



# **Medicare Part B Average Sales Price (ASP) Module**

## **Certifier User Guide**

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**Version 0.1**

**Date: January 22, 2024**

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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-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*.

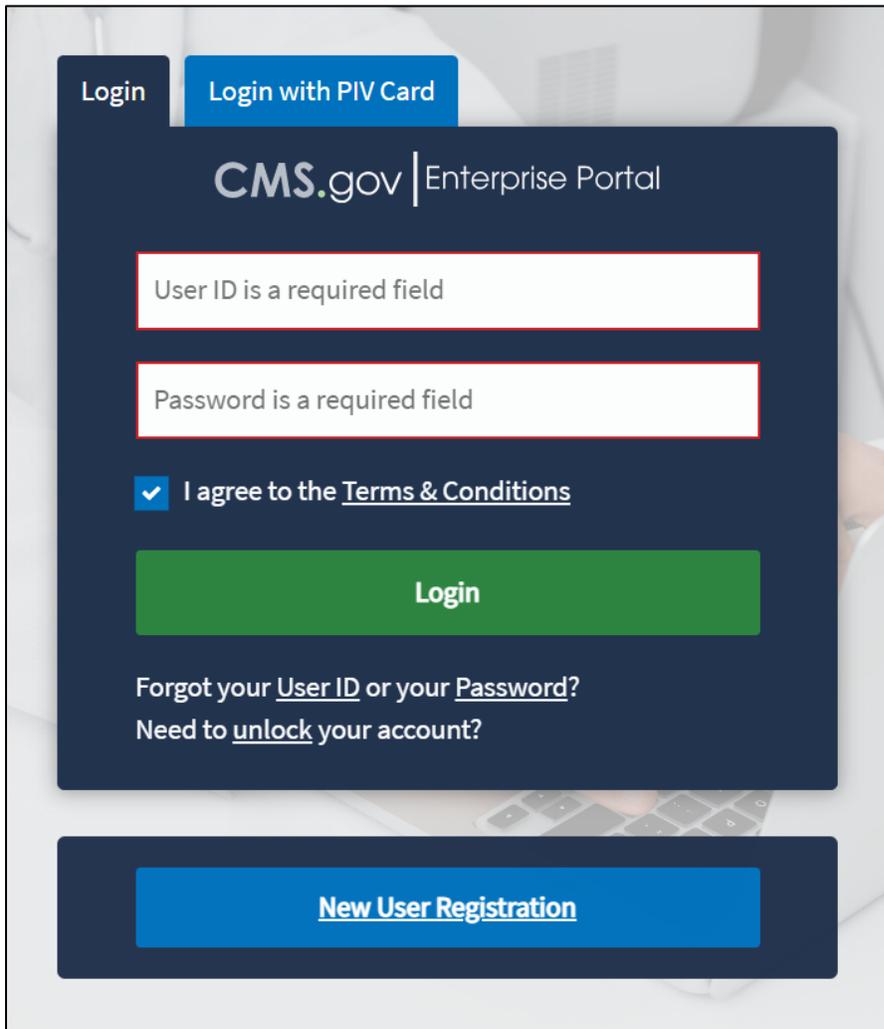


Figure 1: Logging in Using MFA - ASP Module Login

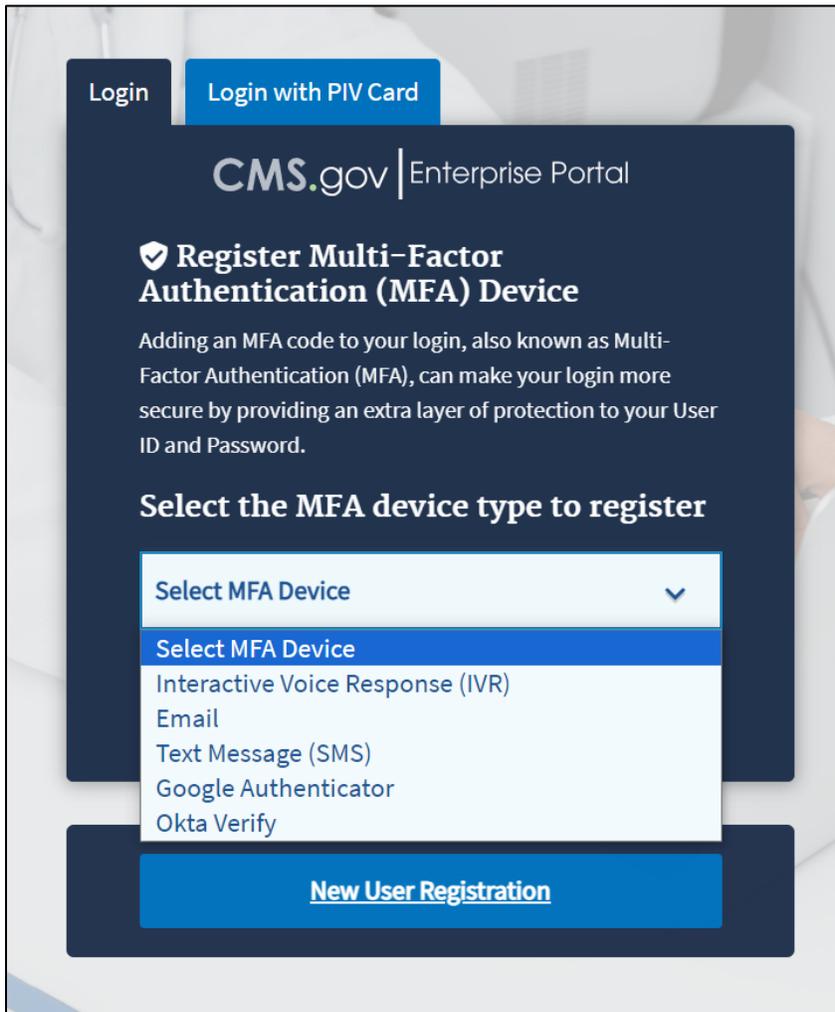
2. Enter your login information into the required **User ID** and **Password** fields.
3. Click the **Terms & Conditions** hyperlink and review the text in the pop-up window; close the window to move on to the next step.
4. Review the terms and conditions and select the **I agree to the Terms & Conditions**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

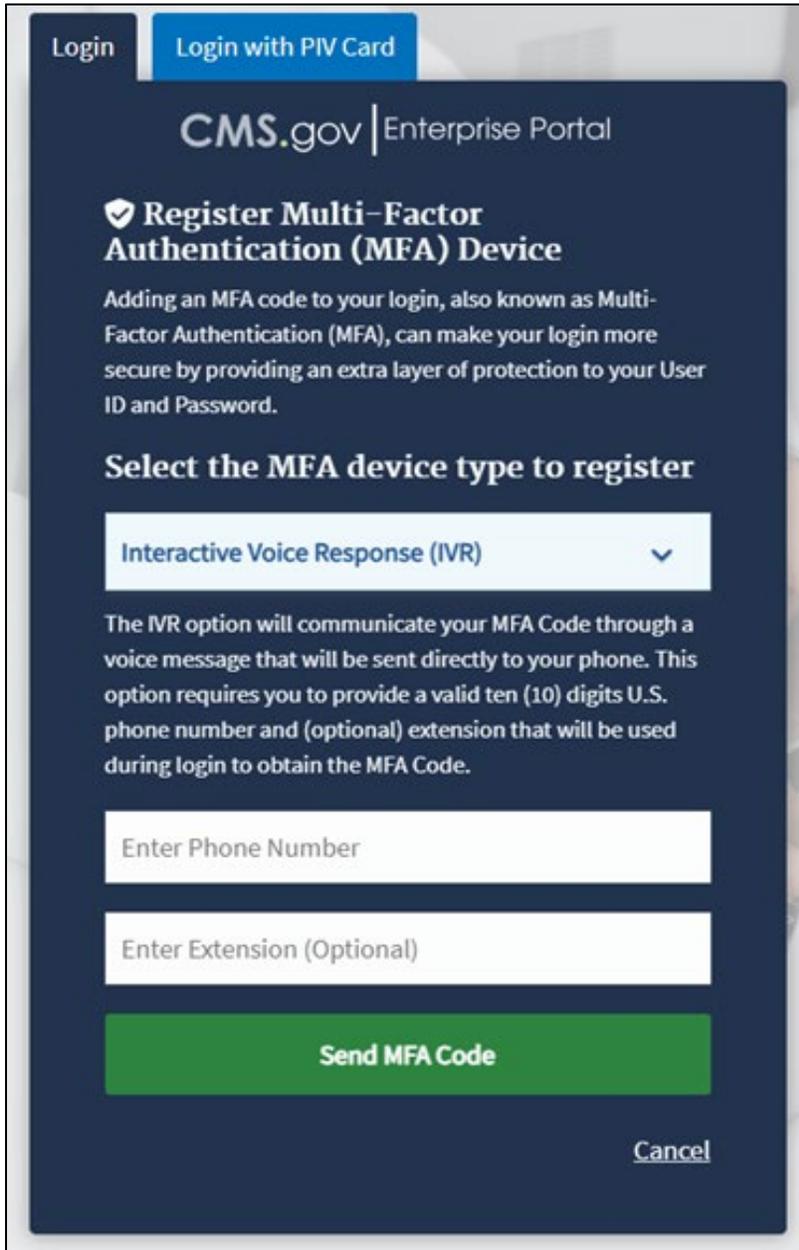


**Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down**

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.

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.



Login | Login with PIV Card

CMS.gov | Enterprise Portal

### Register Multi-Factor Authentication (MFA) Device

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

#### Select the MFA device type to register

Interactive Voice Response (IVR) ▼

The IVR option will communicate your MFA Code through a voice message that will be sent directly to your phone. This option requires you to provide a valid ten (10) digits U.S. phone number and (optional) extension that will be used during login to obtain the MFA Code.

Enter Phone Number

Enter Extension (Optional)

Send MFA Code

Cancel

**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*.

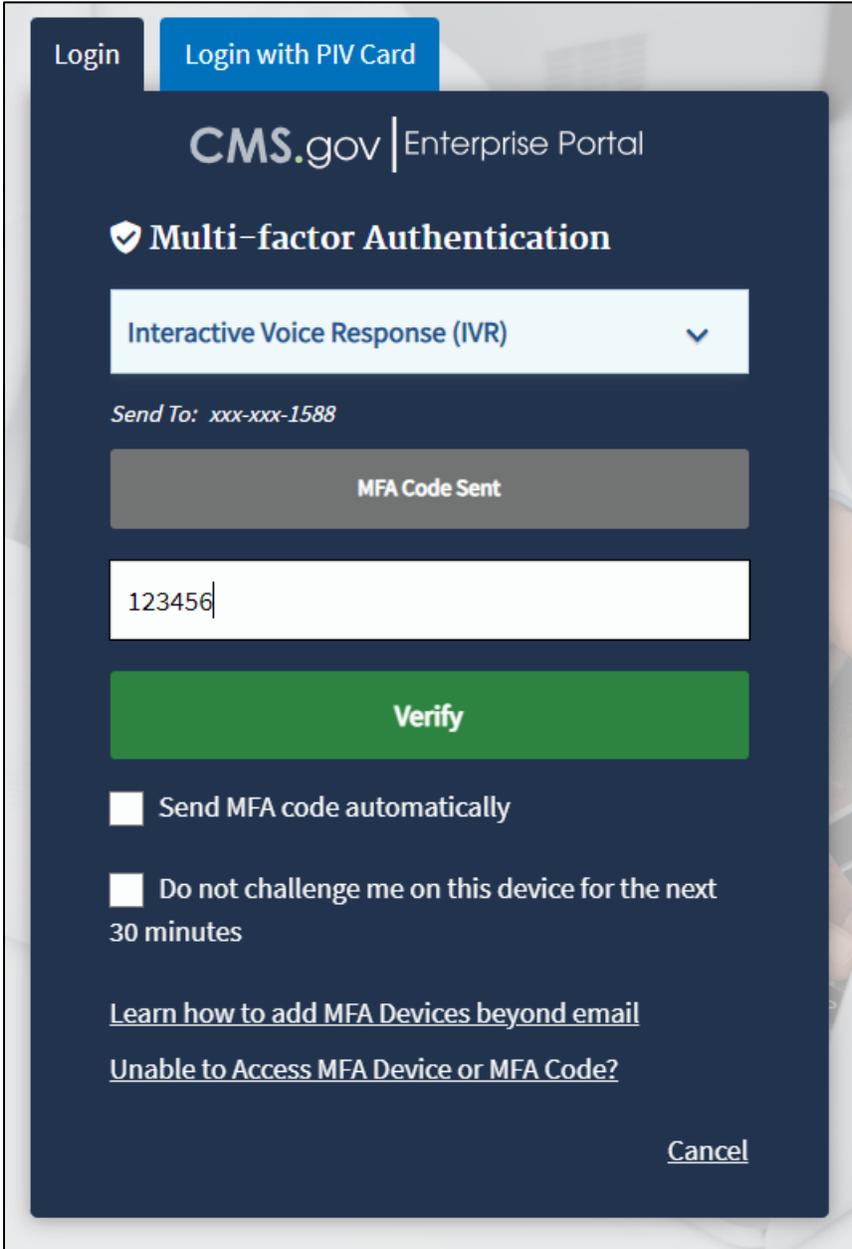


Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

- 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*.

