



Medicare Part B Average Sales Price (ASP) Module

Certifier User Guide

Version 0.1

Date: January 22, 2024

Table of Contents

1. Purpose.....	3
2. Logging in Using MFA.....	4
3. ASP Homepage Menu Tabs.....	11
3.1 One Time Password (OTP) Verification.....	11
3.2 Compliance Summary	13
3.2.1 Missing.....	14
3.2.2 Pending.....	14
3.2.3 Certified	17
3.2.4 New	20
3.2.5 Off Cycle	21
3.2.6 Expired.....	22
3.3 Assumptions.....	23
3.3.1 Create Assumption.....	24
3.3.2 Upload Assumption File	26
3.4 Drug Certification.....	29
3.4.1 Direct Employee.....	32
3.4.2 Contractor	34
3.4.3 Drug Data Pending Certification	36
3.4.4 All Drugs in Period	39
4. Technical Support Contact Information.....	40
Appendix A: Revision History	41
Appendix B: Glossary.....	42
Appendix C: Figures and Tables	44

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-Schedule 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 [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*.

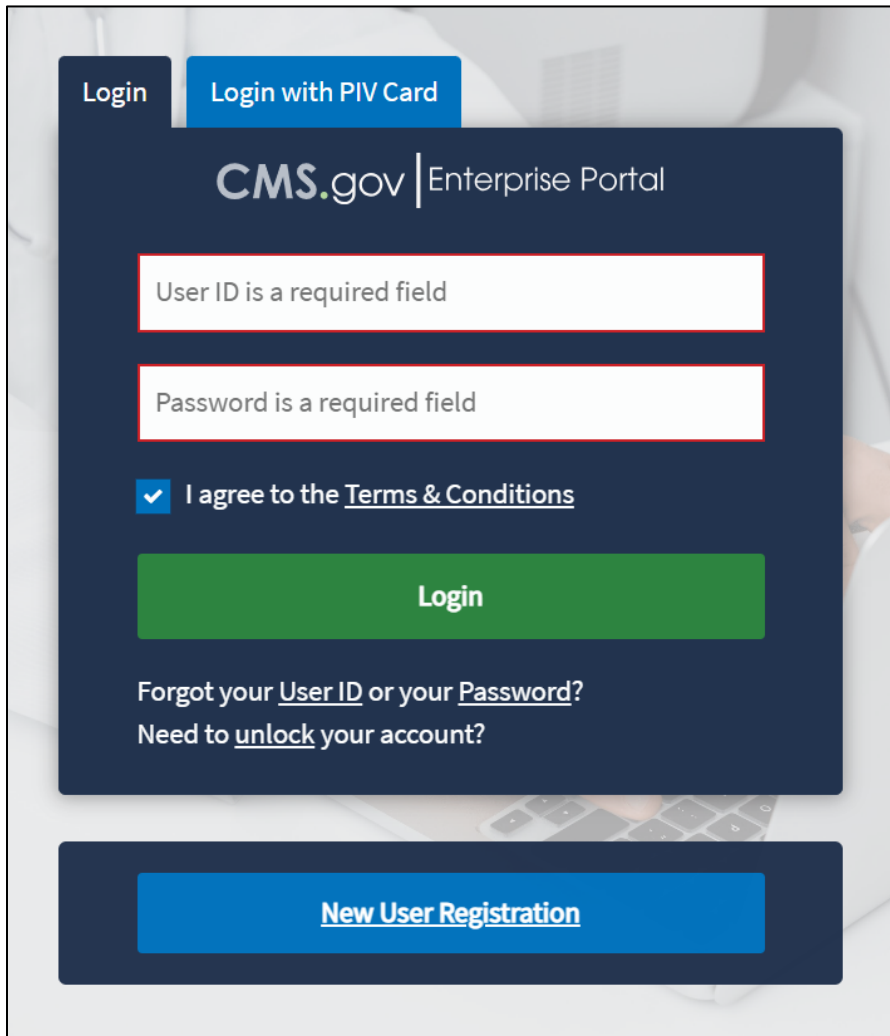


Figure 1: Logging in Using MFA - ASP Module Login

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*.

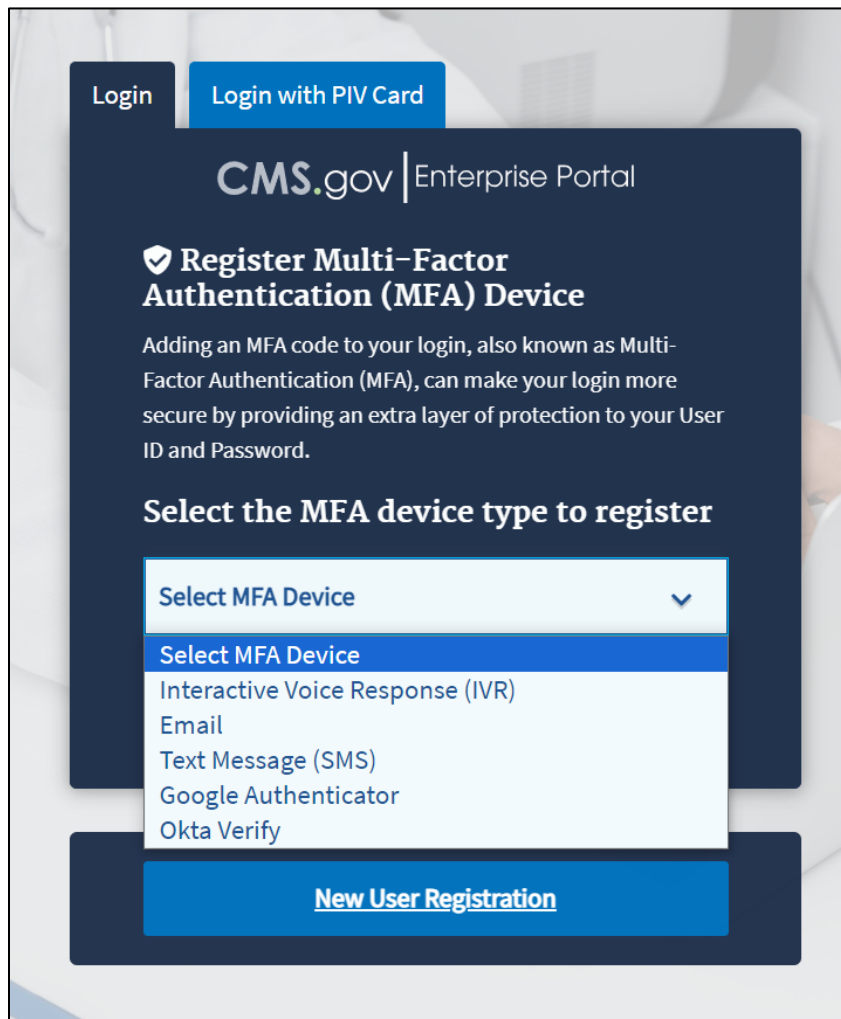
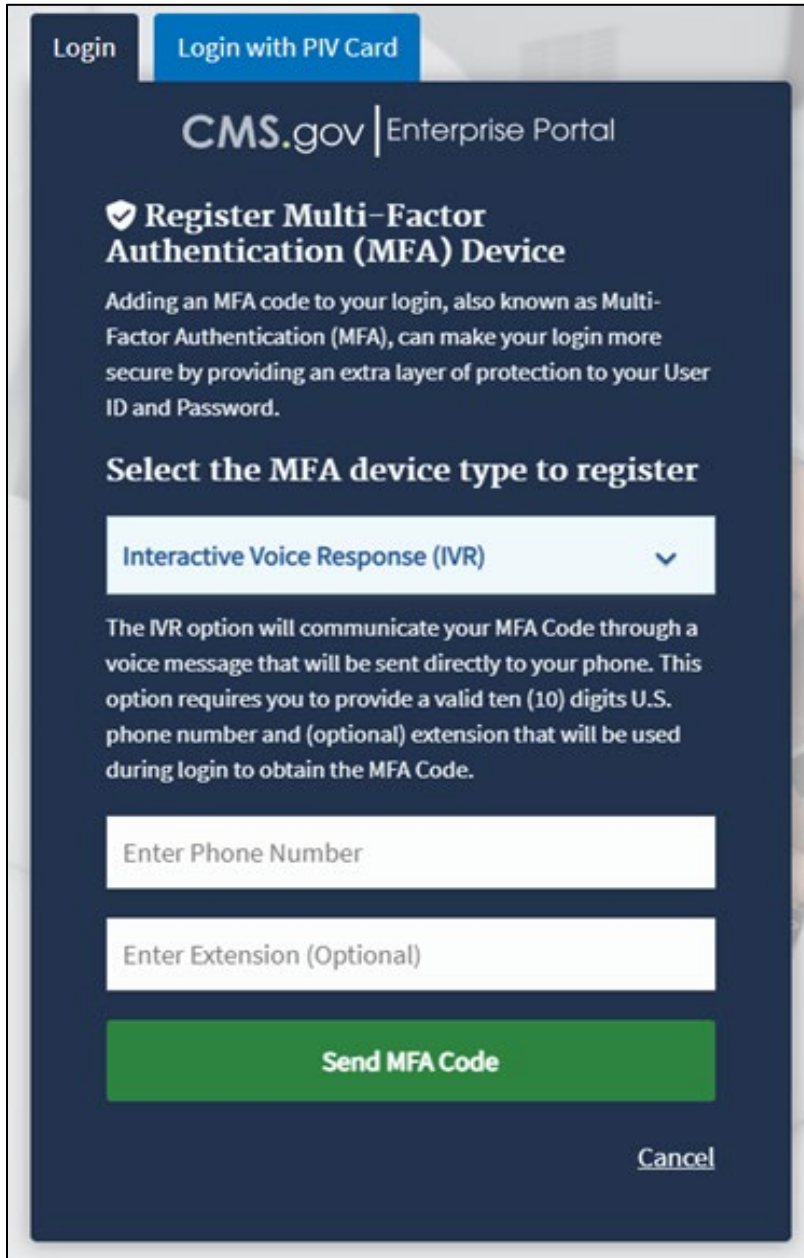


Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down

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.

- 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 'Login' and 'Login with PIV Card' tabs. The main heading is 'Register Multi-Factor Authentication (MFA) Device'. Below this, a paragraph explains that adding an MFA code to the login can make it more secure. A section titled 'Select the MFA device type to register' contains a dropdown menu with 'Interactive Voice Response (IVR)' selected. Below the dropdown, a paragraph explains that the IVR option communicates the MFA code through a voice message to the user's phone, requiring a valid ten-digit U.S. phone number and an optional extension. There are two input fields: 'Enter Phone Number' and 'Enter Extension (Optional)'. A green 'Send MFA Code' button is at the bottom, along with a 'Cancel' link.

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

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

9. Record and enter the six-digit code you received into the **Enter MFA Code** field. Refer to *Figure 4*.

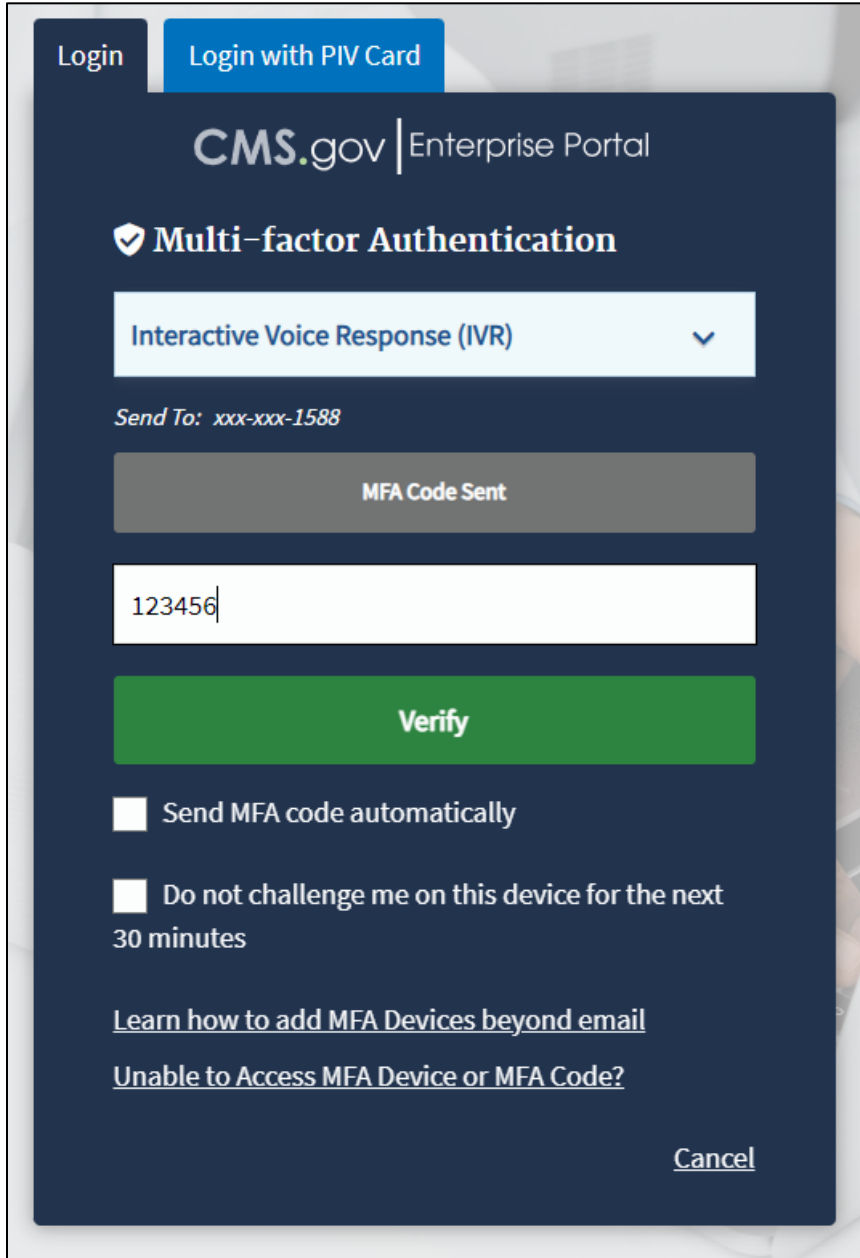


Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

10. 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.

