



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

## **Certifier User Guide**

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**Version 2.1**

**Date: August 29, 2025**

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## 1. Purpose

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

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

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

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

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

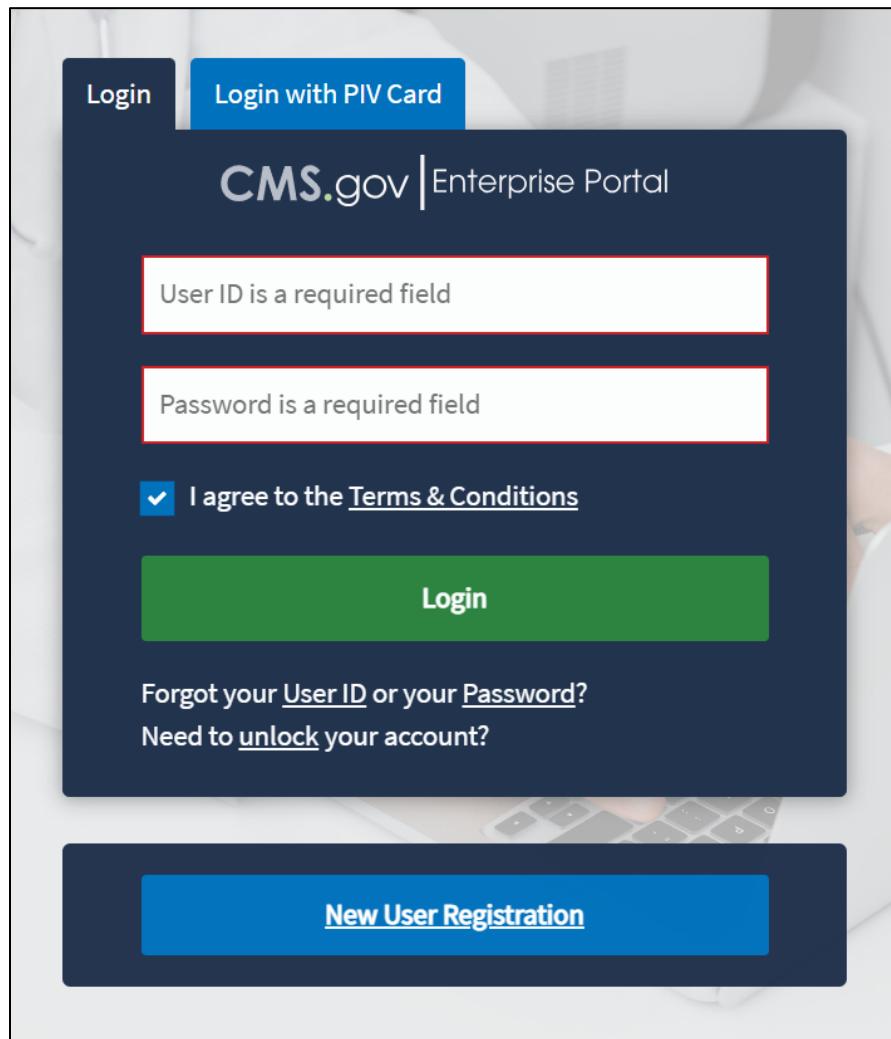
## 2. Logging in Using MFA

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

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

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

The ASP Module Login Page opens. Refer to *Figure 1*.



The screenshot shows the CMS.gov Enterprise Portal login interface. At the top, there are two buttons: 'Login' (in white text on a dark background) and 'Login with PIV Card' (in white text on a blue background). Below these is the CMS.gov logo. The main form area has two red-bordered input fields, both of which have error messages: 'User ID is a required field' and 'Password is a required field'. Below these fields is a checkbox labeled 'I agree to the Terms & Conditions' with a checked checkedmark. A large green 'Login' button is centered at the bottom of the form. At the bottom of the page, there are two links: 'Forgot your User ID or your Password?' and 'Need to unlock your account?'. At the very bottom right, there is a blue button labeled 'New User Registration'.

**Figure 1: Logging in Using MFA - ASP Module Login**

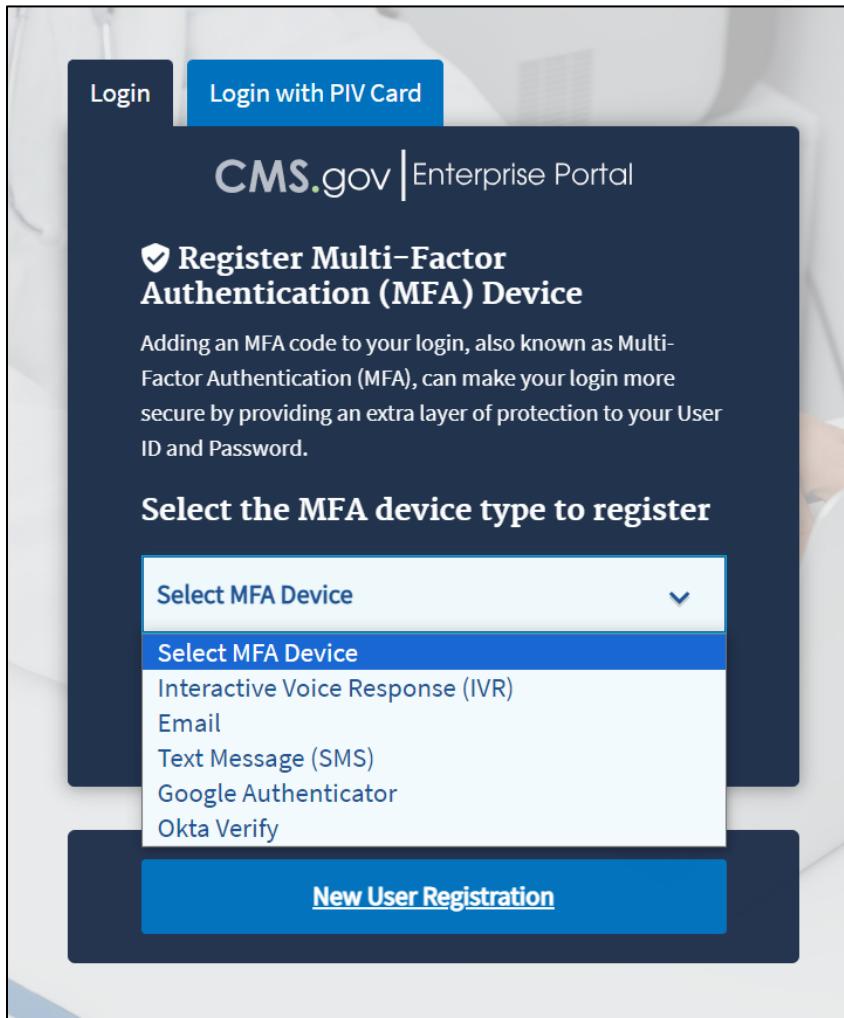
2. Enter your login information into the required **User ID** and **Password** fields.
3. Click the **Terms & Conditions** hyperlink and review the text in the pop-up window; close the window to move on to the next step.
4. Review the terms and conditions and select the **I agree to the Terms & Conditions**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

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

5. Click **Login**.

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

The **Multi-Factor Authentication** page opens. Refer to *Figure 2*.

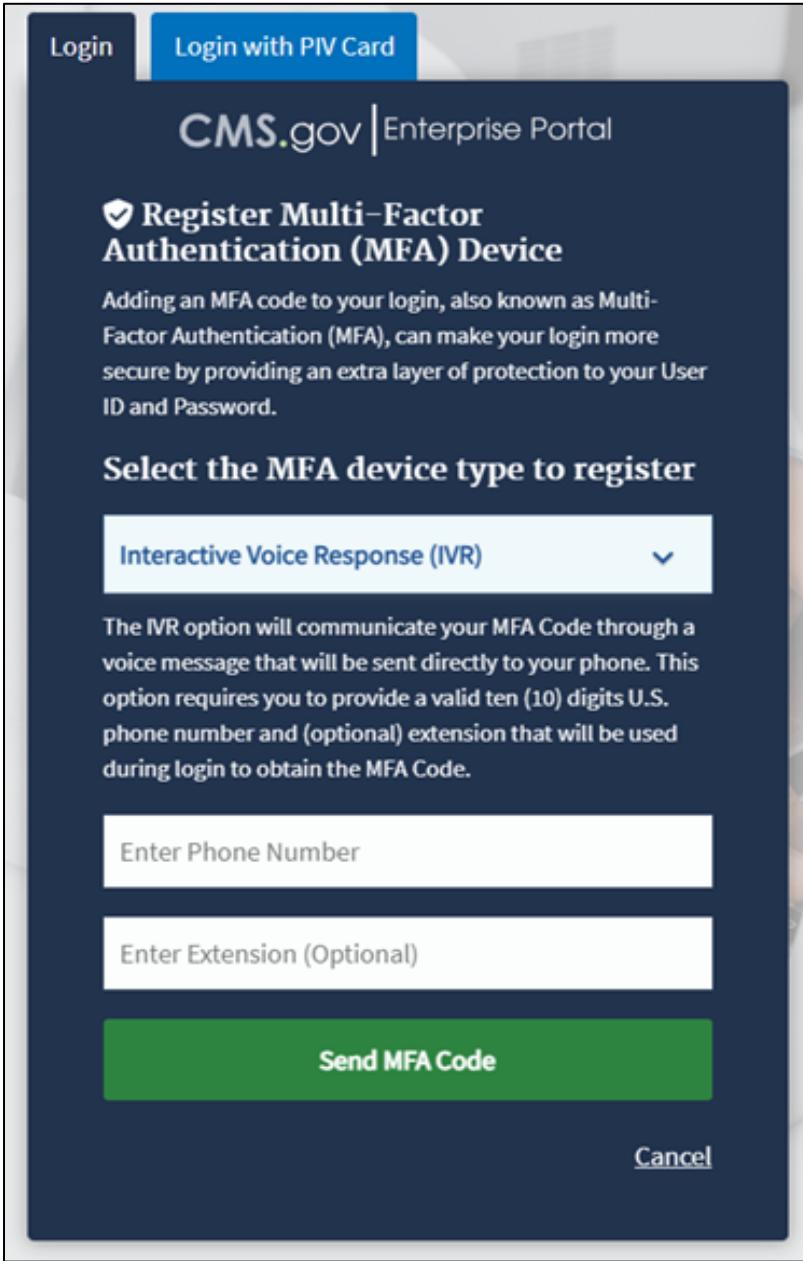


**Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down**

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

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

**Note:** *Figure 3* demonstrates MFA registration using IVR as the selected option.



The screenshot shows a web-based login interface for the CMS.gov Enterprise Portal. At the top, there are two buttons: 'Login' and 'Login with PIV Card'. The 'Login with PIV Card' button is highlighted with a blue background. Below these buttons, the CMS.gov logo and 'Enterprise Portal' text are displayed. A large heading 'Register Multi-Factor Authentication (MFA) Device' is shown with a checked checkbox icon. A descriptive text block explains that adding an MFA code to the login makes it more secure by providing an extra layer of protection. The main action is 'Select the MFA device type to register', with a dropdown menu currently set to 'Interactive Voice Response (IVR)'. A detailed description of the IVR option follows, stating that it communicates the MFA code via a voice message sent to a provided phone number. Below this, there are two input fields: 'Enter Phone Number' and 'Enter Extension (Optional)'. A large green button labeled 'Send MFA Code' is positioned below the input fields. A 'Cancel' link is located at the bottom right of the form area.

**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.

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

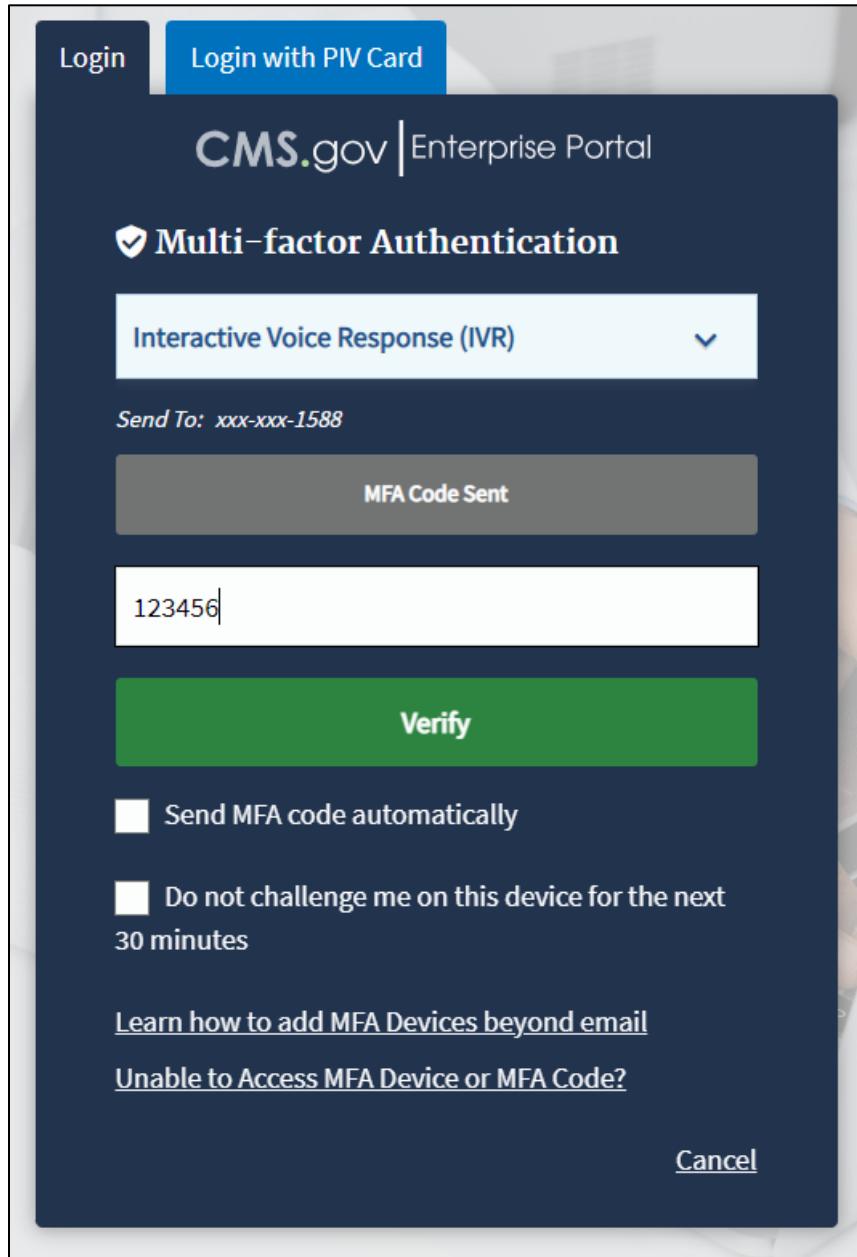


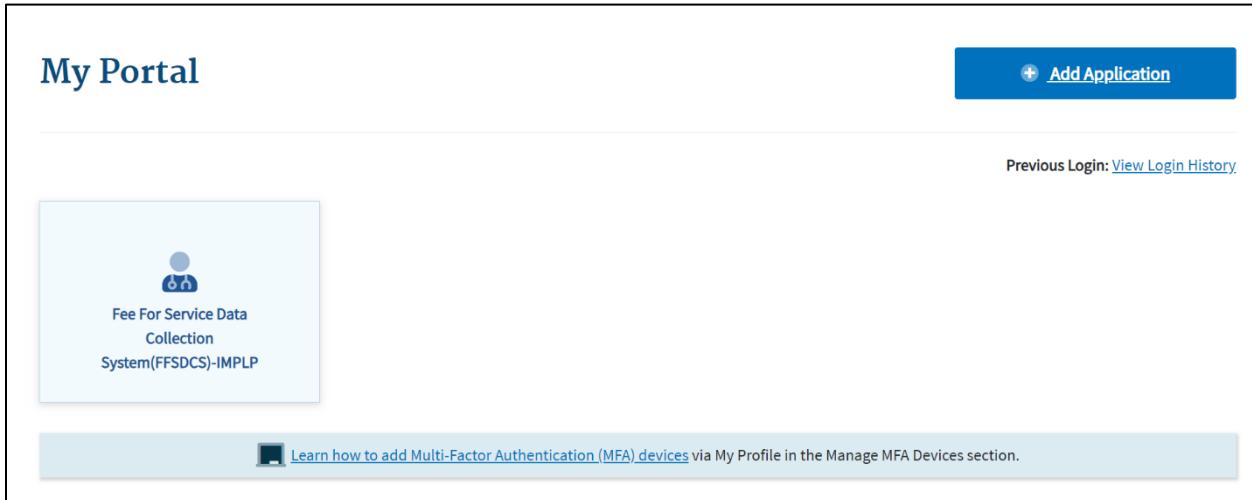
Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

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 Device 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*.