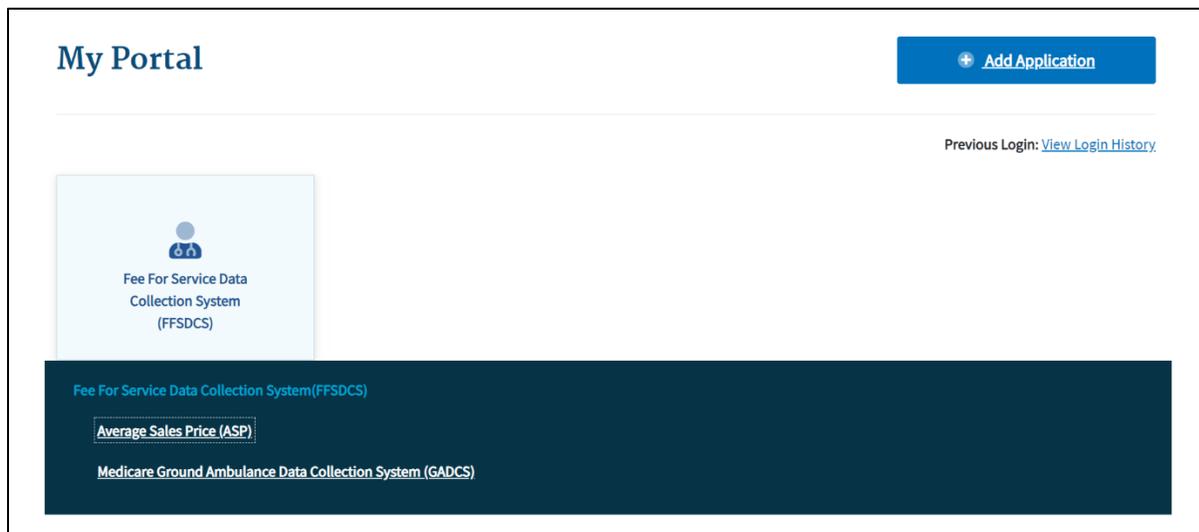


**Figure 5: My Portal Landing Page**

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

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*.

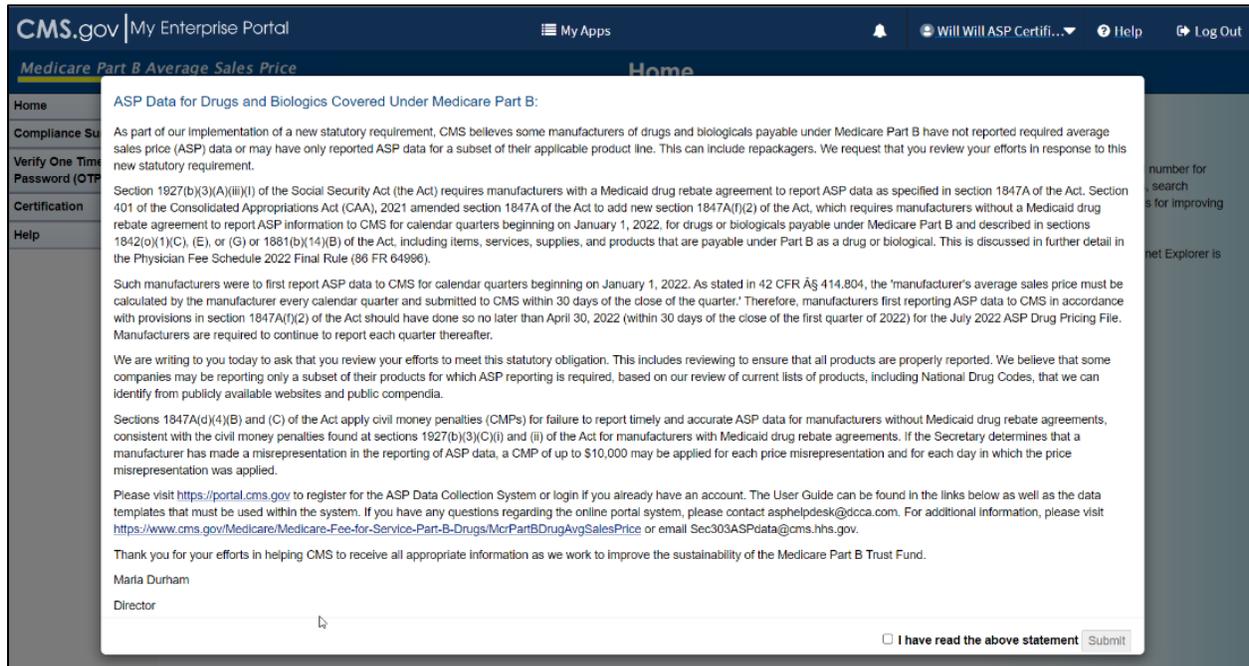


**Figure 6: My Portal Landing Page - FFSDCS Drop-down**

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 \(CAA\)](#),

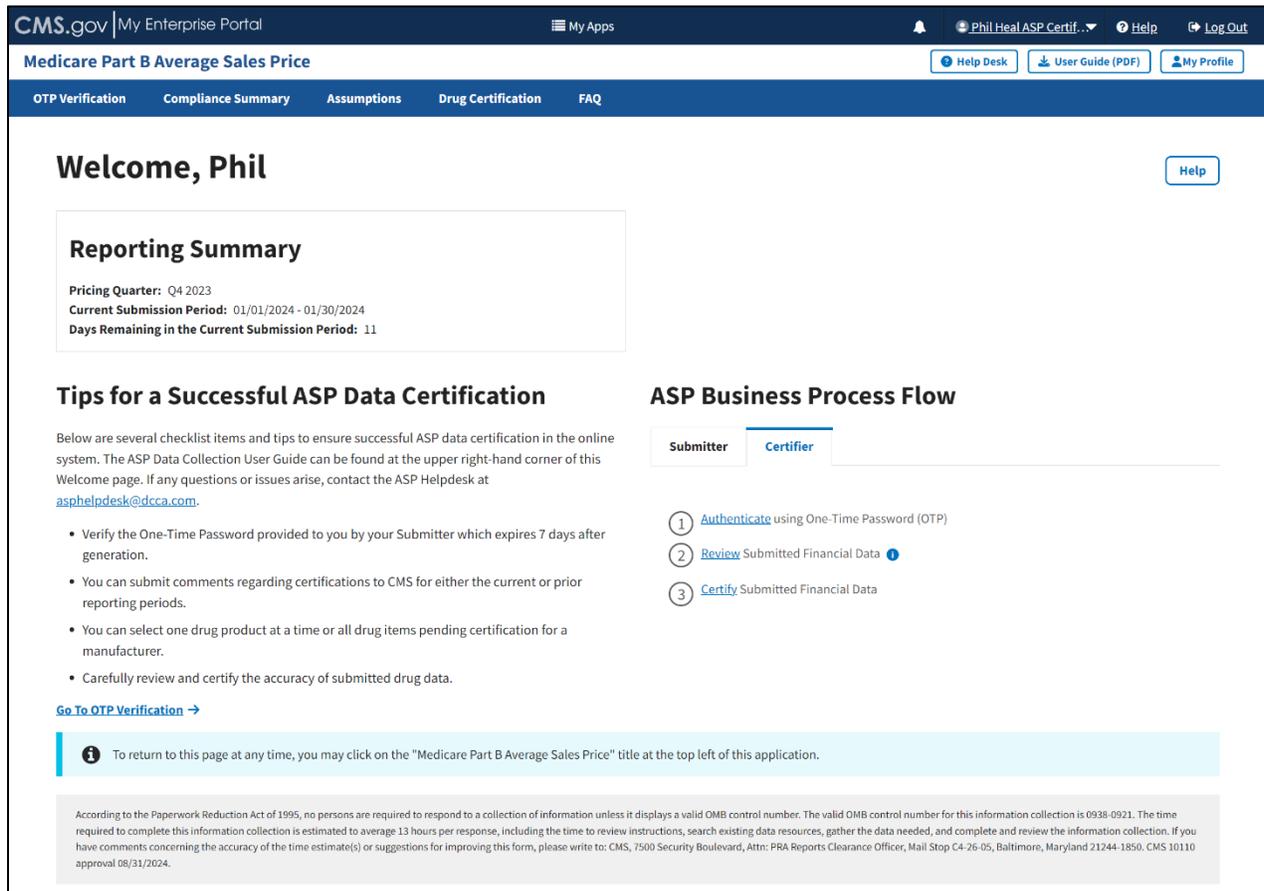
2021. These requirements hold that manufacturers must report their ASP data to CMS with precision on a quarterly basis without errors or miscalculations. Refer to *Figure 7*.



**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*.



**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](mailto: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 →](#)

**ASP Business Process Flow**

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

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.

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

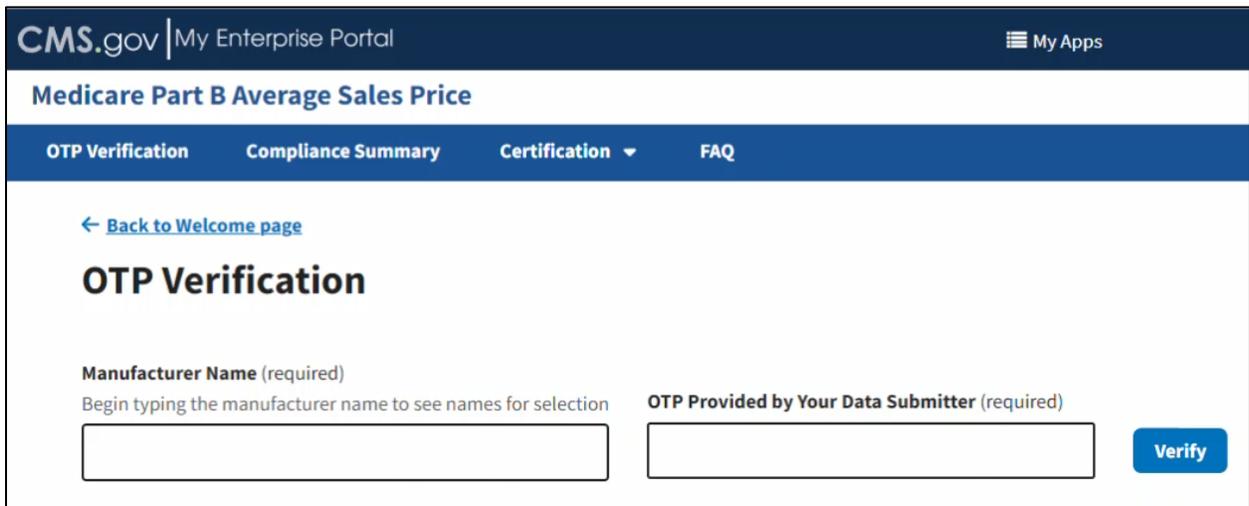
Once the Submitter has completed and submitted product data, the Submitter must share the one-time password (OTP) with the Certifier to establish a relationship within the system. Note the following about OTPs:

- 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:

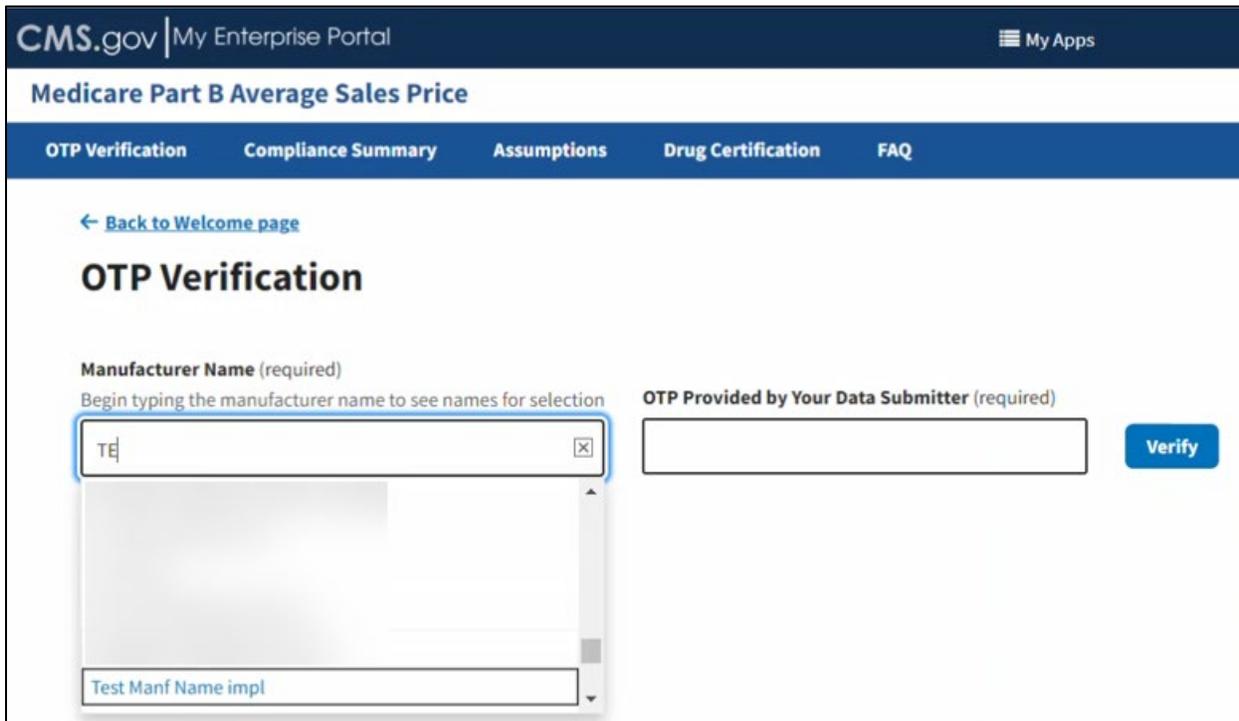
1. From the Medicare Part B Average Sales Price homepage, click the **OTP Verification** tab.