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

The **My Portal** landing page opens. Refer to *Figure 5*.

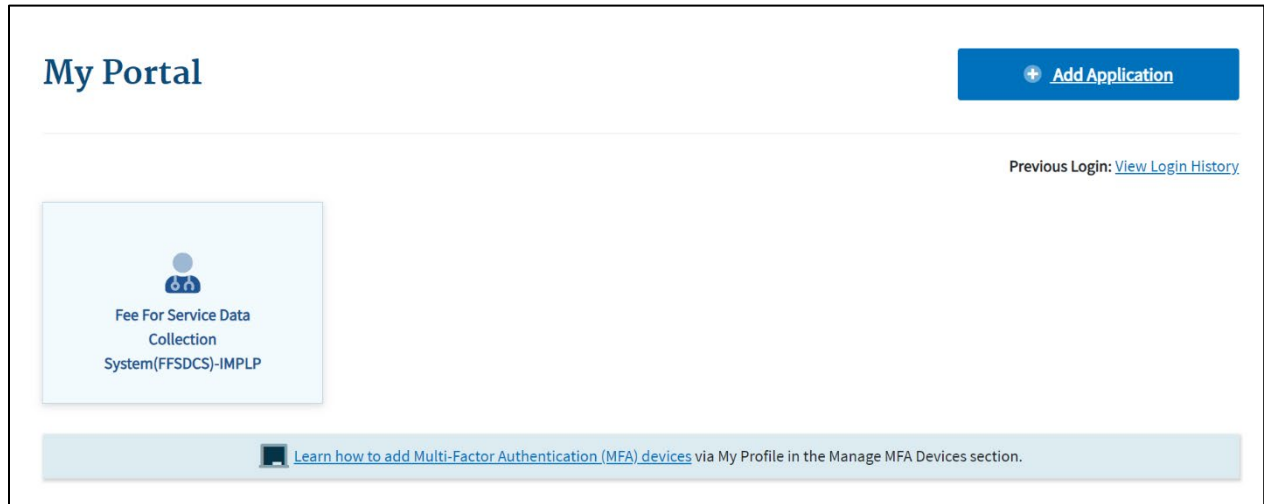


Figure 5: My Portal Landing Page

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

12. 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*.

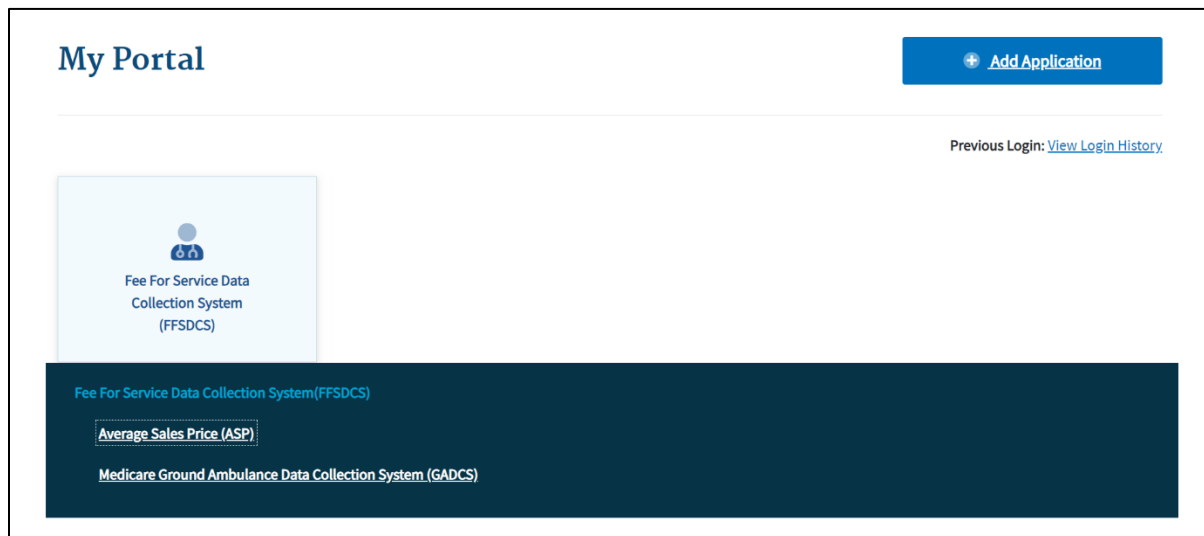
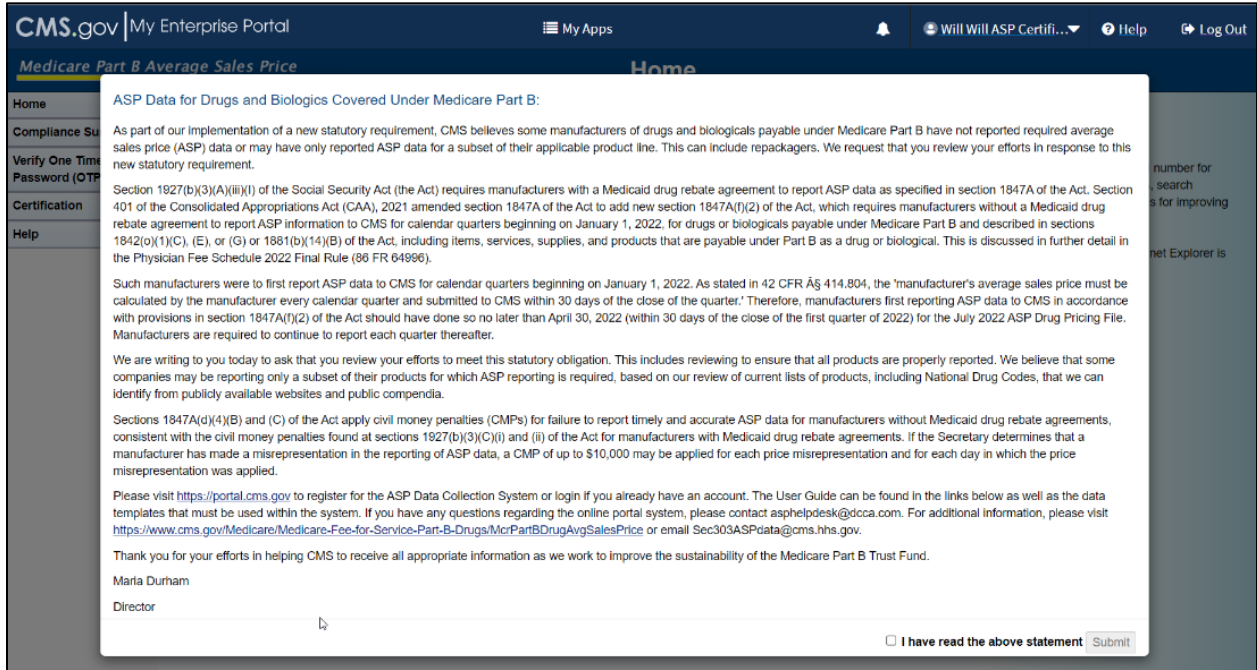


Figure 6: My Portal Landing Page - FFSDCS Drop-down

13. 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*.



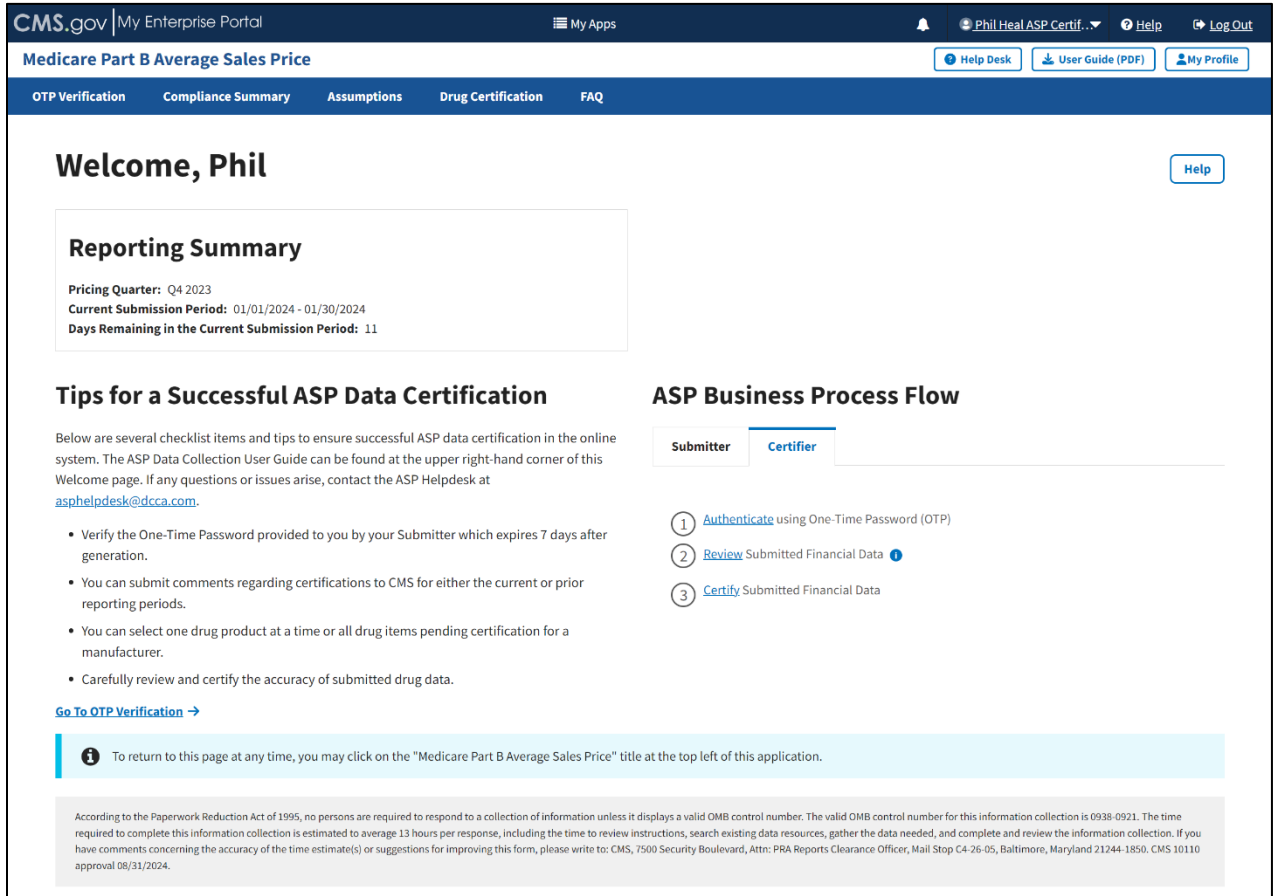
The screenshot shows the CMS.gov My Enterprise Portal. The main content area displays a notification titled "ASP Data for Drugs and Biologics Covered Under Medicare Part B:". The notification text explains the new statutory requirement for manufacturers to report ASP data to CMS for Medicare Part B drugs and biologics starting January 1, 2022. It details the requirements for reporting, including the need to report data for all products covered under Part B, and the consequences of non-compliance, including civil money penalties (CMPs). The notification also provides links to the ASP Data Collection System and the ASP Data User Guide, and offers contact information for assistance.

At the bottom of the notification, there is a checkbox labeled "I have read the above statement" and a "Submit" button.

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*.



CMS.gov | My Enterprise Portal My Apps Phil Heal ASP Certif... Help Log Out

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

[OTP Verification](#) [Compliance Summary](#) [Assumptions](#) [Drug Certification](#) [FAQ](#)

Welcome, Phil

Help

Reporting Summary

Pricing Quarter: Q4 2023
Current Submission Period: 01/01/2024 - 01/30/2024
Days Remaining in the Current Submission Period: 11

Tips for a Successful ASP Data Certification

Below are several checklist items and tips to ensure successful ASP data certification in the online system. The ASP Data Collection User Guide can be found at the upper right-hand corner of this Welcome page. If any questions or issues arise, contact the ASP Helpdesk at asphelpdesk@dcca.com.

- Verify the One-Time Password provided to you by your Submitter which expires 7 days after generation.
- You can submit comments regarding certifications to CMS for either the current or prior reporting periods.
- You can select one drug product at a time or all drug items pending certification for a manufacturer.
- Carefully review and certify the accuracy of submitted drug data.

[Go To OTP Verification](#) →

i To return to this page at any time, you may click on the "Medicare Part B Average Sales Price" title at the top left of this application.

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 0938-0921. 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.