My Portal

+ Add Application

Previous Login: [View Login History](#)

Fee For Service Data Collection System(FFSDCS)-IMPLP

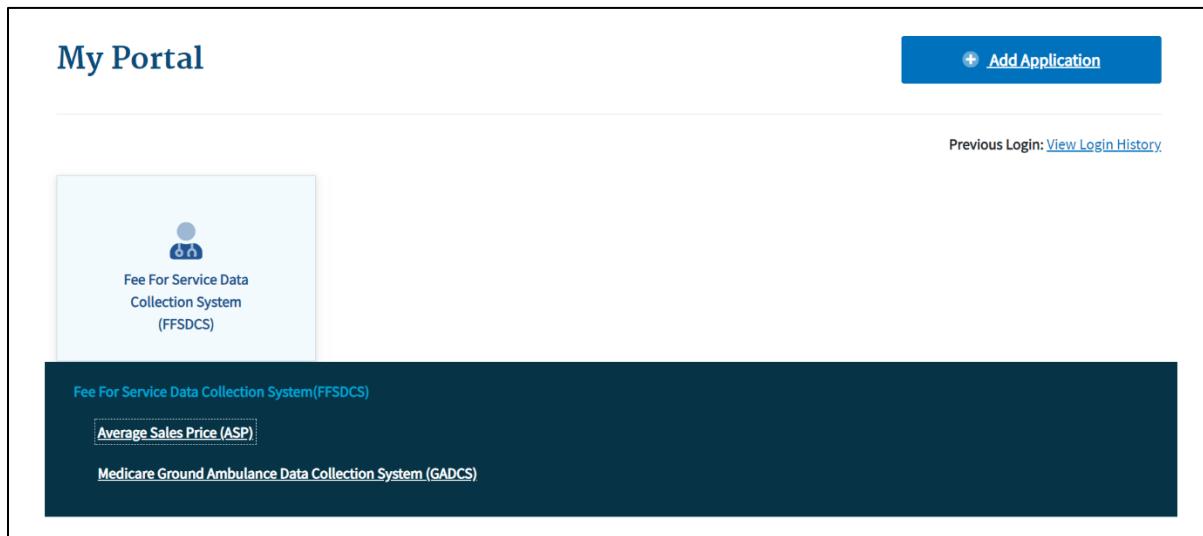
Learn how to add Multi-Factor Authentication (MFA) devices via My Profile in the Manage MFA Devices section.

**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*.



My Portal

+ Add Application

Previous Login: [View Login History](#)

Fee For Service Data Collection System(FFSDCS)

Average Sales Price (ASP)

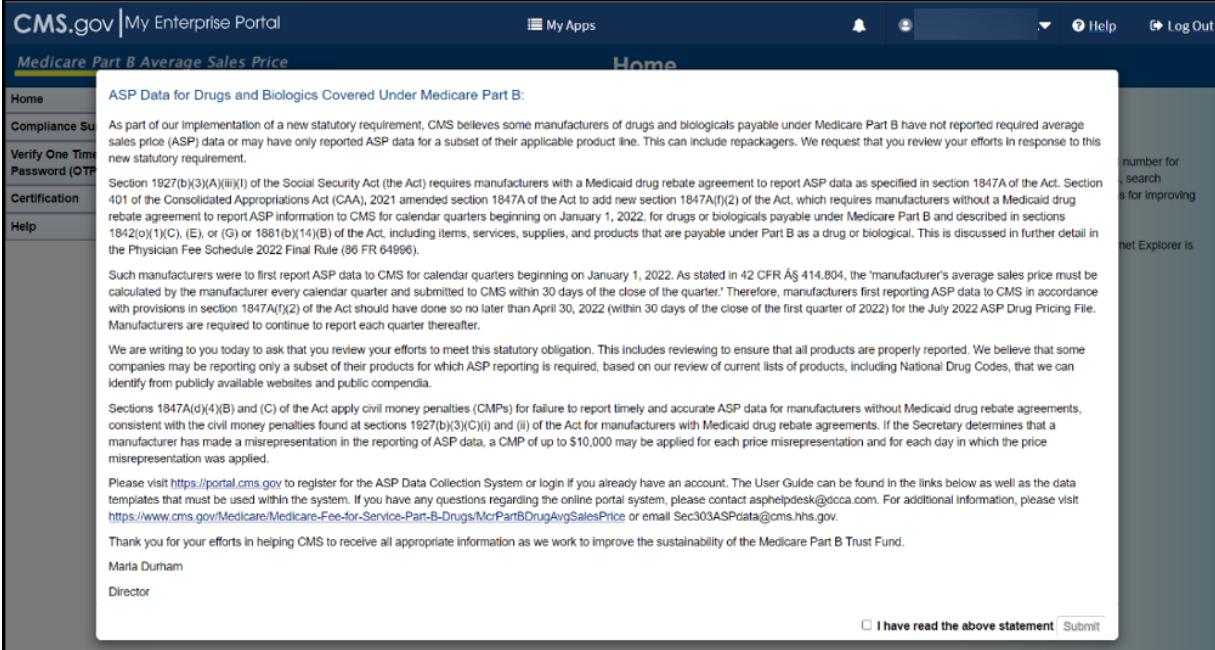
Medicare Ground Ambulance Data Collection System (GADCS)

**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*.



ASP Data for Drugs and Biologics Covered Under Medicare Part B:

As part of our implementation of a new statutory requirement, CMS believes some manufacturers of drugs and biologicals payable under Medicare Part B have not reported required average sales price (ASP) data or may have only reported ASP data for a subset of their applicable product line. This can include repackagers. We request that you review your efforts in response to this new statutory requirement.

Section 1927(b)(3)(A)(iii)(I) of the Social Security Act (the Act) requires manufacturers with a Medicaid drug rebate agreement to report ASP data as specified in section 1847A of the Act. Section 401 of the Consolidated Appropriations Act (CAA), 2021 amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. This is discussed in further detail in the Physician Fee Schedule 2022 Final Rule (86 FR 64996).

Such manufacturers were to first report ASP data to CMS for calendar quarters beginning on January 1, 2022. As stated in 42 CFR § 414.804, the 'manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter.' Therefore, manufacturers first reporting ASP data to CMS in accordance with provisions in section 1847A(f)(2) of the Act should have done so no later than April 30, 2022 (within 30 days of the close of the first quarter of 2022) for the July 2022 ASP Drug Pricing File. Manufacturers are required to continue to report each quarter thereafter.

We are writing to you today to ask that you review your efforts to meet this statutory obligation. This includes reviewing to ensure that all products are properly reported. We believe that some companies may be reporting only a subset of their products for which ASP reporting is required, based on our review of current lists of products, including National Drug Codes, that we can identify from publicly available websites and public compendia.

Sections 1847A(d)(4)(B) and (C) of the Act apply civil money penalties (CMPs) for failure to report timely and accurate ASP data for manufacturers without Medicaid drug rebate agreements, consistent with the civil money penalties found at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with Medicaid drug rebate agreements. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a CMP of up to \$10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied.

Please visit <https://portal.cms.gov> to register for the ASP Data Collection System or login if you already have an account. The User Guide can be found in the links below as well as the data templates that must be used within the system. If you have any questions regarding the online portal system, please contact [asphelpdesk@dcca.com](mailto:asphelpdesk@dcca.com). For additional information, please visit <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice> or email [Sec303ASPdata@cms.hhs.gov](mailto:Sec303ASPdata@cms.hhs.gov).

Thank you for your efforts in helping CMS to receive all appropriate information as we work to improve the sustainability of the Medicare Part B Trust Fund.

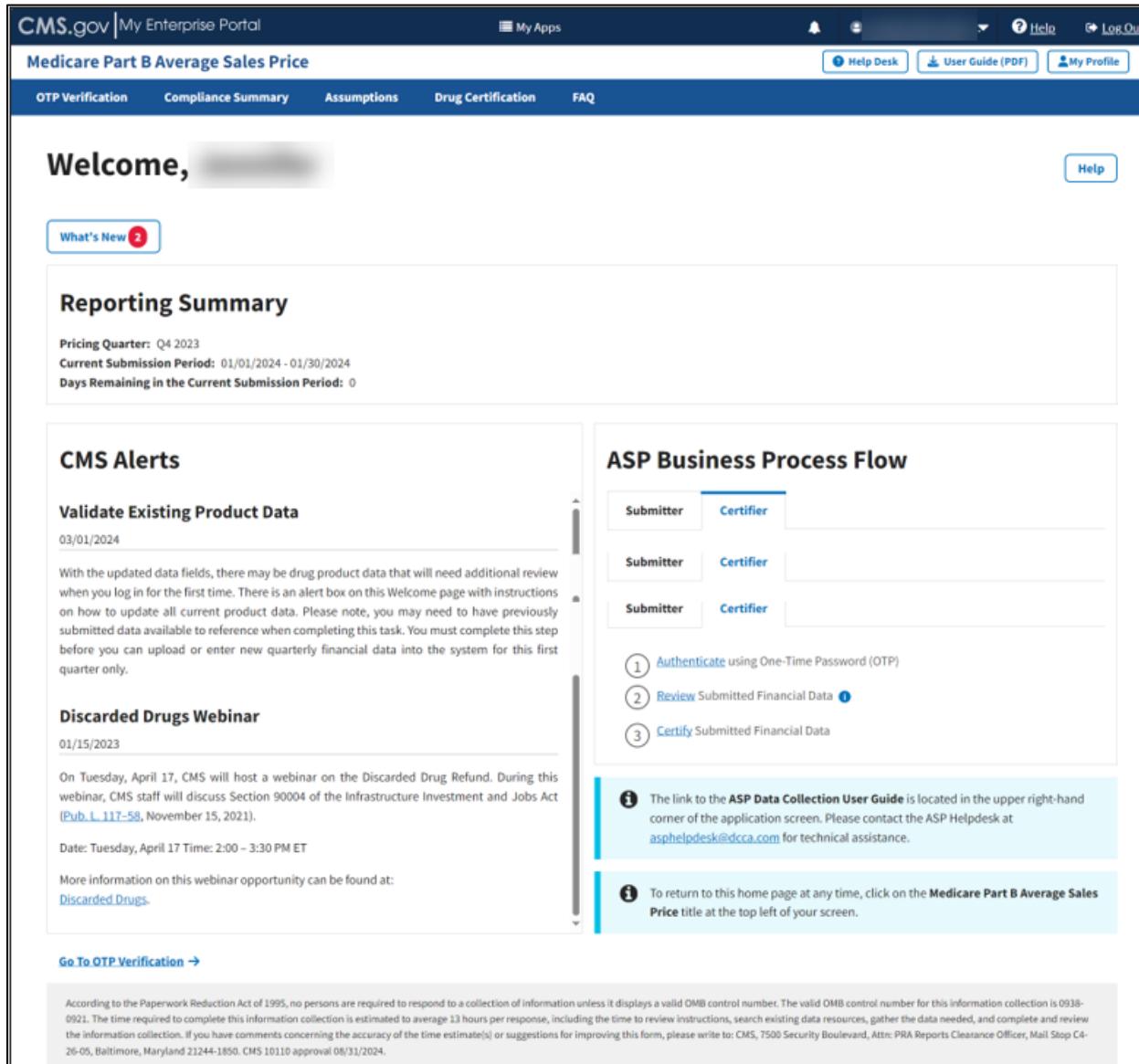
Maria Durham  
Director

I have read the above statement

**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**

**Medicare Part B Average Sales Price**

My Apps     Help Desk     User Guide (PDF)     My Profile

OTP Verification    Compliance Summary    Assumptions    Drug Certification    FAQ

Welcome, [REDACTED]

What's New 2

**Reporting Summary**

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

**CMS Alerts**

**Validate Existing Product Data**  
 03/01/2024  
 With the updated data fields, there may be drug product data that will need additional review when you log in for the first time. There is an alert box on this Welcome page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the system for this first quarter only.

**Discarded Drugs Webinar**  
 01/15/2023  
 On Tuesday, April 17, CMS will host a webinar on the Discarded Drug Refund. During this webinar, CMS staff will discuss Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021).  
 Date: Tuesday, April 17 Time: 2:00 – 3:30 PM ET  
 More information on this webinar opportunity can be found at: [Discarded Drugs](#)

**ASP Business Process Flow**

Submitter    Certifier

Submitter    Certifier

Submitter    Certifier

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

**Information Notes**

**1** The link to the [ASP Data Collection User Guide](#) is located in the upper right-hand corner of the application screen. Please contact the ASP Helpdesk at [asphelpdesk@dcia.com](mailto:asphelpdesk@dcia.com) for technical assistance.

**2** To return to this home page at any time, click on the [Medicare Part B Average Sales Price](#) title at the top left of your screen.

**Go To OTP Verification →**

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

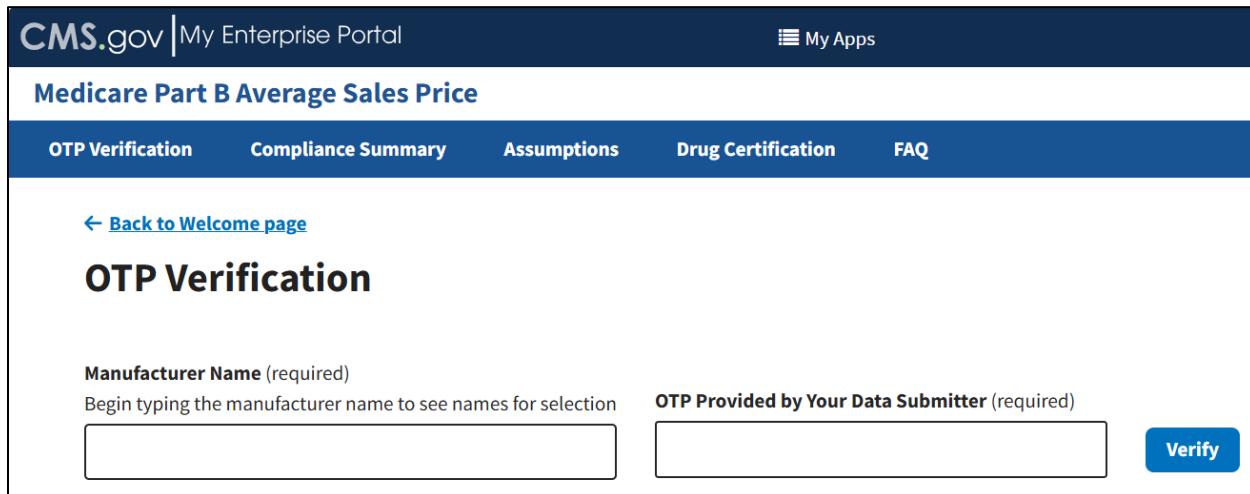
Once the Submitter has completed and submitted product data, the Submitter must share the one-time password (OTP) with the Certifier to establish a relationship within the system. Note the following about OTPs:

- 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*.



The screenshot shows the CMS.gov My Enterprise Portal homepage for Medicare Part B Average Sales Price. The top navigation bar includes links for 'My Apps' and a 'Back to Welcome page'. The main content area is titled 'OTP Verification'. It features two input fields: 'Manufacturer Name (required)' and 'OTP Provided by Your Data Submitter (required)'. A 'Verify' button is located to the right of the second input 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*.

