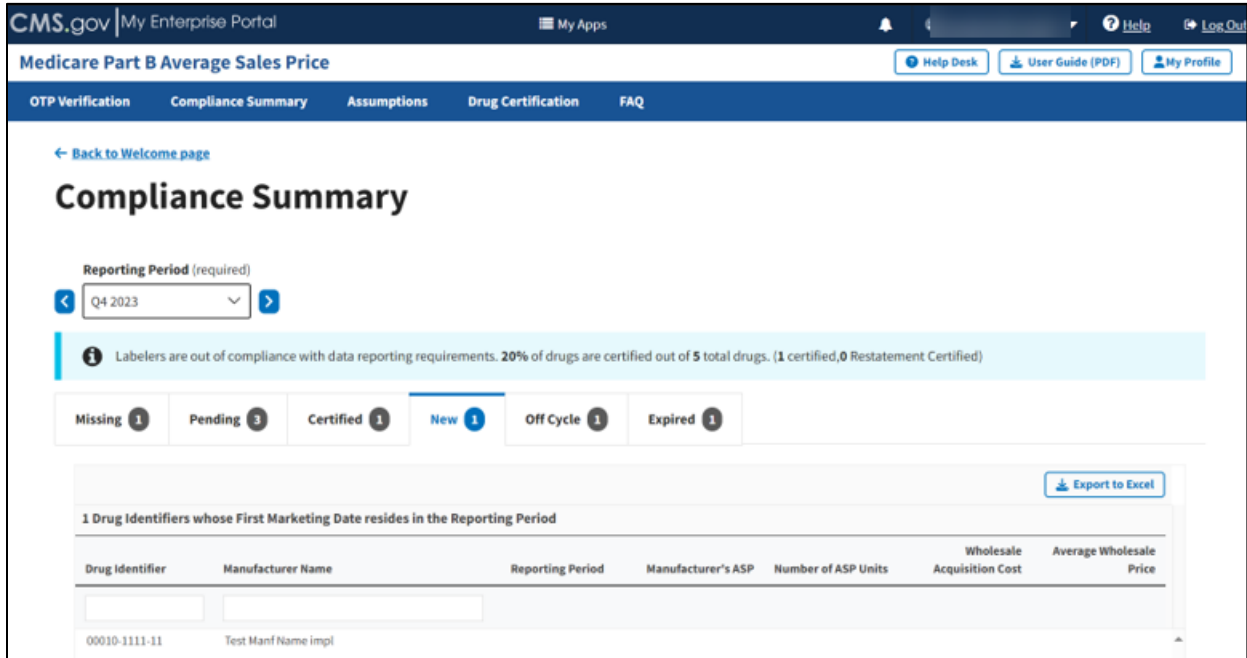
3.2.4 New

Follow these steps to review data in the **New** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **New** tab.

The **New** page displays. Refer to [Figure 20](#).

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OTP Verification | Compliance Summary | Assumptions | Drug Certification | FAQ

[← Back to Welcome page](#)

Compliance Summary

Reporting Period (required)
 Q4 2023

Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)

Missing 1 | Pending 3 | Certified 1 | **New 1** | Off Cycle 1 | Expired 1

[Export to Excel](#)

1 Drug Identifiers whose First Marketing Date resides in the Reporting Period

| Drug Identifier | Manufacturer Name | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|
| 00010-1111-11 | Test Manf Name impl | | | | | |

Figure 20: Compliance Summary - New

Note: Click the **Export to Excel** button to download all products under the **New** tab.

- Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

- Click the **Off Cycle** tab to move on to the next page.

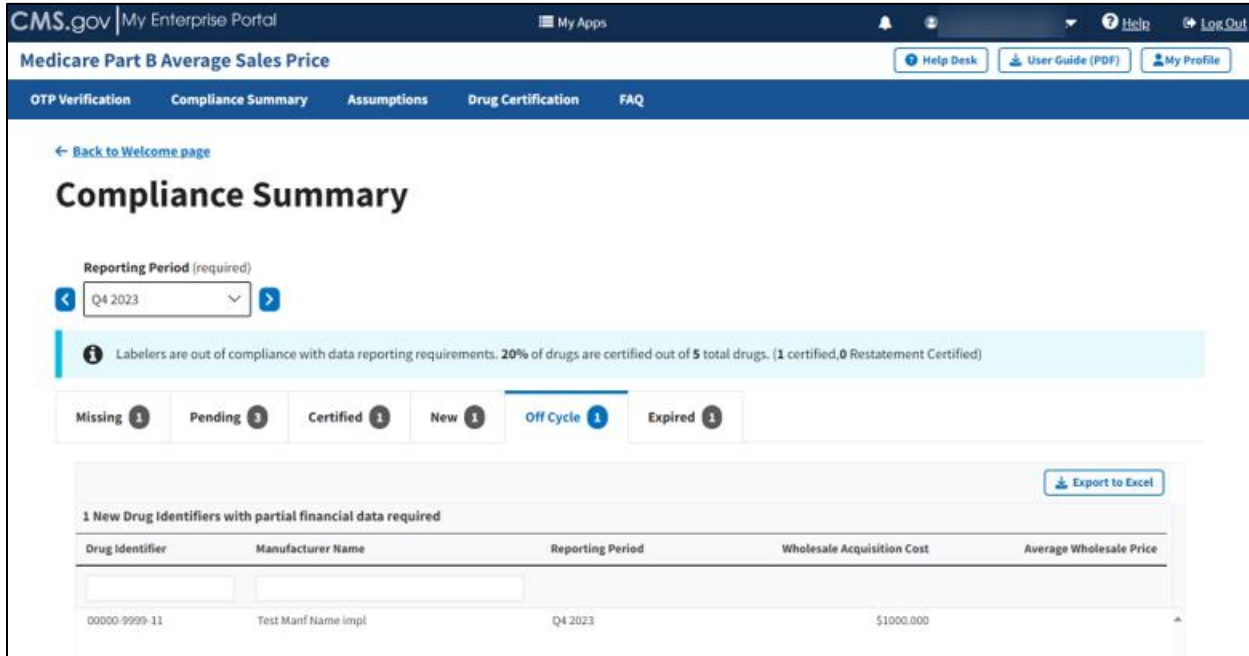
3.2.5 Off Cycle

Follow these steps to review data in the **Off Cycle** tab of the **Compliance Summary**:

- From the default **Compliance Summary** page, click the **Off Cycle** tab.

The **Off Cycle** page displays. Refer to [Figure 21](#).

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Compliance Summary

Reporting Period (required)
 Q4 2023

ⓘ Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)

Missing 1 | Pending 3 | Certified 1 | New 1 | **Off Cycle 1** | Expired 1

Export to Excel

1 New Drug Identifiers with partial financial data required

| Drug Identifier | Manufacturer Name | Reporting Period | Wholesale Acquisition Cost | Average Wholesale Price |
|-----------------|---------------------|------------------|----------------------------|-------------------------|
| 00000-9999-11 | Test Manf Name Impl | Q4 2023 | \$1000.000 | |

Figure 21: Compliance Summary - Off Cycle

Note: Click the **Export to Excel** button to download all products under the **Off Cycle** tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

3. Click the **Expired** tab to move on to the next page.

3.2.6 Expired

Follow these steps to review data in the **Expired** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Expired** tab.

The **Expired** page displays. Refer to [Figure 22](#).

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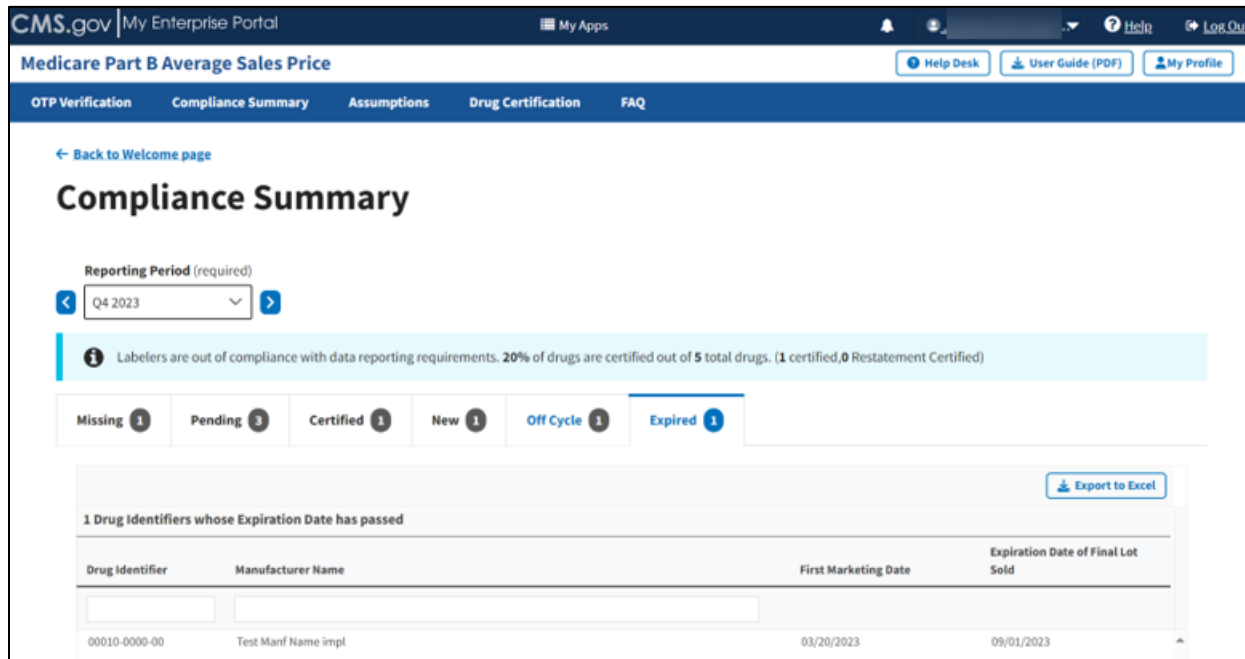


Figure 22: Compliance Summary - Expired

Note: Click the **Export to Excel** button to download all products under the **Expired** tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name** and includes **First Marketing Date** and **Expiration Date of Final Lost Sold**.

3.3 Assumptions

Drug manufacturers can submit comments regarding their certifications to CMS via the **Assumptions** tab. Each quarter, manufacturers will submit these comments for the current reporting period, or they may submit assumptions for any previous quarters they are restating and resubmitting.