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



**Figure 9: OTP Verification**

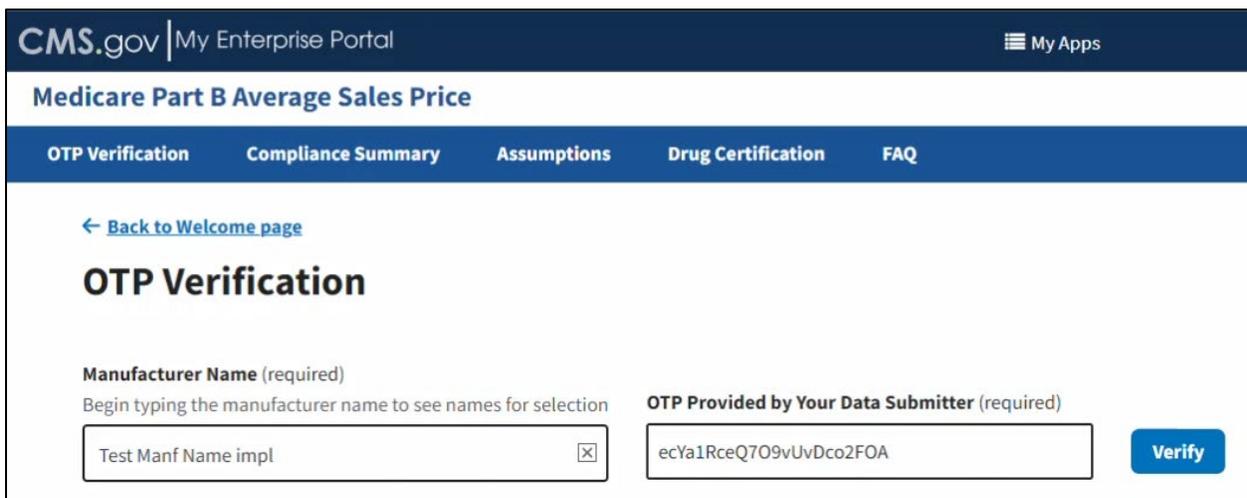
2. In the **Manufacturer Name (required)** field, begin typing the manufacturer name to narrow down names for selection; select the appropriate manufacturer name. Refer to *Figure 10*.



The screenshot shows the 'Medicare Part B Average Sales Price' page with the 'OTP Verification' tab 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 to the right.

Figure 10: OTP Verification - Manufacturer Name

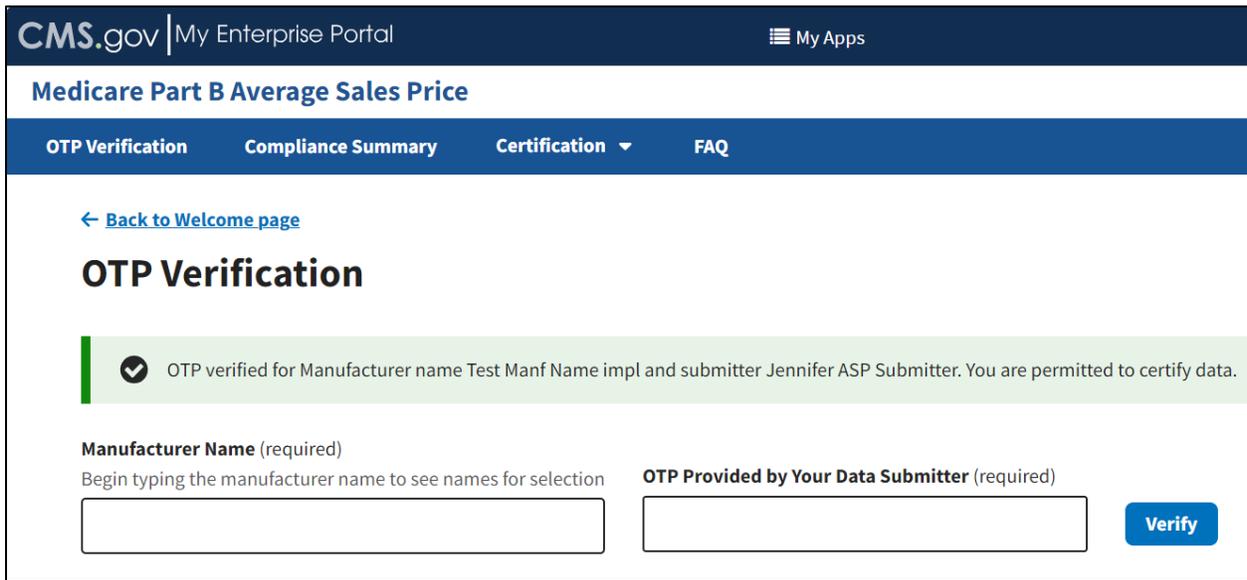
3. Enter the OTP code from the Submitter in the **OTP Provided by Your Data Submitter (required)** field. Refer to *Figure 11*.



The screenshot shows the 'Medicare Part B Average Sales Price' page with the 'OTP Verification' tab selected. The 'Manufacturer Name (required)' field contains 'Test Manf Name impl'. The 'OTP Provided by Your Data Submitter (required)' field contains the code 'ecYa1RceQ709vUvDco2FOA'. A 'Verify' button is visible to the right.

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*.



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Medicare Part B Average Sales Price

OTP Verification Compliance Summary Certification ▼ FAQ

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## OTP Verification

✔ OTP verified for Manufacturer name Test Manf Name impl and submitter Jennifer ASP Submitter. You are permitted to certify data.

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

**OTP Provided by Your Data Submitter** (required)

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.

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## 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

**Drug Identifiers waiting for data entry** [Export to Excel](#)

Drug Identifier ↑	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>					
25357-5486-32	PFIZER	Q1 2023				
59656-0442-10	DRPM	Q1 2023				
59656-0444-10	DRPM	Q1 2023				
59656-0445-05	DRPM	Q1 2023				
74523-9631-45	DCCA	Q1 2023				

1
10 items per page
Displaying 1-5 of 5 items

**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.

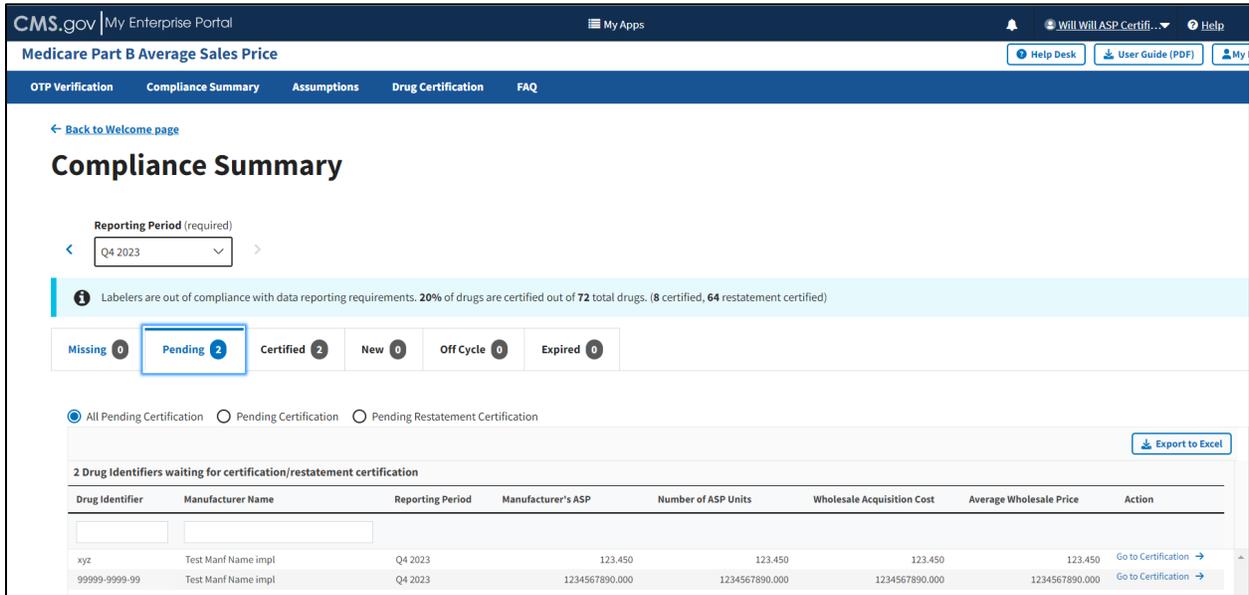
**Note:** Click the **Export to Excel** button to download all products under the **Missing** tab.

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*.



The screenshot shows the 'Compliance Summary' page for Medicare Part B Average Sales Price. The 'Reporting Period' is set to Q4 2023. A notification states: 'Labels are out of compliance with data reporting requirements. 20% of drugs are certified out of 72 total drugs. (8 certified, 64 restatement certified)'. The status tabs are: Missing (0), Pending (2), Certified (2), New (0), Off Cycle (0), and Expired (0). The 'All Pending Certification' radio button is selected. Below, a table titled '2 Drug Identifiers waiting for certification/restatement certification' is shown.