ASP Business Process Flow

Submitter **Certifier**

- 1 [Authenticate](#) using One-Time Password (OTP)
- 2 [Review](#) Submitted Financial Data **i**
- 3 [Certify](#) Submitted Financial Data

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

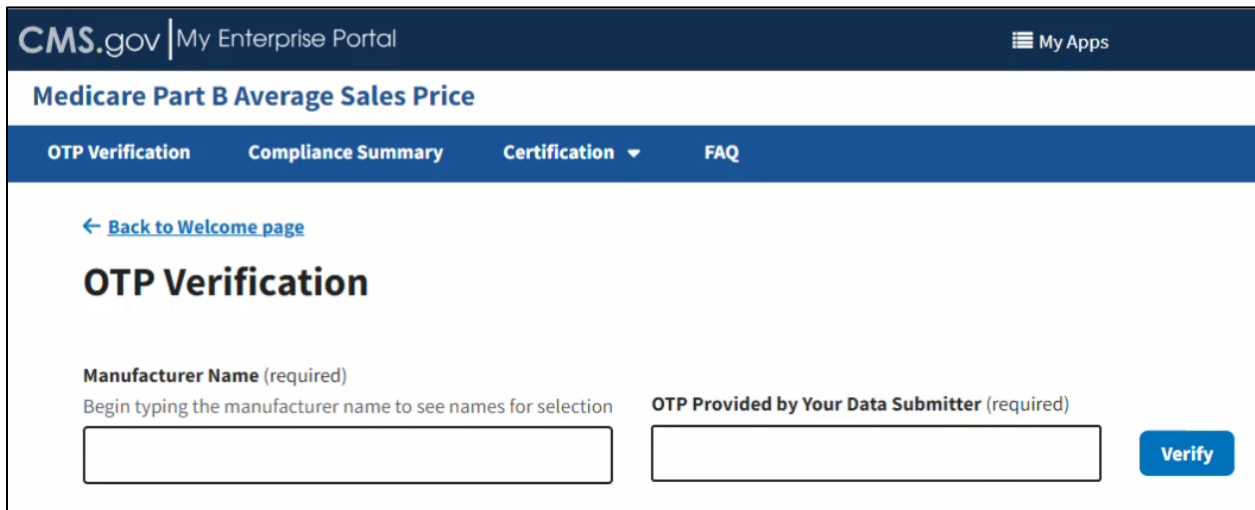
Once the Submitter has completed and submitted product data, the Submitter must share the one-time password (OTP) with the Certifier to establish a relationship within the system. Note the following about OTPs:

- 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.

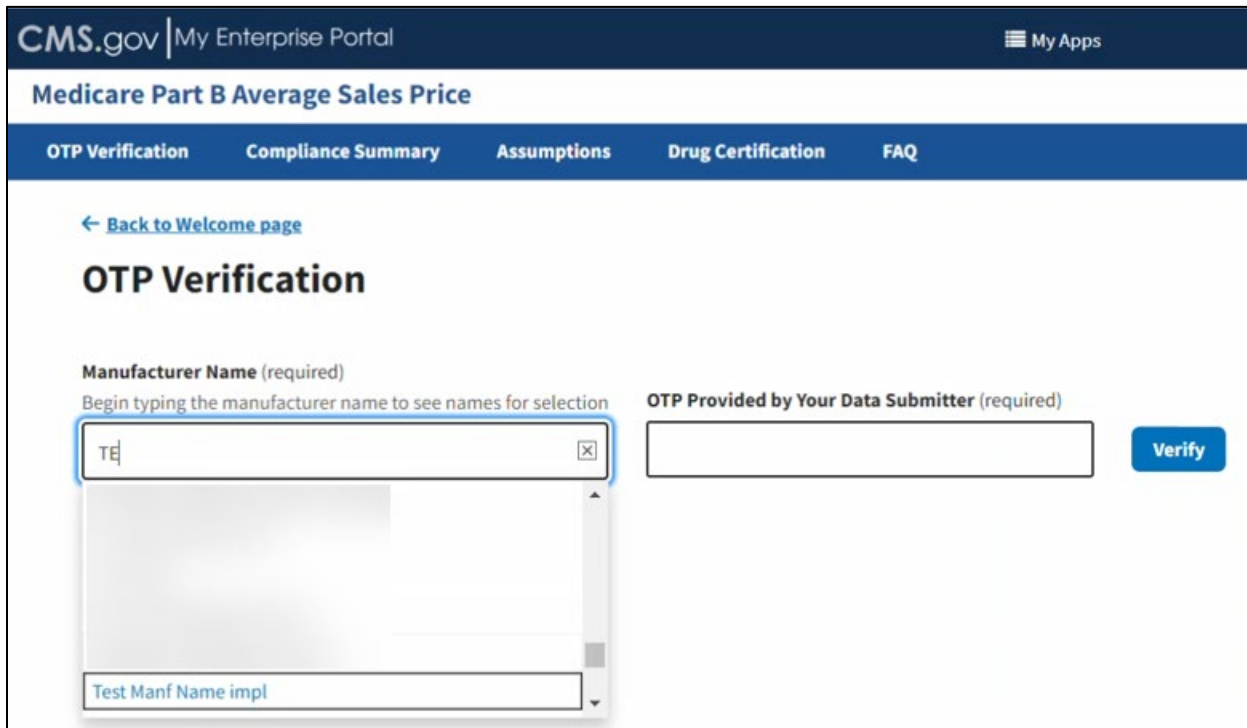
The OTP Verification page opens. Refer to *Figure 9*.



The screenshot shows the CMS.gov My Enterprise Portal interface. The main heading is "Medicare Part B Average Sales Price". Below this is a navigation bar with four tabs: "OTP Verification" (selected), "Compliance Summary", "Certification" (with a dropdown arrow), and "FAQ". The "OTP Verification" section contains a link "← Back to Welcome page" and the title "OTP Verification". There are two input fields: "Manufacturer Name (required)" with a hint "Begin typing the manufacturer name to see names for selection", and "OTP Provided by Your Data Submitter (required)". A blue "Verify" button is located to the right of the OTP field.

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*.



CMS.gov | My Enterprise Portal My Apps

Medicare Part B Average Sales Price

OTP Verification Compliance Summary Assumptions Drug Certification FAQ

[← Back to Welcome page](#)

OTP Verification

Manufacturer Name (required)
Begin typing the manufacturer name to see names for selection

TE

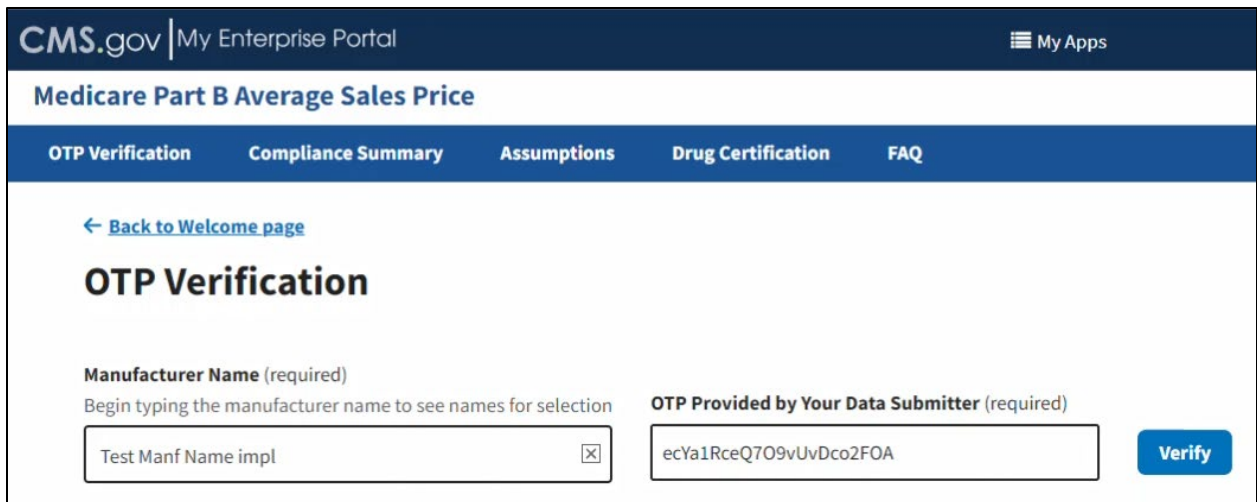
Test Manf Name impl

OTP Provided by Your Data Submitter (required)

Verify

Figure 10: OTP Verification - Manufacturer Name

- Enter the OTP code from the Submitter in the **OTP Provided by Your Data Submitter (required)** field. Refer to *Figure 11*.



CMS.gov | My Enterprise Portal My Apps

Medicare Part B Average Sales Price

OTP Verification Compliance Summary Assumptions Drug Certification FAQ

[← Back to Welcome page](#)

OTP Verification

Manufacturer Name (required)
Begin typing the manufacturer name to see names for selection

Test Manf Name impl

OTP Provided by Your Data Submitter (required)

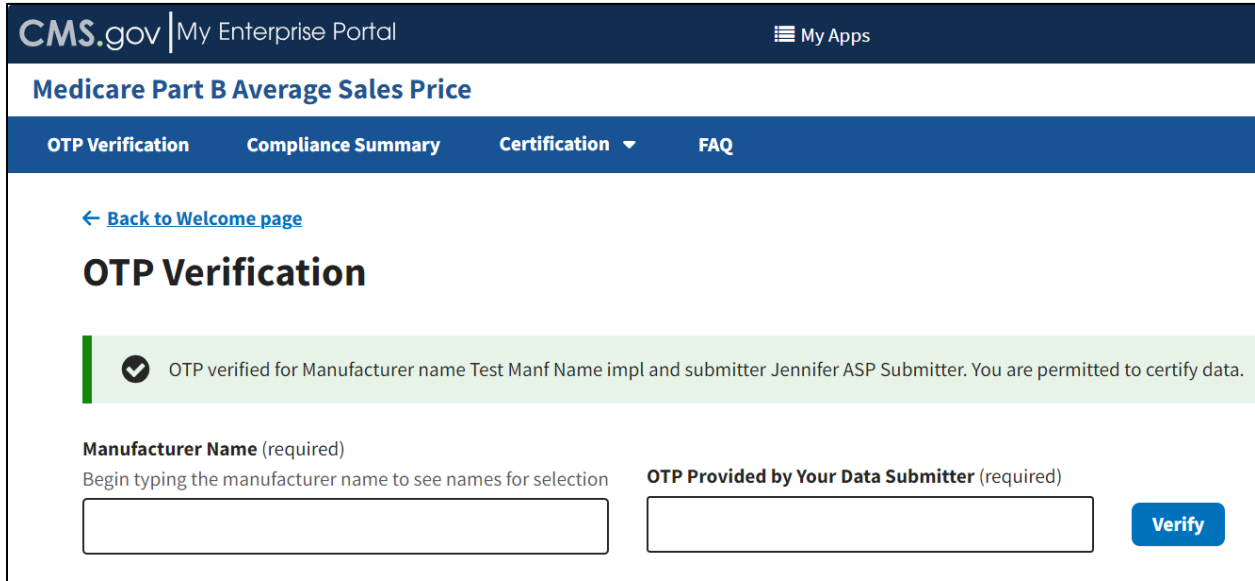
ecYa1RceQ709vUvDco2FOA

Verify

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

- Click **Verify** to confirm the OTP.

A message displaying confirming you have successfully verified the OTP. Refer to *Figure 12*.



The screenshot shows the CMS.gov My Enterprise Portal interface. The main header is dark blue with the CMS.gov logo and 'My Enterprise Portal' text. A navigation bar below the header contains links for 'OTP Verification', 'Compliance Summary', 'Certification', and 'FAQ'. The 'OTP Verification' link is active. The main content area has a light blue background. At the top, there is a link to 'Back to Welcome page'. Below this is the heading 'OTP Verification'. A green success message with a checkmark icon states: 'OTP verified for Manufacturer name Test Manf Name impl and submitter Jennifer ASP Submitter. You are permitted to certify data.' Below the message are two input fields: 'Manufacturer Name (required)' with a hint 'Begin typing the manufacturer name to see names for selection' and 'OTP Provided by Your Data Submitter (required)'. A blue 'Verify' button is positioned to the right of the second input field.

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. 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*.

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

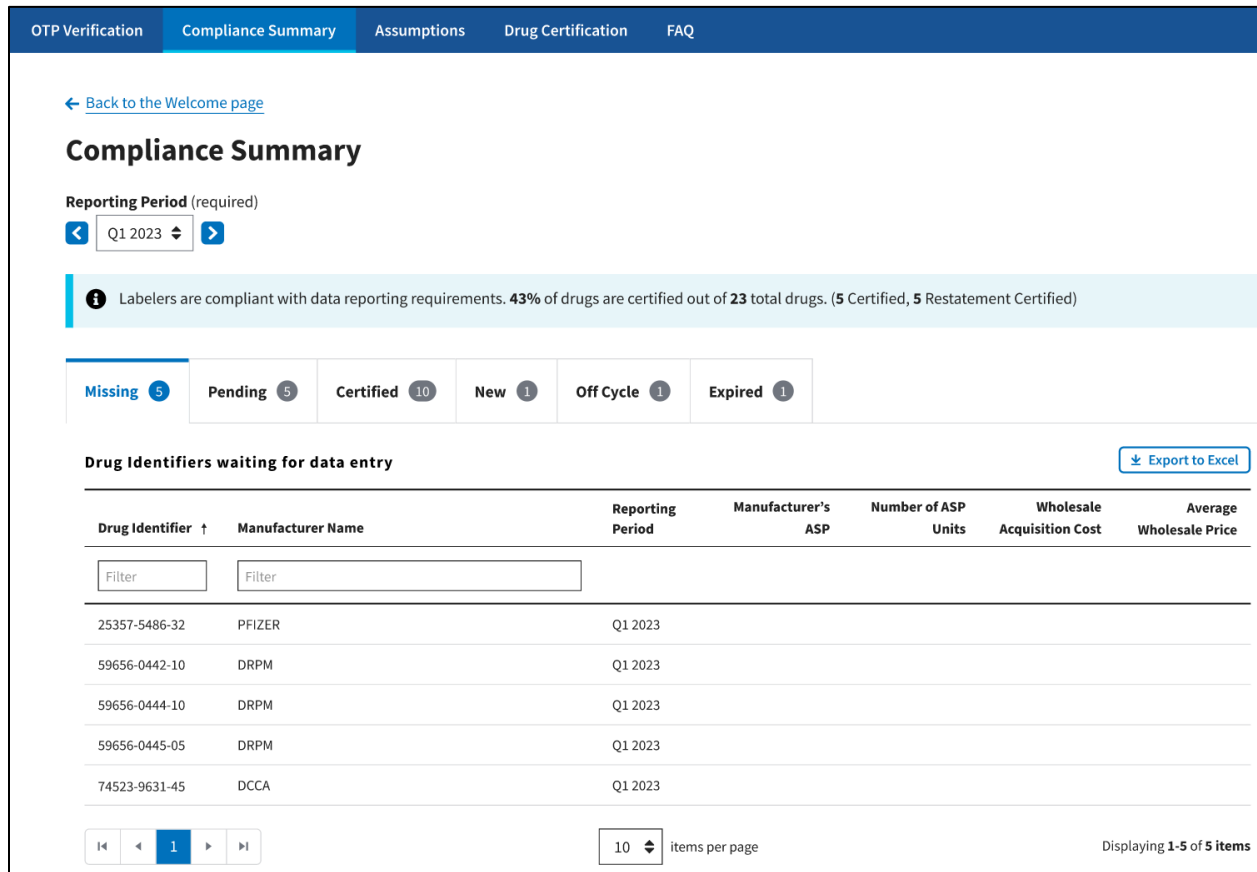


Figure 13: Compliance Summary

Note: Click the **Reporting Period** (required) tab in the top left to scroll through previous quarters. Use the drop-down to navigate 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 fields or incorrect 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.