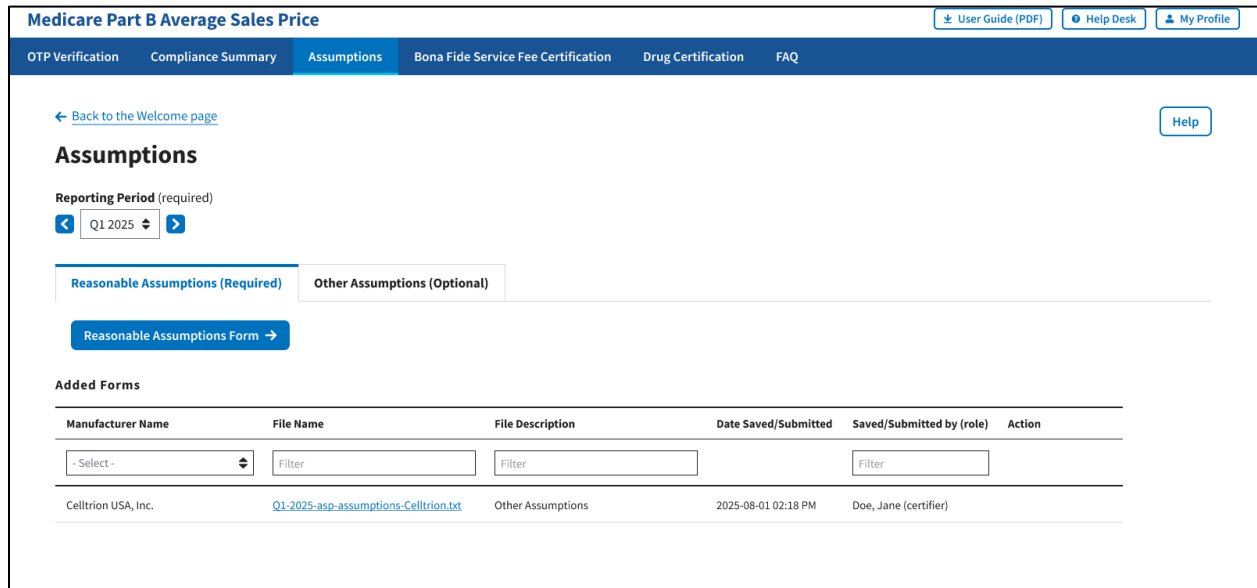
3.3.1 Reasonable Assumptions

Follow these steps to create an assumption:

Note: Certifiers cannot finalize the certification process until the **Reasonable Assumptions** Form is complete. If a drug manufacturer does not have additional information for the required response fields, please enter "N/A".

1. From the **Medicare Part B Average Sales Price** homepage, click the **Assumptions** tab.

The **Assumptions** page opens, and defaults to the current quarter and year. Select the appropriate reporting period before clicking the **Reasonable Assumptions (Required)** tab. Refer to [Error! Reference source not found. Figure 23](#).



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Assumptions

Reporting Period (required)
Q1 2025

Reasonable Assumptions (Required) | Other Assumptions (Optional)

Reasonable Assumptions Form →

Added Forms

| Manufacturer Name | File Name | File Description | Date Saved/Submitted | Saved/Submitted by (role) | Action |
|---------------------|---|-------------------|----------------------|---------------------------|--------|
| - Select - | Filter | Filter | | Filter | |
| Celltrion USA, Inc. | Q1-2025-asp-assumptions-Celltrion.txt | Other Assumptions | 2025-08-01 02:18 PM | Doe, Jane (certifier) | |

Figure 23: Assumptions

Note: Click the **Reporting Period (Required)** tab in the top left to scroll through previous quarters.

1. Click the **Reasonable Assumptions Form** button.

The **Reasonable Assumption Form** window displays. The Module automatically defaults to the **Reporting Period** selected on the **Assumptions** default page with a **Manufacturer Name (required)** drop-down menu and empty required response fields.

Refer to [Figure 24](#).

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Reasonable Assumptions Form

Reporting Period
Q1 2025

Manufacturer Name (required)

i Manufacturers must provide all required information below in the form fields. If you do not have reasonable assumptions for a particular area, put "N/A" in the box. If you have additional verbiage for any of the areas below, attach a cover letter when submitting this form.

Bona Fide Service Fees

Provide an overview of contractual arrangements that the submitting manufacturer has with entities for which it pays a bona fide service fee(s) as well as the fair market value analysis for service arrangements each time an arrangement is issued or renewed.

Response (required)

1,000 characters left

Bundled Sales

Provide an overview of bundled sale arrangements and the discount reallocation for each arrangement.

Response (required)

1,000 characters left

Figure 24: Reasonable Assumptions Form

2. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.

Click "View All" to view all the required response fields. Refer to Figure 25.

- Bona Fide Service Fees
- Bundled Sales
- Price Concessions and Discounts
- Reporting of Products with Zero, Negative, or False Positive ASPs
- Sales Excluded from Best Price
- Sales to U.S. Territories
- Time Value of Money
- Free Goods Not Contingent on a Purchase Requirement
- Value-Based Purchasing Agreements
- Sales to 340B Covered Entities
- Returned Goods
- Billing Corrections

Sales to U.S. Territories

Confirm how the manufacturer considers sales to customers in United States territories in the calculation of ASP.

Response (required)

1,000 characters left

View All

Figure 25: “View All” Required Response Fields

Note: For drug manufacturers with contractual agreements, please enter comments in the Reasonable Assumptions form and complete the **Bona Fide Service Fee Certification**. Refer to Section 3.4 for instructions.

3. Complete all the **required** fields. Enter “N/A” if reasonable assumptions are not available for a particular field.

Note: Each required field allows for 1,000 characters of text to provide a summary of the assumption. If a response exceeds the character limit, please submit or upload the additional verbiage on the **Other Assumptions** tab. Refer to Section 3.3.2 for instructions.

4. Click the **Save Form** button located at the bottom of the form. Refer to [Figure 26](#).

Returned Goods

Confirm how returned goods will be treated in the ASP calculation.

Response (required)

N/A

1,000 characters left

Billing Corrections

Confirm how you process transactional issues that may require a credit or rebill.

Response (required)

N/A

1,000 characters left

Save Form

Figure 26: Save Reasonable Assumptions Form

A message displays confirming you have successfully created your **Reasonable Assumptions**. The Module lists saved forms under **Added Forms**. Refer to [Figure 27](#).

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Assumptions

Reporting Period (required)
 Q1 2025

Reasonable Assumptions (Required) **Other Assumptions (Optional)**

✔ Reasonable Assumptions Form has been saved successfully.

Added Forms

| Manufacturer Name | File Name | File Description | Date Saved/Submitted | Saved/Submitted by (role) | Action |
|-------------------|--|-------------------------------------|----------------------|-------------------------------------|---|
| - Select - | <input type="text" value="Filter"/> | <input type="text" value="Filter"/> | | <input type="text" value="Filter"/> | |
| ClariGenix Pharma | Q1-2025-reasonable-assumptions-Celltrion.pdf | Reasonable Assumptions | 2025-08-04 11:18 AM | Doe, Jane (certifier) | <input type="button" value="Edit"/> <input type="button" value="Submit"/> |
| ClariGenix Pharma | Q1-2025-asp-assumptions-Celltrion.txt | Other Assumptions | 2025-08-01 02:18 PM | Doe, Jane (certifier) | |

Figure 27: New Assumption Successfully Saved

5. To make any necessary revisions before submitting, click the **Edit** button.
6. If the submission does not require additional revisions, click the **Submit** button. A message displays confirming you have successfully submitted your **Reasonable Assumptions**. Refer to [Figure 28](#).

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Assumptions

Reporting Period (required)
 Q1 2025

Reasonable Assumptions (Required) **Other Assumptions (Optional)**

✔ Reasonable Assumptions Form has been submitted successfully.

Added Forms

| Manufacturer Name | File Name | File Description | Date Saved/Submitted | Saved/Submitted by (role) | Action |
|-------------------|--|-------------------------------------|----------------------|-------------------------------------|--------|
| - Select - | <input type="text" value="Filter"/> | <input type="text" value="Filter"/> | | <input type="text" value="Filter"/> | |
| ClariGenix Pharma | Q1-2025-reasonable-assumptions-Celltrion.pdf | Reasonable Assumptions | 2025-08-04 02:18 PM | Doe, Jane (certifier) | |
| ClariGenix Pharma | Q1-2025-asp-assumptions-Celltrion.txt | Other Assumptions | 2025-08-01 02:18 PM | Doe, Jane (certifier) | |

Figure 28: Reasonable Assumptions Successfully Submitted

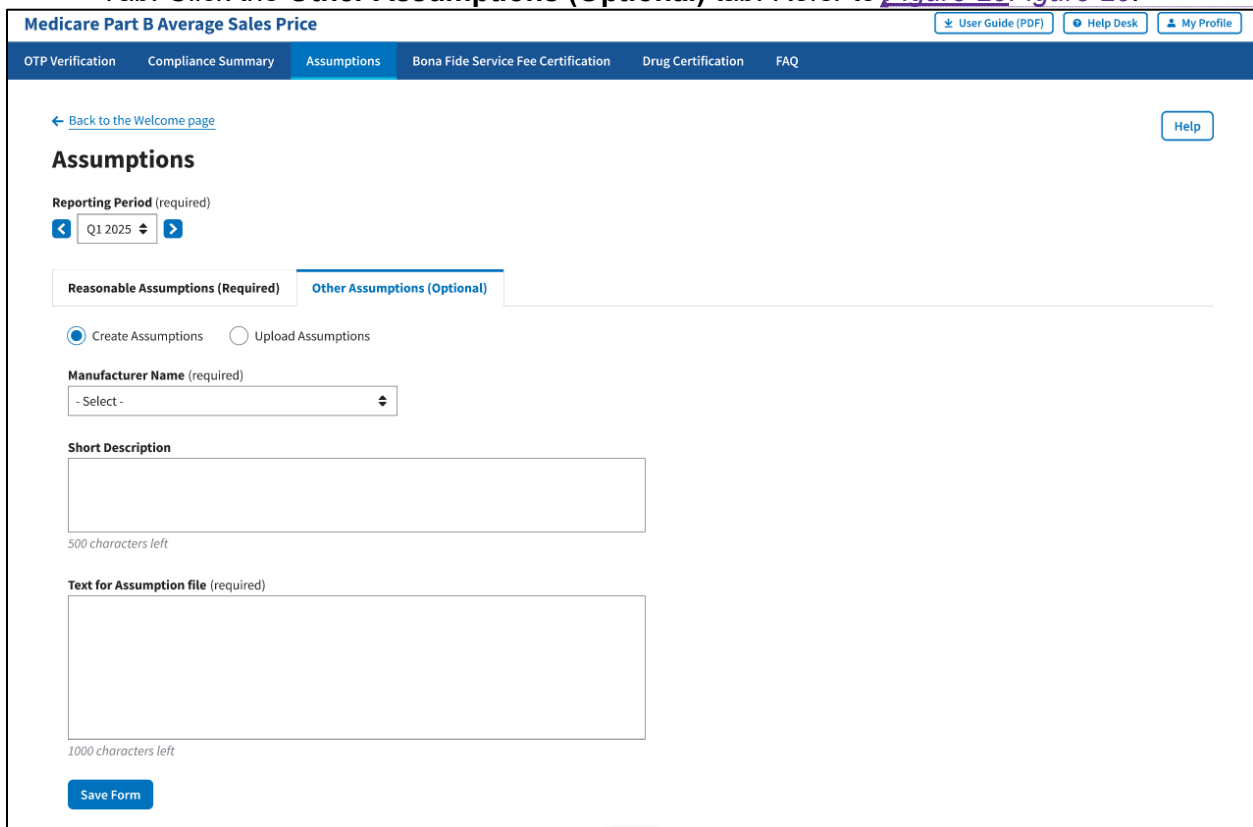
3.3.2 Other Assumptions (Optional)