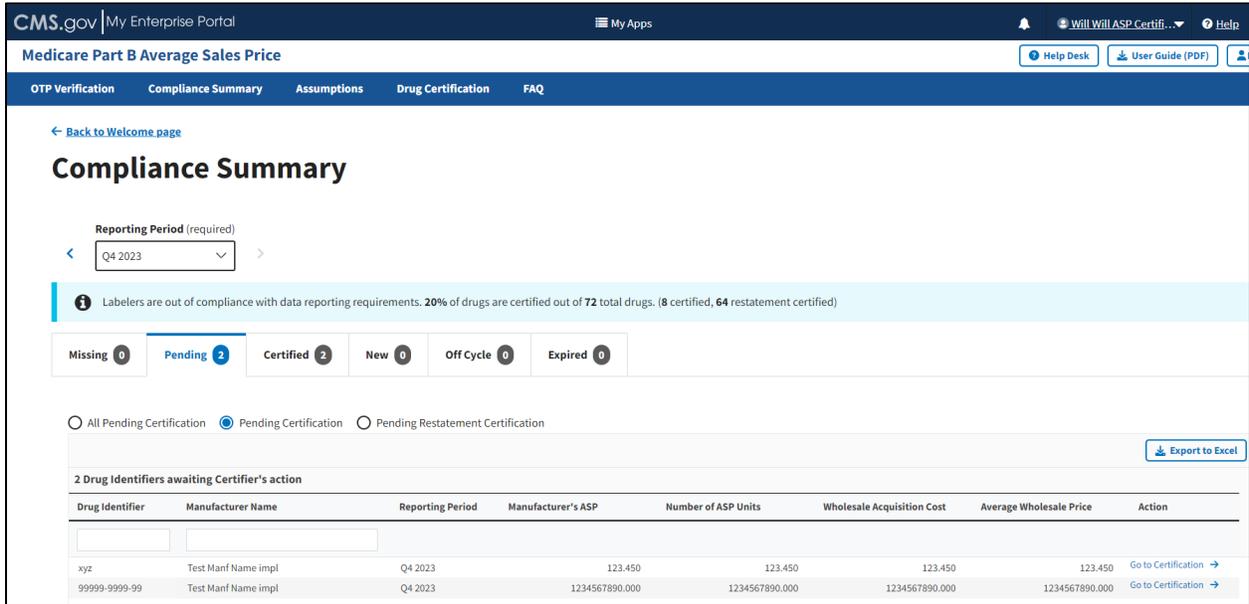
Drug Identifier	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price	Action
xyz	Test Manf Name impl	Q4 2023	123.450	123.450	123.450	123.450	<a href="#">Go to Certification</a>
99999-99999-99	Test Manf Name impl	Q4 2023	1234567890.000	1234567890.000	1234567890.000	1234567890.000	<a href="#">Go to Certification</a>

**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*.



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

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

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## 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	<a href="#">Go to Certification →</a>
99999-9999-99	Test Manf Name impl	Q4 2023	1234567890.000	1234567890.000	1234567890.000	1234567890.000	<a href="#">Go to Certification →</a>

**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**

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## 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

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
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>						
76009-1234-10	MERCK	Q1 2023	\$99.111	123.456	\$99.111		<a href="#">Go to Certification →</a>
76009-1234-11	MERCK	Q1 2023	\$44.666	66.777	\$11.999		<a href="#">Go to Certification →</a>

⏪ 1 ⏩
10 items per page
Displaying 1-3 of 3 items

**Figure 16: Compliance Summary - Pending Restatement Certification**

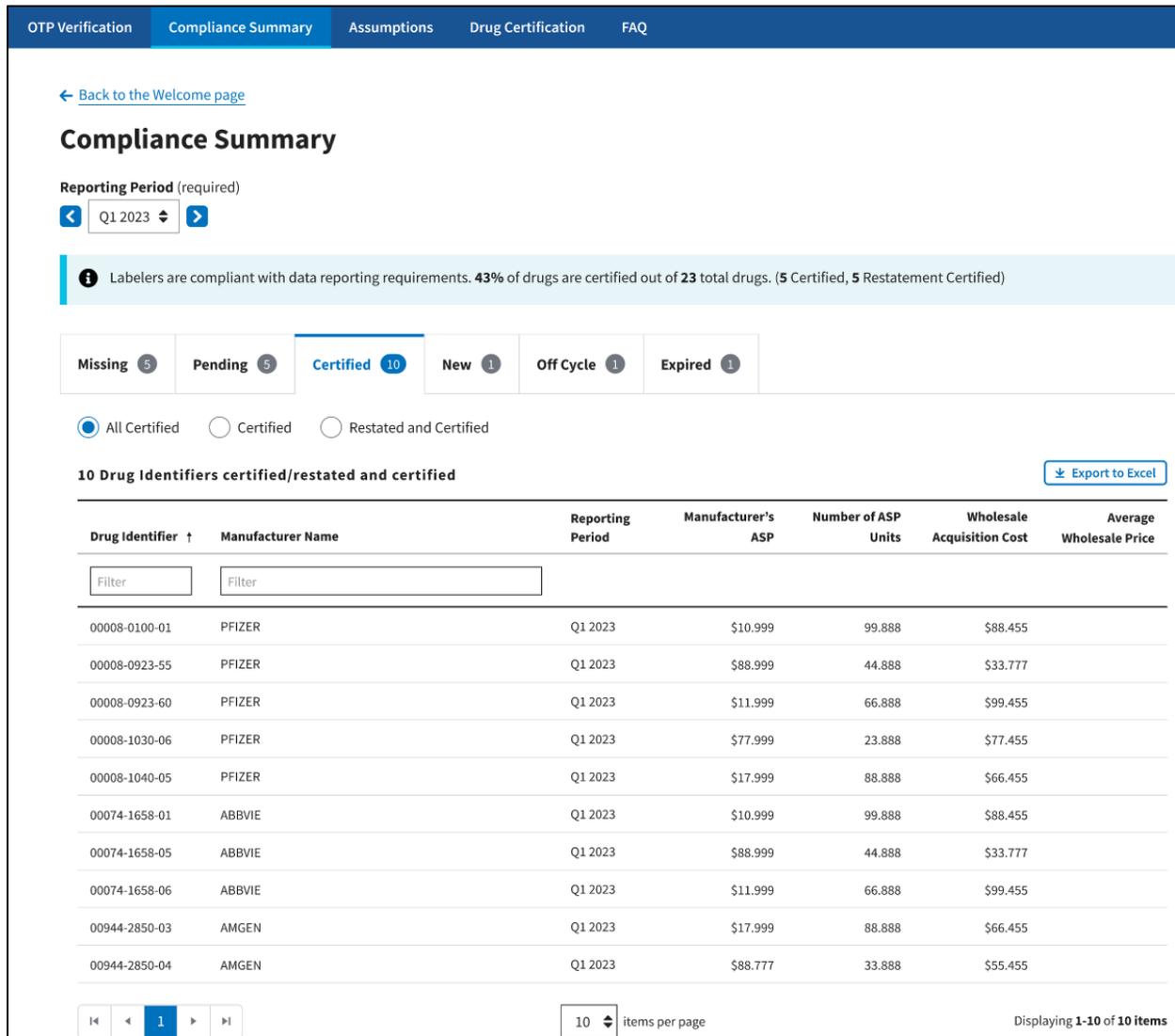
**Note:** Click the **Export to Excel** box to download all products under the **Pending** tab.

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*.

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## 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

All Certified  
  Certified  
  Restated and Certified

**5 Drug Identifiers certified** Export to Excel

Drug Identifier ↑	Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>					
00008-0100-01	PFIZER	Q1 2023	\$10.999	99.888	\$88.455	
00008-0923-55	PFIZER	Q1 2023	\$88.999	44.888	\$33.777	
00008-0923-60	PFIZER	Q1 2023	\$11.999	66.888	\$99.455	
00008-1030-06	PFIZER	Q1 2023	\$77.999	23.888	\$77.455	
00008-1040-05	PFIZER	Q1 2023	\$17.999	88.888	\$66.455	

1

items per page

Displaying 1-3 of 3 items

**Figure 18: Compliance Summary - Certified**

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

4. 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**.