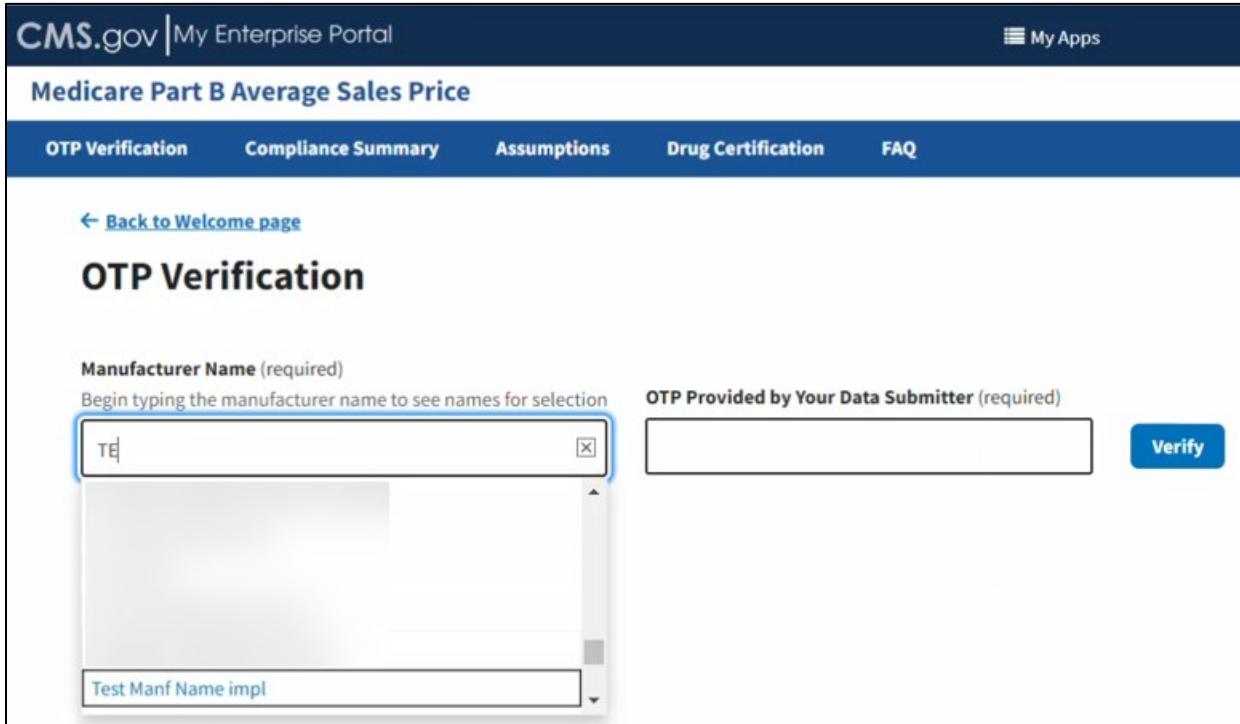

 This screenshot shows the CMS.gov My Enterprise Portal for Medicare Part B Average Sales Price. The user is on the OTP Verification page. A search bar for 'Manufacturer Name' is highlighted with a blue border, showing the letters 'TE' as the user has typed. To the right, there is a field for 'OTP Provided by Your Data Submitter' which is currently empty. A blue 'Verify' button is positioned to the right of this field.

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*.

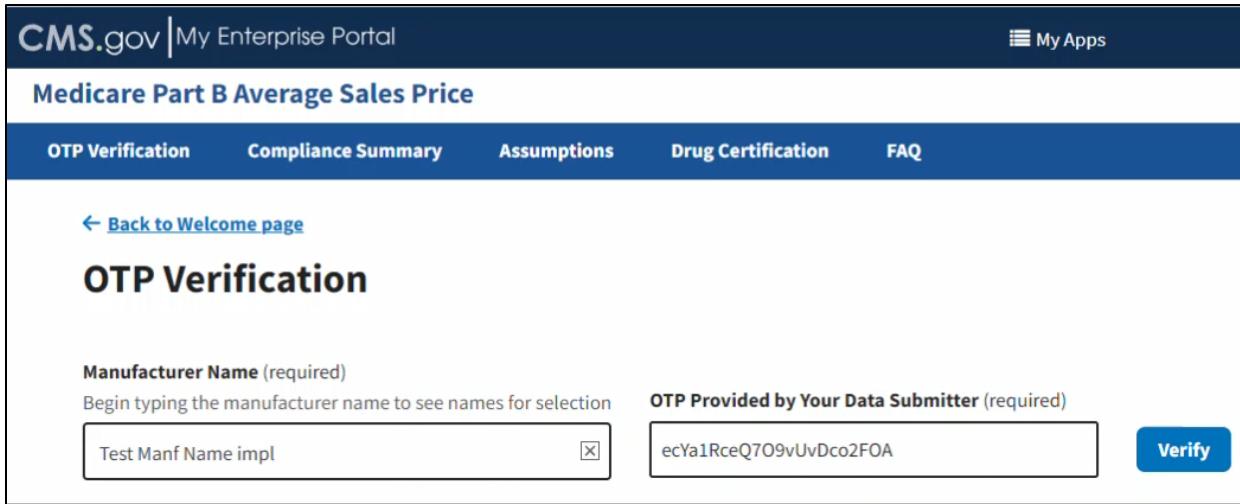

 This screenshot shows the same CMS.gov My Enterprise Portal interface as Figure 10, but the focus is on the 'OTP Provided by Your Data Submitter' field. This field is highlighted with a blue border and contains the OTP code 'ecYa1RceQ709vUvDco2FOA'. The 'Verify' button is visible to the right of this field.

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*.

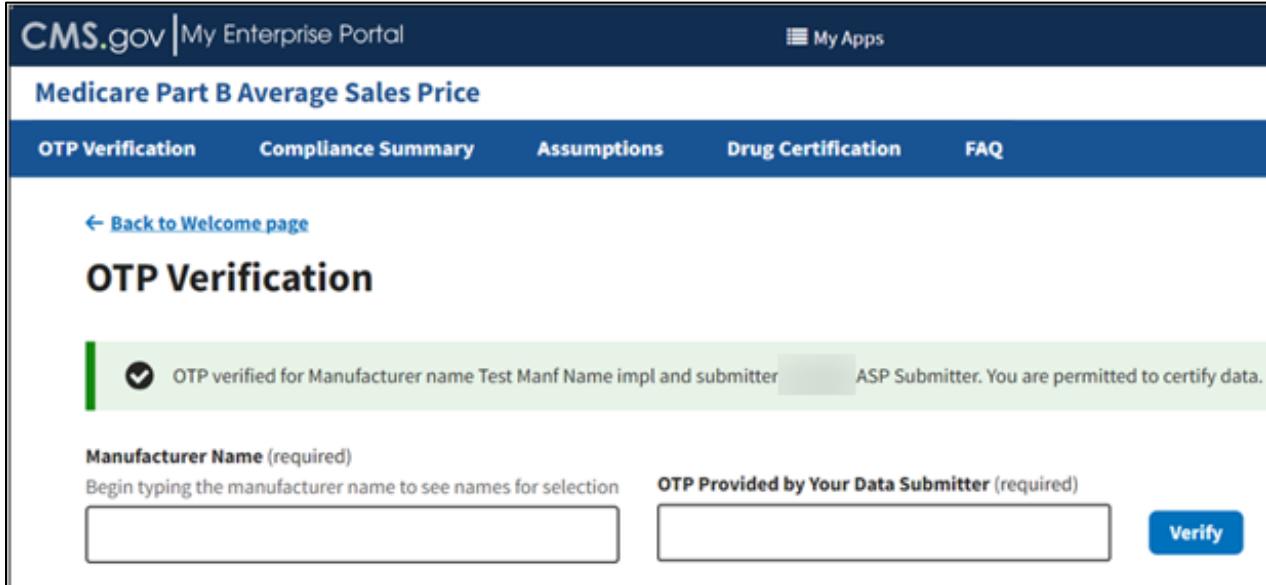

 A screenshot of the CMS.gov My Enterprise Portal. The top navigation bar includes the CMS logo, "My Enterprise Portal", and "My Apps". Below this is a header for "Medicare Part B Average Sales Price" with tabs for "OTP Verification", "Compliance Summary", "Assumptions", "Drug Certification", and "FAQ". A "Back to Welcome page" link is also present. The main content area is titled "OTP Verification" and displays a success message: "OTP verified for Manufacturer name Test Manf Name impl and submitter" with a checkmark icon, and "ASP Submitter. You are permitted to certify data." Below this are input fields for "Manufacturer Name (required)" and "OTP Provided by Your Data Submitter (required)", both with placeholder text "Begin typing the manufacturer name to see names for selection" and "OTP Provided by Your Data Submitter (required)". A "Verify" button is located to the right of the input fields.

Figure 12: OTP Verification Successful

## 3.2 Compliance Summary

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

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

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

**Note:** Financial data will be suppressed for prior quarters.

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

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

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

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

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

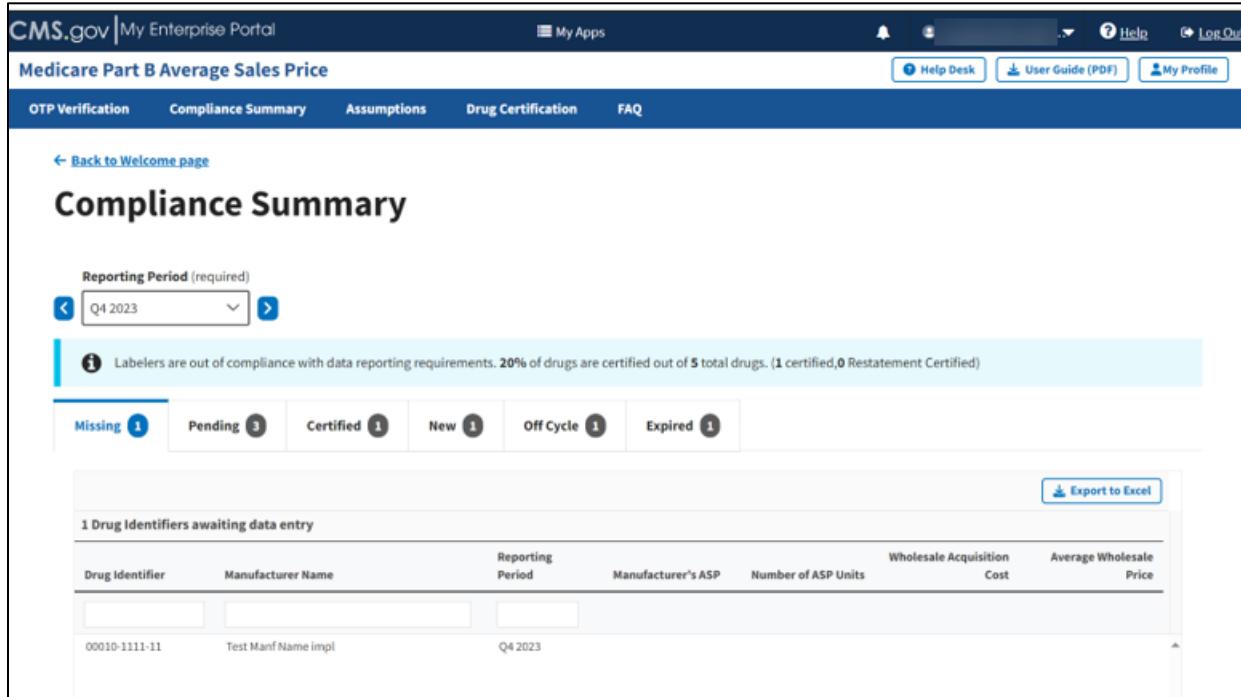


Figure 13: Compliance Summary

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

### 3.2.1 Missing

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

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

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

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

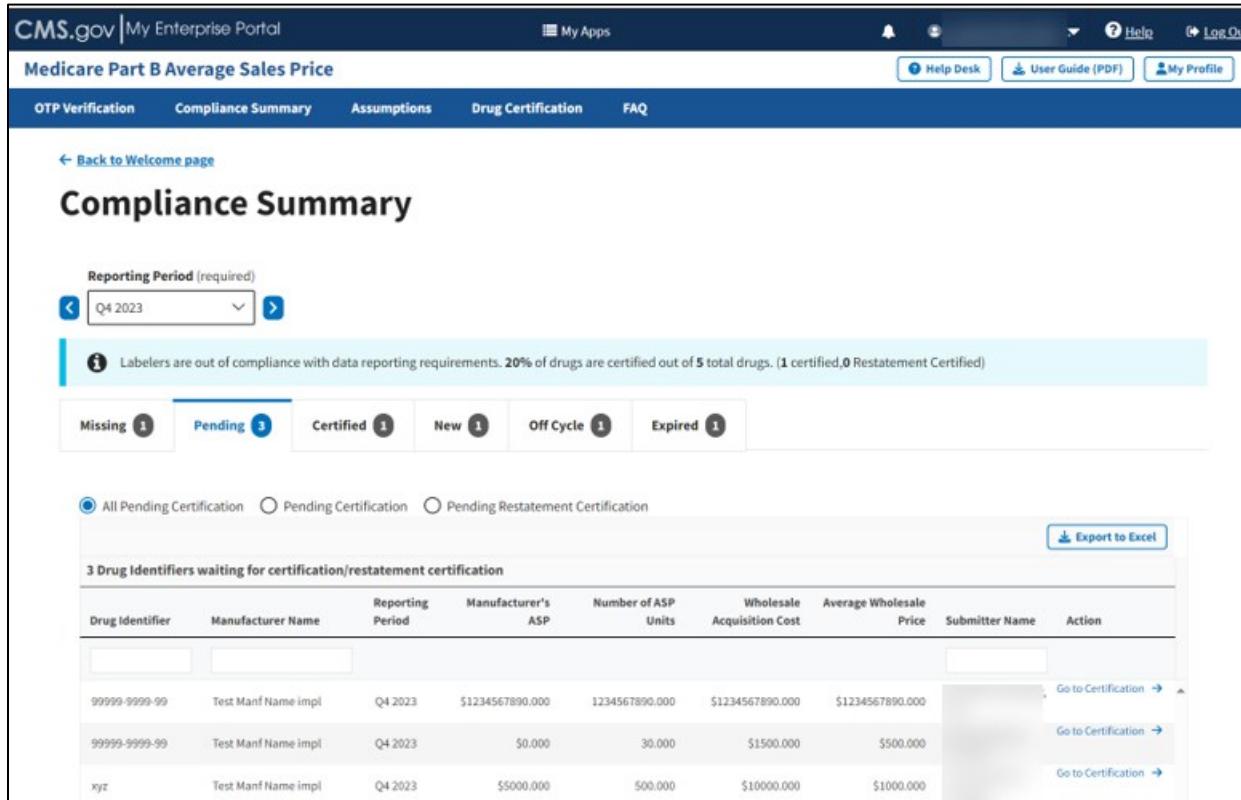
2. Inform the Submitter of any missing financial information to ensure the inclusion of all data collected in the Module.
3. Click the **Pending** tab to move on to the next page.

### 3.2.2 Pending

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

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

The **Pending** page displays. Refer to *Figure 14*.


 A screenshot of the CMS ASP Module Compliance Summary page. The top navigation bar includes links for 'My Apps', 'Help Desk', 'User Guide (PDF)', and 'My Profile'. Below the navigation is a blue header bar with tabs for 'OTP Verification', 'Compliance Summary', 'Assumptions', 'Drug Certification', and 'FAQ'. A 'Back to Welcome page' link is also present. The main content area is titled 'Compliance Summary' and features a reporting period dropdown set to 'Q4 2023'. A message box indicates 'Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)'. Below this are tabs for 'Missing' (1), 'Pending' (3), 'Certified' (1), 'New' (1), 'Off Cycle' (1), and 'Expired' (1). The 'Pending' tab is selected. A radio button group at the top of the table allows filtering by 'All Pending Certification', 'Pending Certification', or 'Pending Restatement Certification', with 'All Pending Certification' selected. An 'Export to Excel' button is located in the top right of the table area. The table lists three drug identifiers: '99999-9999-99', '99999-9999-99', and 'xyz', each with details like manufacturer name, reporting period, and costs. Each row has a 'Go to Certification' link in the 'Action' column.
 