This section provides instructions on how drug manufacturers can submit comments regarding their certifications to CMS via **Create Assumptions** or **Upload Assumptions**.

3.3.2.1 Create Assumptions

Follow these steps to submit certification assumptions CMS:

1. From the **Medicare Part B Average Sales Price** homepage, click the **Assumptions** tab. The Module automatically defaults to the **Reasonable Assumptions (Required)** Tab. Click the **Other Assumptions (Optional)** tab. Refer to [Figure 29](#).



The screenshot shows the 'Medicare Part B Average Sales Price' homepage. The 'Assumptions' tab is selected in the navigation bar. The 'Other Assumptions (Optional)' sub-tab is active. The 'Create Assumptions' radio button is selected. The 'Reporting Period' is set to 'Q1 2025'. The 'Manufacturer Name' dropdown menu is open, showing '- Select -'. The 'Short Description' and 'Text for Assumption file' fields are empty. A 'Save Form' button is at the bottom.

Figure 29: Create Other Assumptions

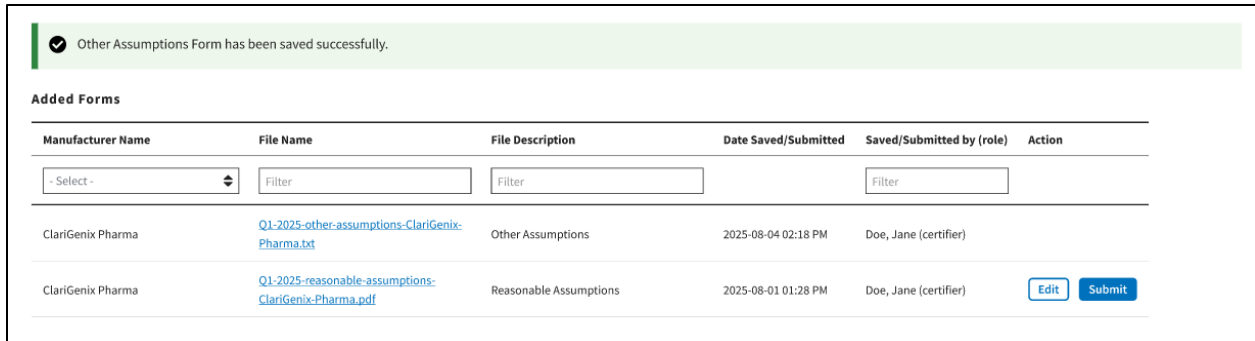
Note: Click the **Reporting Period (required)** tab in the top left to view previous quarters. Use the drop-down menu to navigate to select the appropriate quarter.

2. The Module automatically defaults to the **Create Assumption** radio button with a **Manufacturer Name (required)** drop-down menu and empty **Short Description** and **Text for Assumption file (required)** fields. Refer to [Figure 29](#).
3. From the Manufacturer Name (required) drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.
4. Complete the **Short Description** and **Text for Assumption file** fields.

Note: The **Short Description** field is optional and allows 500 characters of text to provide a summary of the complete assumption you are submitting to CMS. The **Text for Assumption file** field is required and allows for 1,000 characters to provide as much detail as possible related to the selected period's financial submission.

5. Click the **Save Form** button.

A message displays confirming you have successfully created your **Assumption**. Refer to [Figure 30](#)[Figure 30](#).



Other Assumptions Form has been saved successfully.

Added Forms

| Manufacturer Name | File Name | File Description | Date Saved/Submitted | Saved/Submitted by (role) | Action |
|-------------------|--|------------------------|----------------------|---------------------------|---|
| - Select - | Filter | Filter | | Filter | |
| ClariGenix Pharma | Q1-2025-other-assumptions-ClariGenix-Pharma.txt | Other Assumptions | 2025-08-04 02:18 PM | Doe, Jane (certifier) | |
| ClariGenix Pharma | Q1-2025-reasonable-assumptions-ClariGenix-Pharma.pdf | Reasonable Assumptions | 2025-08-01 01:28 PM | Doe, Jane (certifier) | Edit Submit |

Figure 30: Other Assumptions Saved Successfully

3.3.2.2 Upload Assumption File

Follow these steps to upload an assumption file to the Module:

1. Click the **Other Assumptions (Optional)** file tab.

The **Create Assumption or Upload Assumption File** window displays. The Module automatically defaults to the **Create Assumption** radio button.

2. Select the **Upload Assumption File** radio button.

A **Manufacturer Name (required)** drop-down menu and empty **File Description (required)** field display. Refer to [Figure 31](#)[Figure 31](#).

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Assumptions

Reporting Period (required)
 Q1 2025

Reasonable Assumptions (Required)
 Other Assumptions (Optional)

Create Assumptions
 Upload Assumptions

Manufacturer Name (required)

File Description (required)

500 characters left

Upload .pdf, .docx, .txt, or .xlsx File (required)
Maximum file size is 10 MB

or drag file here

Figure 31: Upload Assumptions

3. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.
4. In the **File Description** field, enter your assumption about a data submission. You have 500 characters of total text to comment about your submission in this section.
5. Click **Select File** to browse your desktop and upload your **Assumption File** to the Module. You may also drag your **Assumption File** into the **Select File** box. A message opens to confirm you have successfully uploaded your assumption file. Refer to [Figure 32](#) ~~Figure 34~~.

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Other Assumptions Form has been uploaded successfully.

Added Forms

| Manufacturer Name | File Name | File Description | Date Saved/Submitted | Saved/Submitted by (role) | Action |
|-------------------|--|-------------------------------------|----------------------|-------------------------------------|---|
| - Select - | <input type="text" value="Filter"/> | <input type="text" value="Filter"/> | | <input type="text" value="Filter"/> | |
| ClariGenix Pharma | Q1-2025-other-assumptions-ClariGenix-Pharma.docx | Other Assumptions | 2025-08-04 02:38 PM | Doe, Jane (certifier) | |
| ClariGenix Pharma | Q1-2025-reasonable-assumptions-ClariGenix-Pharma.pdf | Reasonable Assumptions | 2025-08-01 02:18 PM | Doe, Jane (certifier) | <input type="button" value="Edit"/> <input type="button" value="Submit"/> |

Figure 3234: Upload Assumption File - Successfully Added

3.4 Bona Fide Service Fee Certification

Follow these steps to submit a Bona Fide Service Fee Certification to CMS:

1. From the **Medicare Part B Average Sales Price** homepage, click the **Bona Fide Service Fee Certification** tab. The **Bona Fide Service Fee Certification** page opens and defaults to the current quarter and year. Refer to [Figure 33](#)~~Figure 35~~.
2. The Module automatically defaults to the current reporting period. Select the accurate reporting period before proceeding.
3. Select the Manufacturer Name in the drop-down menu.
4. Download, complete, and sign the Bona Fide Service Fee Certification Form.

The fields to complete are as follows:

Section 1: Enter all drug and manufacturer information associated with the bona fide service fee

- Drug Name(s):
- HCPCS code(s):
- Manufacturer name:
- Manufacturer address:

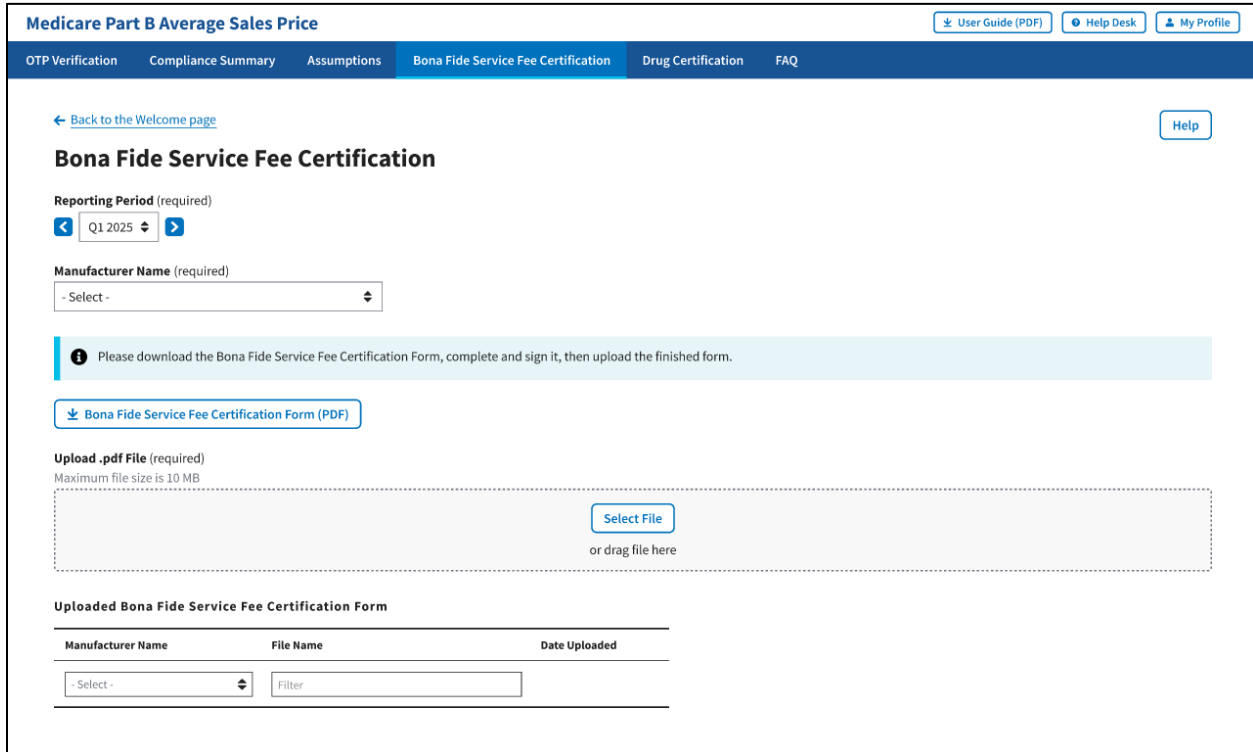
Section 2: Recipient of BFSF information