5. Click the **Restated and Certified** radio button to filter only for and certified drugs. Refer to *Figure 19*.

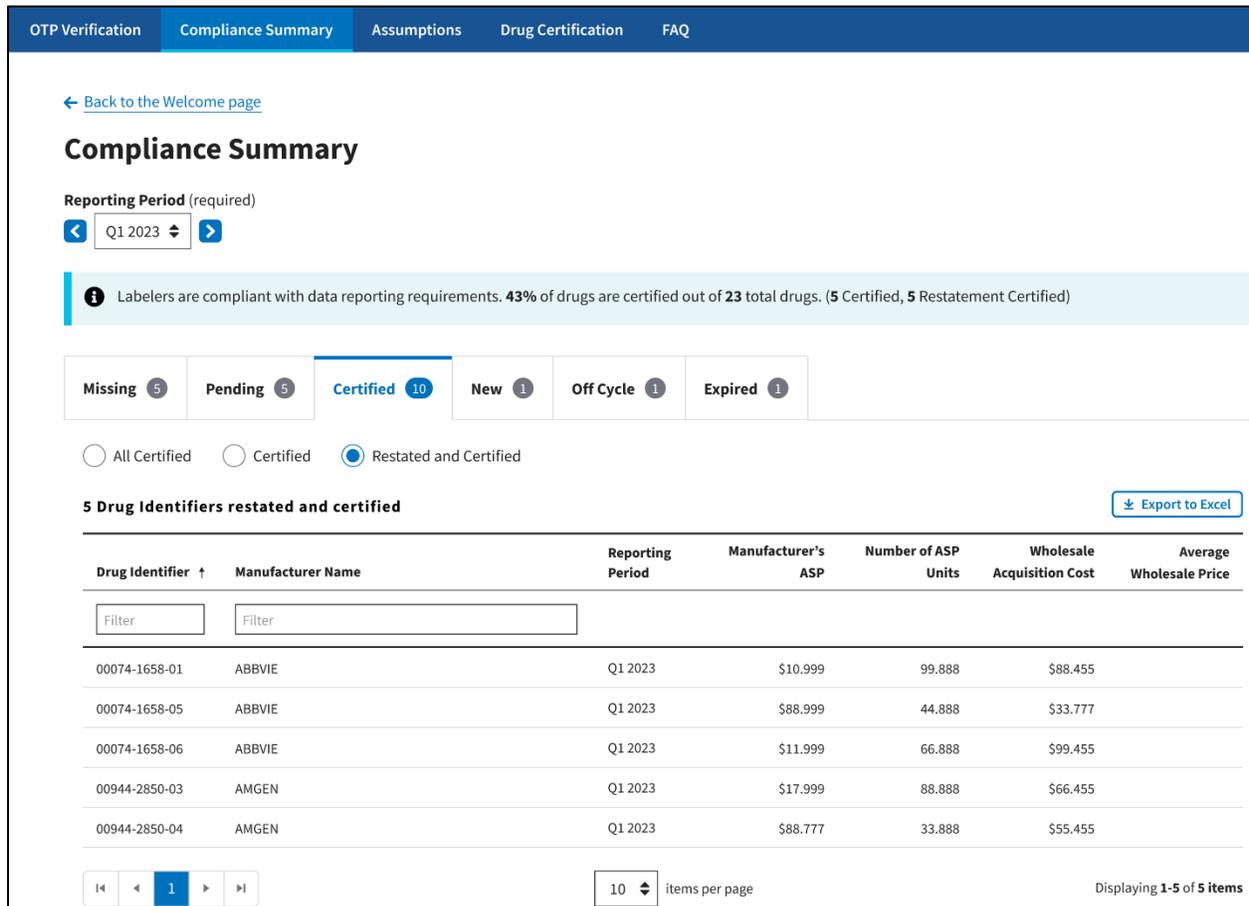


Figure 19: Compliance Summary - Restated and Certified

**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*.

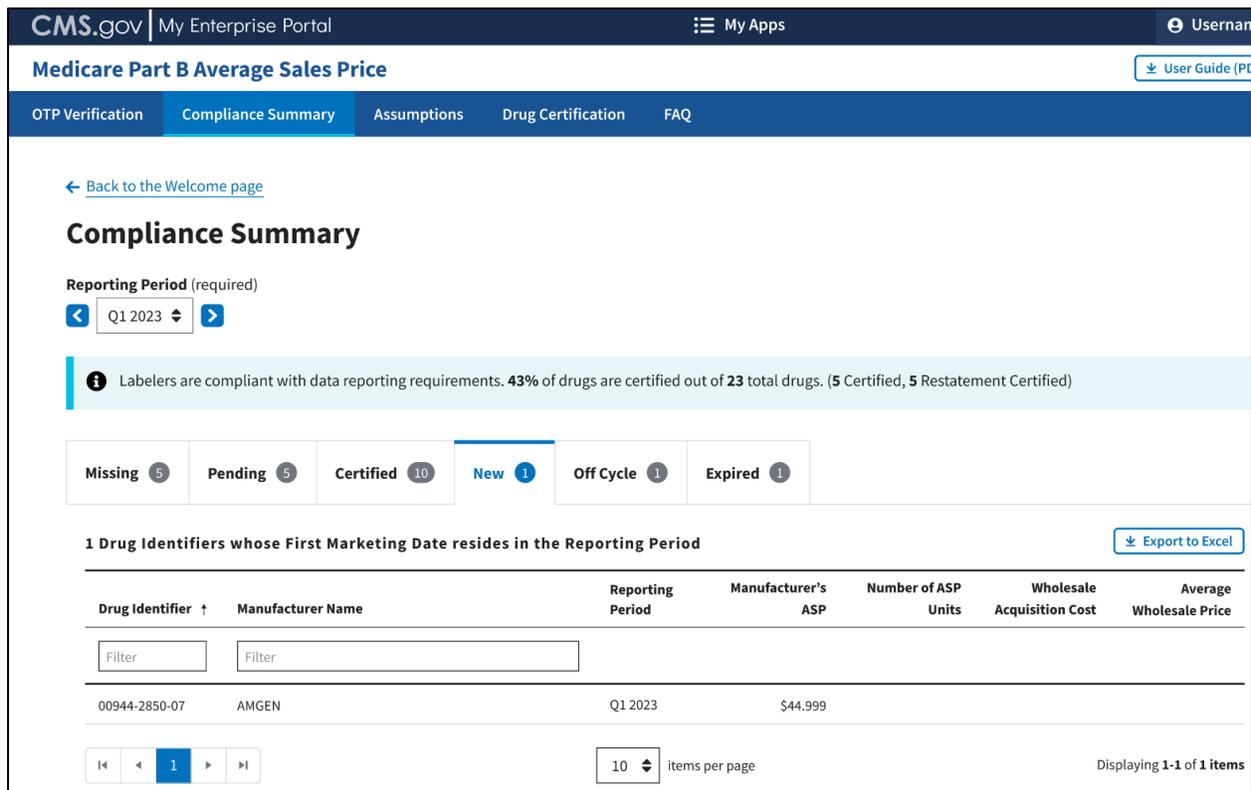


Figure 20: Compliance Summary - New

**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**.

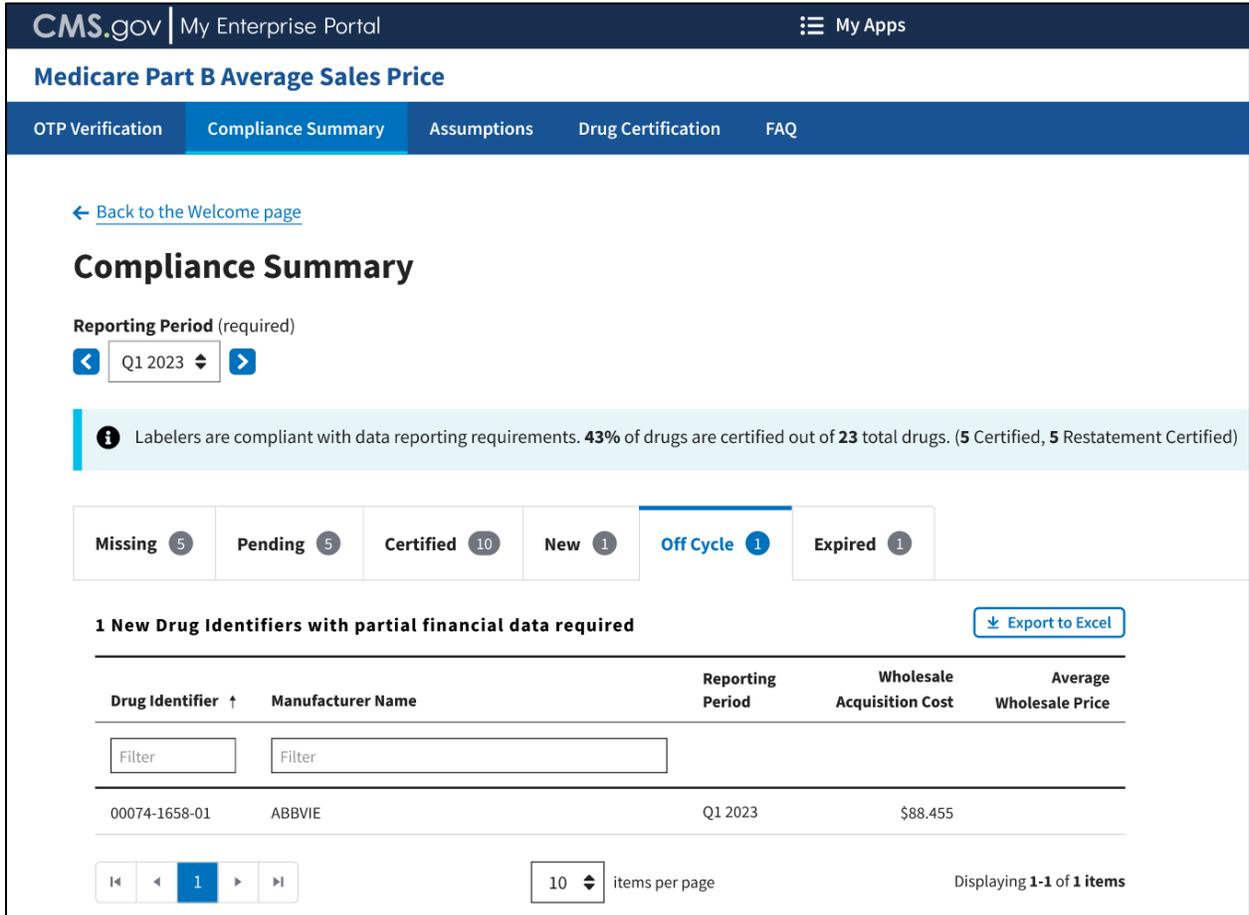
3. Click the **Off Cycle** tab to move on to the next page.

### 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*.



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## 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 New Drug Identifiers with partial financial data required** [Export to Excel](#)

Drug Identifier ↑	Manufacturer Name	Reporting Period	Wholesale Acquisition Cost	Average Wholesale Price
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>			
00074-1658-01	ABBVIE	Q1 2023	\$88.455	

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.

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**.

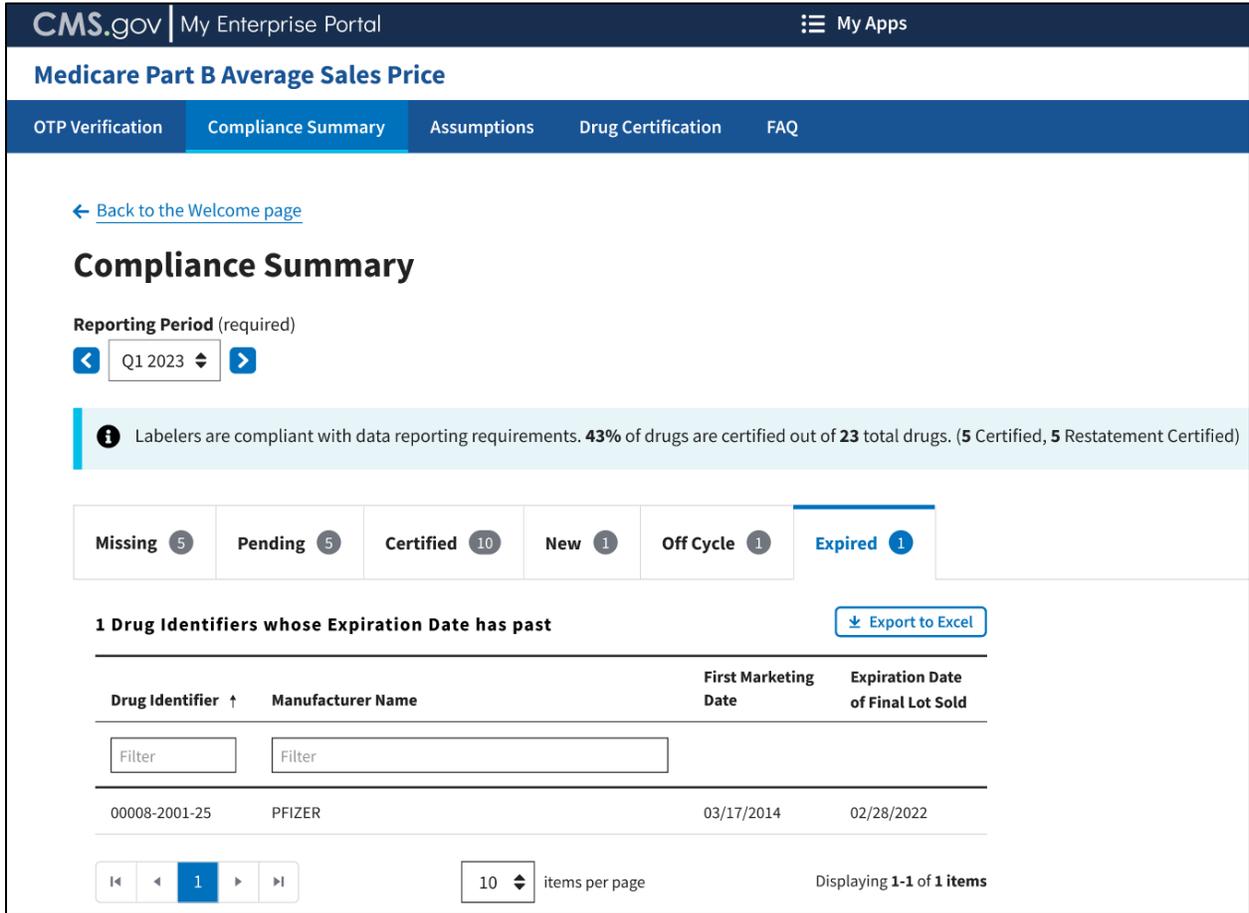
3. Click the **Expired** tab to move on to the next page.

### 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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## Compliance Summary

Reporting Period (required)

Q1 2023

📘 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 Expiration Date has past** 📄 Export to Excel

Drug Identifier ↑	Manufacturer Name	First Marketing Date	Expiration Date of Final Lot Sold
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>		
00008-2001-25	PFIZER	03/17/2014	02/28/2022

1

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.

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**.

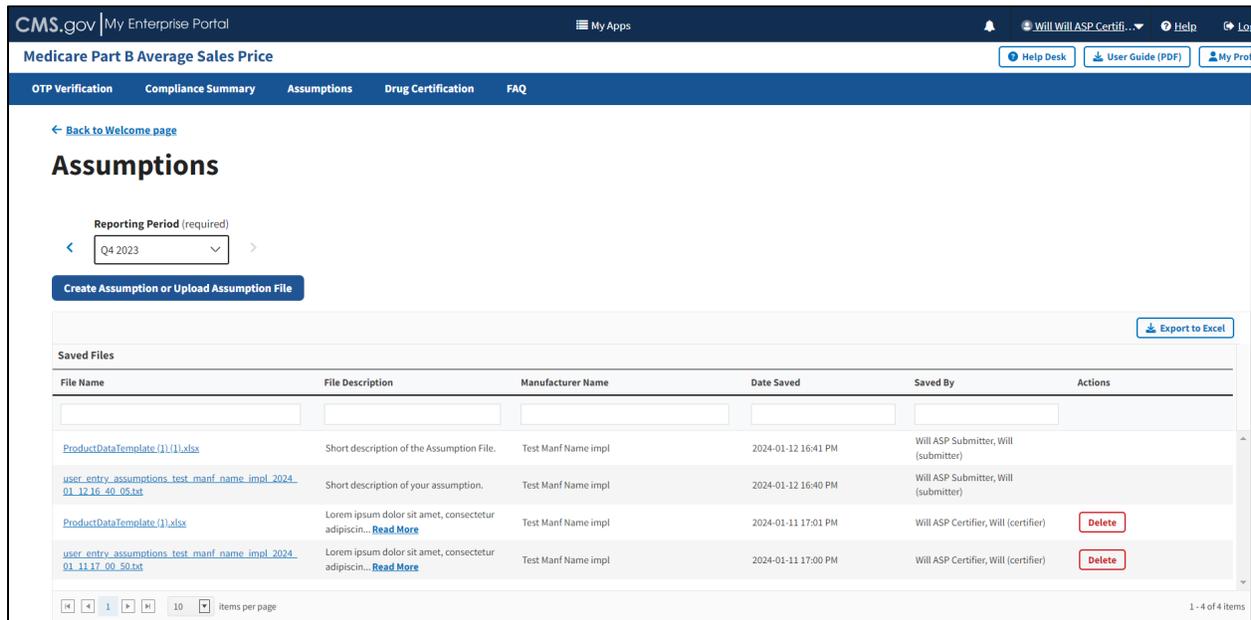
### 3.3 Assumptions

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

Follow these steps to submit certification assumptions to CMS:

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. Refer to *Figure 23*.