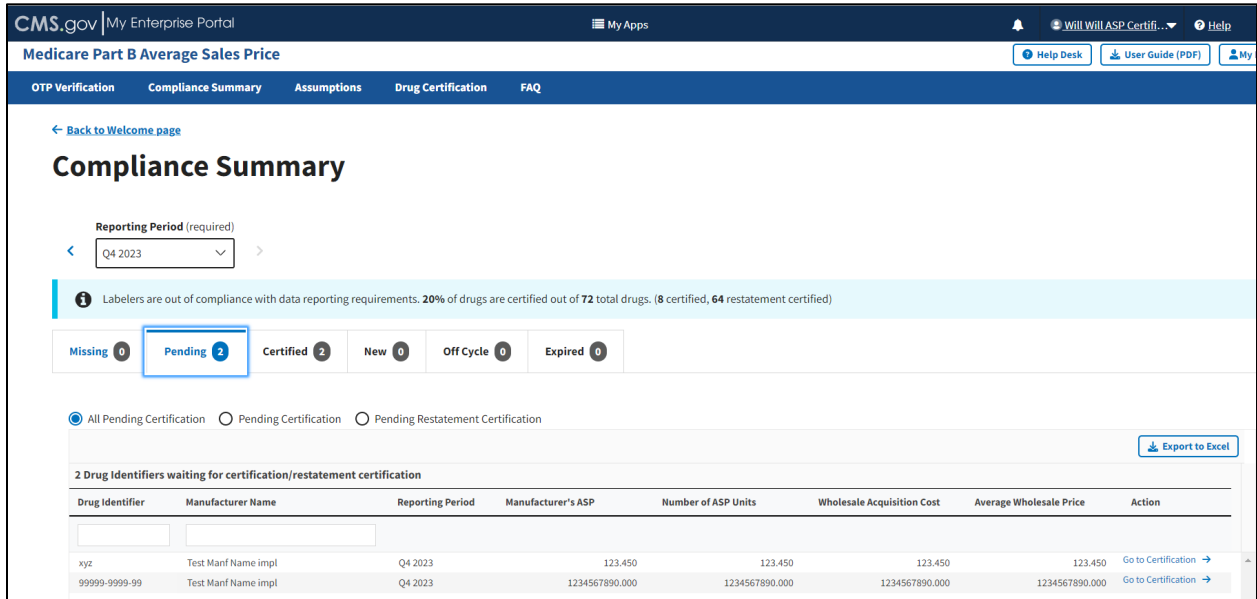
2. Inform the Submitter of any missing financial information or incorrect data to ensure the accuracy of data collected in the Module.
3. Click the **Pending** tab to move on to the next page.

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*.



Compliance Summary

Reporting Period (required)
Q4 2023

Labels are out of compliance with data reporting requirements. 20% of drugs are certified out of 72 total drugs. (8 certified, 64 restatement certified)

Missing 0 Pending 2 Certified 2 New 0 Off Cycle 0 Expired 0

☒ All Pending Certification ☐ Pending Certification ☐ Pending Restatement Certification

Export to Excel

2 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	Action
xyz	Test Manf Name impl	Q4 2023	123.450	123.450	123.450	123.450	Go to Certification →
99999-9999-99	Test Manf Name impl	Q4 2023	1234567890.000	1234567890.000	1234567890.000	1234567890.000	Go to Certification →

Figure 14: Compliance Summary - All Pending Certification

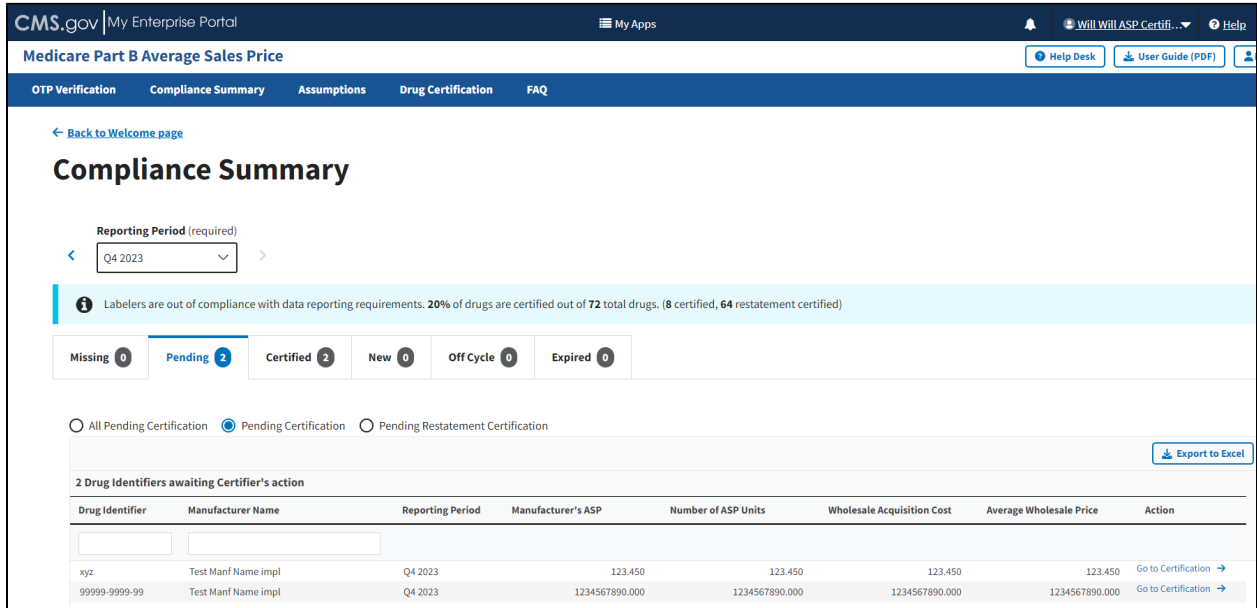
The Module automatically selects the **All Pending Certification** radio button, and the page displays the drug identifiers waiting for certification/restatement certification.

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 3.4 - Drug Certification*.)
4. Click the **Pending Certification** radio button to filter only for drugs pending certification. Refer to *Figure 15*.



← Back to Welcome page

Compliance Summary

Reporting Period (required)
Q4 2023

Labels are out of compliance with data reporting requirements. 20% of drugs are certified out of 72 total drugs. (8 certified, 64 restatement certified)

Missing 0 Pending 2 Certified 2 New 0 Off Cycle 0 Expired 0

☐ All Pending Certification ☒ Pending Certification ☐ Pending Restatement Certification

[Export to Excel](#)

2 Drug Identifiers awaiting Certifier's action

Drug Identifier	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price	Action
xyz	Test Manf Name impl	Q4 2023	123.450	123.450	123.450	123.450	Go to Certification
99999-9999-99	Test Manf Name impl	Q4 2023	1234567890.000	1234567890.000	1234567890.000	1234567890.000	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.
- Click the **Pending Restatement Certification** radio button to filter only for drugs that are pending restatement certification. Refer to *Figure 15*.
- Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to *Section 3.4 - Drug Certification*.)
- Click the **Pending Certification** radio button to filter only for drugs pending certification. Refer to *Figure 16*.

Medicare Part B Average Sales Price

User Guide (PDF)
Help Desk

OTP Verification
Compliance Summary
Assumptions
Drug Certification
FAQ

[Back to the Welcome page](#)

Compliance Summary

Reporting Period (required)

Q1 2023

Labels are compliant with data reporting requirements. 43% of drugs are certified out of 23 total drugs. (5 Certified, 5 Restatement Certified)

Missing 5

Pending 5

Certified 10

New 1

Off Cycle 1

Expired 1

☐ All Pending Certification
☐ Pending Certification
☒ Pending Restatement Certification

2 Drug Identifiers awaiting Certifier's restatement action

Export to Excel

Drug Identifier ↑	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price	Action
Filter	Filter						
76009-1234-10	MERCK	Q1 2023	\$99.111	123.456	\$99.111		Go to Certification →
76009-1234-11	MERCK	Q1 2023	\$44.666	66.777	\$11.999		Go to Certification →

1

10 items per page

Displaying 1-3 of 3 items

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 3.4 - 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**:

12. From the default **Compliance Summary** page, click the **Certified** tab.
The **Certified** page displays. Refer to *Figure 17*.

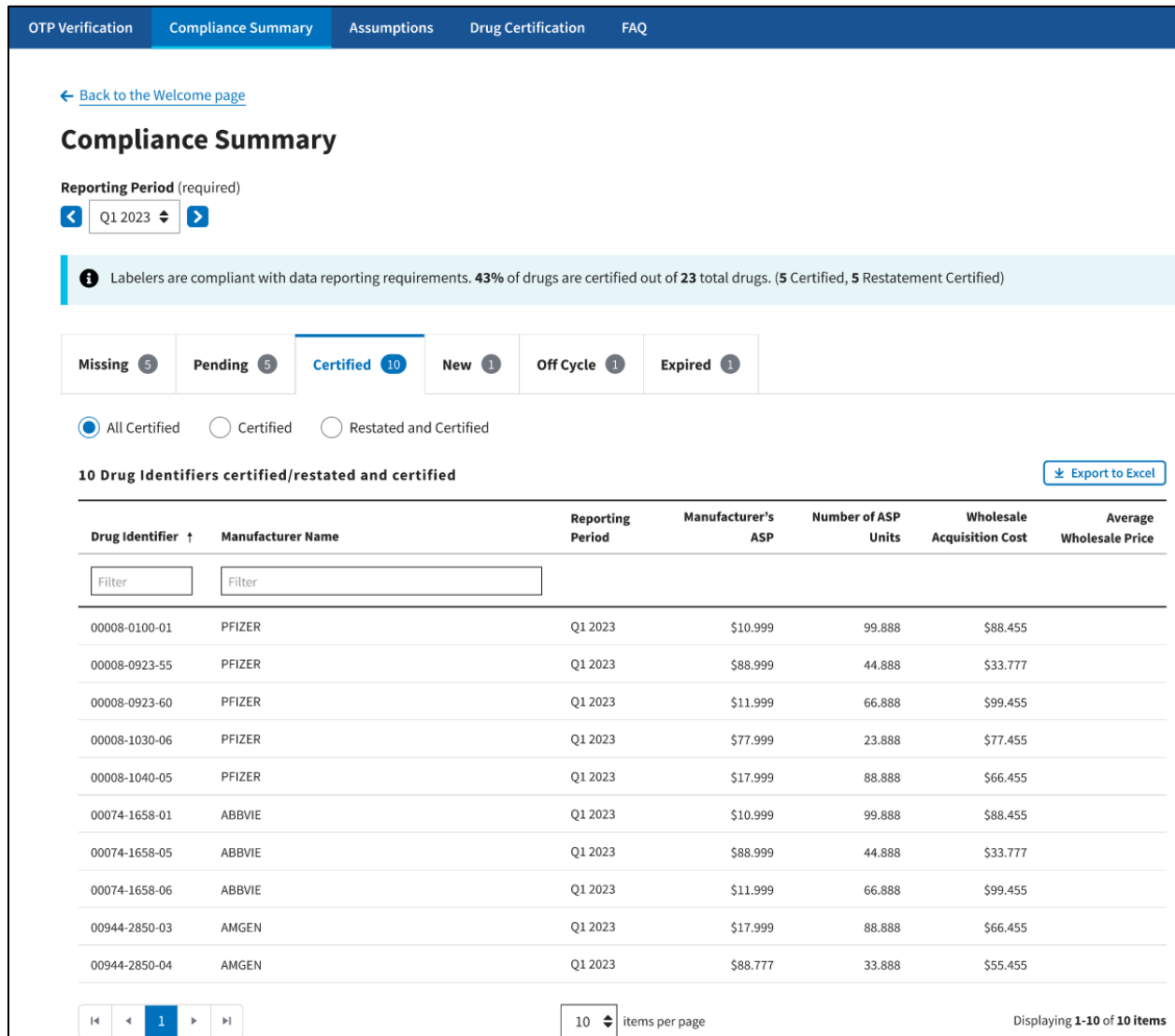


Figure 17: Compliance Summary - Certified

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.

- 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 **Certified** radio button to filter only for certified drugs. Refer to *Figure 18*.