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

**Figure 14: Compliance Summary - All Pending Certification**

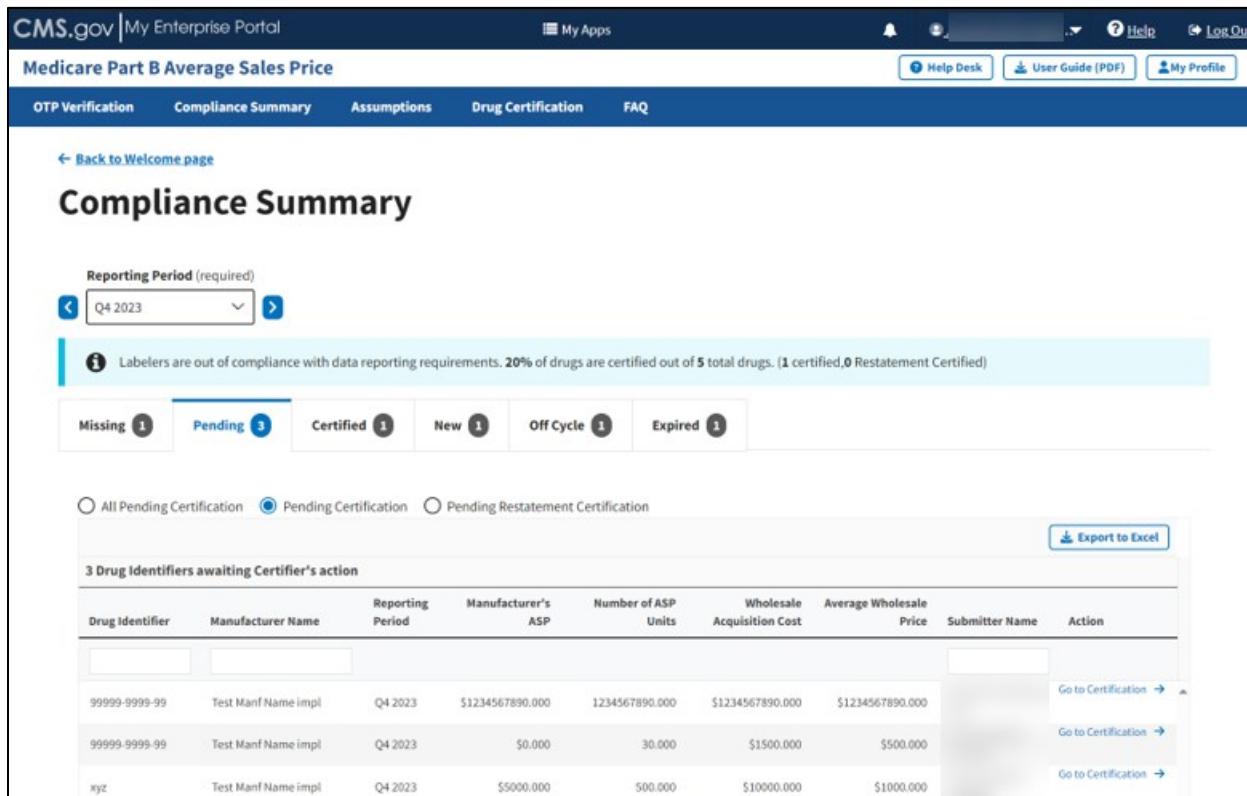
The Module automatically selects the **All Pending Certification** radio button, and the page displays the drug identifiers waiting for certification/restatement certification.

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



Reporting Period (required)

Q4 2023

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

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

All Pending Certification Pending Certification Pending Restatement Certification

Export to Excel

3 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	Submitter Name	Action
99999-9999-99	Test Manf Name impl	Q4 2023	\$1234567890.000	1234567890.000	\$1234567890.000	\$1234567890.000		Go to Certification →
99999-9999-99	Test Manf Name impl	Q4 2023	\$0.000	30.000	\$1500.000	\$500.000		Go to Certification →
xyz	Test Manf Name impl	Q4 2023	\$5000.000	500.000	\$10000.000	\$1000.000		Go to Certification →

Figure 15: Compliance Summary - Pending Certification

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

- Review the submitted drug information.

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

- Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to *Section 3.5 - Drug Certification*.)
- Click the **Pending Restatement Certification** radio button to filter only for drugs that are pending restatement certification. Refer to *Figure 16*.
- Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to *Section 3.5 - Drug Certification*.)

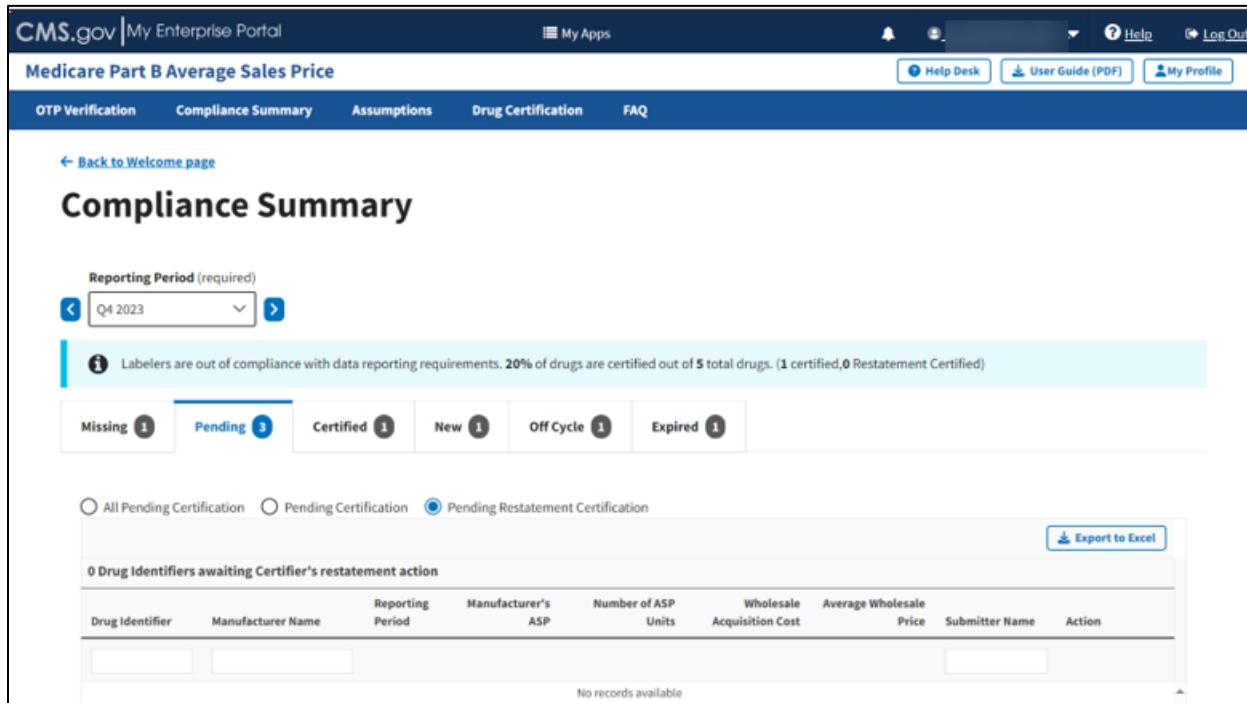


Figure 16: Compliance Summary - Pending Restatement Certification

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

9. Review the submitted drug information.

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

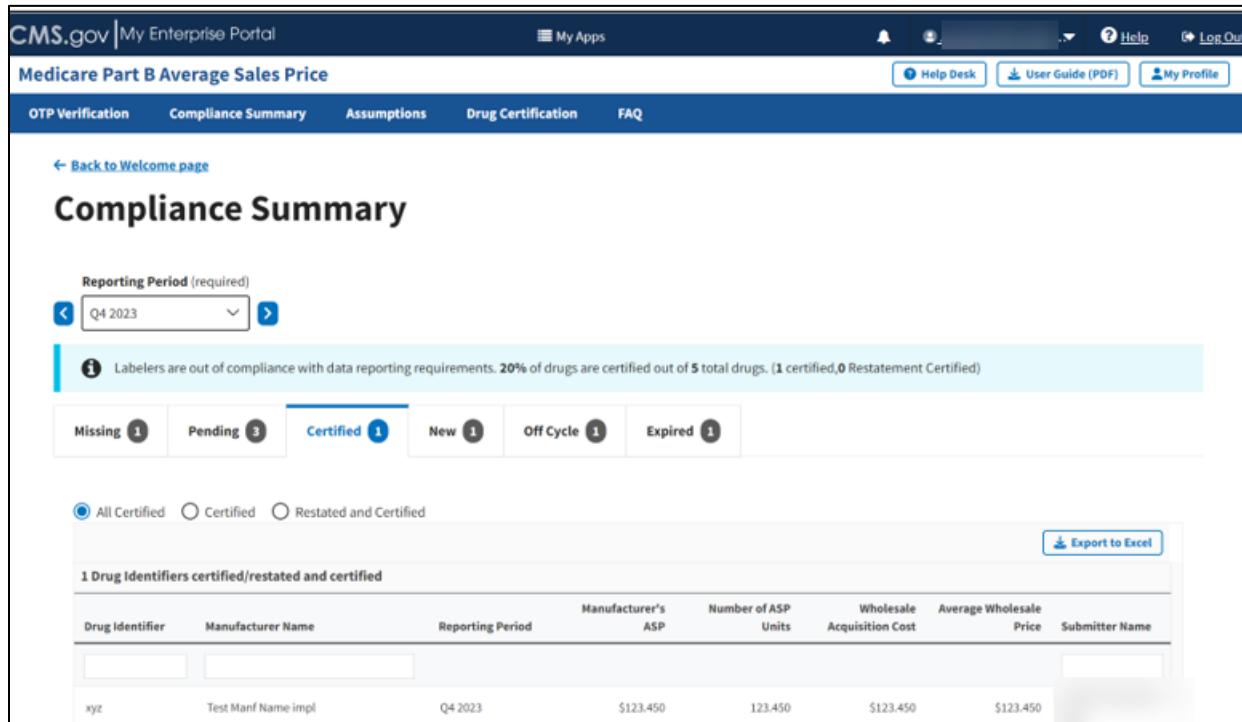
10. Under **Action**, click the **Go to Certification** hyperlink to navigate to **Drug Certification**. (Refer to *Section 3.5 - Drug Certification*.)
11. Click the **Certified** tab to move on to the next page.

### 3.2.3 Certified

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

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

The **Certified** page displays. Refer to *Figure 17*.



Reporting Period (required)

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

**Certified** (1)

All Certified  Certified  Restated and Certified

**1 Drug Identifiers certified/restated and certified**

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

**Figure 17: Compliance Summary - Certified**

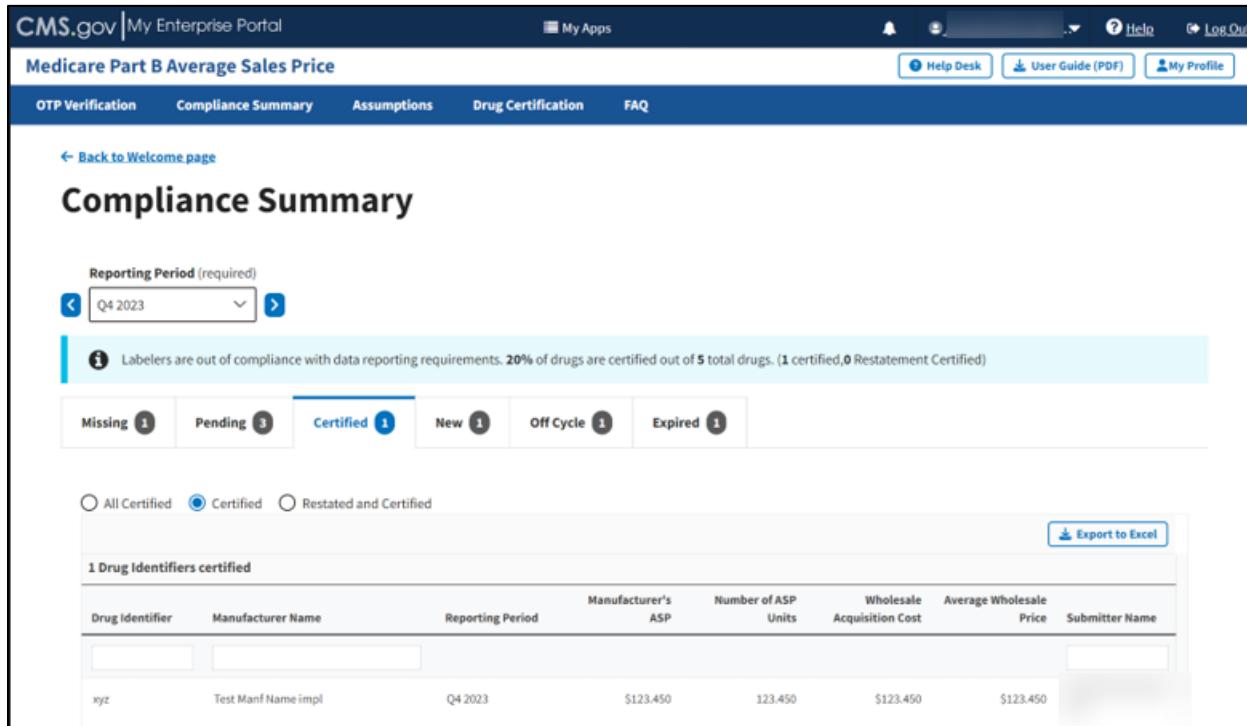
The Module automatically selects the **All Certified** radio button, and the page displays the certified/restated drug identifiers.

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

2. Review the submitted drug information.

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

3. Click the **Certified** radio button to filter only for certified drugs. Refer to *Figure 18*.



Reporting Period (required)

Q4 2023

**Compliance Summary**

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

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

All Certified Certified Restated and Certified

1 Drug Identifiers certified

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

[Export to Excel](#)

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 certified drugs that were restated. Refer to *Figure 19*.

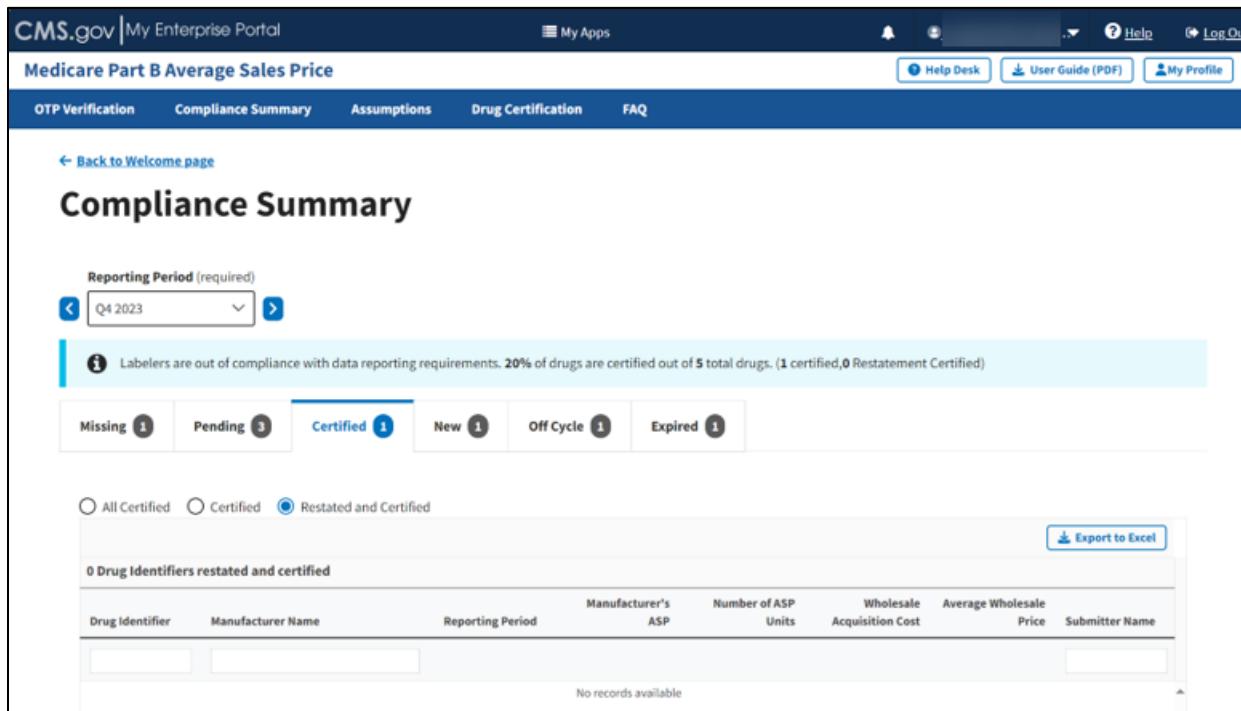

 The screenshot shows the CMS.gov My Enterprise Portal. The top navigation bar includes 'My Apps', 'Help', 'User Guide (PDF)', and 'My Profile'. Below the navigation is a sub-navigation bar with tabs: 'OTP Verification', 'Compliance Summary', 'Assumptions', 'Drug Certification', and 'FAQ'. A link to 'Back to Welcome page' is also present. The main content area is titled 'Compliance Summary' and displays a reporting period selector set to 'Q4 2023'. A message box states: 'Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)'. Below this are tabs for 'Missing' (0), 'Pending' (0), 'Certified' (1), 'New' (1), 'Off Cycle' (0), and 'Expired' (0). A radio button group allows selecting 'All Certified', 'Certified', or 'Restated and Certified' (which is selected). An 'Export to Excel' button is located on the right. A table below shows drug identifier information, with a note 'No records available'. The table columns are: Drug Identifier, Manufacturer Name, Reporting Period, Manufacturer's ASP, Number of ASP Units, Wholesale Acquisition Cost, Average Wholesale Price, and Submitter Name.