**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.

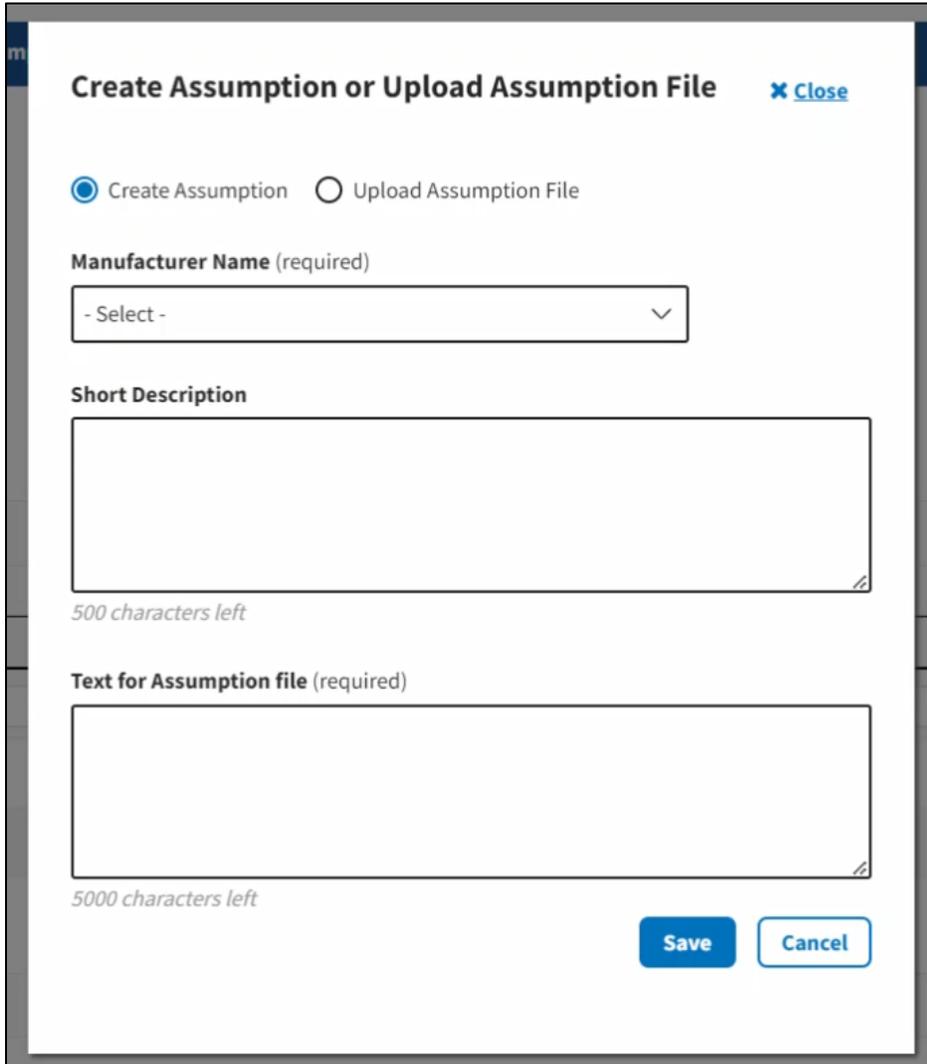
**Note:** Click the **Export to Excel** box to download all products under the **Assumptions** tab.

### 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*.



The screenshot shows a web form titled "Create Assumption or Upload Assumption File" with a "Close" button. It features two radio buttons: "Create Assumption" (selected) and "Upload Assumption File". Below are three input fields: a required "Manufacturer Name" drop-down menu currently showing "- Select -", a "Short Description" text area with a "500 characters left" indicator, and a required "Text for Assumption file" text area with a "5000 characters left" indicator. At the bottom right are "Save" and "Cancel" buttons.

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*.

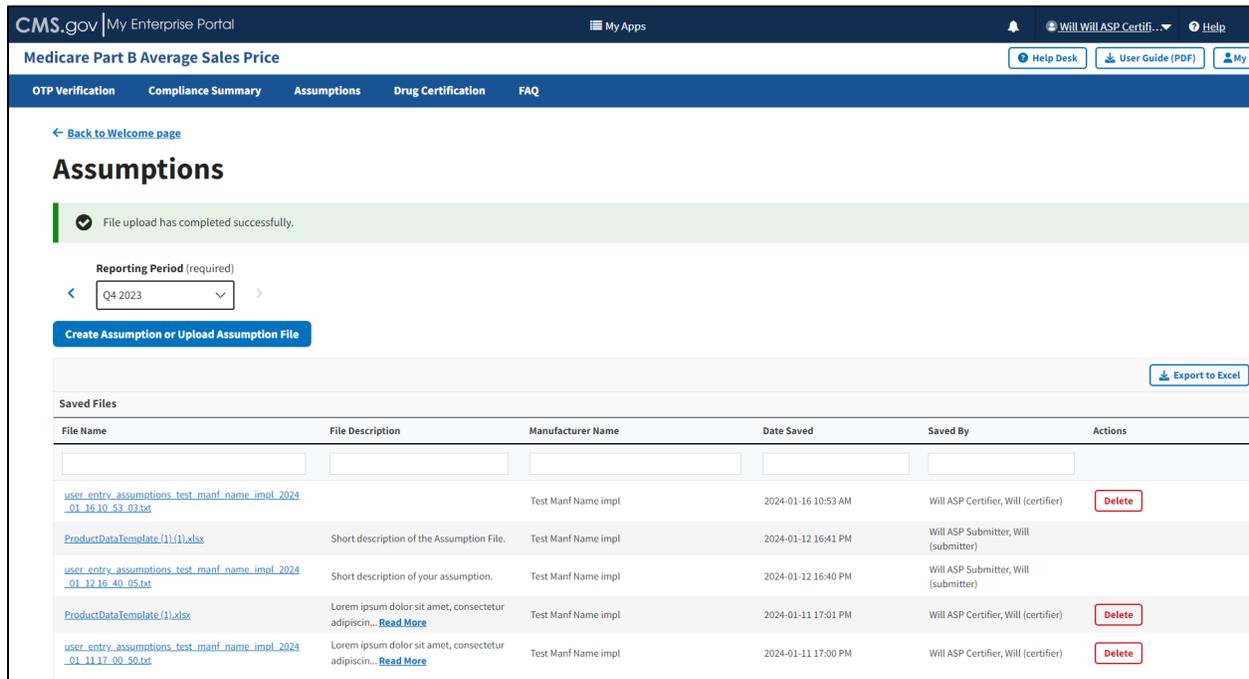


Figure 25: New Assumption Successfully Created

### 3.3.2 Upload Assumption File

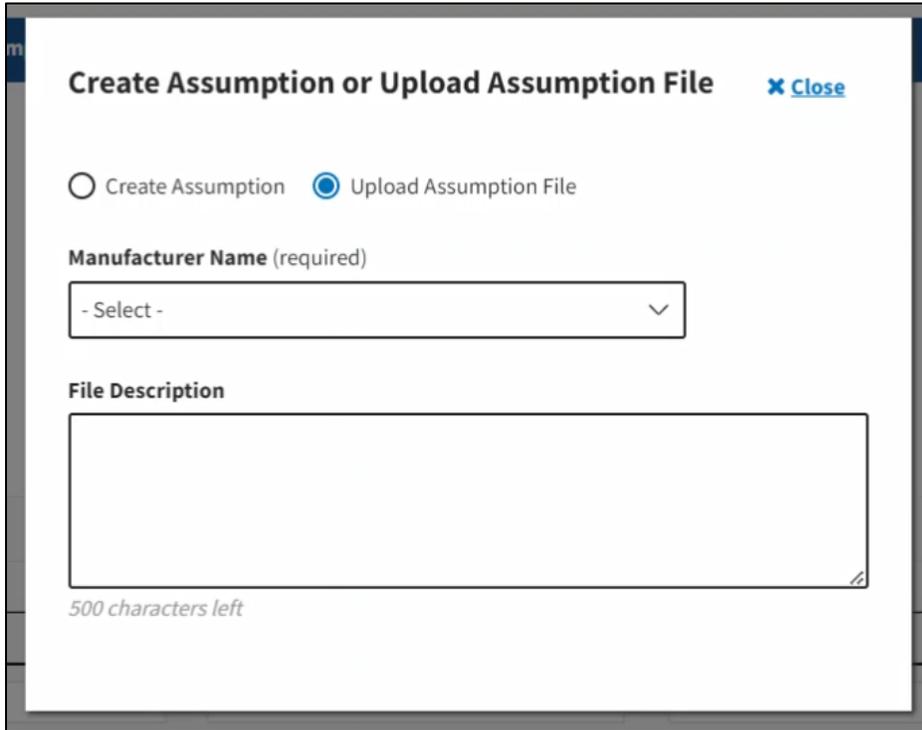
Follow these steps to upload an assumption file to the Module:

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*.

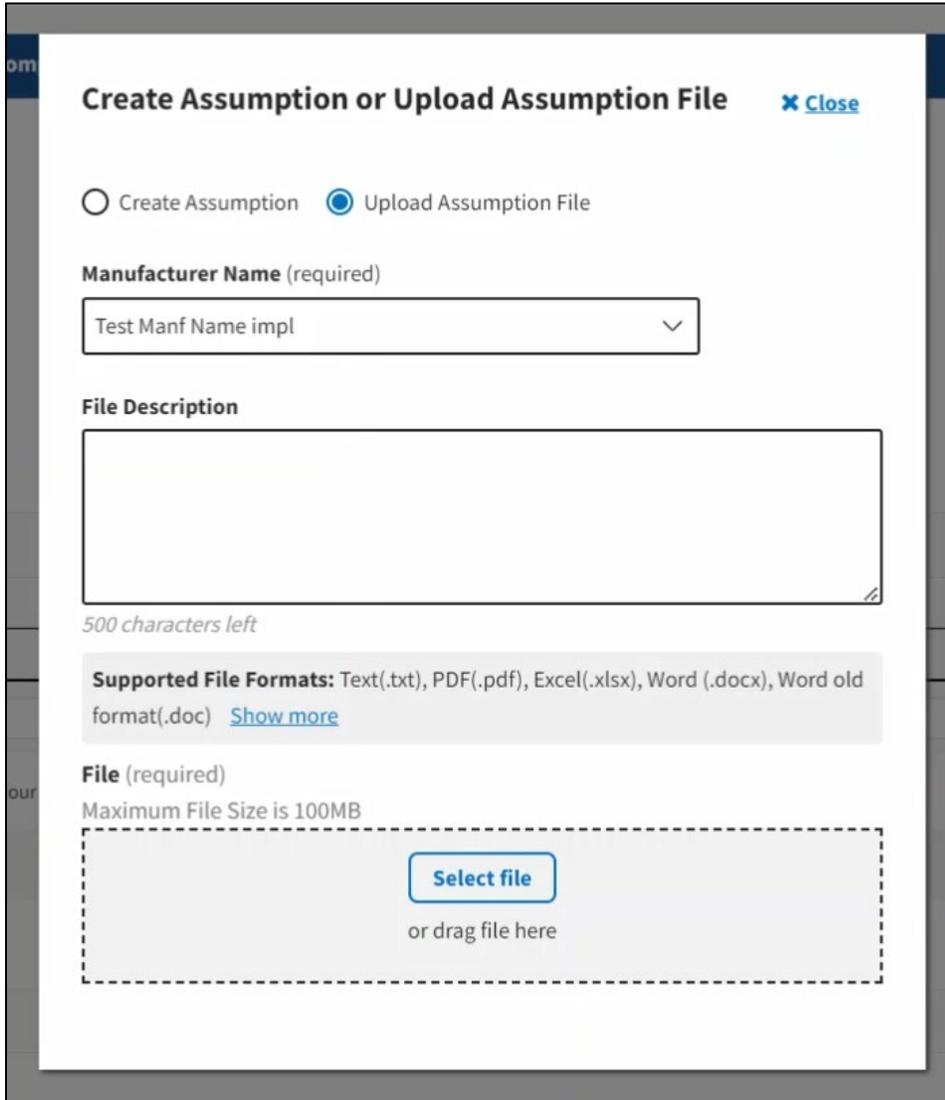


The screenshot shows a dialog box titled "Create Assumption or Upload Assumption File" with a "Close" button in the top right corner. Below the title, there are two radio buttons: "Create Assumption" (unselected) and "Upload Assumption File" (selected). Underneath, there is a label "Manufacturer Name (required)" followed by a drop-down menu showing "- Select -". Below the drop-down menu is a large text area labeled "File Description". At the bottom left of the text area, it says "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*.

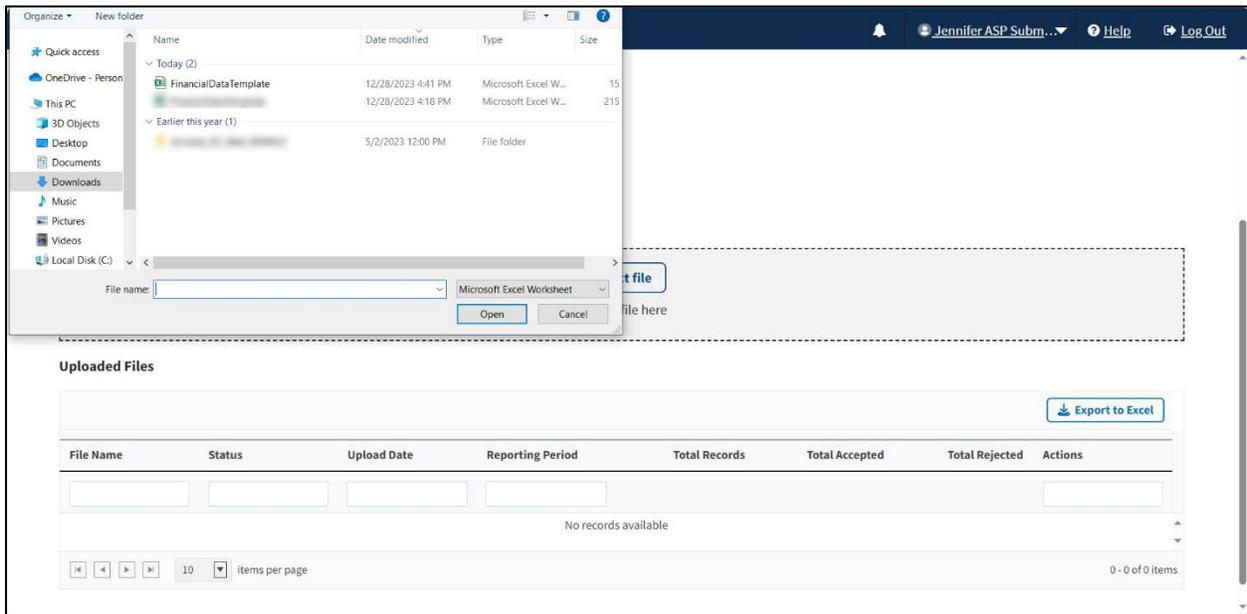


**Figure 27: Upload Assumption File - Expanded Fields**

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.