- Name and title of certifying individual:
- Organization or entity name:
- Organization or entity address:
- Bona fide service:
- ~~Bona fide service fee amount (if the fee varies based on certain metrics, describe the conditions of the fee and how it is determined):~~

Section 3.: Certification Statement

- I certify that the fee is not passed on in whole or in part to an **affiliate**, client, or customer of the recipient of the fee an entity.
- Manufacturer Signature:
- Fee Recipient Signature:

5. Save the completed form to your computer. Upload the form once completed.



The screenshot shows the 'Medicare Part B Average Sales Price' page with the 'Bona Fide Service Fee Certification' tab selected. The form includes a 'Reporting Period' dropdown set to 'Q1 2025', a 'Manufacturer Name' dropdown set to '- Select -', and an 'Upload .pdf File' section with a 'Select File' button and a note that the maximum file size is 10 MB. Below the upload section is a table titled 'Uploaded Bona Fide Service Fee Certification Form' with columns for 'Manufacturer Name', 'File Name', and 'Date Uploaded'. The table currently has a '- Select -' dropdown for the manufacturer name and a 'Filter' input field.

Figure 3335: Bona Fide Service Fee Certification Submission

3.5 Drug Certification

Drug certification is the process in which a drug manufacturer certifies the accuracy of submitted drug data. This process marks data for immediate certification or pending certification to be completed later. Selection may include one drug product item, a list of drugs, or all items pending certification for a manufacturer.

The Submitter gathers the required quarterly drug data and submits it to the Module. Once the Submitter has successfully submitted the data, they will notify the Certifier to log in to the system to review and certify their submission.

Follow these steps to certify drug product data:

1. From the Medicare Part B Average Sales Price homepage, select **Drug Certification** tab from the **Certification** tab. Refer to [Figure 34](#)~~Figure 30~~.

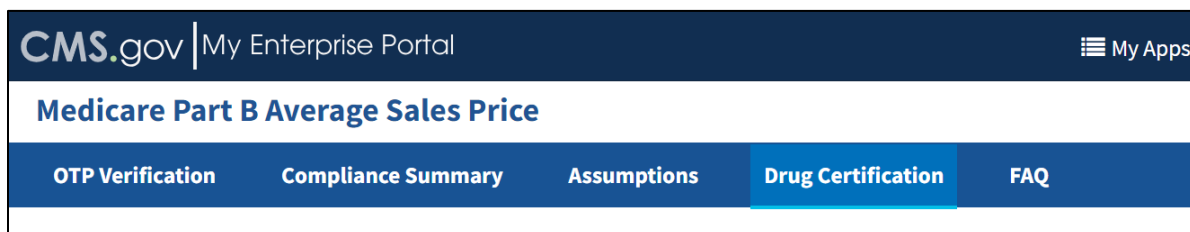


Figure 3436: Certification - Drop-down

The **Drug Certification** page opens. Refer to [Figure 35](#)~~Figure 31~~.

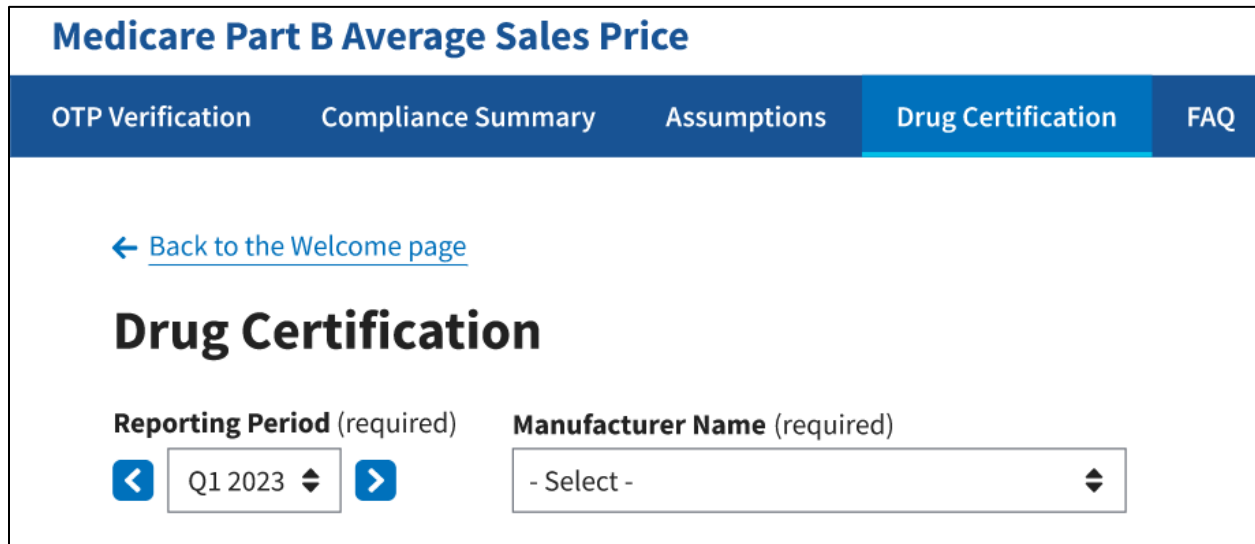


Figure 3537: Drug Certification

Note: Click the **Reporting Period** (required) tab in the top left to scroll through previous quarters. Use the drop-down menu to navigate to a previous quarter starting with the most recent quarter.

2. Click the **-Select-** box under **Manufacturer Name (required)** to expand the list. Refer to [Figure 36](#)[Figure 32](#).

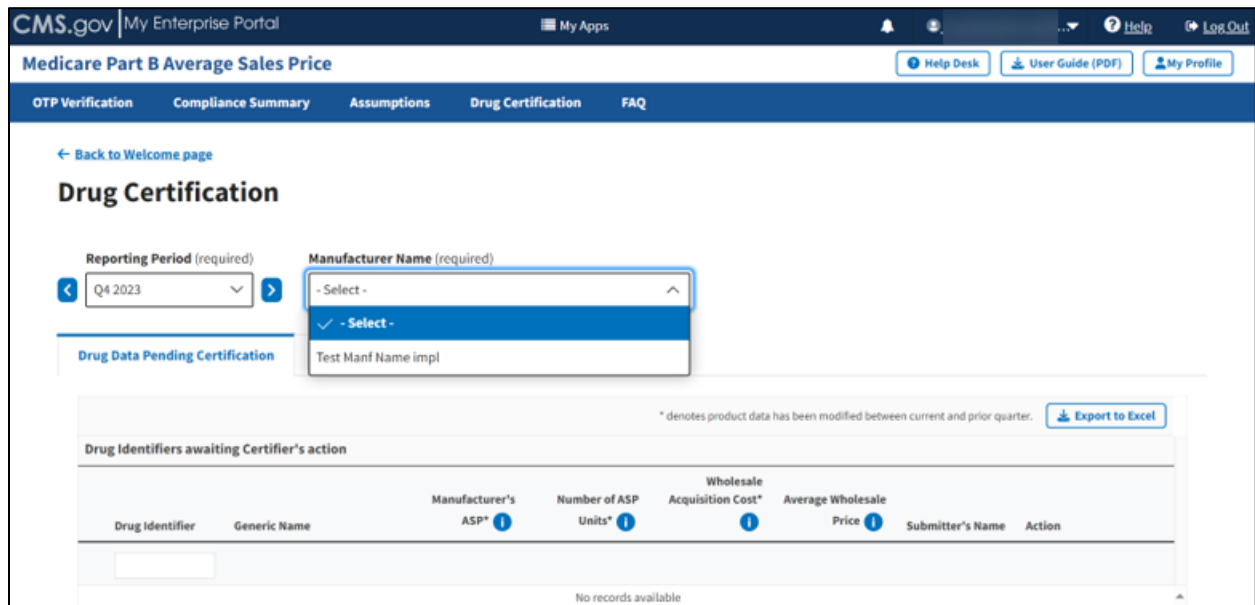
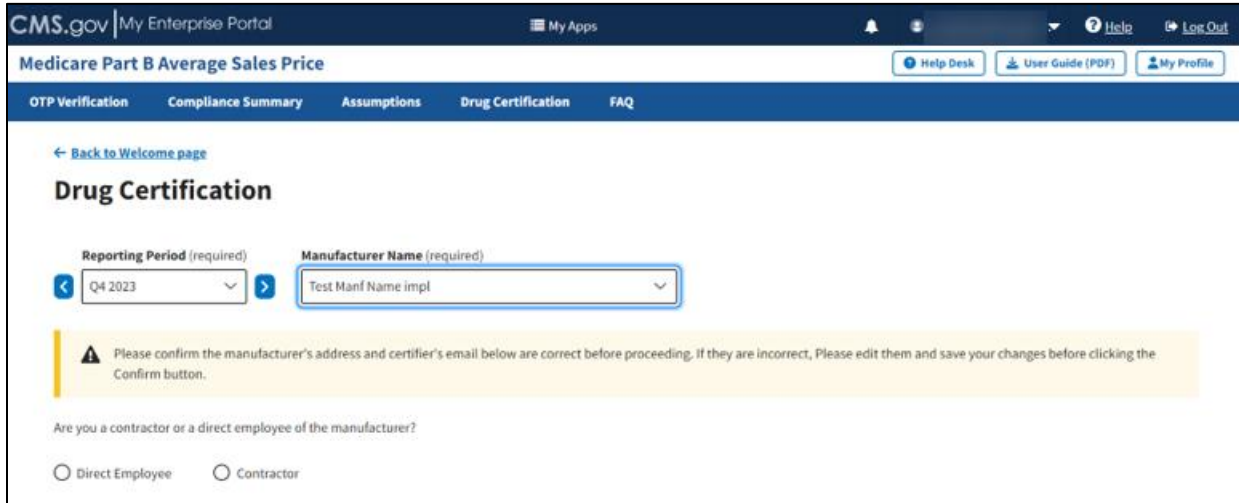


Figure 3638: Drug Certification - Manufacturer Name

3. Select the appropriate manufacturer name.
The page displays two new radio buttons asking you to confirm if you are certifying as a direct employee or contractor. Refer to [Figure 37](#)[Figure 33](#).