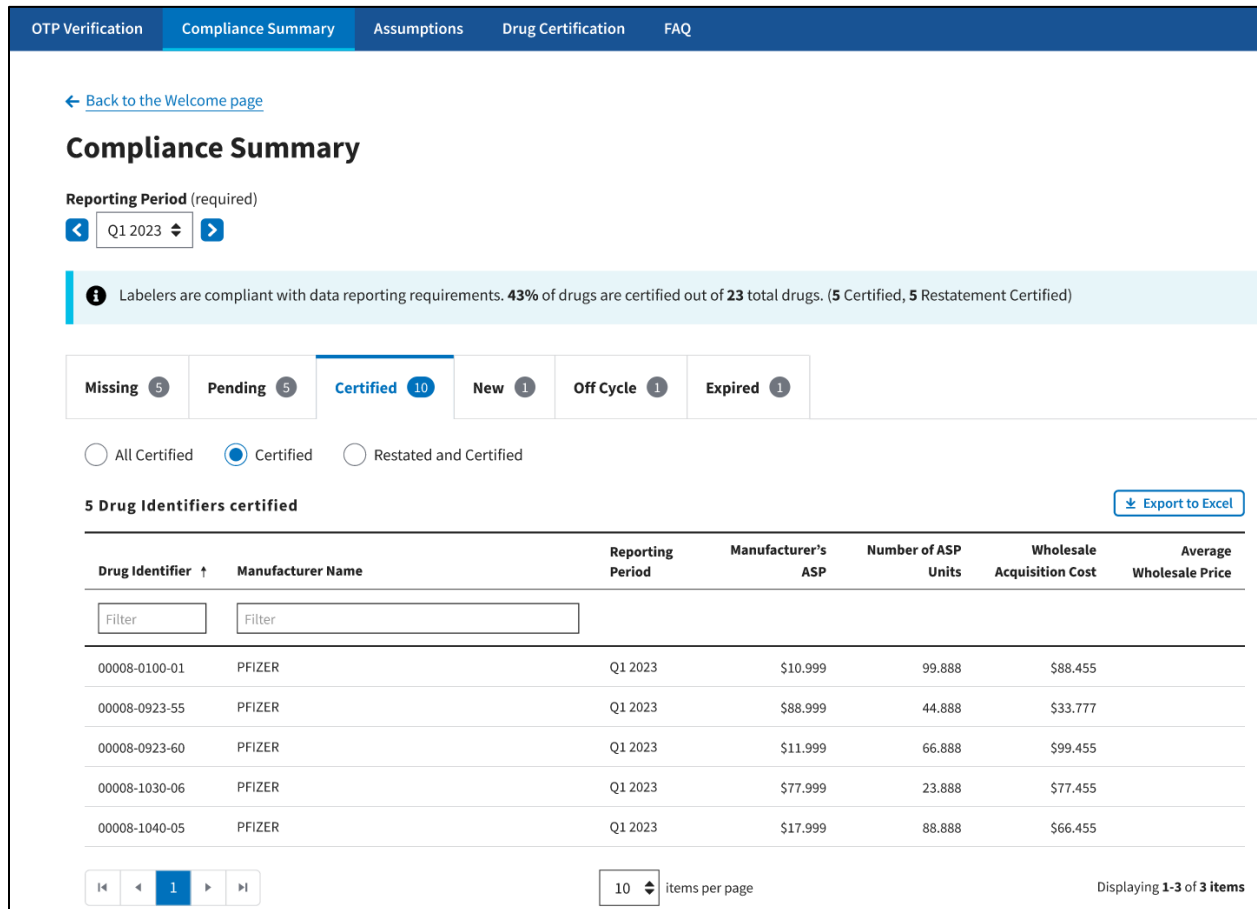


Figure 18: Compliance Summary - Certified

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 and certified drugs. Refer to *Figure 19*.

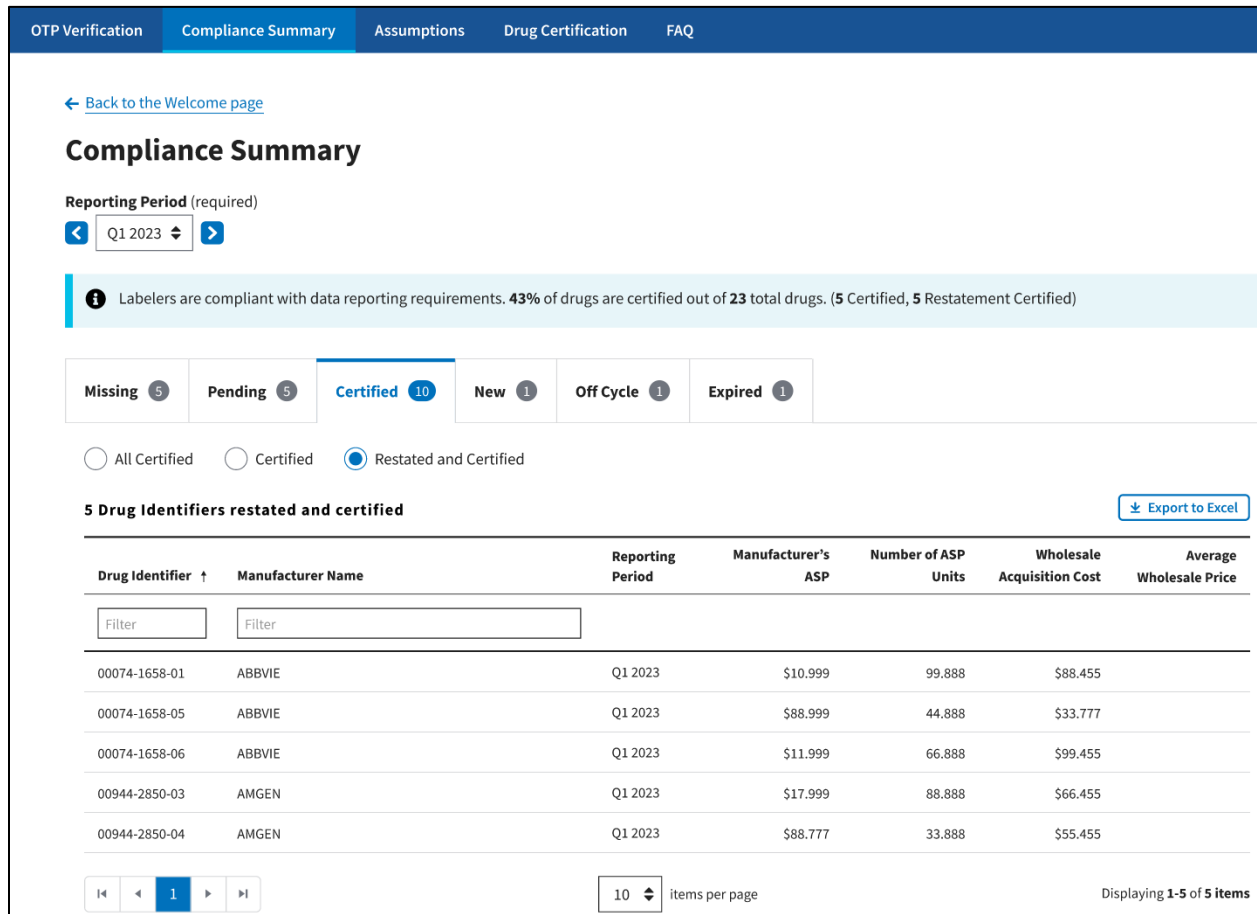


Figure 19: Compliance Summary - Restated and Certified

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**.

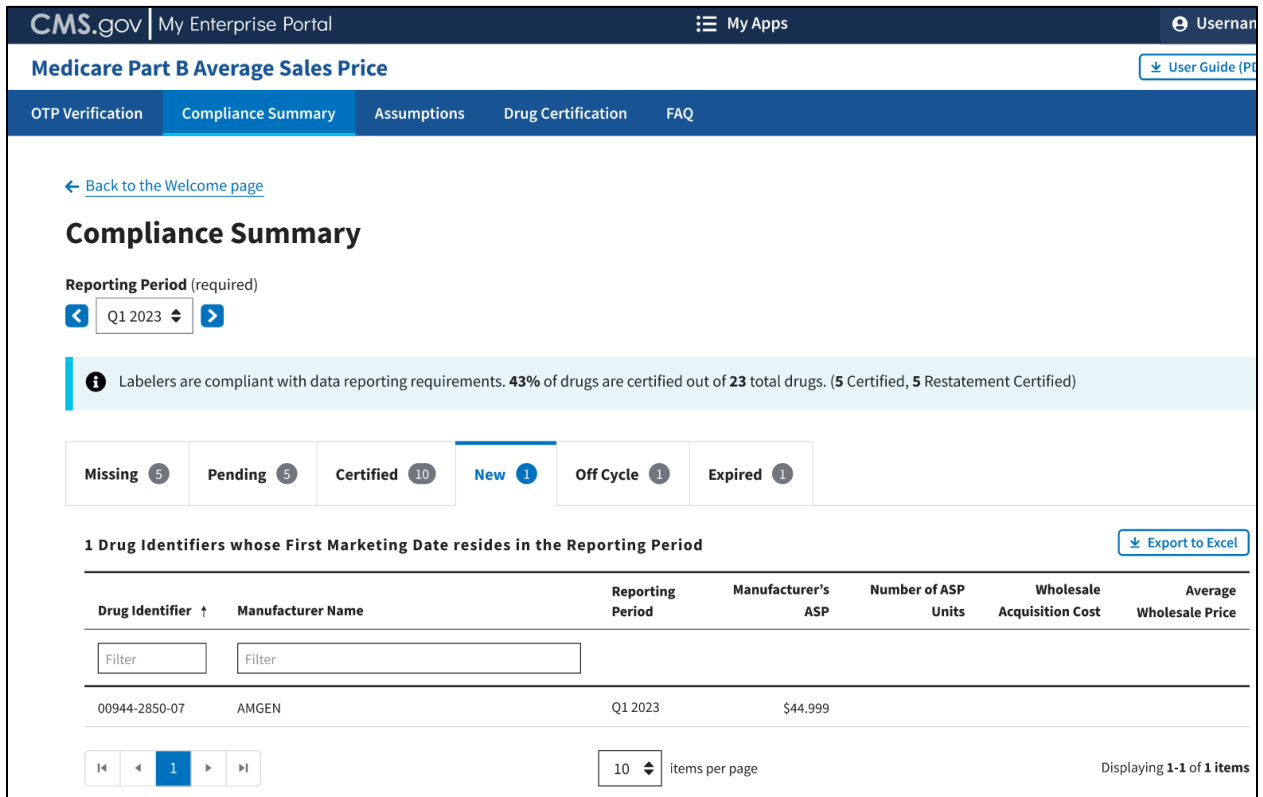
- Click the **New** tab to move on to the next page.

3.2.4 New

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

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

The **New** page displays. Refer to *Figure 20*.



← Back to the Welcome page

Compliance Summary

Reporting Period (required)
 < Q1 2023 >

i Labelers are compliant with data reporting requirements. **43%** of drugs are certified out of **23** total drugs. (5 Certified, 5 Restatement Certified)

Missing 5 Pending 5 Certified 10 **New 1** Off Cycle 1 Expired 1

1 Drug Identifiers whose First Marketing Date resides in the Reporting Period [Export to Excel](#)

Drug Identifier ↑	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price
00944-2850-07	AMGEN	Q1 2023	\$44.999			

Filter Filter

10 items per page

Displaying 1-1 of 1 items

Figure 20: Compliance Summary - New

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

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

The **Off Cycle** page displays. Refer to *Figure 21*.

CMS.gov

My Enterprise Portal

My Apps

Medicare Part B Average Sales Price

OTP Verification

Compliance Summary

Assumptions

Drug Certification

FAQ

[← Back to the Welcome page](#)

Compliance Summary

Reporting Period (required)

Q1 2023

Labels are compliant with data reporting requirements. 43% of drugs are certified out of 23 total drugs. (5 Certified, 5 Restatement Certified)

Missing 5

Pending 5

Certified 10

New 1

Off Cycle 1

Expired 1

1 New Drug Identifiers with partial financial data required

Export to Excel

Drug Identifier ↑	Manufacturer Name	Reporting Period	Wholesale Acquisition Cost	Average Wholesale Price
Filter	Filter			
00074-1658-01	ABBVIE	Q1 2023	\$88.455	

1

10 items per page

Displaying 1-1 of 1 items

Figure 21: Compliance Summary - Off Cycle

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

- 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**.

- 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**:

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

The **Expired** page displays. Refer to *Figure 22*.

CMS.gov

My Enterprise Portal

My Apps

Medicare Part B Average Sales Price

OTP Verification

Compliance Summary

Assumptions

Drug Certification

FAQ

[← Back to the Welcome page](#)

Compliance Summary

Reporting Period (required)

Q1 2023

Labels are compliant with data reporting requirements. **43%** of drugs are certified out of **23** total drugs. (**5** Certified, **5** Restatement Certified)

Missing 5

Pending 5

Certified 10

New 1

Off Cycle 1

Expired 1

1 Drug Identifiers whose Expiration Date has past

Export to Excel

Drug Identifier ↑	Manufacturer Name	First Marketing Date	Expiration Date of Final Lot Sold
Filter	Filter		
00008-2001-25	PFIZER	03/17/2014	02/28/2022

1

10 items per page

Displaying 1-1 of 1 items

Figure 22: Compliance Summary - Expired

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

- 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**.