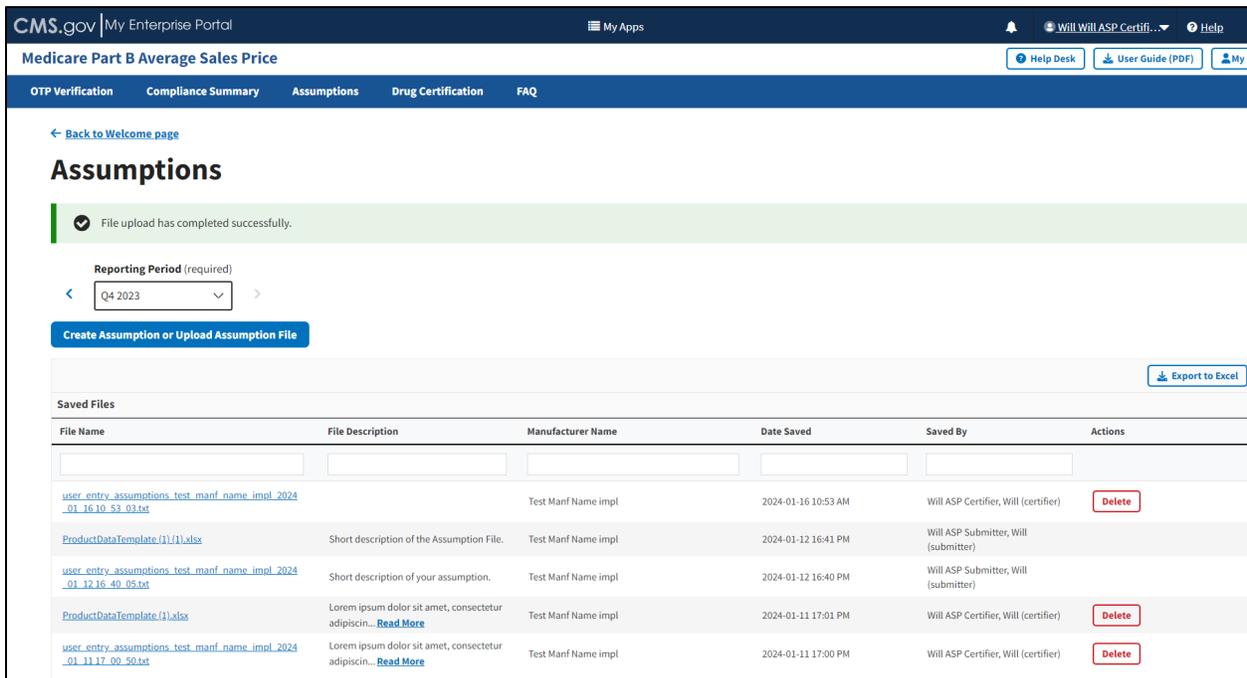
**Note:** Click the **Show More** tab to display all **Supported File Formats** available in the Module for you to use in your **Assumption File** upload.

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. 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.

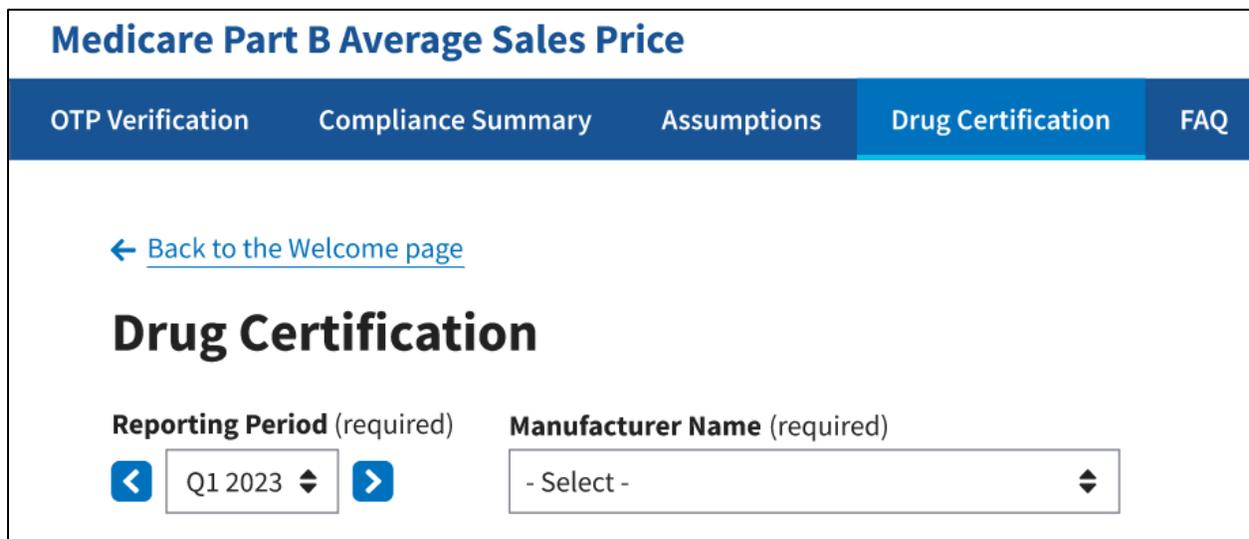
Follow these steps to certify drug product data:

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

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### Drug Certification

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

Q1 2023   - 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*.

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### 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:

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 34*.

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## 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)

**Street Address line 2**

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

NY
 10017

[Edit](#)

**Certifier's Contact Info**

**Name** (required)

**Email Address** (required)

**Phone Number** (required)

[Edit](#)

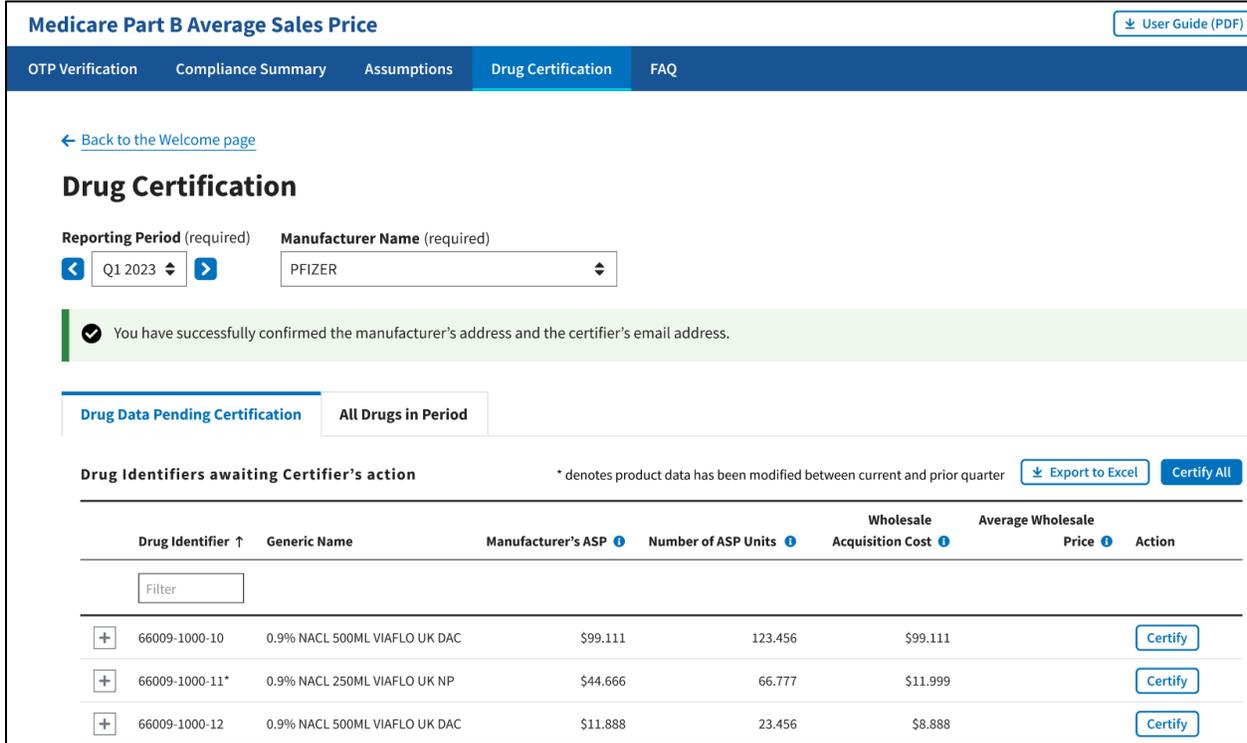
I confirm the accuracy of the information provided above.

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 \(PDF\)](#)

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### 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
<input type="text" value="Filter"/>						
<input type="checkbox"/> 66009-1000-10	0.9% NAACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		<a href="#">Certify</a>
<input type="checkbox"/> 66009-1000-11*	0.9% NAACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		<a href="#">Certify</a>
<input type="checkbox"/> 66009-1000-12	0.9% NAACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		<a href="#">Certify</a>

**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)**

**Street Address line 2**

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

[Edit](#)

---

**PFIZER Point of Contact Info**

**Name (required)**

**Email Address (required)**

**Phone Number (required)**

[Edit](#)

---

**Certifier's Contact Info**

**Name (required)**

**Email Address (required)**

**Phone Number (required)**

[Edit](#)

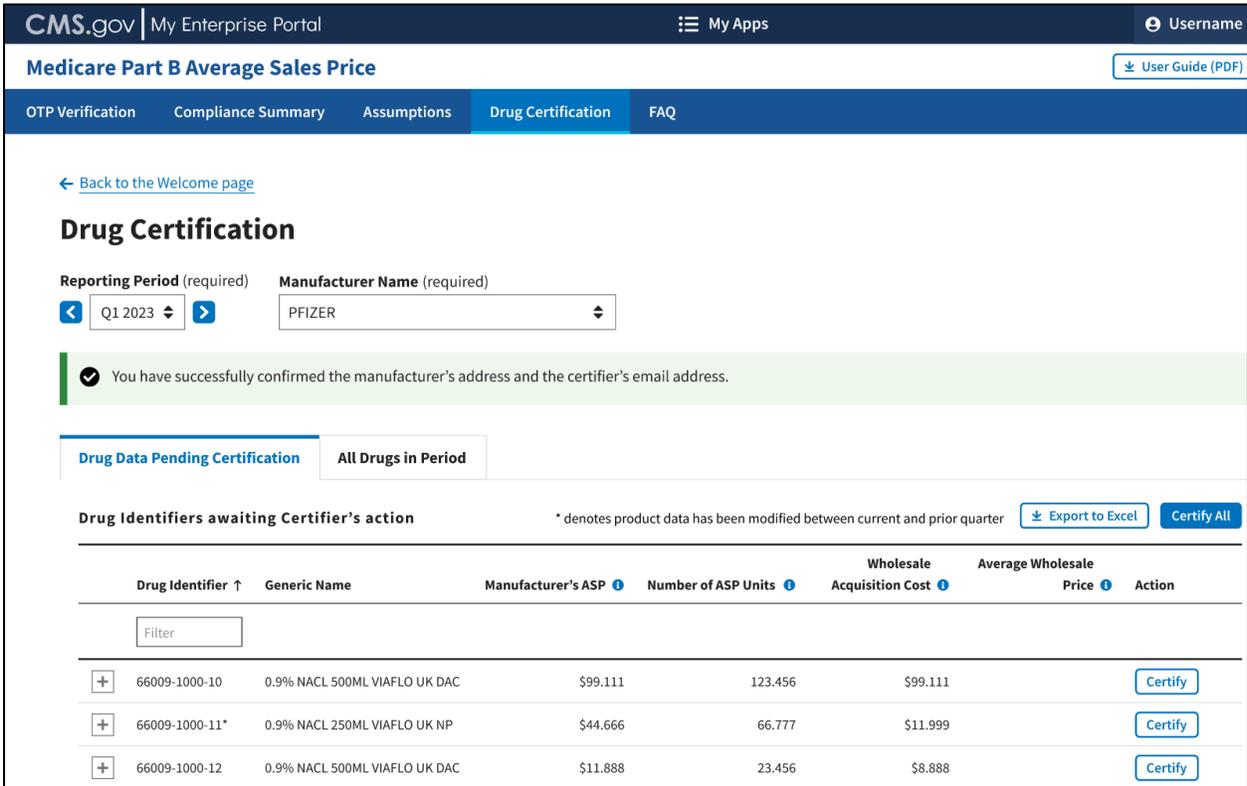
I confirm the accuracy of the information provided above.