The screenshot shows the 'Drug Certification' page in the CMS.gov My Enterprise Portal. The page has a navigation bar with 'Medicare Part B Average Sales Price' and links for 'Help Desk', 'User Guide (PDF)', and 'My Profile'. Below the navigation bar, there are tabs for 'OTP Verification', 'Compliance Summary', 'Assumptions', 'Drug Certification', and 'FAQ'. The main content area is titled 'Drug Certification' and includes a 'Back to Welcome page' link. There are two dropdown menus: 'Reporting Period (required)' set to 'Q4 2023' and 'Manufacturer Name (required)' set to 'Test Manf Name impl'. A yellow warning box contains the text: 'Please confirm the manufacturer's address and certifier's email below are correct before proceeding. If they are incorrect, Please edit them and save your changes before clicking the Confirm button.' Below the warning, there is a question: 'Are you a contractor or a direct employee of the manufacturer?' with two radio buttons: 'Direct Employee' and 'Contractor'.

Figure 3739: Drug Certification - Direct Employee or Contractor

Note: In the updated ASP Data Collection System, CMS requests verification of your contact information prior to certifying data.

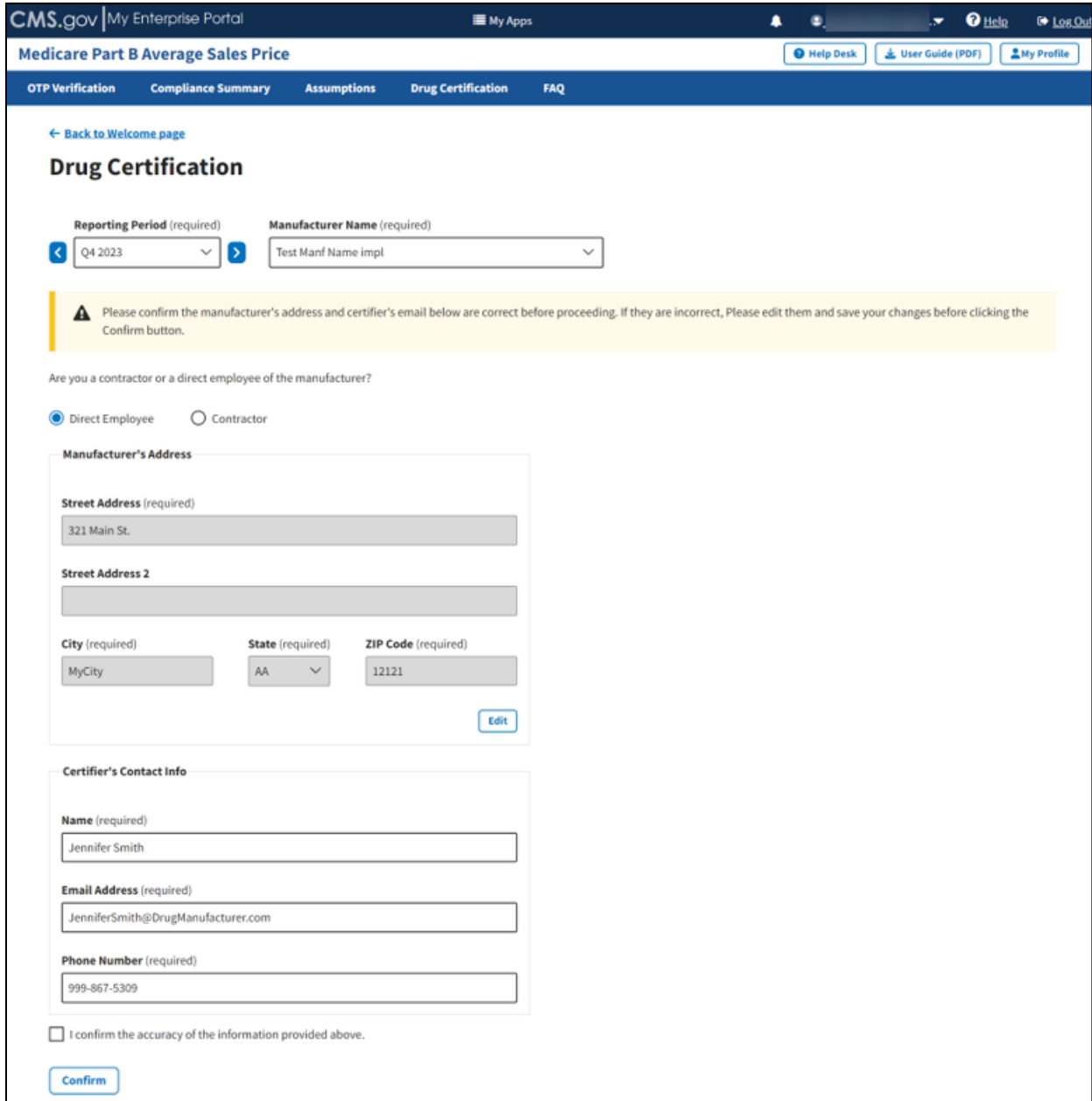
The following sections describe how to complete the drug certification process as a direct employee or contractor.

3.5.1 Direct Employee

Follow these steps to complete the drug certification process as a direct employee:

1. Click the **Direct Employee** radio button.
New fields display asking for more information about the manufacturer's address and contact information.
2. Enter or select the required information as follows:
 - a. Enter the street address in the **Street Address (required)** field.
 - b. Enter the street address in the **Street Address Line 2 (optional)** field, if necessary.
 - c. Enter the city in the **City (required)** field.
 - d. Enter the state in the **State (required)** field.
 - e. Enter the ZIP code in the **ZIP Code (required)** field.
 - f. Enter the name in the **Name (required)** field.
 - g. Enter the email address in the **Email Address (required)** field.
 - h. Enter the phone number in the **Phone Number (required)** field.
3. Click the **Edit** button under **Manufacturer's Address and Certifier's Contact Info** if you need to correct information already populated in a field. Refer to [Figure 38](#) [Figure 34](#).

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Drug Certification

Reporting Period (required) Manufacturer Name (required)

⚠️ Please confirm the manufacturer's address and certifier's email below are correct before proceeding. If they are incorrect, Please edit them and save your changes before clicking the Confirm button.

Are you a contractor or a direct employee of the manufacturer?

Direct Employee Contractor

Manufacturer's Address

Street Address (required)

Street Address 2

City (required) State (required) ZIP Code (required)

Certifier's Contact Info

Name (required)

Email Address (required)

Phone Number (required)

I confirm the accuracy of the information provided above.

Figure 3840: Drug Certification - Direct Employee - Fields Populated

- Once you complete the fields, select the **I confirm the accuracy of the information provided above** checkbox; click **Confirm and Save**.

A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to [Figure 39](#)/[Figure 35](#).

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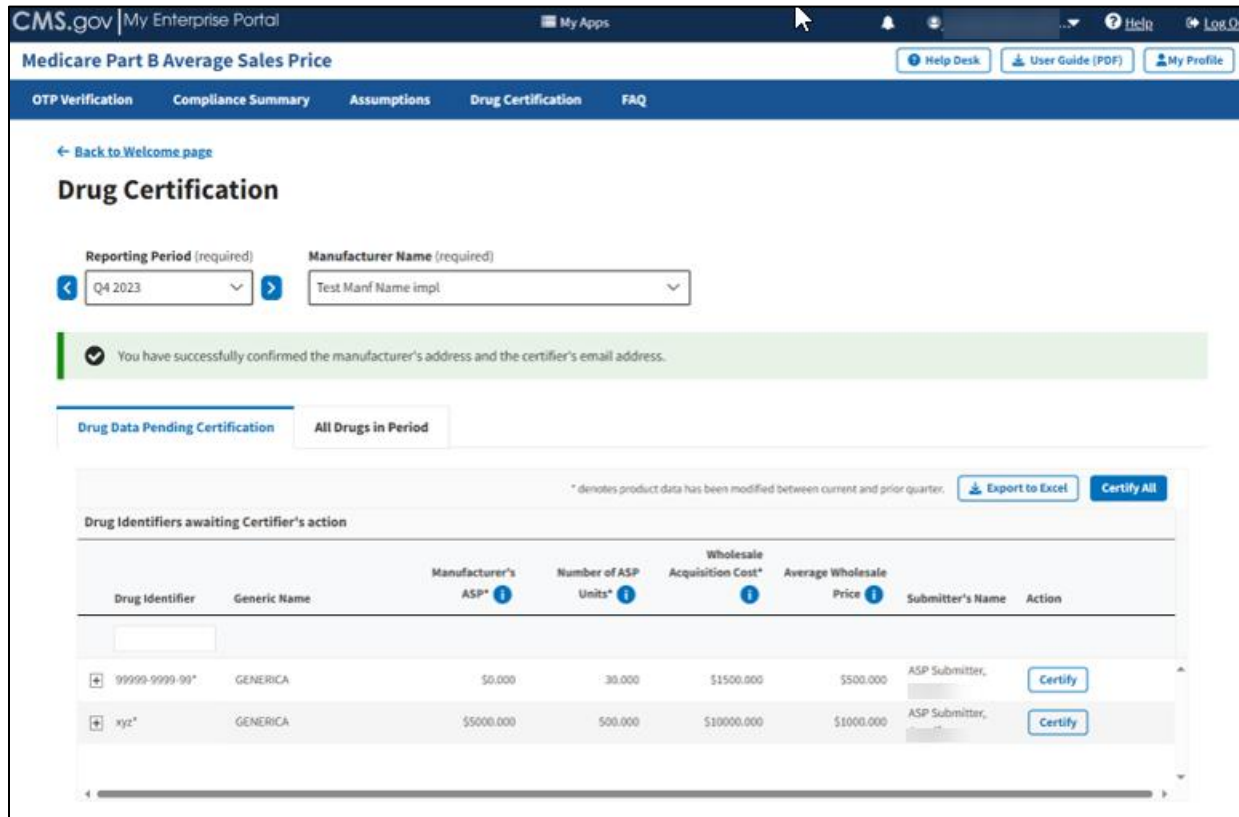


Figure 3944: Drug Certification - Direct Employee Confirmation

3.5.2 Contractor

Follow these steps to complete the drug certification process as a contractor:

1. Click the **Contractor** radio button.
New fields display asking for more information about the manufacturer's address, your manufacturer's point of contact (POC), and your contact information.
2. Enter or select the required information as follows:
 - a. Enter the street address in the **Street Address (required)** field.
 - b. Enter the street address in the **Street Address Line 2 (optional)** field, if necessary.
 - c. Enter the city in the **City (required)** field.
 - d. Enter the state in the **State (required)** field.
 - e. Enter the ZIP code in the **ZIP Code (required)** field.
 - f. Enter the point of contact name in the **Point of Contact's Name (required)** field.
 - g. Enter the point of contact email address in the **Point of Contact's Email Address (required)** field.
 - h. Enter the point of contact phone number in the **Point of Contact's Phone Number (required)** field.
 - i. Enter the certifier name in the **Certifier's Name (required)** field.
 - j. Enter the certifier email address in the **Certifier's Email Address (required)** field.
 - k. Enter the certifier phone number in the **Certifier's Phone Number (required)** field.