Figure 19: Compliance Summary - Restated and Certified

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

6. Review the submitted drug information.

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

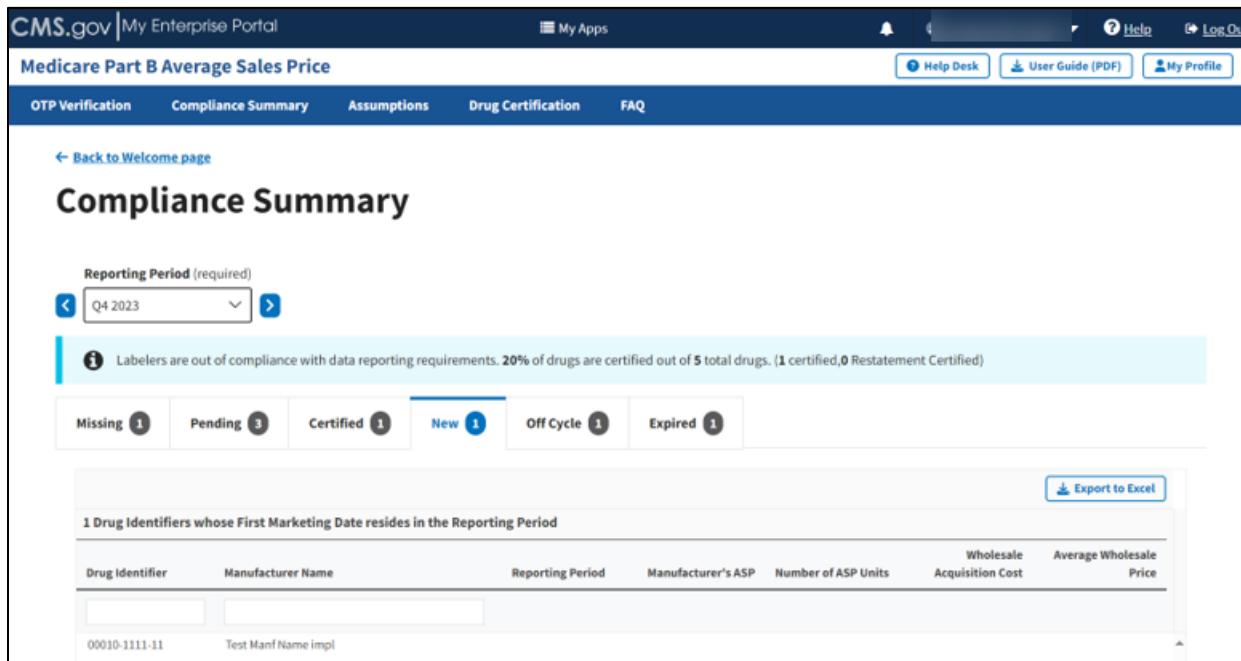
7. Click the **New** tab to move on to the next page.

### 3.2.4 New

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

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

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


 The screenshot shows the CMS.gov My Enterprise Portal. The top navigation bar includes "My Apps", a bell icon, a help icon, and "Log Out". Below the navigation is a blue header bar with tabs: "OTP Verification", "Compliance Summary", "Assumptions", "Drug Certification", and "FAQ". A "Help Desk", "User Guide (PDF)", and "My Profile" link are also in the top right. A "Back to Welcome page" link is in the top left of the main content area. The main content is titled "Compliance Summary". It features a "Reporting Period (required)" dropdown set to "Q4 2023". Below it is a message: "Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)". Below the message are tabs: "Missing" (1), "Pending" (3), "Certified" (1), "New" (1) (which is selected and highlighted in blue), "Off Cycle" (1), and "Expired" (1). An "Export to Excel" button is located in the top right of the data table. The data table has columns: "Drug Identifier", "Manufacturer Name", "Reporting Period", "Manufacturer's ASP", "Number of ASP Units", "Wholesale Acquisition Cost", and "Average Wholesale Price". One row is shown: "00010-1111-11" and "Test Manf Name impl". The "Reporting Period" column shows "Q4 2023".

**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*.

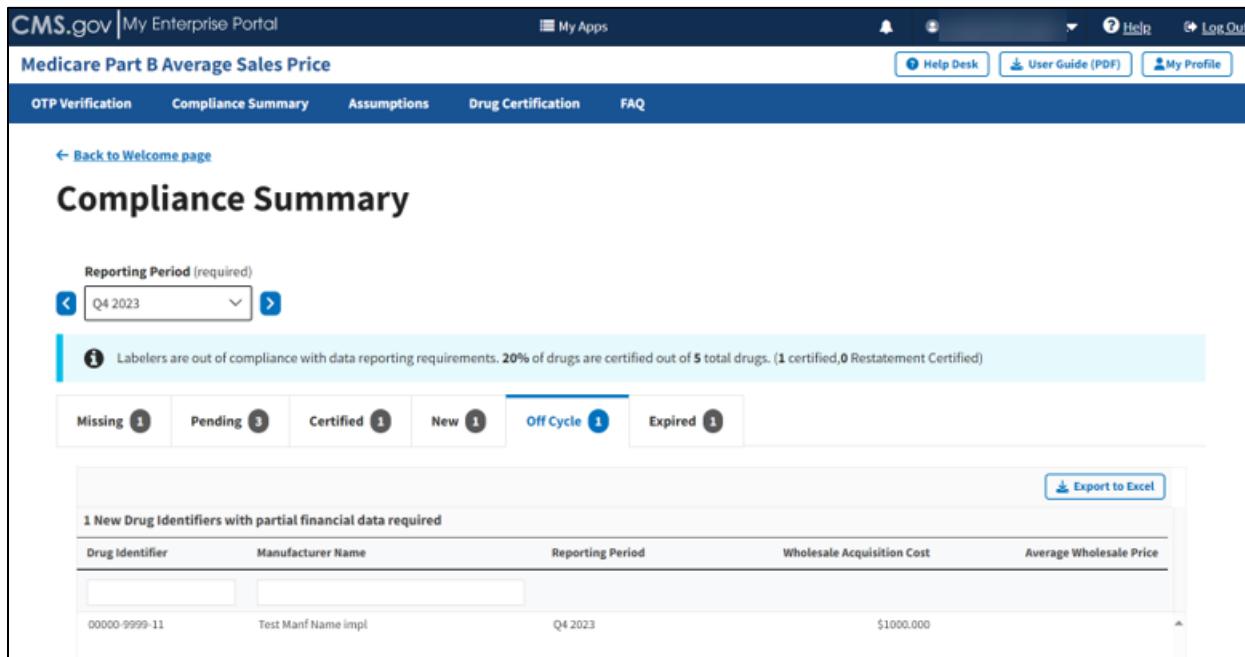

 A screenshot of the CMS.gov My Enterprise Portal. The top navigation bar includes "My Apps", "Help", "User Guide (PDF)", "My Profile", and "Log Out". Below the navigation is a blue header bar with links for "OTP Verification", "Compliance Summary", "Assumptions", "Drug Certification", and "FAQ". A "Back to Welcome page" link is also present. The main content area is titled "Compliance Summary" and shows a "Reporting Period (required)" dropdown set to "Q4 2023". A note below the dropdown states: "Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)". Below the note are six tabs: "Missing" (1), "Pending" (3), "Certified" (1), "New" (1), "Off Cycle" (1, currently selected), and "Expired" (1). A table below the tabs shows one row of data: Drug Identifier 00000-9999-11, Manufacturer Name Test Manf Name impl, Reporting Period Q4 2023, Wholesale Acquisition Cost \$1000.00, and Average Wholesale Price \$1000.00. An "Export to Excel" button is located in the top right corner of the table area.

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*.

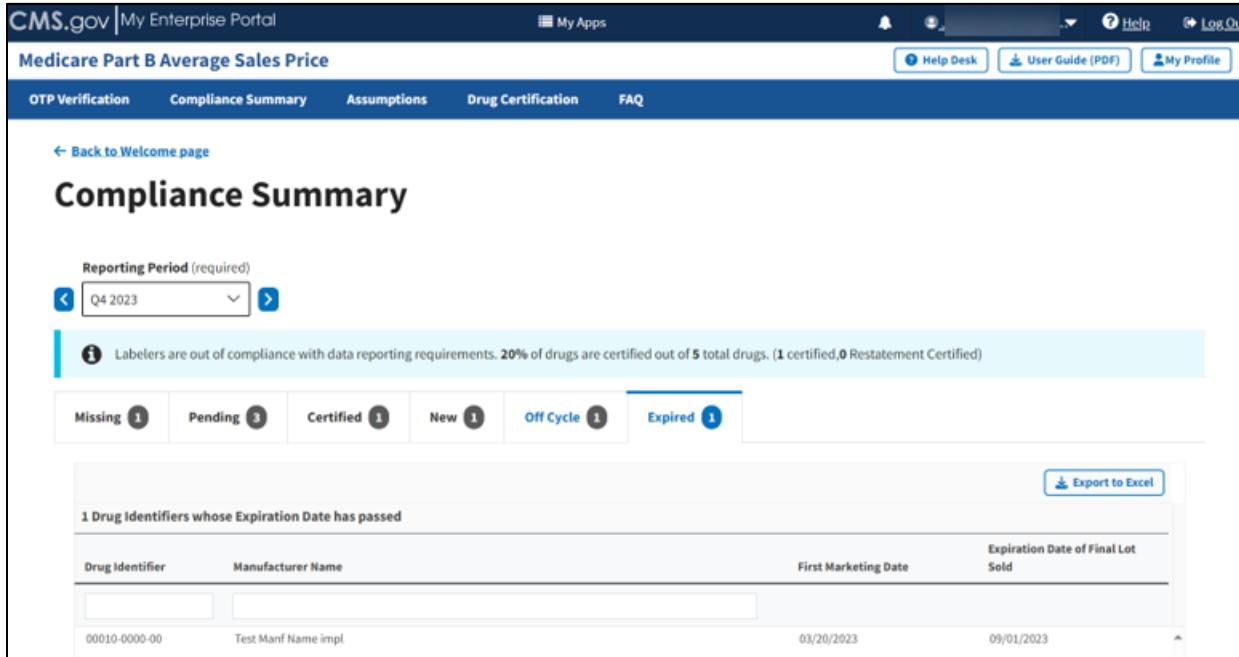

 A screenshot of the CMS.gov Compliance Summary page. The top navigation bar includes links for "My Enterprise Portal", "My Apps", "Help", "User Guide (PDF)", and "Log Out". Below the navigation, a sub-menu bar has links for "OTP Verification", "Compliance Summary", "Assumptions", "Drug Certification", and "FAQ". A "Back to Welcome page" link is also present. The main content area is titled "Compliance Summary" and features a "Reporting Period (required)" dropdown set to "Q4 2023". A message box states: "Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 5 total drugs. (1 certified, 0 Restatement Certified)". Below this are six buttons: "Missing" (1), "Pending" (3), "Certified" (1), "New" (1), "Off Cycle" (1), and "Expired" (1). A table below shows one row of data: "00010-0000-00" (Drug Identifier), "Test Manf Name impl" (Manufacturer Name), "03/20/2023" (First Marketing Date), and "09/01/2023" (Expiration Date of Final Lot Sold). An "Export to Excel" button is located in the top right corner of the table.

Figure 22: Compliance Summary - Expired

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

2. Review the submitted drug information.

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

### 3.3 Assumptions

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

#### 3.3.1 Reasonable Assumptions

Follow these steps to create an assumption:

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

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

The **Assumptions** page opens, and defaults to the current quarter and year. Select the appropriate reporting period before clicking the **Reasonable Assumptions (Required)** tab. Refer to *Figure 23*.

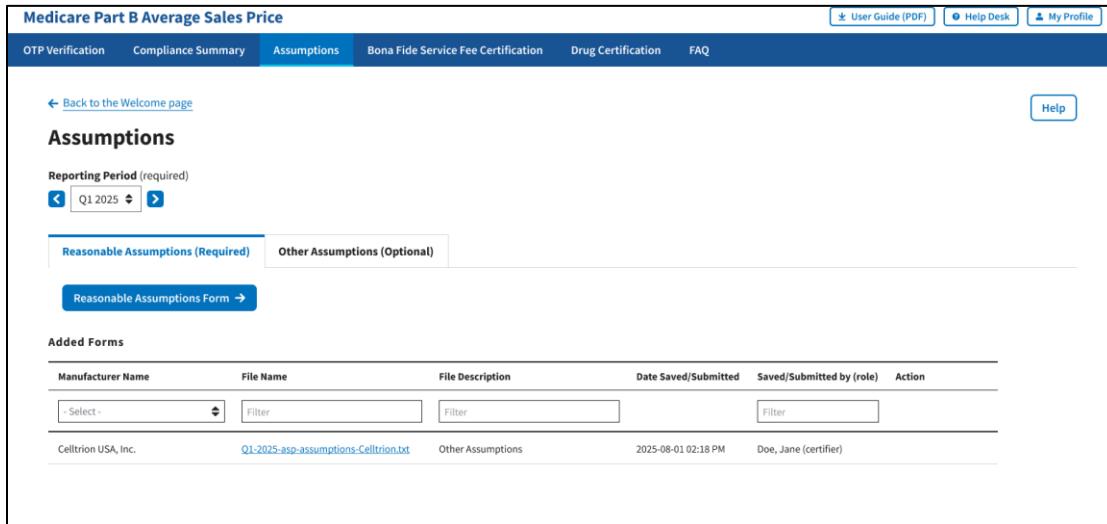


Figure 23: Assumptions

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

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

The **Reasonable Assumption Form** window displays. The Module automatically defaults to the **Reporting Period** selected on the **Assumptions** default page with a **Manufacturer Name (required)** drop-down menu and empty required response fields. Refer to *Figure 24*.

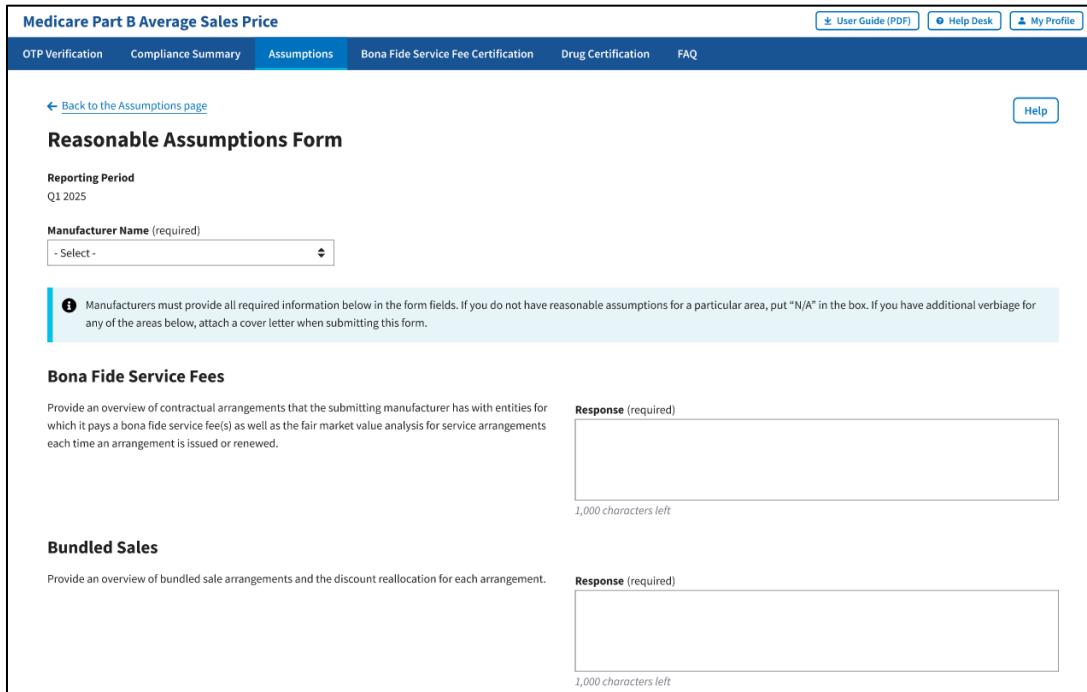


Figure 24: Reasonable Assumptions Form

3. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** drop-down menu to expand the list and select the manufacturer name.
4. Click **View All** to view all the required response fields. Refer to *Figure 25*.