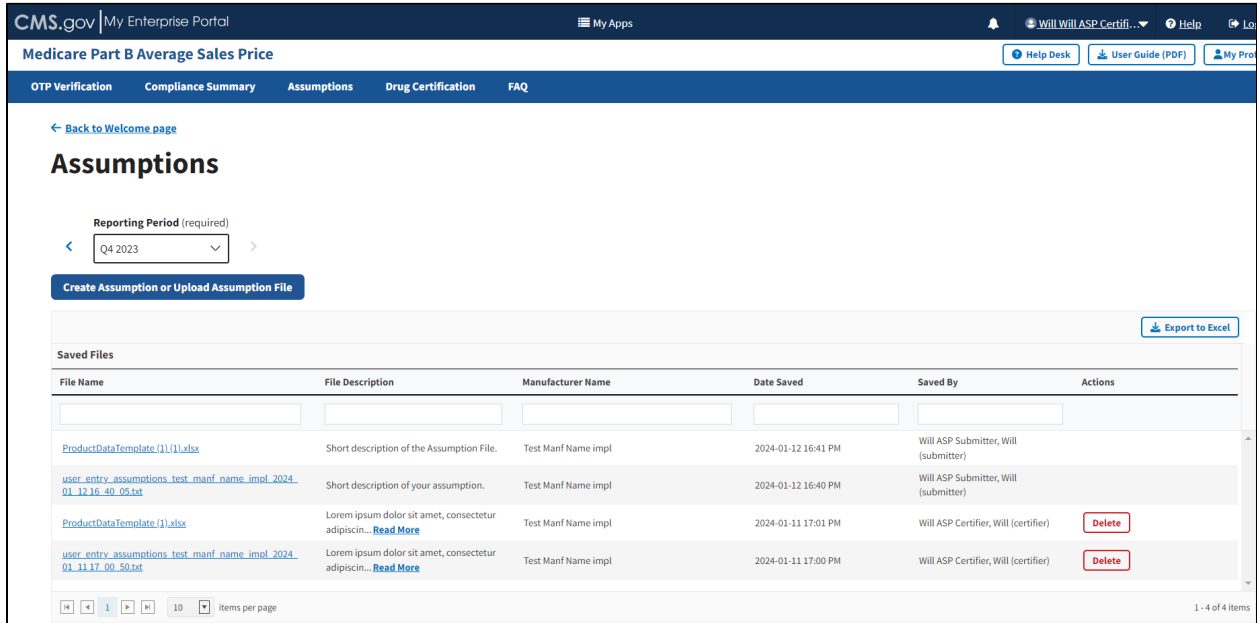
3.3 Assumptions

Drug manufacturers can submit comments regarding their certifications to CMS. Manufacturers may submit these comments for either the current or prior reporting periods.

Follow these steps to submit certification assumptions to CMS:

- 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. Refer to *Figure 23*.



Back to Welcome page

Assumptions

Reporting Period (required)
 < Q4 2023 >

Create Assumption or Upload Assumption File

Export to Excel

File Name	File Description	Manufacturer Name	Date Saved	Saved By	Actions
ProductDataTemplate (1) (1).xlsx	Short description of the Assumption File.	Test Manf Name impl	2024-01-12 16:41 PM	Will ASP Submitter, Will (submitter)	
user_entry_assumptions_test_manf_name_impl_2024-01-12 16:40:05.txt	Short description of your assumption.	Test Manf Name impl	2024-01-12 16:40 PM	Will ASP Submitter, Will (submitter)	
ProductDataTemplate (1).xlsx	Lorem ipsum dolor sit amet, consectetur adipiscing... Read More	Test Manf Name impl	2024-01-11 17:01 PM	Will ASP Certifier, Will (certifier)	Delete
user_entry_assumptions_test_manf_name_impl_2024-01-11 17:00:50.txt	Lorem ipsum dolor sit amet, consectetur adipiscing... Read More	Test Manf Name impl	2024-01-11 17:00 PM	Will ASP Certifier, Will (certifier)	Delete

1 - 4 of 4 items

Figure 23: Assumptions

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

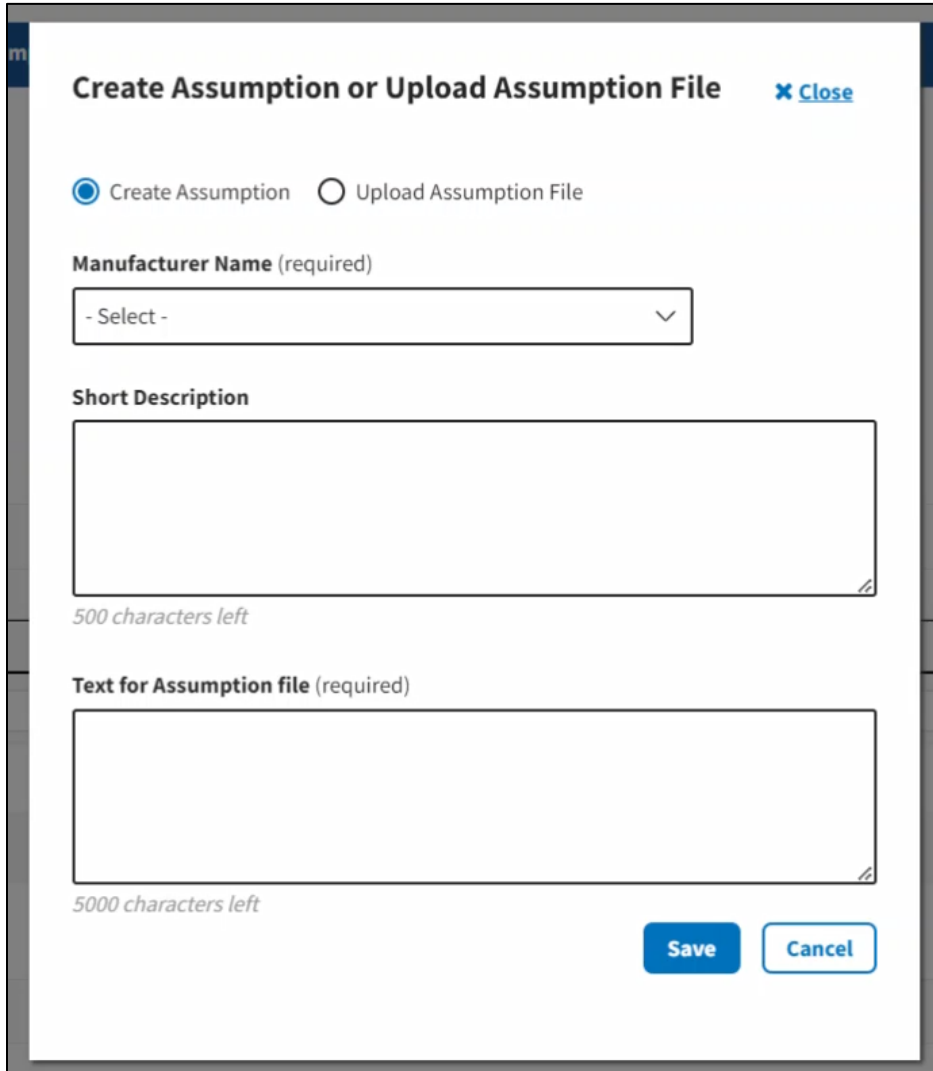
Note: Click the **Export to Excel** box to download all products under the **Assumptions** tab.

3.3.1 Create Assumption

Follow these steps to create an assumption:

1. Click the Create Assumption or Upload Assumption File button.

The **Create Assumption or Upload Assumption File** window displays. 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** fields. Refer to *Figure 24*.



Create Assumption or Upload Assumption File [X Close](#)

☒ Create Assumption ☐ Upload Assumption File

Manufacturer Name (required)

- Select -

Short Description

500 characters left

Text for Assumption file (required)

5000 characters left

Save **Cancel**

Figure 24: Assumptions - Create Assumption or Upload Assumption File

2. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.
3. Complete the **Short Description** and **Text for Assumption file** fields.

Note: The **Short Description** field is optional and allows for 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 5000 characters to provide as much detail as possible related to the selected period's financial submission.

4. Click the **Save** button.

A message displays confirming you have successfully created your **Assumption**. Refer to *Figure 25*.

CMS.gov

My Enterprise Portal

My Apps

Will Will ASP Certifi...

Help

Medicare Part B Average Sales Price

Help Desk

User Guide (PDF)

My

OTP Verification

Compliance Summary

Assumptions

Drug Certification

FAQ

Back to Welcome page

Assumptions

File upload has completed successfully.

Reporting Period (required)

Q4 2023

Create Assumption or Upload Assumption File

Export to Excel

Saved Files

File Name	File Description	Manufacturer Name	Date Saved	Saved By	Actions
user_entry_assumptions_test_manf_name_impl_2024_01_16_10_53_03.txt		Test Manf Name impl	2024-01-16 10:53 AM	Will ASP Certifier, Will (certifier)	Delete
ProductDataTemplate (1) (1).xlsx	Short description of the Assumption File.	Test Manf Name impl	2024-01-12 16:41 PM	Will ASP Submitter, Will (submitter)	
user_entry_assumptions_test_manf_name_impl_2024_01_12_16_40_05.txt	Short description of your assumption.	Test Manf Name impl	2024-01-12 16:40 PM	Will ASP Submitter, Will (submitter)	
ProductDataTemplate (1).xlsx	Lorem ipsum dolor sit amet, consectetur adipiscing... Read More	Test Manf Name impl	2024-01-11 17:01 PM	Will ASP Certifier, Will (certifier)	Delete
user_entry_assumptions_test_manf_name_impl_2024_01_11_17_00_50.txt	Lorem ipsum dolor sit amet, consectetur adipiscing... Read More	Test Manf Name impl	2024-01-11 17:00 PM	Will ASP Certifier, Will (certifier)	Delete

Figure 25: New Assumption Successfully Created

3.3.2 Upload Assumption File

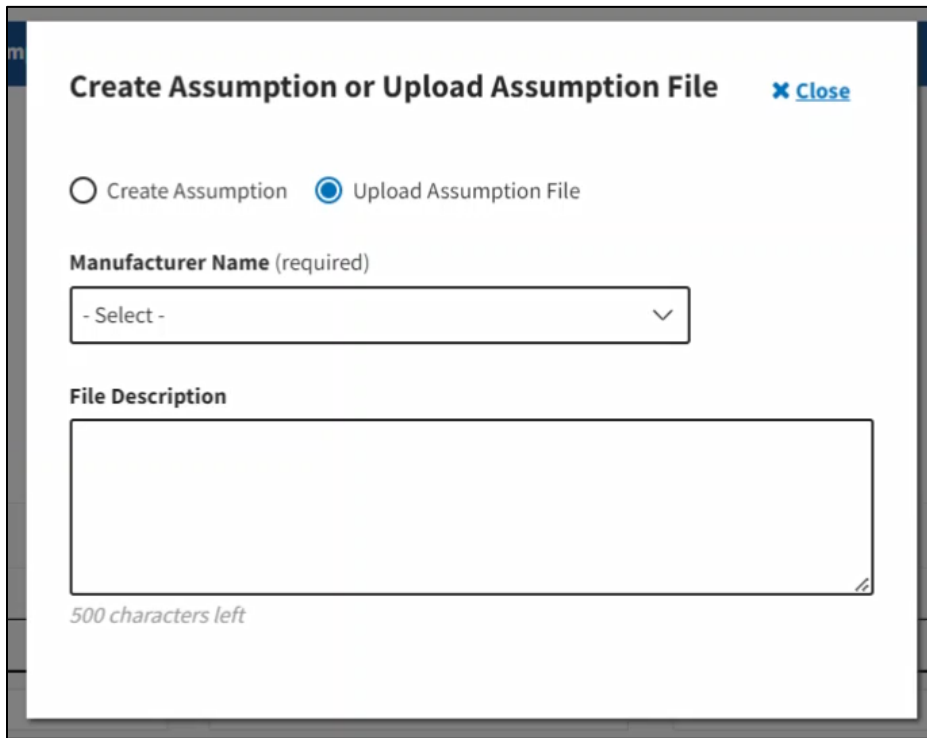
Follow these steps to upload an assumption file to the Module:

1. Click the **Create Assumption or Upload Assumption 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** field display. Refer to *Figure 26*.



Create Assumption or Upload Assumption File [✕ Close](#)

☐ Create Assumption ☒ Upload Assumption File

Manufacturer Name (required)

- Select -

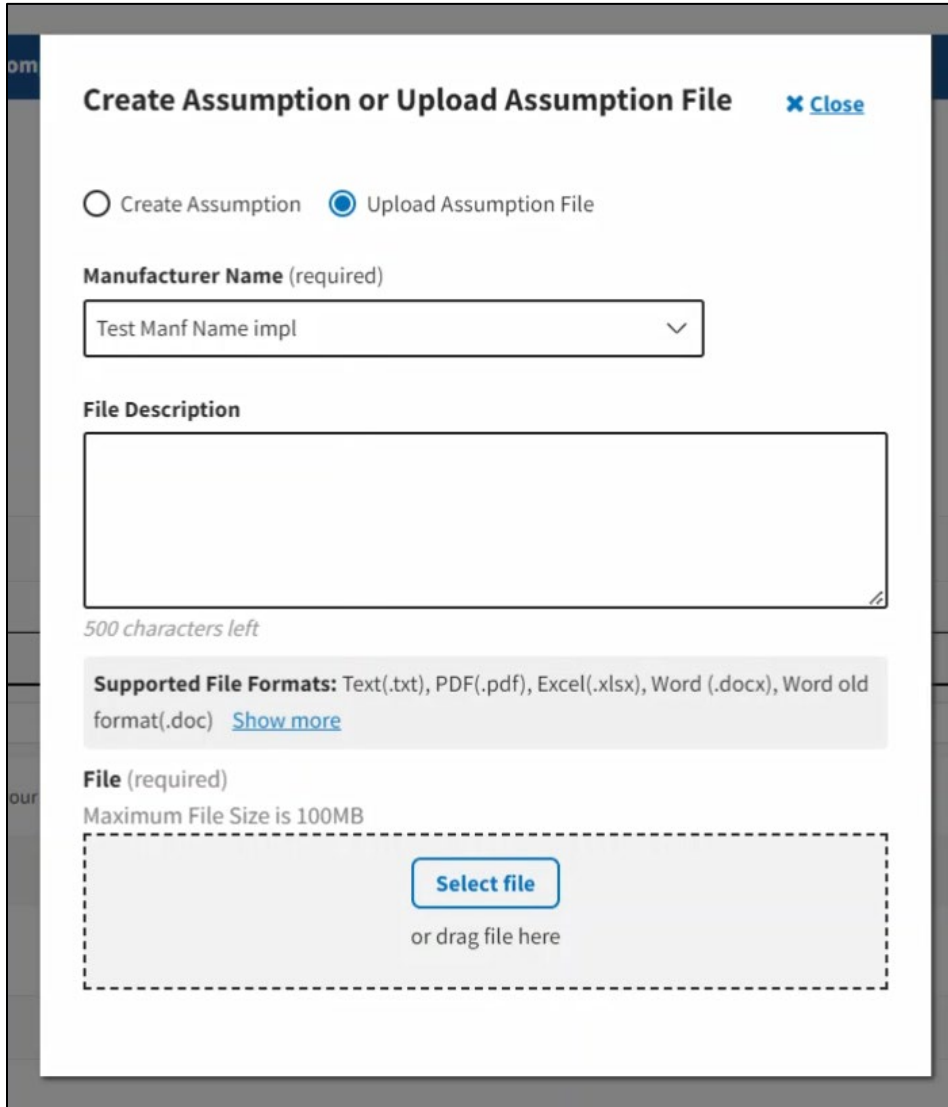
File Description

500 characters left

Figure 26: Upload Assumption File

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

As you select your manufacturer name, new fields display on the screen. Refer to *Figure 27*.