- Click the **Edit** button under **Manufacturer's Address**, **Point of Contact Info**, and **Certifier's Contact Info** if you need to correct information already populated in a field. Refer to [Figure 40](#)[Figure 36](#).

Are you a contractor or a direct employee of the manufacturer?

Direct Employee Contractor

Manufacturer's Address

Street Address (required)

Street Address line 2

City (required) **State** (required) **ZIP Code** (required)

Point of Contact Info

Name (required)

Email Address (required)

Phone Number (required)

Certifier's Contact Info

Name (required)

Email Address (required)

Phone Number (required)

I confirm the accuracy of the information provided above.

Figure 4042: Drug Certification - Contractor - Fields Populated

- Once you complete the fields, select the **I confirm the accuracy of the information provided above** checkbox; click **Confirm and Save**.

A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to [Figure 41](#)[Figure 37](#).

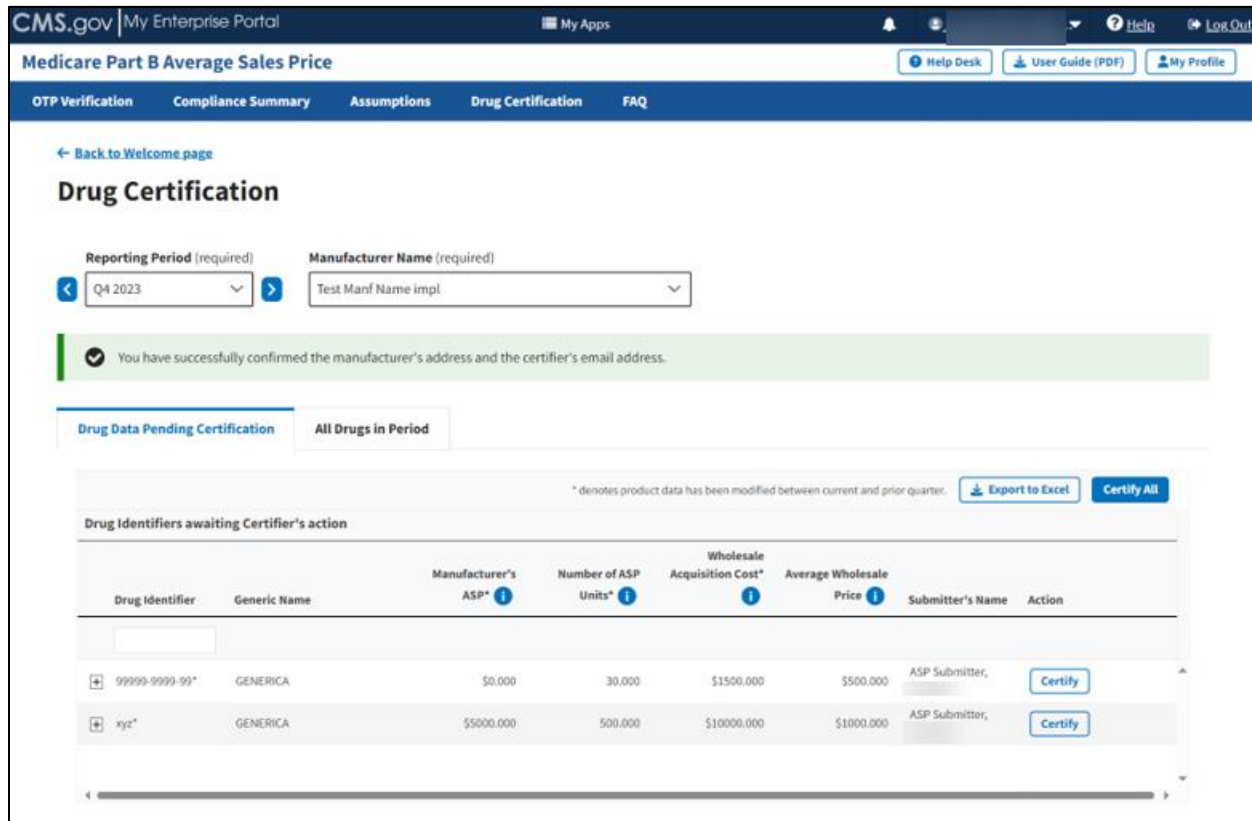


Figure 4143: Drug Certification - Contractor Confirmation

3.5.3 Drug Data Pending Certification

Follow these steps to complete the drug data certification process and certify your products:

1. Confirm that your preferred drug product is selected under **Manufacturer Name (required)** field on the Drug Certification homepage. Refer to [Figure 41](#)[Figure 37](#) and [Figure 42](#)[Figure 38](#).

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Use the drop-down to navigate to a previous quarter starting with the most recent quarter.

The Module displays the **Drug Data Pending Certification** tab by default. (Click the tab if the Module does not automatically open the page to the default setting.)

This page also lists all drug products by **Drug Identifier** and **Generic Name** as well as **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action**. Refer to [Figure 42](#)[Figure 38](#).

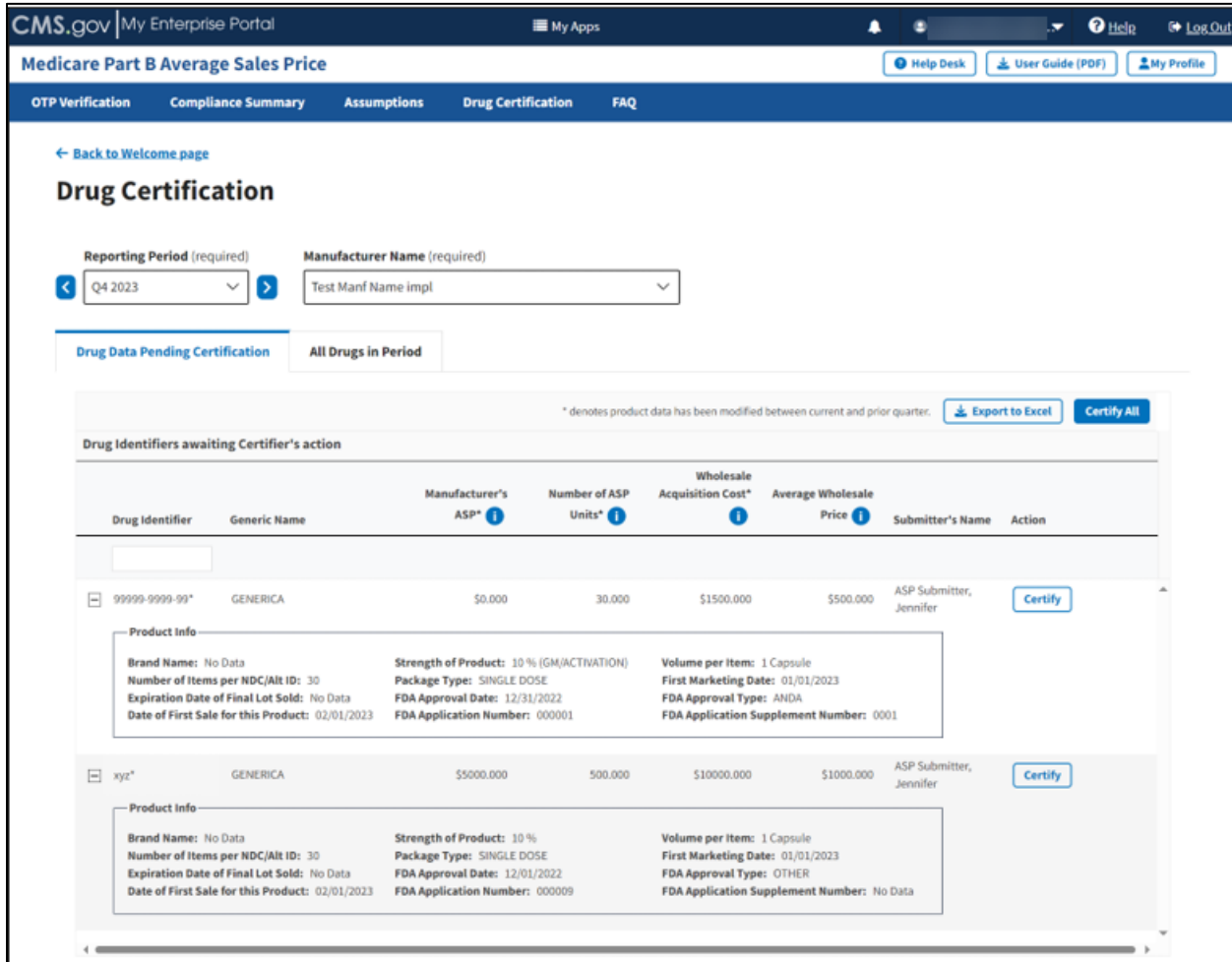
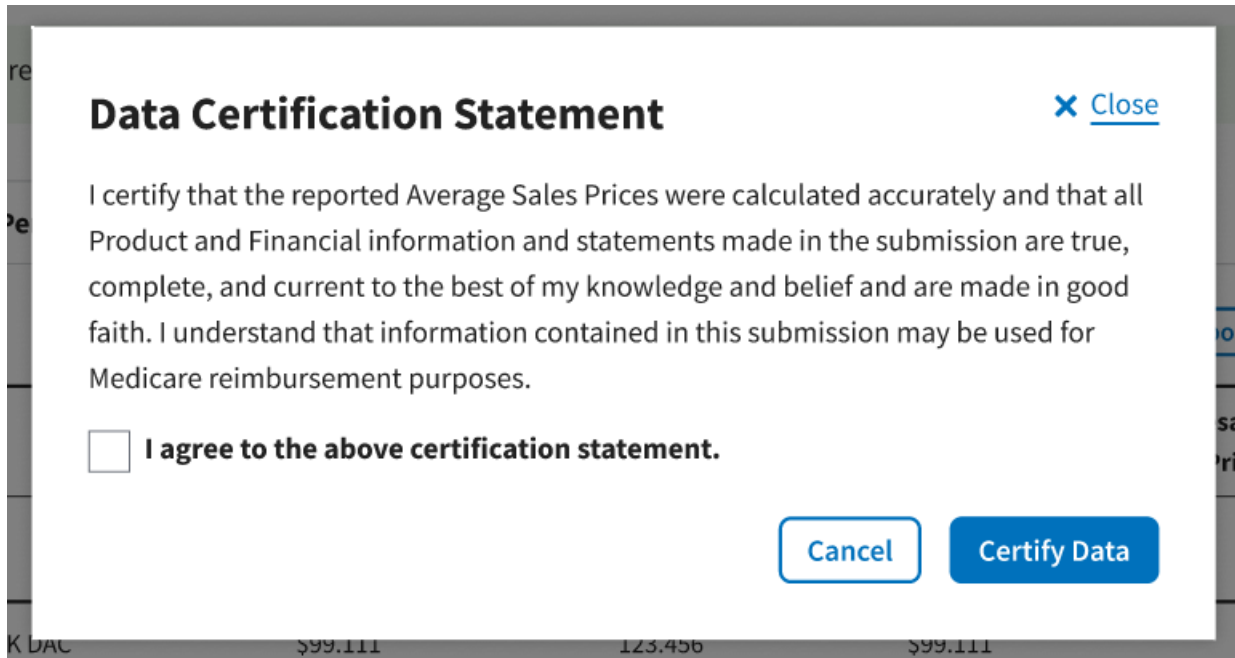