The following response fields display:

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

**Sales to U.S. Territories**

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

**Response (required)**

1,000 characters left

[View All](#)

**Figure 25: View All Required Response Fields**

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

5. Complete all the required fields. Enter **NA** if reasonable assumptions are not available for a particular field.

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

6. Click the **Save Form** button located at the bottom of the form. Refer to *Figure 26*.

**Returned Goods**

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

**Response (required)**

N/A

1,000 characters left

**Billing Corrections**

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

**Response (required)**

N/A

1,000 characters left

**Save Form**

**Figure 26: Save Reasonable Assumptions Form**

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

Medicare Part B Average Sales Price

[User Guide \(PDF\)](#) [Help Desk](#) [My Profile](#)

OTP Verification

Compliance Summary

Assumptions

Bona Fide Service Fee Certification

Drug Certification

FAQ

[Back to the Welcome page](#)

[Help](#)

**Assumptions**

Reporting Period (required)

Q1 2025

[Reasonable Assumptions \(Required\)](#)

[Other Assumptions \(Optional\)](#)

[Reasonable Assumptions Form →](#)

Reasonable Assumptions Form has been saved successfully.

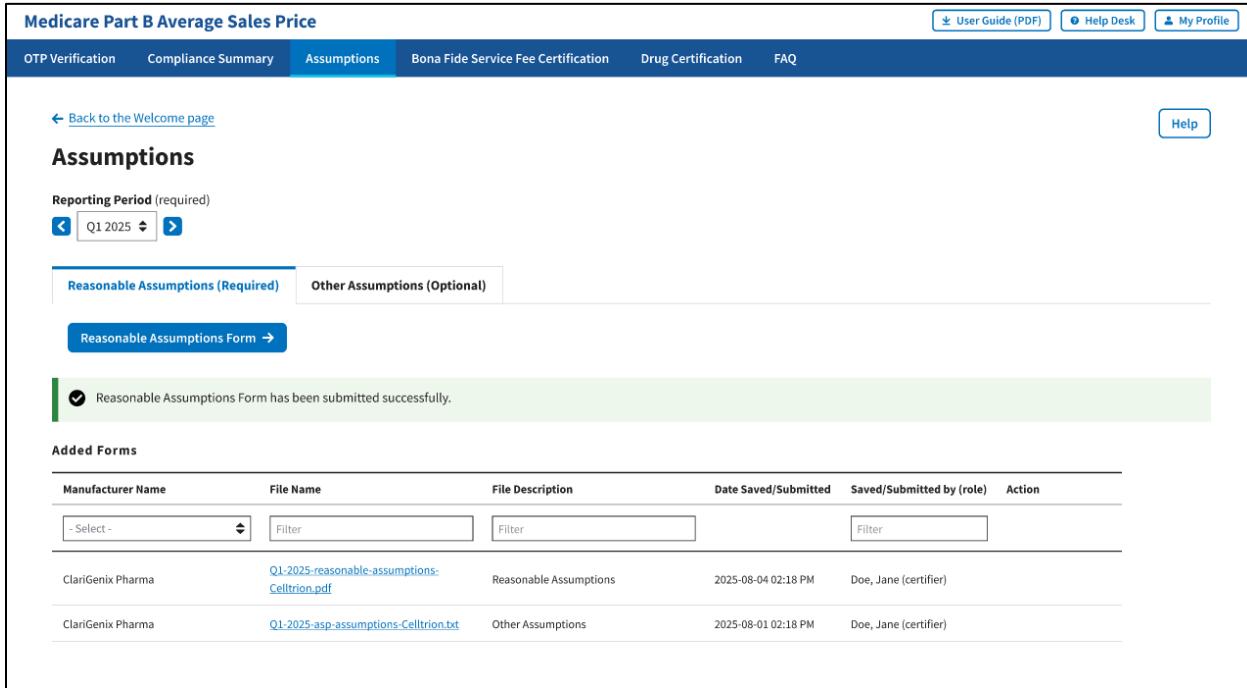
**Added Forms**

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

**Figure 27: New Assumption Successfully Saved**

7. To make any necessary revisions before submitting, click the **Edit** button.
8. If the submission does not require additional revisions, click the **Submit** button.

A message displays confirming you have successfully submitted your **Reasonable Assumptions**. Refer to *Figure 28*.


 A screenshot of the Medicare Part B Average Sales Price Assumptions page. The top navigation bar includes links for OTP Verification, Compliance Summary, Assumptions (which is highlighted in blue), Bona Fide Service Fee Certification, Drug Certification, and FAQ. On the far right are links for User Guide (PDF), Help Desk, and My Profile. Below the navigation is a "Reporting Period (required)" dropdown set to "Q1 2025". There are two tabs: "Reasonable Assumptions (Required)" (which is selected and highlighted in blue) and "Other Assumptions (Optional)". A "Reasonable Assumptions Form" button is visible. A success message in a green box states: "Reasonable Assumptions Form has been submitted successfully." Below this is a table titled "Added Forms" with columns: Manufacturer Name, File Name, File Description, Date Saved/Submitted, Saved/Submitted by (role), and Action. The table contains two rows for ClariGenix Pharma, showing PDF and TXT files for Q1 2025 assumptions, both submitted on August 4, 2025, by Doe, Jane (certifier).
 

Manufacturer Name	File Name	File Description	Date Saved/Submitted	Saved/Submitted by (role)	Action
ClariGenix Pharma	Q1-2025-reasonable-assumptions-Celtrion.pdf	Reasonable Assumptions	2025-08-04 02:18 PM	Doe, Jane (certifier)	<a href="#">Filter</a>
ClariGenix Pharma	Q1-2025-asp-assumptions-Celtrion.txt	Other Assumptions	2025-08-01 02:18 PM	Doe, Jane (certifier)	<a href="#">Filter</a>

**Figure 28: Reasonable Assumptions Successfully Submitted**

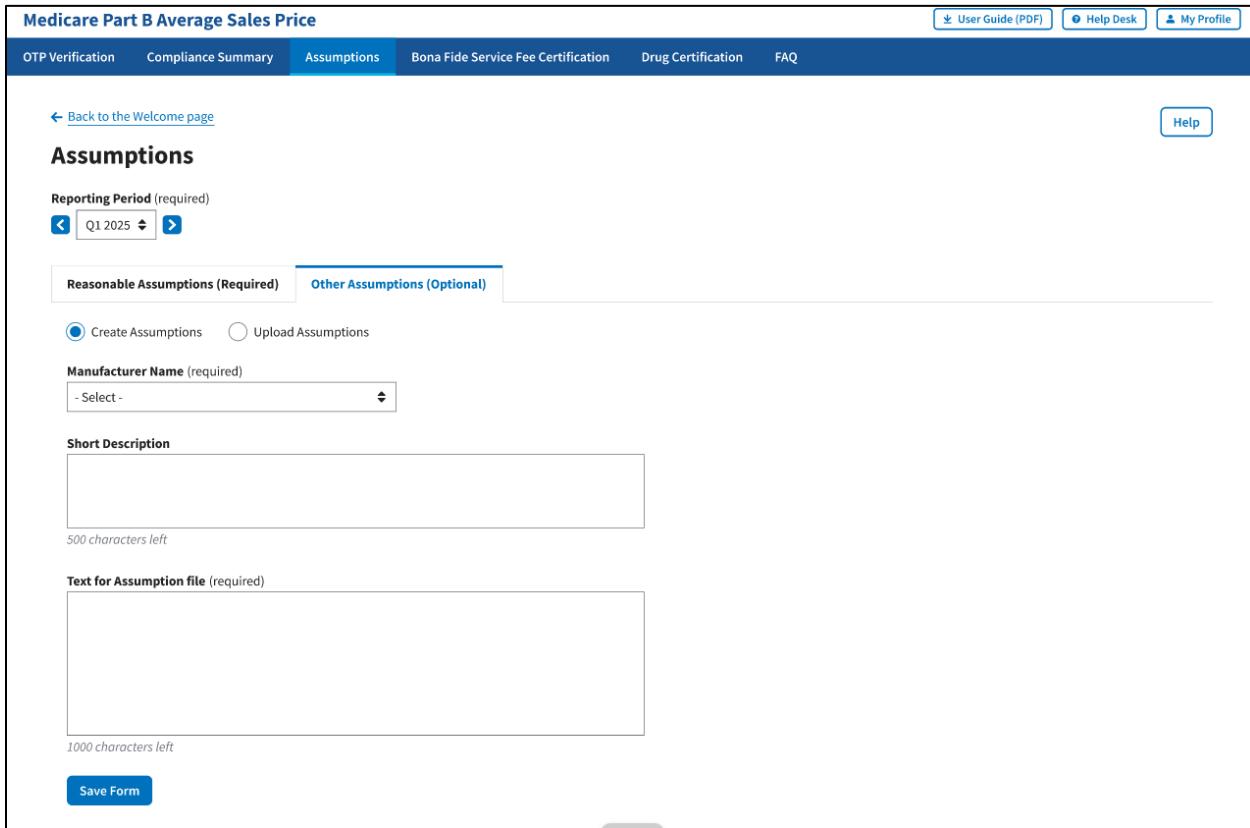
### 3.3.2 Other Assumptions (Optional)

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

#### 3.3.2.1 Create Assumptions

Follow these steps to submit certification assumptions to CMS:

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


 A screenshot of a web page titled "Medicare Part B Average Sales Price". The top navigation bar includes links for "OTP Verification", "Compliance Summary", "Assumptions", "Bona Fide Service Fee Certification", "Drug Certification", and "FAQ". On the right side of the top bar are links for "User Guide (PDF)", "Help Desk", and "My Profile". Below the top bar, there is a "Back to the Welcome page" link and a "Help" button. The main content area is titled "Assumptions". It features a "Reporting Period (required)" dropdown menu set to "Q1 2025". Below this are two tabs: "Reasonable Assumptions (Required)" (selected) and "Other Assumptions (Optional)". Under "Reasonable Assumptions (Required)", there is a radio button for "Create Assumptions" (selected) and another for "Upload Assumptions". A "Manufacturer Name (required)" dropdown menu is shown with the placeholder "- Select -". A "Short Description" text area is present with a note "500 characters left". A "Text for Assumption file (required)" text area is also present with a note "1000 characters left". At the bottom is a "Save Form" button.

**Figure 29: Create Other Assumptions**

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

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

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

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

A message displays confirming you have successfully created your assumption. Refer to *Figure 30*.



Other Assumptions Form has been saved successfully.

Added Forms					
Manufacturer Name	File Name	File Description	Date Saved/Submitted	Saved/Submitted by (role)	Action
- Select -	<input type="text" value="Filter"/>	<input type="text" value="Filter"/>			<input type="button" value="Filter"/>
ClariGenix Pharma	<a href="#">Q1-2025-other-assumptions-ClariGenix-Pharma.txt</a>	Other Assumptions	2025-08-04 02:18 PM	Doe, Jane (certifier)	
ClariGenix Pharma	<a href="#">Q1-2025-reasonable-assumptions-ClariGenix-Pharma.pdf</a>	Reasonable Assumptions	2025-08-01 01:28 PM	Doe, Jane (certifier)	<input type="button" value="Edit"/> <input type="button" value="Submit"/>

Figure 30: Other Assumptions Saved Successfully

### 3.3.2.2 Upload Assumption File

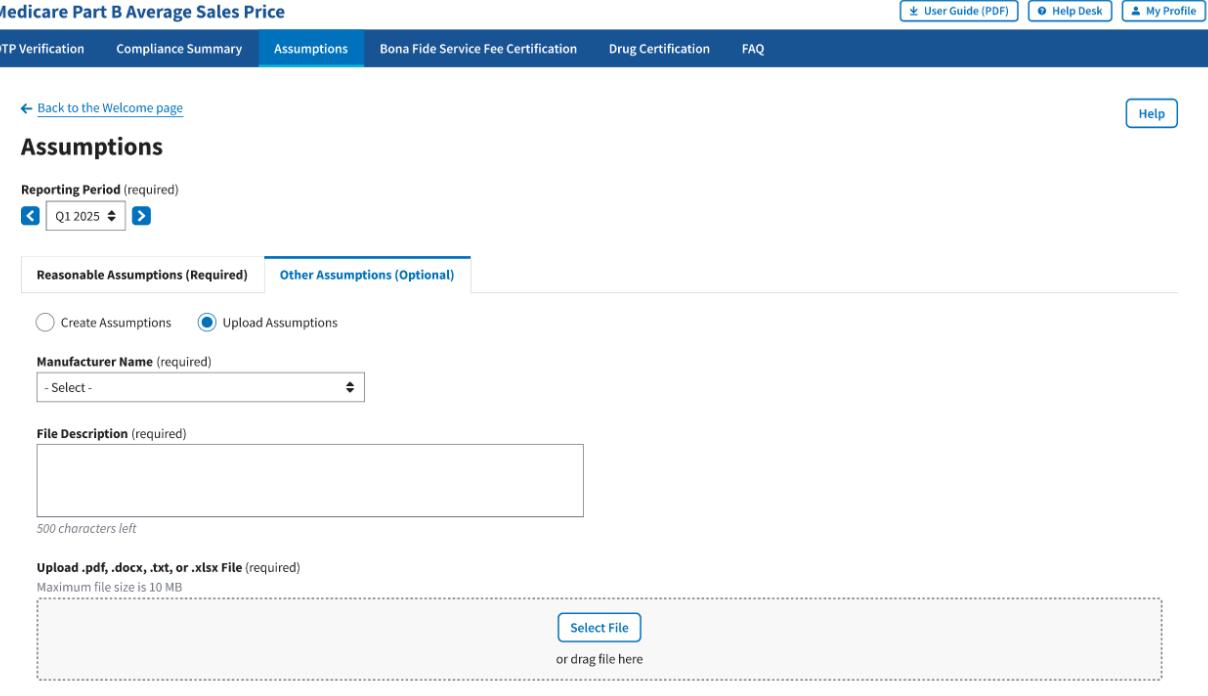
Follow these steps to upload an assumption file to the Module:

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

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

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

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



Medicare Part B Average Sales Price

User Guide (PDF) Help Desk My Profile

OTP Verification Compliance Summary Assumptions Bona Fide Service Fee Certification Drug Certification FAQ

Back to the Welcome page Help

**Assumptions**

Reporting Period (required)

Q1 2025

Reasonable Assumptions (Required) Other Assumptions (Optional)

Create Assumptions  Upload Assumptions

Manufacturer Name (required)

- Select -

File Description (required)

500 characters left

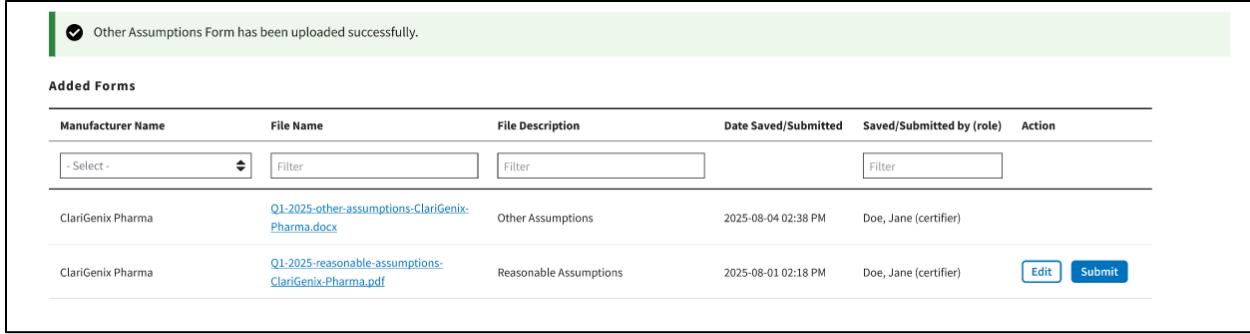
Upload .pdf, .docx, .txt, or .xlsx File (required)  
Maximum file size is 10 MB

Select File or drag file here

Figure 31: Upload Assumptions

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

4. In the **File Description** field, enter your assumption about a data submission. You have 500 characters of total text to comment about your submission in this section.
5. Click **Select File** to browse your desktop and upload your **Assumption File** to the Module. You may also drag your **Assumption File** into the **Select File** box. A message opens to confirm you have successfully uploaded your assumption file. Refer to *Figure 32*.