Create Assumption or Upload Assumption File [Close](#)

☐ Create Assumption ☒ Upload Assumption File

Manufacturer Name (required)

Test Manf Name impl

File Description

500 characters left

Supported File Formats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (.docx), Word old format(.doc) [Show more](#)

File (required)
Maximum File Size is 100MB

Select file

or drag file here

Figure 27: Upload Assumption File - Expanded Fields

- 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.

Note: Click the **Show More** tab to display all **Supported File Formats** available in the Module for you to use in your **Assumption File** upload.

- 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. Refer to *Figure 28*.

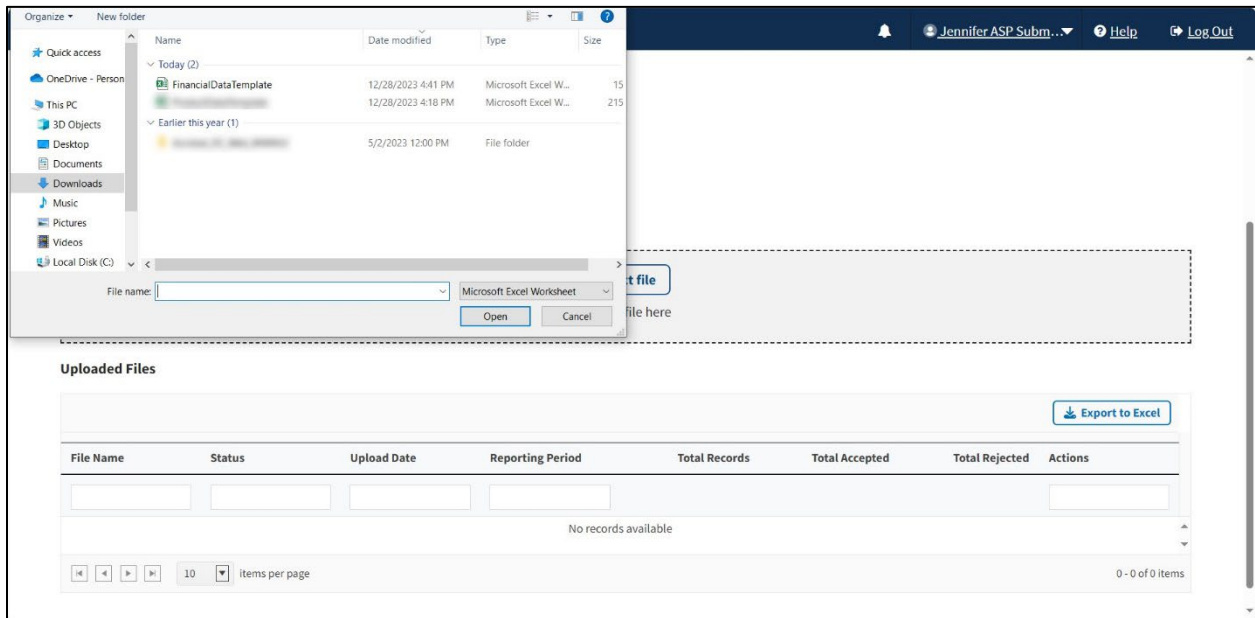


Figure 28: Upload Assumption File - Uploading Files from Desktop

A download bar displays as your file uploads. A message opens to confirm you have successfully uploaded your assumption file. Refer to *Figure 29*.

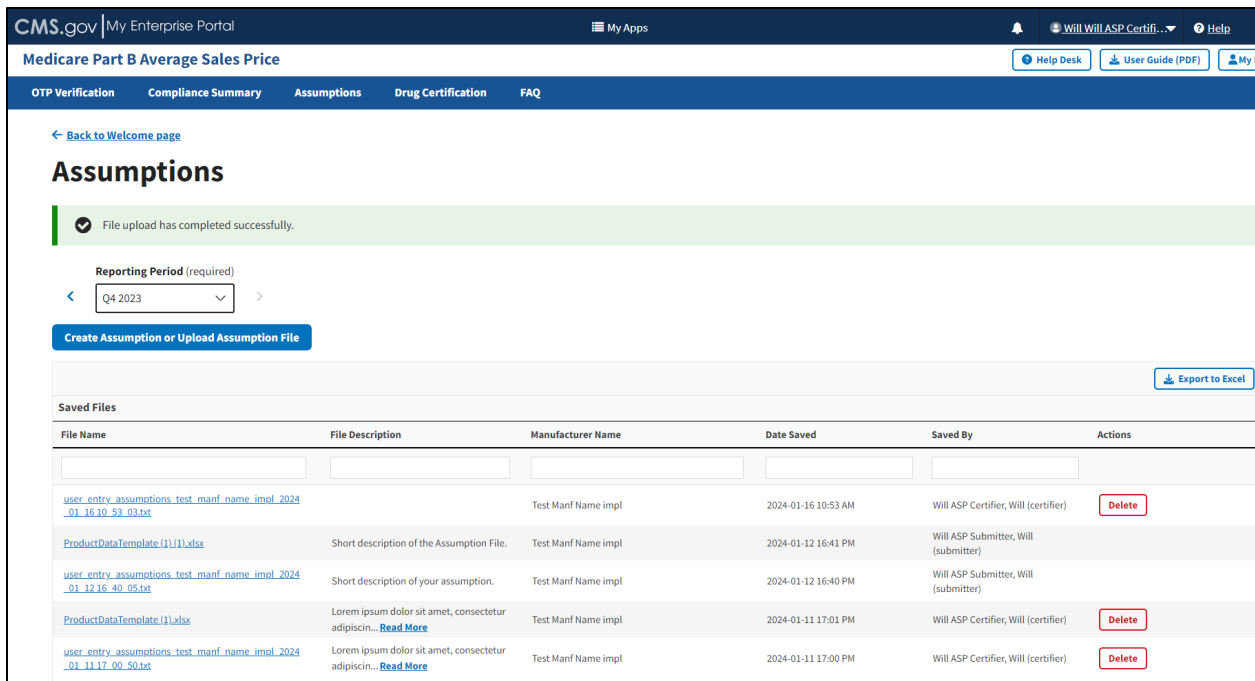


Figure 29: Upload Assumption File - Successfully Added

3.4 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 30*.



Figure 30: Certification - Drop-down

The **Drug Certification** page opens. Refer to *Figure 31*.

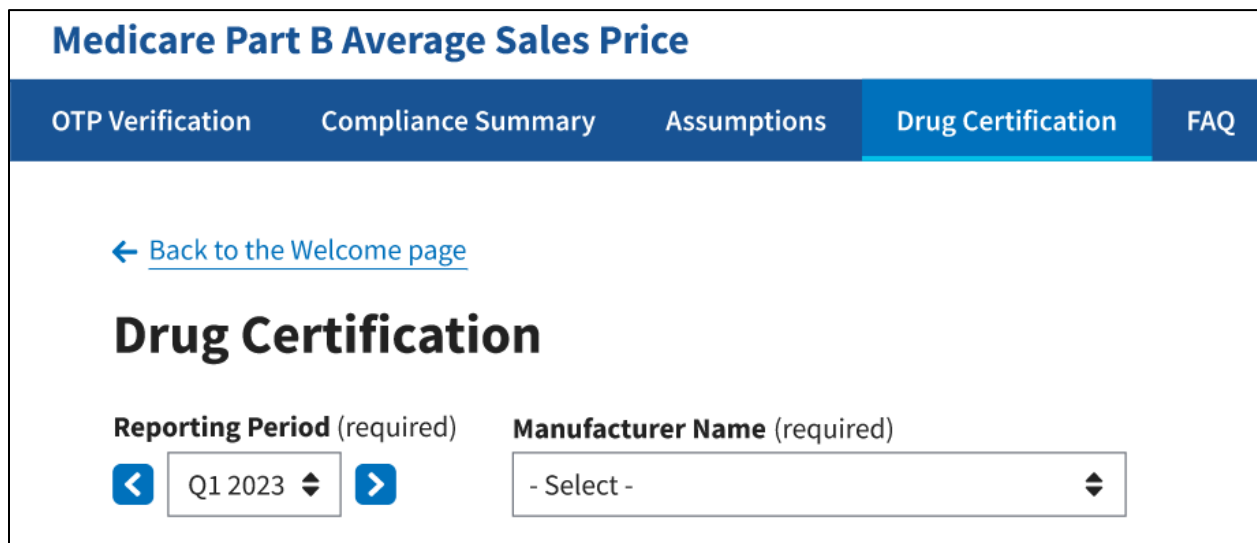


Figure 31: Drug Certification

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

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

Medicare Part B Average Sales Price

[OTP Verification](#)[Compliance Summary](#)[Assumptions](#)[Drug Certification](#)[FAQ](#)

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required)

<

Q1 2023

>

Manufacturer Name (required)

- Select -

PFIZER

MERCK

MODERNA

NOVARTIS

Figure 32: 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 33*.

Medicare Part B Average Sales Price

OTP Verification
Compliance Summary
Assumptions
Drug Certification
FAQ

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required)

Q1 2023

Manufacturer Name

PFIZER

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

Figure 33: 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.

3.4.1 Direct Employee

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

- Click the **Direct Employee** radio button.
New fields display asking for more information about the manufacturer's address and contact information.
- Enter or select the required information as follows:
 - Enter the street address in the **Street Address (required)** field.
 - Enter the street address in the **Street Address Line 2 (optional)** field, if necessary.
 - Enter the city in the **City (required)** field.
 - Enter the state in the **State (required)** field.
 - Enter the ZIP code in the **ZIP Code (required)** field.
 - Enter the name in the **Name (required)** field.
 - Enter the email address in the **Email Address (required)** field.
 - Enter the phone number in the **Phone Number (required)** field.
- 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 34*.

OTP Verification
Compliance Summary
Assumptions
Drug Certification
FAQ

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required)
Manufacturer Name (required)

Q1 2023
PFIZER

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)
235 East 42nd Street

Street Address line 2

City (required)
New York

State (required)
NY

ZIP Code (required)
10017

Edit

Certifier's Contact Info

Name (required)
John Doe

Email Address (required)
john.doe@pfizer.com

Phone Number (required)
410-555-1234

Edit

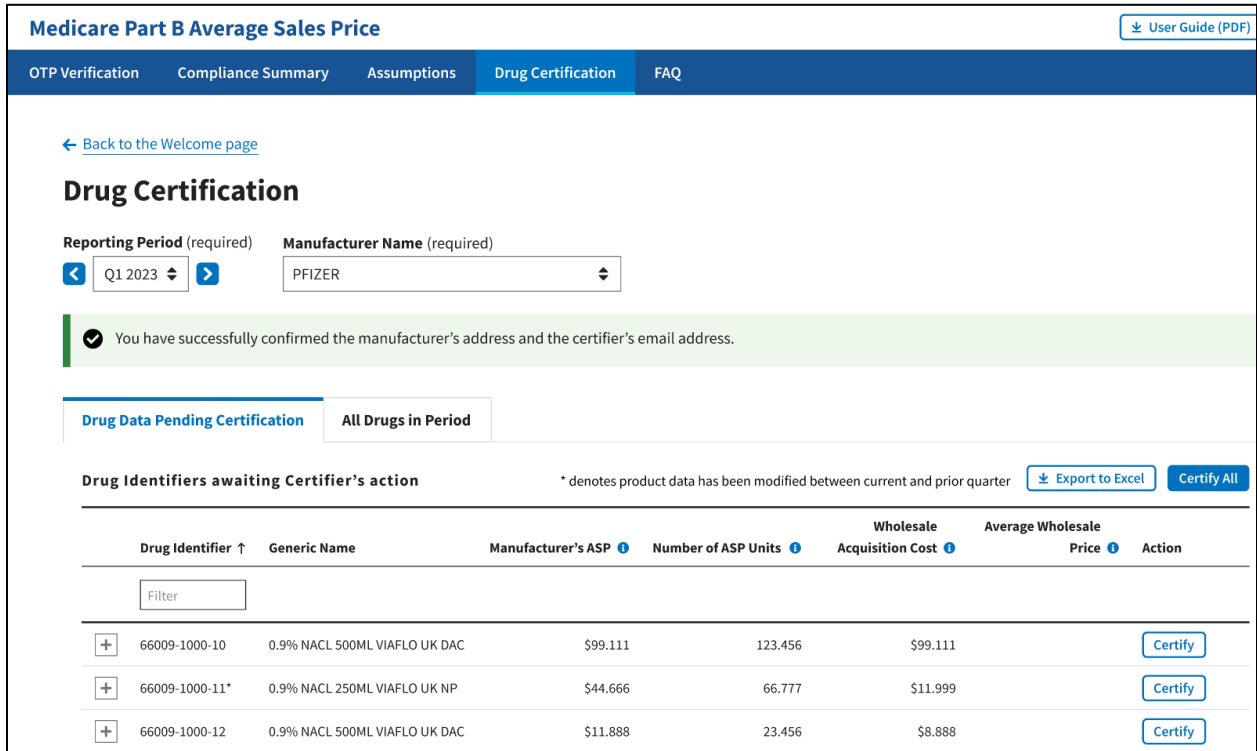
☐ I confirm the accuracy of the information provided above.