Figure 4244: Drug Data Pending Certification

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

2. Click the plus symbol on each row of the table to expand each product's information and view additional drug product fields, such as **Brand Name**, **First Marketing Date**, **Volume per Item**, and all other information the Submitter previously reported. Refer to [Figure 42Figure 38](#).
3. Select the drug product and click the **Certify** box to open a new Data Certification Statement. Refer to [Figure 43Figure 39](#).

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The image shows a dialog box titled "Data Certification Statement" with a "Close" button in the top right corner. The text inside the dialog reads: "I certify that the reported Average Sales Prices were calculated accurately and that all Product and Financial information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes." Below this text is a checkbox followed by the text "I agree to the above certification statement." At the bottom right of the dialog are two buttons: "Cancel" and "Certify Data".

Figure 4345: Data Certification Statement

4. Read the statement; select the I agree to the above certification statement checkbox and select **Certify Data** to confirm approval of the submitted data.

A message displays confirming you have successfully certified the drug data. Refer to [Figure 44](#)~~Figure 40~~.

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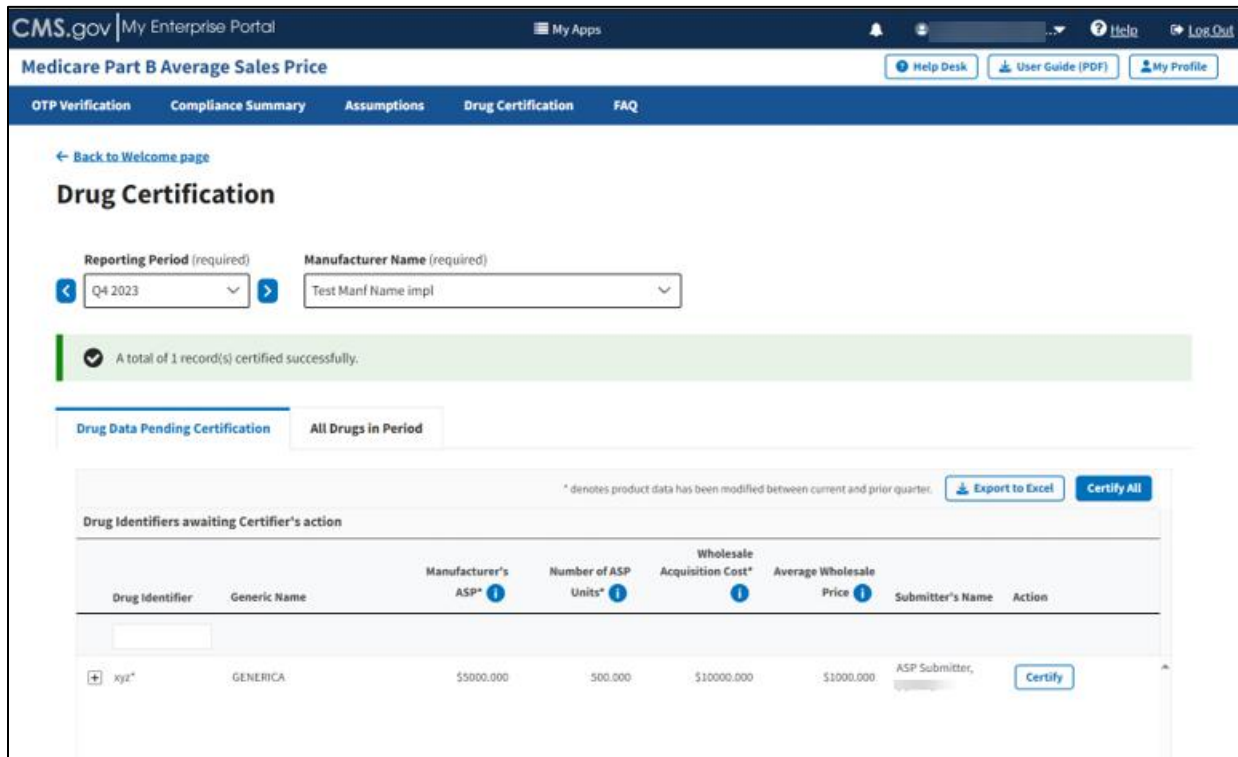


Figure 4446: Data Certification - Confirmation Message

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

5. Continue this process for each individual drug product until all your products have been certified. Click **Certify All** to certify all products at the same time.

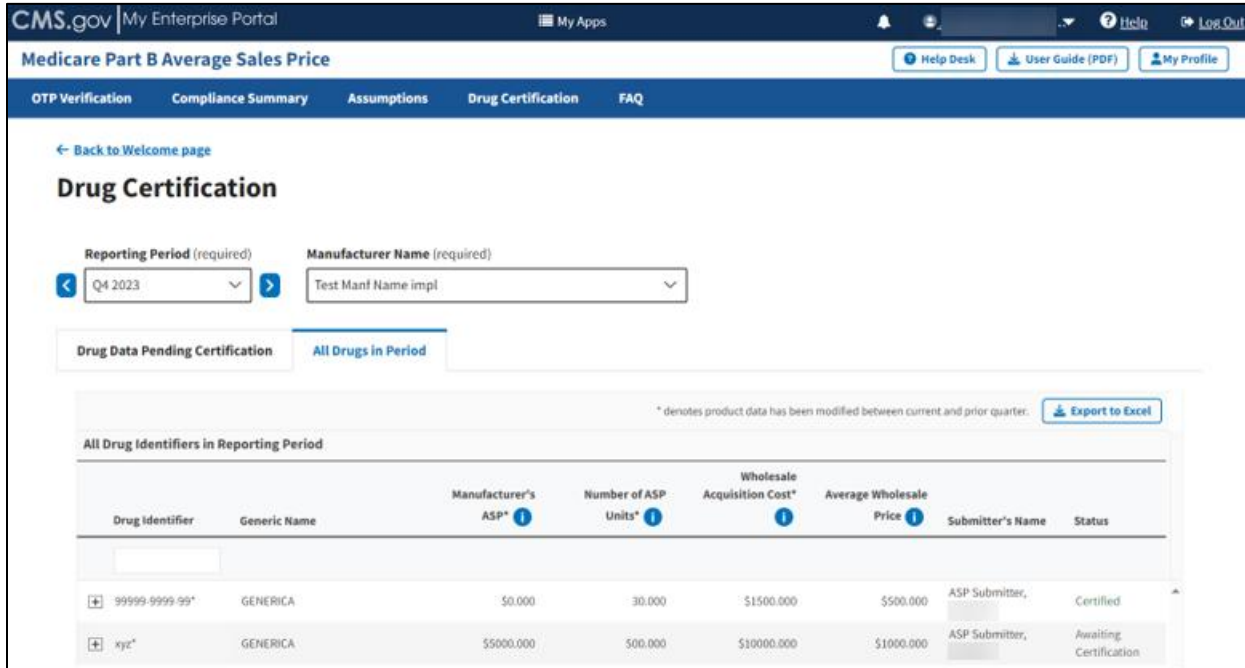
3.5.4 All Drugs in Period

Follow these steps to review all drug products and biologicals for the current reporting period:

1. From the **Drug Certification** homepage, click the **All Drugs in Period** tab.

The **All Drugs in Period** page opens. Refer to [Figure 45Figure 41](#).

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Reporting Period (required): Q4 2023
 Manufacturer Name (required): Test Manf Name impl

Drug Data Pending Certification | All Drugs in Period

* denotes product data has been modified between current and prior quarter. [Export to Excel](#)

| Drug Identifier | Generic Name | Manufacturer's ASP* | Number of ASP Units* | Wholesale Acquisition Cost* | Average Wholesale Price | Submitter's Name | Status |
|-----------------|----------------|---------------------|----------------------|-----------------------------|-------------------------|------------------|---------------------------------------|
| + | 99999-9999-99* | GENERICA | 50.000 | 30.000 | \$1500.000 | \$500.000 | ASP Submitter, Certified |
| + | xyz* | GENERICA | \$5000.000 | 500.000 | \$10000.000 | \$1000.000 | ASP Submitter, Awaiting Certification |

Figure 4547: Drug Certification - All Drugs in Period

This page lists all drug products the Submitter entered for the current reporting period. The Module organizes the full list by **Drug Identifier and Generic Name, the Manufacturer's ASP, the Number of ASP Units, the Wholesale Acquisition Cost, the Average Wholesale Price, and Status.**

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

- Click the plus symbol on each row of the table to expand each product's information and view additional Drug Product data fields, such as **Brand Name, First Marketing Date, Volume per Item**, and all other information the Submitter previously reported.
- Review the information for accuracy.
- Return to the **Compliance Summary** tab to review your certified products after they have undergone drug certification. Refer to [Section 3.2.3 - Certified](#).