 A screenshot of a web-based application interface. At the top, a green banner displays a success message: "✓ Other Assumptions Form has been uploaded successfully." Below this, a table titled "Added Forms" lists two entries. The columns are "Manufacturer Name", "File Name", "File Description", "Date Saved/Submitted", "Saved/Submitted by (role)", and "Action". The first row shows "ClariGenix Pharma" as the manufacturer, "Q1-2025-other-assumptions-ClariGenix-Pharma.docx" as the file name, "Other Assumptions" as the description, "2025-08-04 02:38 PM" as the date, "Doe, Jane (certifier)" as the user, and "Edit" and "Submit" buttons. The second row shows the same manufacturer and file name, but with a different description: "Reasonable Assumptions", the same date, the same user, and also "Edit" and "Submit" buttons. The "Action" column for the second row is currently empty.
 

Added Forms					
Manufacturer Name	File Name	File Description	Date Saved/Submitted	Saved/Submitted by (role)	Action
Select -	Q1-2025-other-assumptions-ClariGenix-Pharma.docx	Other Assumptions	2025-08-04 02:38 PM	Doe, Jane (certifier)	<a href="#">Edit</a> <a href="#">Submit</a>
ClariGenix Pharma	Q1-2025-reasonable-assumptions-ClariGenix-Pharma.pdf	Reasonable Assumptions	2025-08-01 02:18 PM	Doe, Jane (certifier)	<a href="#">Edit</a> <a href="#">Submit</a>

**Figure 32: Upload Assumption File - Successfully Added**

### 3.4 Bona Fide Service Fee Certification

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

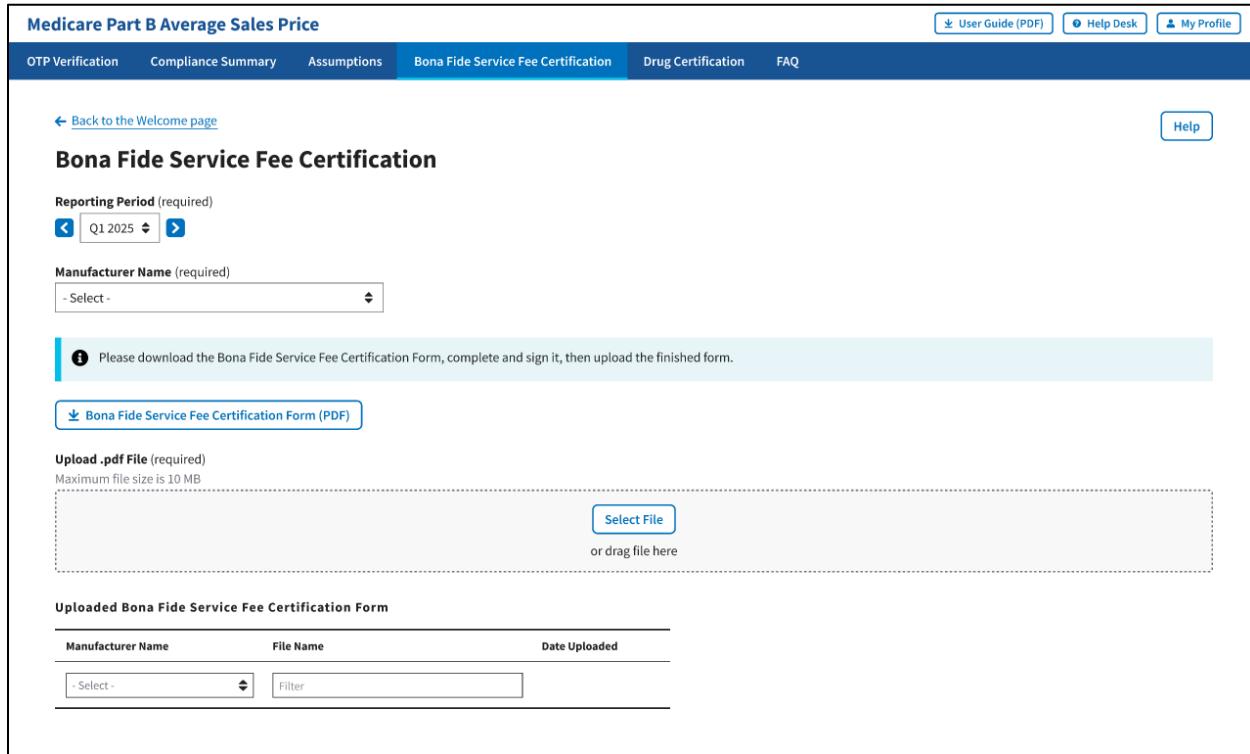
1. From the **Medicare Part B Average Sales Price** homepage, click the **Bona Fide Service Fee Certification** tab.

The **Bona Fide Service Fee Certification** page opens and defaults to the current quarter and year. Refer to *Figure 33*.

2. The Module automatically defaults to the current reporting period. Select the accurate reporting period before proceeding.
3. Select the **Manufacturer Name** in the drop-down menu.
4. Download and complete the **Bona Fide Service Fee Certification Form**.
  - a. Complete **Section 1** by entering all drug and manufacturer information associated with the bona fide service fee:
    - Drug Name(s)
    - HCPCS code(s)
    - Manufacturer name
    - Manufacturer address
  - b. Complete **Section 2** recipient of bona fide service fee information:
    - Name and title of certifying individual
    - Organization or entity name
    - Organization or entity address
    - Bona fide service
    - Bona fide service fee amount (if the fee varies based on certain metrics, describe the conditions of the fee and how it is determined)
  - c. Complete the **Section 3** Certification Statement:
    - I certify that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity.

- Manufacturer Signature
- Fee Recipient Signature

5. Sign the save the form; upload it to your computer.  
 6. Upload the form to the Module. Refer to *Figure 33*.


 The screenshot shows the "Medicare Part B Average Sales Price" homepage. The top navigation bar includes links for "User Guide (PDF)", "Help Desk", and "My Profile". The main content area is titled "Bona Fide Service Fee Certification". It features a reporting period selector set to "Q1 2025", a dropdown for "Manufacturer Name" (set to "- Select -"), and a note about downloading and uploading the certification form. A "Select File" button and a "or drag file here" placeholder are provided for file uploads. Below this, a table lists uploaded forms with columns for "Manufacturer Name", "File Name", and "Date Uploaded". A "Filter" input field is also present.

**Figure 33: Bona Fide Service Fee Certification Submission**

## 3.5 Drug Certification

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

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

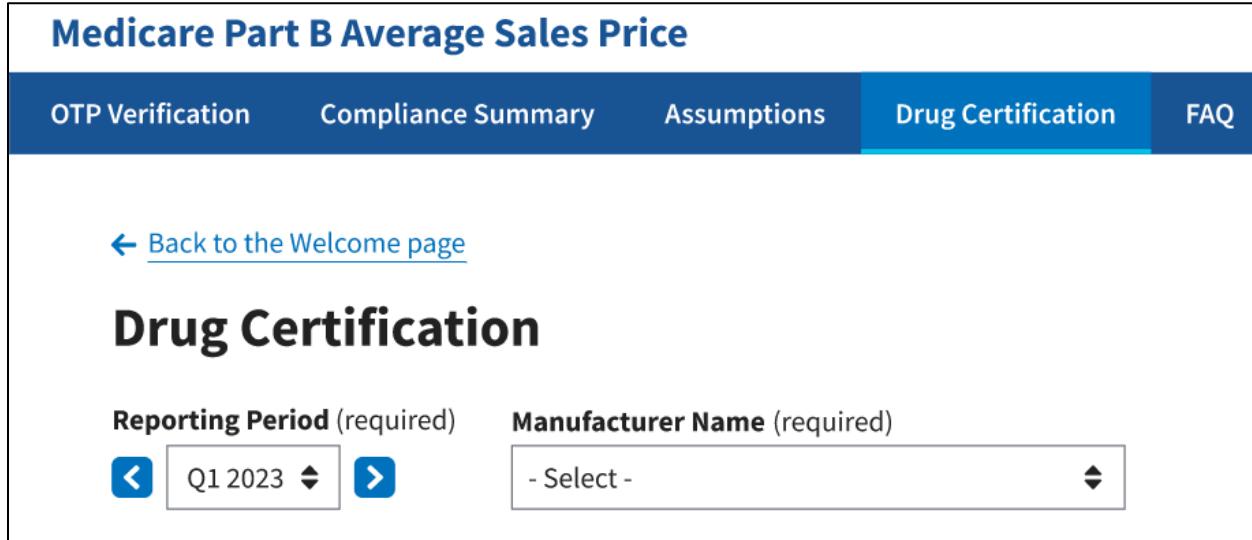
Follow these steps to certify drug product data:

1. From the Medicare Part B Average Sales Price homepage, select **Drug Certification** tab from the **Certification** tab. Refer to *Figure 34*.



Figure 34: Certification - Drop-down

The **Drug Certification** page opens. Refer to *Figure 35*.

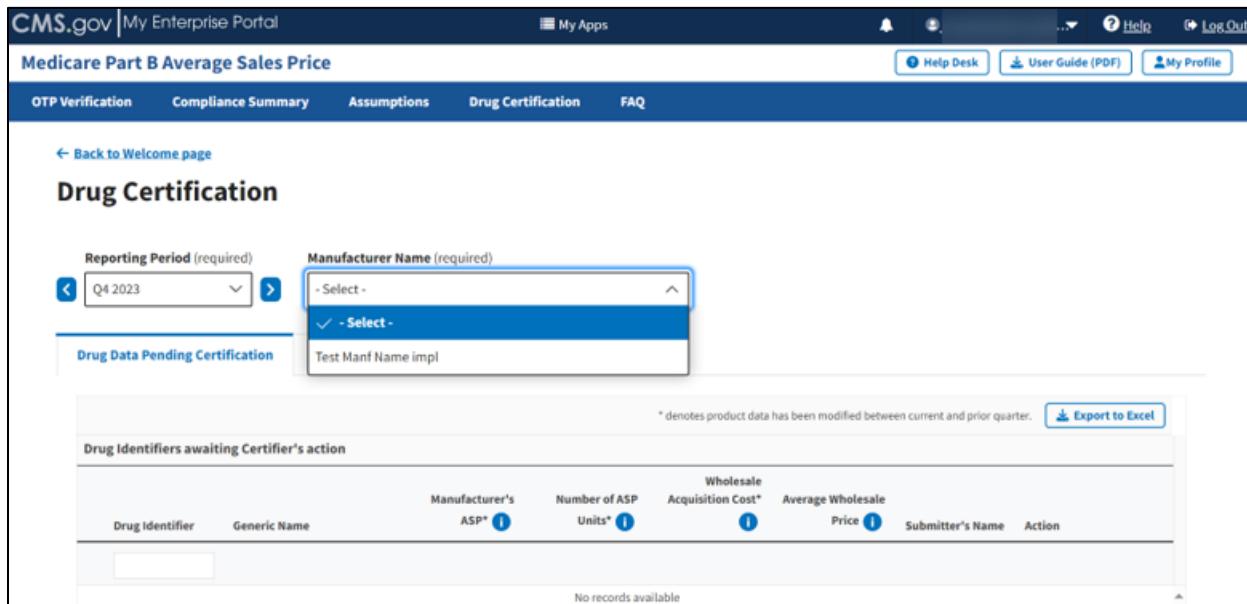


The screenshot shows the 'Medicare Part B Average Sales Price' page with the 'Drug Certification' tab selected. At the top, there is a backlink '← Back to the Welcome page'. Below the backlink, the section title 'Drug Certification' is displayed in a large, bold, black font. Underneath the title, there are two input fields: 'Reporting Period (required)' and 'Manufacturer Name (required)'. The 'Reporting Period' field contains a dropdown menu with 'Q1 2023' selected, and arrows for navigating between quarters. The 'Manufacturer Name' field is a dropdown menu with the placeholder text '- Select -'.

Figure 35: Drug Certification

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

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



Reporting Period (required)  
Q4 2023

Manufacturer Name (required)  
- Select -  
✓ - Select -  
Test Manf Name impl

Drug Data Pending Certification

Drug Identifiers awaiting Certifier's action

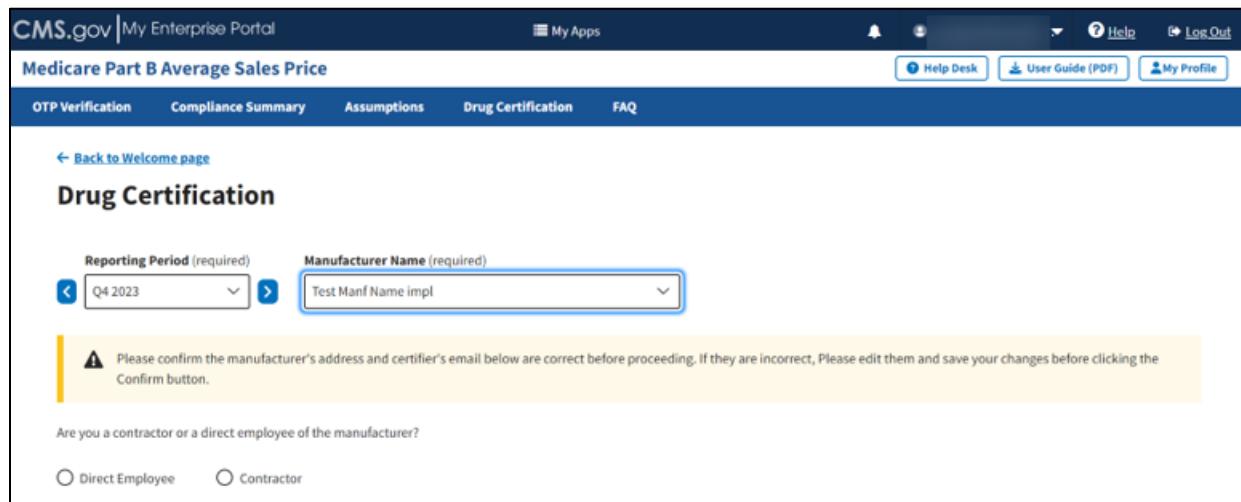
Drug Identifier	Generic Name	Manufacturer's ASP* <small>i</small>	Number of ASP Units* <small>i</small>	Acquisition Cost* <small>i</small>	Average Wholesale Price <small>i</small>	Submitter's Name	Action
No records available							

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

Figure 36: Drug Certification - Manufacturer Name

3. Select the appropriate manufacturer name.

The page displays two new radio buttons asking you to confirm if you are certifying as a direct employee or contractor. Refer to *Figure 37*.