[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*.



**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
66009-1000-10	0.9% NAACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		<a href="#">Certify</a>
66009-1000-11*	0.9% NAACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		<a href="#">Certify</a>
66009-1000-12	0.9% NAACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		<a href="#">Certify</a>

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*.

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## 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% NAACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111		<a href="#">Certify</a>												
<div style="border: 1px solid #ccc; padding: 5px; margin: 0;"> <p><b>Product Info</b></p> <table style="width: 100%; font-size: small;"> <tr> <td>Brand Name: No Data</td> <td>Strength of Product: 200mg</td> <td>Volume per Item: 120</td> </tr> <tr> <td>Number of Items per NDC/Alt ID: 45</td> <td>First Marketing Date: 07/02/2021</td> <td>Expiration Date of Final Lot Sold: No Data</td> </tr> <tr> <td>FDA Approval Date: 07/01/2021</td> <td>FDA Application Number: 54897</td> <td>FDA Application Supplement Number: 5489723</td> </tr> <tr> <td>FDA Approval Type: 510(k)</td> <td></td> <td></td> </tr> </table> </div>							Brand Name: No Data	Strength of Product: 200mg	Volume per Item: 120	Number of Items per NDC/Alt ID: 45	First Marketing Date: 07/02/2021	Expiration Date of Final Lot Sold: No Data	FDA Approval Date: 07/01/2021	FDA Application Number: 54897	FDA Application Supplement Number: 5489723	FDA Approval Type: 510(k)		
Brand Name: No Data	Strength of Product: 200mg	Volume per Item: 120																
Number of Items per NDC/Alt ID: 45	First Marketing Date: 07/02/2021	Expiration Date of Final Lot Sold: No Data																
FDA Approval Date: 07/01/2021	FDA Application Number: 54897	FDA Application Supplement Number: 5489723																
FDA Approval Type: 510(k)																		
+	66009-1000-11* 0.9% NAACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999		<a href="#">Certify</a>												
+	66009-1000-12 0.9% NAACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888		<a href="#">Certify</a>												

**Figure 38: Drug Data Pending Certification**

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

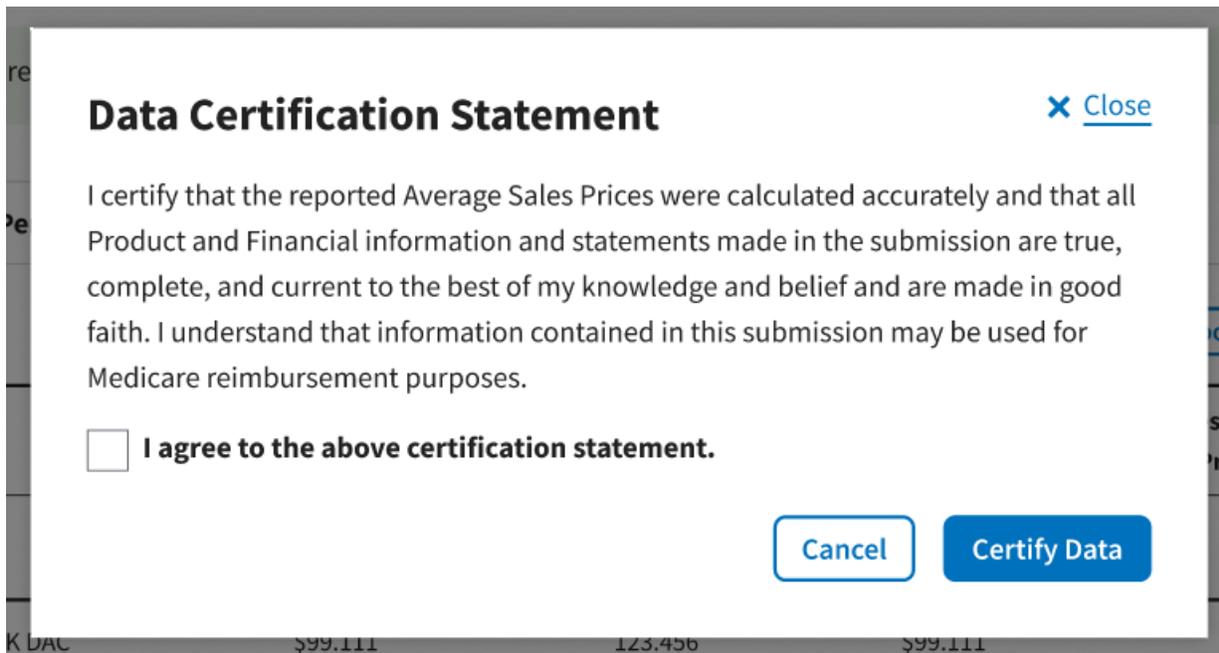


Figure 39: Data Certification Statement

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 40*.

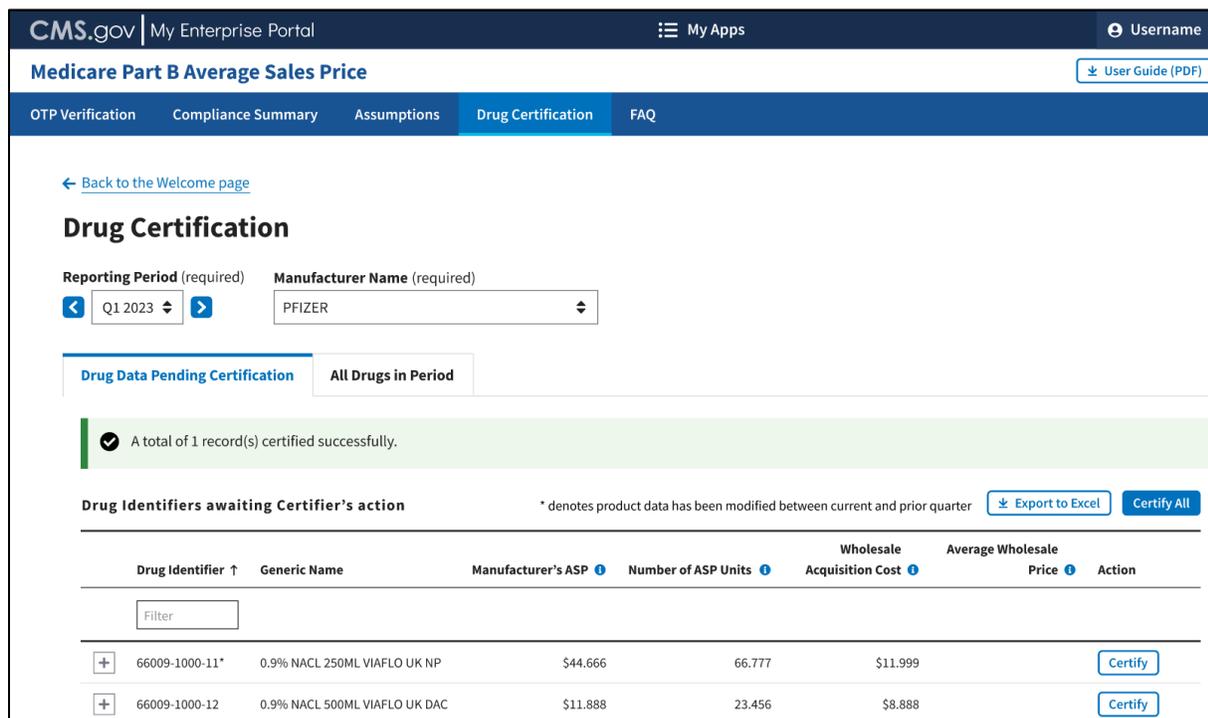


Figure 40: Data Certification - Confirmation Message

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

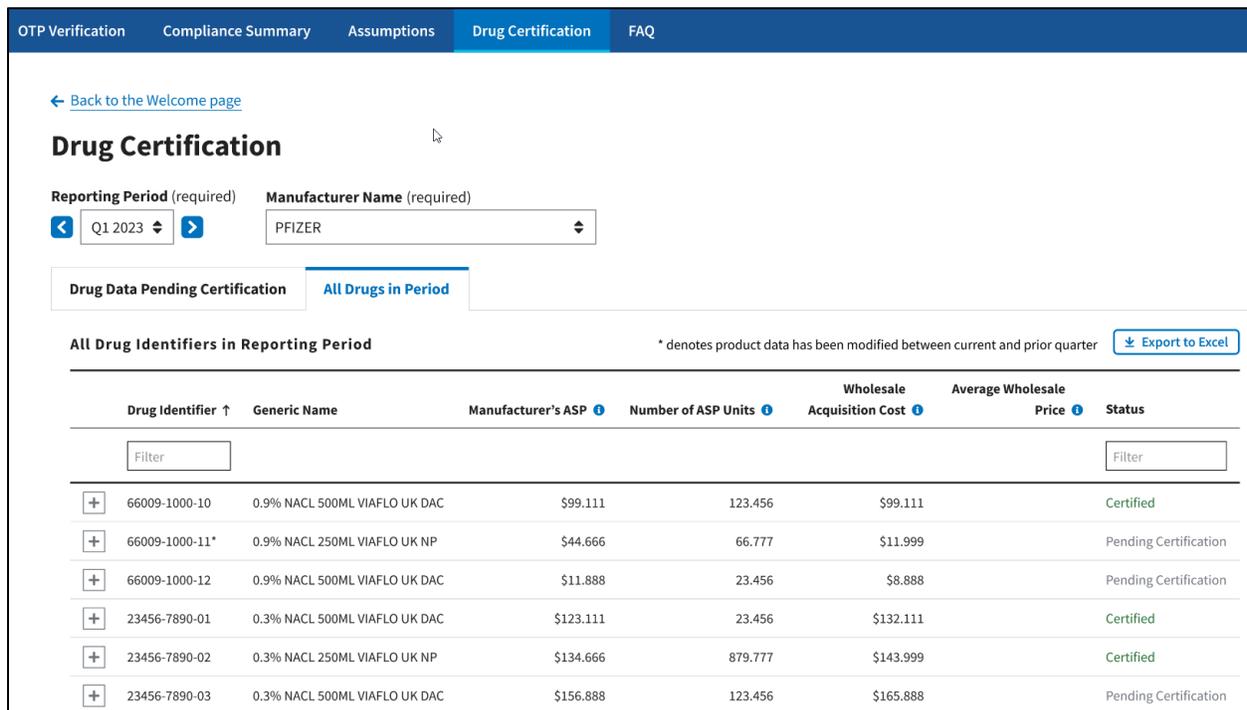
- Continue this process for each individual drug product until all your products have been certified. Click **Certify All** to certify all products at the same time.

### 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*.



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## 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
<input type="text" value="Filter"/>	<input type="text" value="Filter"/>					
<input type="checkbox"/>	66009-1000-10	0.9% NACL 500ML VIAFLO UK DAC	\$99.111	123.456	\$99.111	Certified
<input type="checkbox"/>	66009-1000-11*	0.9% NACL 250ML VIAFLO UK NP	\$44.666	66.777	\$11.999	Pending Certification
<input type="checkbox"/>	66009-1000-12	0.9% NACL 500ML VIAFLO UK DAC	\$11.888	23.456	\$8.888	Pending Certification
<input type="checkbox"/>	23456-7890-01	0.3% NACL 500ML VIAFLO UK DAC	\$123.111	23.456	\$132.111	Certified
<input type="checkbox"/>	23456-7890-02	0.3% NACL 250ML VIAFLO UK NP	\$134.666	879.777	\$143.999	Certified
<input type="checkbox"/>	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
<a href="mailto:ASPHelpDesk@dcca.com">ASPHelpDesk@dcca.com</a>	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 <ul style="list-style-type: none"><li>Initial draft following collaboration between DCCA and Index Analytics and incorporation of feedback from CMS</li><li>Various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections</li></ul>

## 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.

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