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4. Technical Support Contact Information

Contact the FFSDCS (ASP) Application Helpdesk for issues such as:

- Account unlock
- Password reset
- Registration process questions
- System availability escalations

Table 1 provides contact information for technical support.

Table 1: Technical Support Contacts

| Email Address | Phone Number | Hours |
|--|----------------|---|
| ASPHelpDesk@dcca.com | 1-844-876-0765 | 9:00 a.m. to 6:00 p.m. Eastern Standard Time (EST), Monday through Friday |

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Appendix A: Field Definitions

Table 2 provides an overview of field definitions for this document.

Table 2: Field Definitions

| Column/Field Name | Format | Allowed/Sample Values | Required/Optional | Notes |
|--------------------------|----------------|---|-------------------|---|
| Manufacturer Name | Alphanumeric | Maximum of 250 characters | Required | <ul style="list-style-type: none"> When entering product data for the same Manufacturer more than once, be sure the spelling matches. Special characters (comma, dash, period) allowed. |
| NDC1 | 5-digit number | e.g., 12345 | Required | <ul style="list-style-type: none"> First segment of the National Drug Code (NDC) that identifies the labeler. Products that do not have an NDC should only use the Alternate ID column. Not required if the product has an Alternate ID. Leading zero allowed. |
| NDC2 | 4-digit number | e.g., 1234 | Required | <ul style="list-style-type: none"> Not required if the product has an Alternate ID. The NDC2 is the sixth through the ninth digits of the 11-digit NDC that identifies the product. |
| NDC3 | 2-digit number | e.g., 12 | Required | <ul style="list-style-type: none"> Not required if the product has an Alternate ID. The NDC3 is the last two digits of the 11-digit NDC that identify the package size. |
| Alternate ID | alphanumeric | maximum of 23 characters | Required | <ul style="list-style-type: none"> Not required if the product has an NDC. Must match product ID exactly as listed publicly on the manufacturer's website. Special characters (colon, dash, period) allowed. |
| Alternate ID Website URL | NA | e.g., http://www.medicare.gov | NA | Must have http:// or https:// prefix. |

| Column/Field Name | Format | Allowed/Sample Values | Required/Optional | Notes |
|--|--------------|--|-------------------|---|
| Brand Name | Alphanumeric | Maximum of 250 characters | Optional | Enter strength and package size in their respective fields unless it is a part of the registered brand name. |
| Generic Name | Alphanumeric | Maximum of 250 characters | Required | Refer to valid values in Generic Name. |
| Volume Per Item | Numeric | NA | Required | For Alternate ID, report the volume amount in one item. (For instance, enter 10 for 10 ml in one vial, and enter 1 for powders, sheets, or patches.) |
| Unit for Volume per Item | NA | NA | NA | See valid value in Unit of Volume per Item. For example, for Alternate ID, select EACH for powders, sheets, or patches. |
| Number of Items Per NDC or Alternate ID | Numeric | Maximum of 9 digits and 2 decimal places | Required | <ul style="list-style-type: none"> For NDCs: Indicates the number units within the NDC package (for instance, enter 5 for 5 vials in a package). For Alternate IDs: Indicates the number of units within the Alternate ID. (for instance, enter 5 for 5 grafts in a package). |
| Package Type | Alphanumeric | 2 characters | Required | Enter SD, MD, or NA. (SD = Single dose, MD = Multi dose, NA = Not Applicable) |
| Strength | Numeric | e.g., 300 | Required | NA |
| Unit for Strength | NA | NA | NA | See valid values in Unit for Strength |
| FDA Application Number/Registration Number | Alphanumeric | Maximum of 6 characters | Required | <ul style="list-style-type: none"> Enter FDA Application Number for NDCs and Registration Number for Alternate IDs. Enter Facility Registration Number for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). |
| FDA Application Supplement Number | Alphanumeric | Maximum of 9 characters | Optional | NA |

| Column/Field Name | Format | Allowed/Sample Values | Required/Optional | Notes |
|---|--------------|-------------------------|-------------------|---|
| Additional FDA Application Number #1 | Alphanumeric | Maximum of 6 characters | Optional | NA |
| Additional FDA Application Supplement Number #1 | Alphanumeric | Maximum of 9 characters | Optional | NA |
| Additional FDA Application Number #2 | Alphanumeric | Maximum of 6 characters | Optional | NA |
| Additional FDA Application Supplement Number #2 | Alphanumeric | Maximum of 9 characters | Optional | NA |
| FDA Approval/Registration Date | MM/DD/YYYY | e.g., 01/01/2023 | Required | Must be prior to the current submission period start date. |
| FDA Approval Type | NA | NA | Required | Refer to valid values in FDA Approval Type. |
| First Marketing Date | MM/DD/YYYY | e.g., 01/01/2023 | Required | <ul style="list-style-type: none"> • Must be on or after the FDA Approval Date. • Must be prior to the current submission period start date. If the date is after the current submission period start date, it must be submitted as an off-cycle submission. • NDC: For drugs marketed under an FDA-approved application (e.g., Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), New Drug Application (NDA)), the earliest date the drug was first marketed under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the First Marketing Date should be equal to the First Marketing Date of the original product. |

| Column/Field Name | Format | Allowed/Sample Values | Required/Optional | Notes |
|-------------------------------------|------------|-----------------------|-------------------|--|
| First Marketing Date (continued) | MM/DD/YYYY | e.g., 01/01/2023 | Required | <ul style="list-style-type: none"> • Alternate ID: For products marketed under an FDA-approved application/registration (e.g., 510(k), HCT/P, Premarket Approval (PMA)), the earliest date the product was first marketed under the application/registration number by any labeler. If a product was purchased or otherwise acquired from another labeler, the date should be equal to the First Marketing Date of the original product. |
| Date of First Sale for this Product | MM/DD/YYYY | e.g., 01/01/2023 | Required | <ul style="list-style-type: none"> • Must be after the First Marketing Date. • Must be prior to the current submission reporting period start date unless it is an off-cycle submission. • NDC: The date of first sale of individual NDCs. • Alternate ID: The date of first sale of individual Alternate IDs. |

Appendix B: Revision History

Table 3 provides a revision history for this document.

Table 3: Revision History

| Version Number | Date | Author/Editor | Description of Change |
|----------------|------------|----------------------|---|
| 1.0 | 03/15/2024 | Index Analytics/DCCA | Initial version of ASP Data Collection System Certifier User Guide |
| 2.0 | 08/08/2025 | Index Analytics/DCCA | <ul style="list-style-type: none"> Updated Figure 9 and Figure 12 based on updates to the ASP Data Collection System. Made various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections. |

Appendix C: Glossary

[Table 4](#) presents a list of terms, acronyms, and definitions in this document.

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Table 4: Glossary

| Expanded Form | Acronym/Term | Definition |
|---|--------------|--|
| 510(k) | NA | A 510(k) submission is the mechanism through which the majority of medical devices obtain U.S. marketing clearance. Such devices include catheters, contact lenses, and absorbable sutures. |
| Abbreviated New Drug Application | ANDA | An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. Authorized generics do not require ANDAs. |
| Average Sales Price | ASP | ASP refers to the price at which an organization typically sells a certain class of good or service. CMS uses manufacturer-reported ASPs, based on manufacturers' actual quarterly drug sales, to calculate provider payment amounts for these drugs. Federal law defines the price. |
| Biologics License Application | BLA | A BLA is used to request permission to introduce or deliver a biologic product into interstate commerce. |
| Center for Medicare Management | CMM | The CMM oversees the fee-for-service Medicare program. |
| Centers for Medicare & Medicaid Services | CMS | CMS is a federal agency within the U.S. Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards. |
| Consolidated Appropriations Act, 2021 | CAA | The CAA establishes protections for consumers related to surprise billing and transparency in health care. The No Surprises Act (NSA) is part of the CAA. |
| Eastern Standard Time | EST | EST is the standard time in the 5th time zone west of Greenwich, reckoned at the 75th meridian. This time zone is in the eastern part of the United States. |
| Fee-for-Service Data Collection System | FFSDCS | The FFSDCS is an instrument to collect cost, revenue, utilization, and other information for FFS claims. |
| Human Cells, Tissues, and Cellular Products | HCT/P | HCT/Ps include human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient. The FDA Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps. |
| Interactive Voice Response | IVR | IVR is a technology that allows a computer to detect voice and DTMF keypad inputs. |

| Expanded Form | Acronym/Term | Definition |
|----------------------------|--------------|--|
| Medicare | NA | Medicare is the federal system of health insurance for people over 65 years of age and for certain younger people with disabilities. |
| Medicare Part B | NA | Medicare Part B is the part of Medicare that covers doctor services, outpatient hospital care, and other medical services that Part A does not cover such as physical and occupational therapy, X-rays, medical equipment, or limited ambulance service. |
| Multifactor Authentication | MFA | MFA is a security system that implements more than one form of authentication to verify the legitimacy of a transaction. |
| National Drug Code | NDC | The NDC is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologics the FDA recognizes. |
| New Drug Application | NDA | An NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical drug for sale and marketing. |
| Okta | NA | Okta is an enterprise-grade, identity management service, built for the cloud, but compatible with many on-premises applications. |
| One-Time Password | OTP | An OTP is a password that is valid for only one login session or transaction. |
| Point of Contact | POC | The POC identifies the key person or group serving as the coordinator on a given project. |
| Premarket Approval | PMA | PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Such devices include implants, ventilators, and pacemakers. |
| Short Message Service | SMS | SMS is a text messaging service component of phone, web, or mobile communication systems. It uses standardized communication protocols to allow fixed-line or mobile phone devices to exchange short text messages. |
| Social Security Act | SSA | The SSA is a law that provides income to retired workers aged 65 or older. |

Appendix D: Figures and Tables

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