Confirm and Save

Figure 34: 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 35*.



Medicare Part B Average Sales Price [User Guide \(PDF\)](#)

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

[Back to the Welcome page](#)

Drug Certification

Reporting Period (required) **Q1 2023** Manufacturer Name (required) **PFIZER**

✓ You have successfully confirmed the manufacturer's address and the certifier's email address.

Drug Data Pending Certification All Drugs in Period

Drug Identifiers awaiting Certifier's action * denotes product data has been modified between current and prior quarter [Export to Excel](#) [Certify All](#)

Drug Identifier ↑	Generic Name	Manufacturer's ASP ⓘ	Number of ASP Units ⓘ	Wholesale Acquisition Cost ⓘ	Average Wholesale Price ⓘ	Action
Filter						
☐ 66009-1000-10	0.9% NACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		Certify
☐ 66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		Certify
☐ 66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		Certify

Figure 35: Drug Certification - Direct Employee Confirmation

3.4.2 Contractor

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

- 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.
- Enter or select the required information as follows:
 - Enter the street address in the **Street Address (required)** field.
 - Enter the street address in the **Street Address Line 2 (optional)** field, if necessary.
 - Enter the city in the **City (required)** field.
 - Enter the state in the **State (required)** field.
 - Enter the ZIP code in the **ZIP Code (required)** field.
 - Enter the point of contact name in the **Point of Contact's Name (required)** field.
 - Enter the point of contact email address in the **Point of Contact's Email Address (required)** field.
 - Enter the point of contact phone number in the **Point of Contact's Phone Number (required)** field.
 - 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.
3. 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 36*.

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

☐ Direct Employee ☒ Contractor

Manufacturer's Address

Street Address (required)
235 East 42nd Street

Street Address line 2

City (required) **State (required)** **ZIP Code (required)**
New York NY 10017

[Edit](#)

PFIZER Point of Contact Info

Name (required)
John Doe

Email Address (required)
john.doe@pfizer.com

Phone Number (required)
410-555-1234

[Edit](#)

Certifier's Contact Info

Name (required)
Jane Doe

Email Address (required)
jane.doe@contractor.com

Phone Number (required)
410-555-5678

[Edit](#)

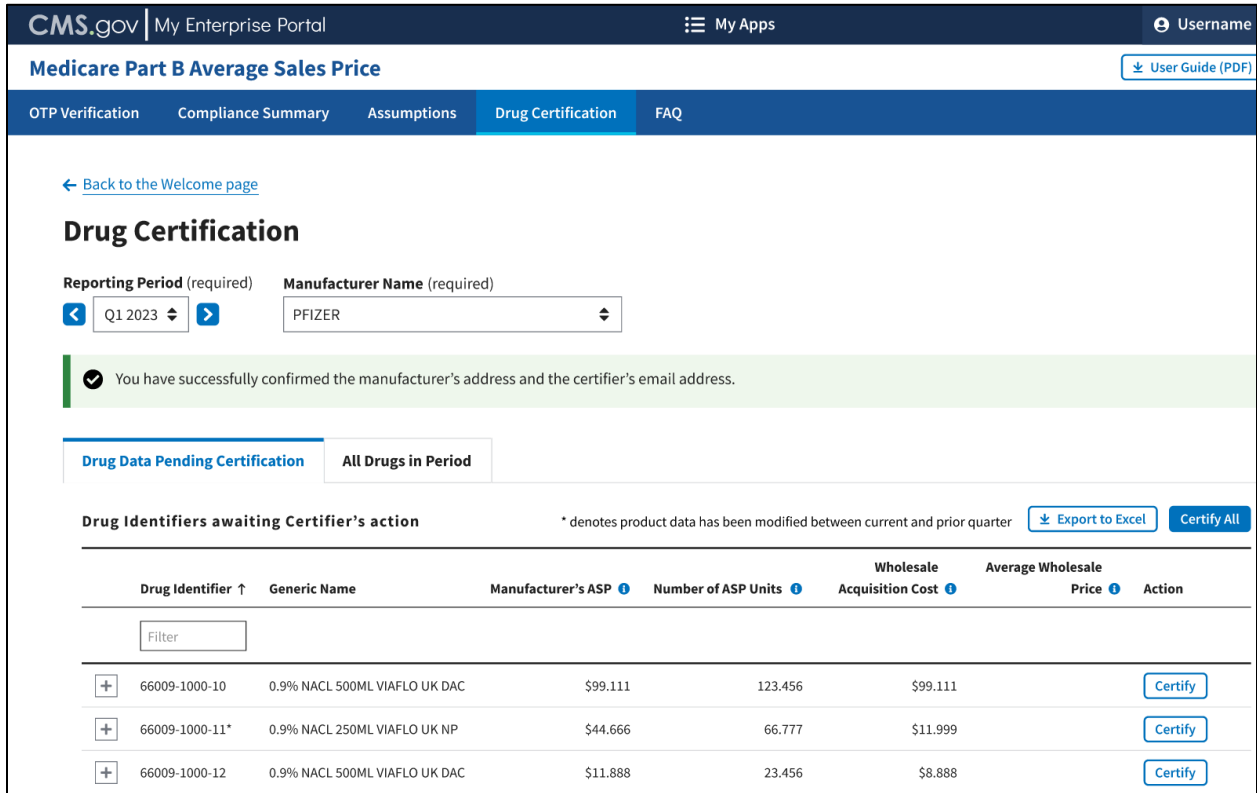
☐ I confirm the accuracy of the information provided above.

[Confirm and Save](#)

Figure 36: 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 37*.



CMS.gov | My Enterprise Portal My Apps Username

Medicare Part B Average Sales Price User Guide (PDF)

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

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required) **Manufacturer Name (required)**

Q1 2023 PFIZER

✓ You have successfully confirmed the manufacturer's address and the certifier's email address.

Drug Data Pending Certification All Drugs in Period

Drug Identifiers awaiting Certifier's action * denotes product data has been modified between current and prior quarter Export to Excel Certify All

Drug Identifier ↑	Generic Name	Manufacturer's ASP ⓘ	Number of ASP Units ⓘ	Wholesale Acquisition Cost ⓘ	Average Wholesale Price ⓘ	Action
Filter						
☐ 66009-1000-10	0.9% NACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		Certify
☐ 66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		Certify
☐ 66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		Certify

Figure 37: Drug Certification - Contractor Confirmation

3.4.3 Drug Data Pending Certification

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

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

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Use the drop-down to navigate a previous quarter starting with the most recent, or the next 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 38*.

OTP Verification
Compliance Summary
Assumptions
Drug Certification
FAQ

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required) **Manufacturer Name** (required)
 Q1 2023

☒ You have successfully confirmed the manufacturer's address and the certifier's email address.

Drug Data Pending Certification
All Drugs in Period

Drug Identifiers awaiting Certifier's action * denotes product data has been modified between current and prior quarter [Export to Excel](#) [Certify All](#)

Drug Identifier ↑	Generic Name	Manufacturer's ASP ⓘ	Number of ASP Units ⓘ	Wholesale Acquisition Cost ⓘ	Average Wholesale Price ⓘ	Action
Filter						
− 66009-1000-10	0.9% NACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		Certify
Product Info Brand Name: No Data Number of Items per NDC/Alt ID: 45 FDA Approval Date: 07/01/2021 FDA Approval Type: 510(k) Strength of Product: 200mg First Marketing Date: 07/02/2021 FDA Application Number: 54897 Volume per Item: 120 Expiration Date of Final Lot Sold: No Data FDA Application Supplement Number: 5489723						
+ 66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		Certify
+ 66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		Certify

Figure 38: Drug Data Pending Certification

Note: Click the **Export to Excel** box to convert all 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 categories, such as **Brand Name**, **First Marketing Date**, **Volume per Item**, and all other information the Submitter previously reported. Refer to *Figure 38*.
- Select the drug product and click the **Certify** box to open a new Data Certification Statement. Refer to *Figure 39*.

re

pe

io

sa

ri

Data Certification Statement

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.

☐ I agree to the above certification statement.

[Cancel](#)
[Certify Data](#)

K DAC

\$99.111

123.456

\$99.111

Figure 39: Data Certification Statement

- 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 40*.

CMS.gov

My Enterprise Portal

My Apps

Username

Medicare Part B Average Sales Price

User Guide (PDF)

OTP Verification

Compliance Summary

Assumptions

Drug Certification

FAQ

[Back to the Welcome page](#)

Drug Certification

Reporting Period (required)

Manufacturer Name (required)

Q1 2023

PFIZER

Drug Data Pending Certification

All Drugs in Period

✓

A total of 1 record(s) certified successfully.

Drug Identifiers awaiting Certifier's action

* denotes product data has been modified between current and prior quarter

[Export to Excel](#)
[Certify All](#)

Drug Identifier ↑	Generic Name	Manufacturer's ASP ⓘ	Number of ASP Units ⓘ	Wholesale Acquisition Cost ⓘ	Average Wholesale Price ⓘ	Action
Filter						
+ 66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		Certify
+ 66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		Certify

Figure 40: Data Certification - Confirmation Message

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

- 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.

3.4.4 All Drugs in Period

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

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

The **All Drugs in Period** page opens. Refer to *Figure 41*.

OTP Verification
Compliance Summary
Assumptions
Drug Certification
FAQ

[← Back to the Welcome page](#)

Drug Certification

Reporting Period (required)

Q1 2023

Manufacturer Name (required)

PFIZER

Drug Data Pending Certification

All Drugs in Period

All Drug Identifiers in Reporting 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 ⓘ	Status
Filter						Filter
+ 66009-1000-10	0.9% NACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		Certified
+ 66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		Pending Certification
+ 66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		Pending Certification
+ 23456-7890-01	0.3% NACL 500ML VIAFLO UK DAC	\$123.111	23.456	\$132.111		Certified
+ 23456-7890-02	0.3% NACL 250ML VIAFLO UK NP	\$134.666	879.777	\$143.999		Certified
+ 23456-7890-03	0.3% NACL 500ML VIAFLO UK DAC	\$156.888	123.456	\$165.888		Pending Certification

Figure 41: 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 convert all 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 categories, 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*.

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

Appendix A: Revision History

Table 2 provides a revision history for this document.

Table 2: Revision History

Version Number	Date	Author/Editor	Description of Change
0.1	01/22/2024	Index Analytics	DTS-ASP-Certifier-UserGuide - Initial draft following collaboration between DCCA and Index Analytics and incorporation of feedback from CMS - Various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections

Appendix B: Glossary

Table 3 a list of terms, acronyms, and definitions in this document.

Table 3: Glossary

Expanded Form	Acronym/Term	Definition
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.
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.
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.
Interactive Voice Response	IVR	IVR is a technology that allows a computer to detect voice and DTMF keypad inputs.
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.
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 contact information (i.e., name, organization, title, e-mail, and office number) for each key person working on a given project.

Expanded Form	Acronym/Term	Definition
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 C: Figures and Tables

List of Figures

Figure 1: Logging in Using MFA - ASP Module Login.....	4
Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down	5
Figure 3: Logging in Using MFA - Multi-Factor Authentication - (IVR) Example	6
Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code	7
Figure 5: My Portal Landing Page	8
Figure 6: My Portal Landing Page - FFSDCS Drop-down	8
Figure 7: ASP Data for Drugs and Biologics Under Medicare Part B.....	9
Figure 8: Medicare Part B Average Sales Price Homepage	10
Figure 9: OTP Verification	11
Figure 10: OTP Verification - Manufacturer Name.....	12
Figure 11: OTP Verification - OTP Provided by Your Data Submitter	12
Figure 12: OTP Verification Successful.....	13
Figure 13: Compliance Summary	14
Figure 14: Compliance Summary - All Pending Certification	15
Figure 15: Compliance Summary - Pending Certification	16
Figure 16: Compliance Summary - Pending Restatement Certification	17
Figure 17: Compliance Summary - Certified.....	18
Figure 18: Compliance Summary - Certified.....	19
Figure 19: Compliance Summary - Restated and Certified.....	20
Figure 20: Compliance Summary - New.....	21
Figure 21: Compliance Summary - Off Cycle	22
Figure 22: Compliance Summary - Expired.....	23
Figure 23: Assumptions	24
Figure 24: Assumptions - Create Assumption or Upload Assumption File	25
Figure 25: New Assumption Successfully Created	26
Figure 26: Upload Assumption File	27
Figure 27: Upload Assumption File - Expanded Fields	28
Figure 28: Upload Assumption File - Uploading Files from Desktop	29
Figure 29: Upload Assumption File - Successfully Added	29
Figure 30: Certification - Drop-down.....	30
Figure 31: Drug Certification	30
Figure 32: Drug Certification - Manufacturer Name	31
Figure 33: Drug Certification - Direct Employee or Contractor.....	32
Figure 34: Drug Certification - Direct Employee - Fields Populated	33
Figure 35: Drug Certification - Direct Employee Confirmation	34
Figure 36: Drug Certification - Contractor - Fields Populated	35
Figure 37: Drug Certification - Contractor Confirmation.....	36
Figure 38: Drug Data Pending Certification	37
Figure 39: Data Certification Statement	38
Figure 40: Data Certification - Confirmation Message	38
Figure 41: Drug Certification - All Drugs in Period	39

List of Tables

Table 1: Technical Support Contacts	40
Table 2: Revision History	41
Table 3: Glossary	42