Reporting Period (required)  
Q4 2023

Manufacturer Name (required)  
Test Manf Name impl

⚠ 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 37: Drug Certification - Direct Employee or Contractor

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

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

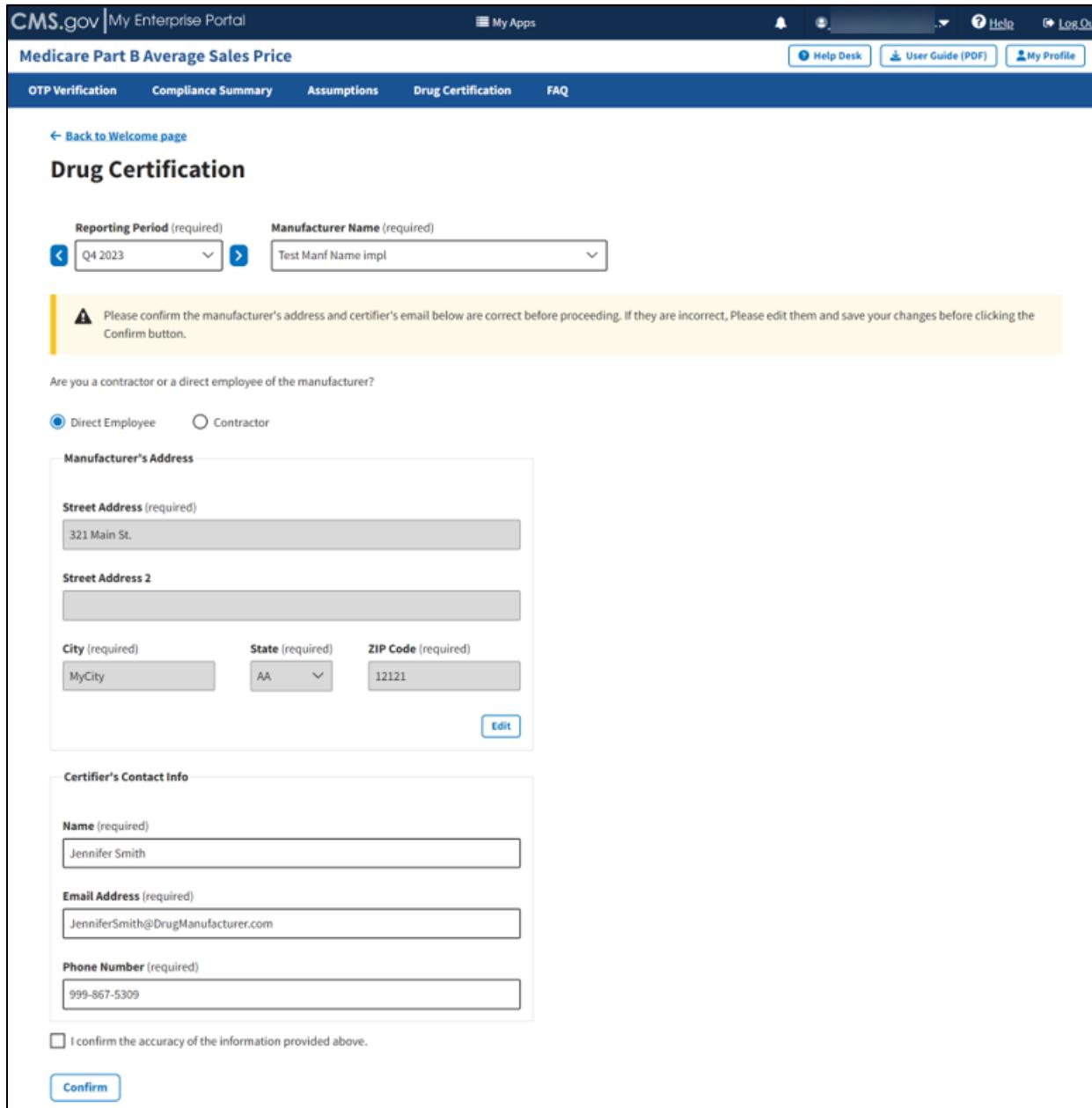
### 3.5.1 Direct Employee

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

1. Click the **Direct Employee** radio button.

New fields display asking for more information about the manufacturer's address and contact information.

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



**Reporting Period (required)** Q4 2023

**Manufacturer Name (required)** Test Manf Name impl

**Warning:** 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)** 321 Main St.

**Street Address 2** [empty]

**City (required)** MyCity **State (required)** AA **ZIP Code (required)** 12121

**Certifier's Contact Info**

**Name (required)** Jennifer Smith

**Email Address (required)** JenniferSmith@DrugManufacturer.com

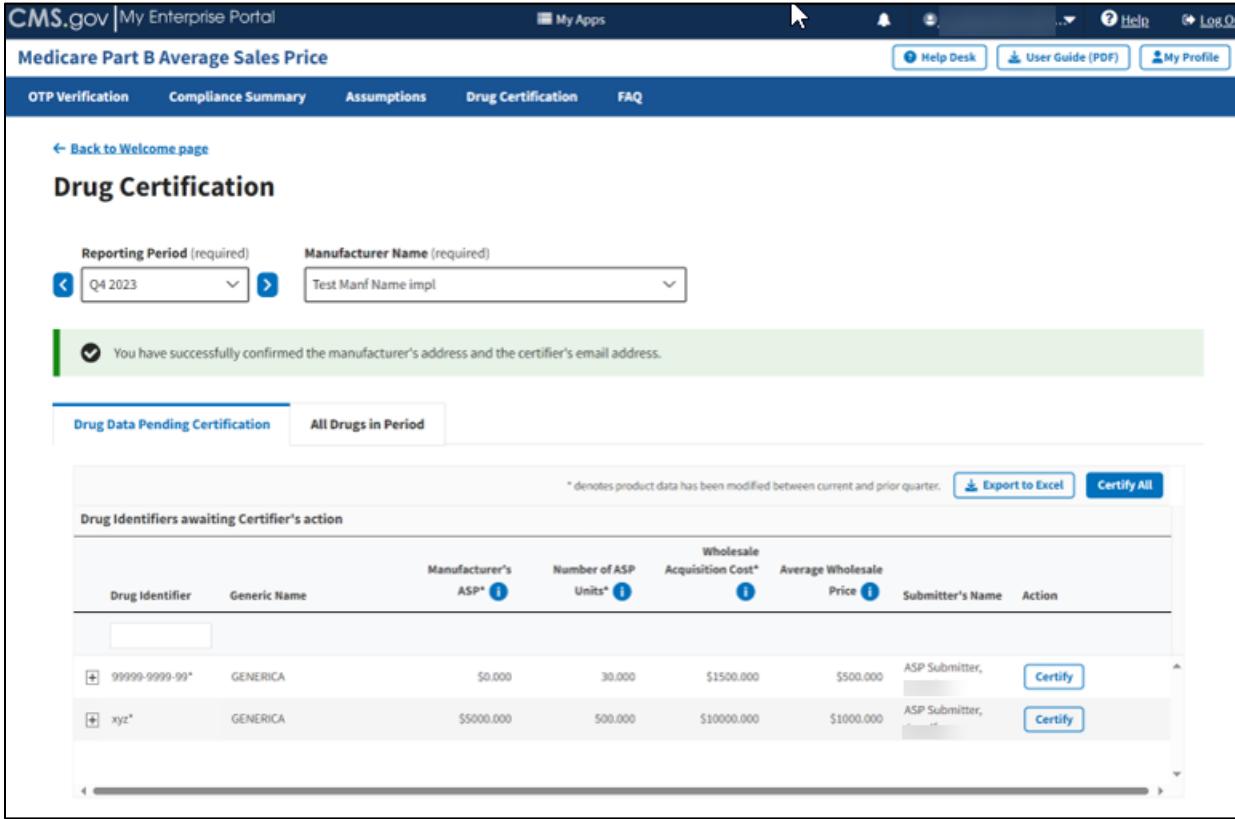
**Phone Number (required)** 999-867-5309

I confirm the accuracy of the information provided above.

**Confirm**

**Figure 38: Drug Certification - Direct Employee - Fields Populated**

- Once you complete the fields, select the **I confirm the accuracy of the information provided above** checkbox; click **Confirm and Save**.  
A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to *Figure 39*.



The screenshot shows the CMS.gov My Enterprise Portal interface for Medicare Part B Average Sales Price Drug Certification. At the top, there are navigation links for OTP Verification, Compliance Summary, Assumptions, Drug Certification, and FAQ. Below the header, a message indicates successful confirmation of manufacturer address and certifier email. The main content area displays a table of drug data pending certification, with two entries for 'GENERICA'. Each entry includes a 'Certify' button. The table columns include Drug Identifier, Generic Name, Manufacturer's ASP, Number of ASP Units, Wholesale Acquisition Cost, Average Wholesale Price, Submitter's Name, and Action.

Drug Identifier	Generic Name	Manufacturer's ASP*	Number of ASP Units*	Wholesale Acquisition Cost*	Average Wholesale Price	Submitter's Name	Action
99999-9999-99*	GENERICA	\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter, [REDACTED]	<b>Certify</b>
xyz*	GENERICA	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, [REDACTED]	<b>Certify</b>

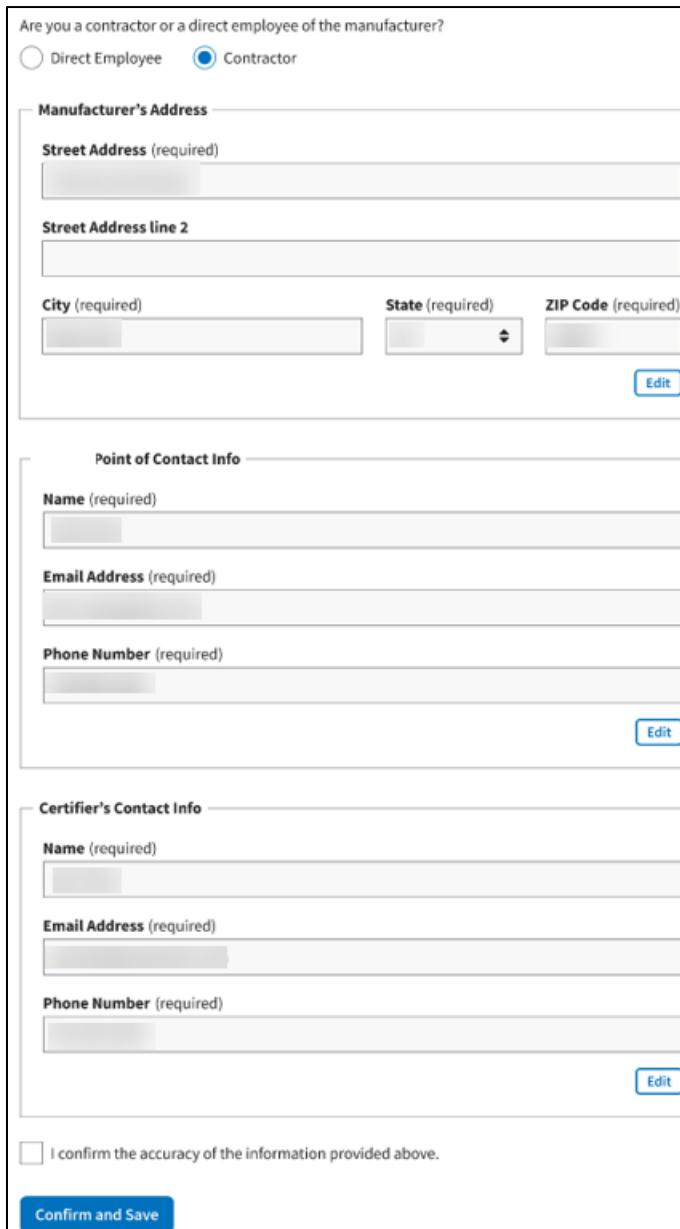
Figure 39: Drug Certification - Direct Employee Confirmation

### 3.5.2 Contractor

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

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

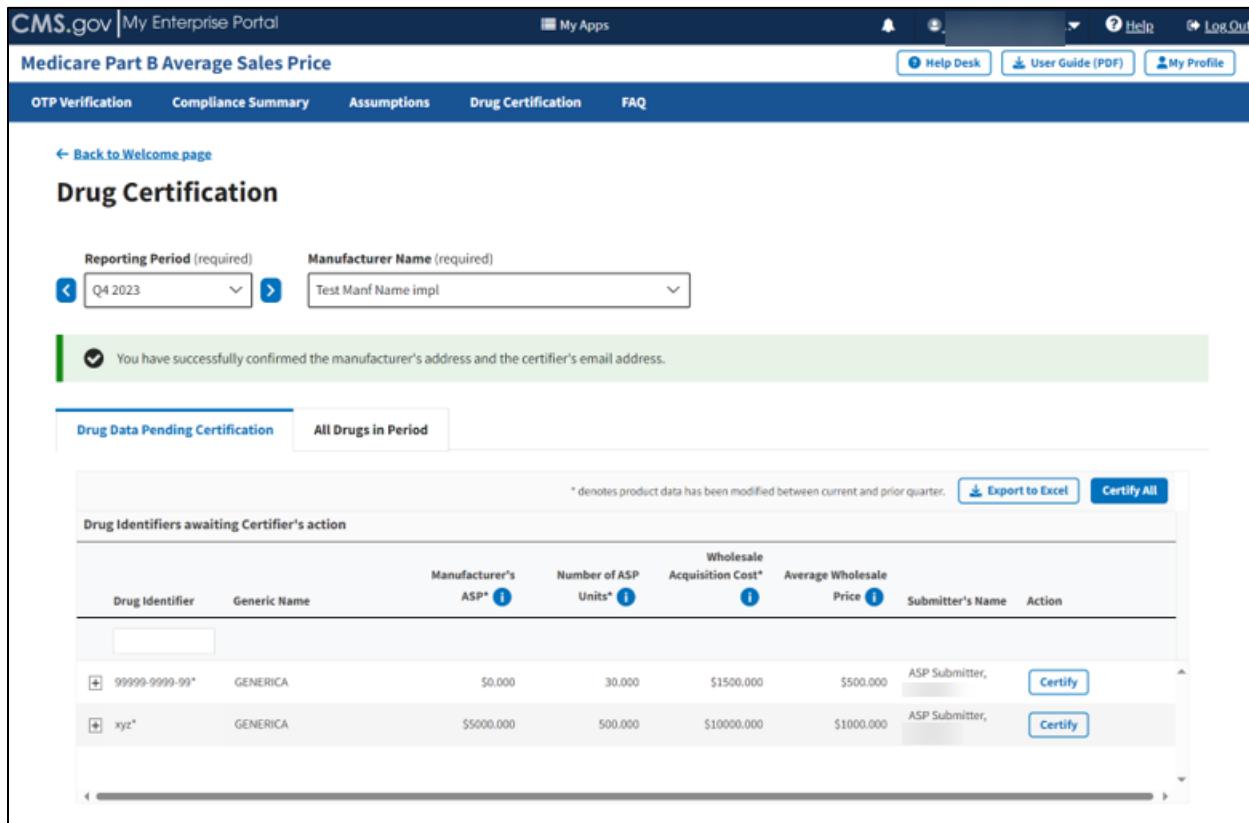
3. Click the **Edit** button under **Manufacturer's Address**, **Point of Contact Info**, and **Certifier's Contact Info** if you need to correct information already populated in a field. Refer to *Figure 40*.


 A screenshot of a web-based form titled "Drug Certification - Contractor - Fields Populated". The form is divided into three main sections: "Manufacturer's Address", "Point of Contact Info", and "Certifier's Contact Info". 
 - \*\*Manufacturer's Address\*\*: Contains fields for "Street Address (required)" and "Street Address line 2". Below these are fields for "City (required)", "State (required)", and "ZIP Code (required)". An "Edit" button is located to the right of the ZIP code field.
 - \*\*Point of Contact Info\*\*: Contains fields for "Name (required)", "Email Address (required)", and "Phone Number (required)". An "Edit" button is located to the right of the phone number field.
 - \*\*Certifier's Contact Info\*\*: Contains fields for "Name (required)", "Email Address (required)", and "Phone Number (required)". An "Edit" button is located to the right of the phone number field.
 At the bottom of the form is a checkbox labeled "I confirm the accuracy of the information provided above." and a "Confirm and Save" button.

**Figure 40: Drug Certification - Contractor - Fields Populated**

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

A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to *Figure 41*.



Reporting Period (required) **Q4 2023**

Manufacturer Name (required) **Test Manf Name impl**

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

Drug Identifier	Generic Name	Manufacturer's ASP* <small>i</small>	Number of ASP Units* <small>i</small>	Wholesale Acquisition Cost* <small>i</small>	Average Wholesale Price <small>i</small>	Submitter's Name	Action
99999-9999-99*	GENERICA	\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter,	<b>Certify</b>
xyz*	GENERICA	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter,	<b>Certify</b>

Figure 41: Drug Certification - Contractor Confirmation

### 3.5.3 Drug Data Pending Certification

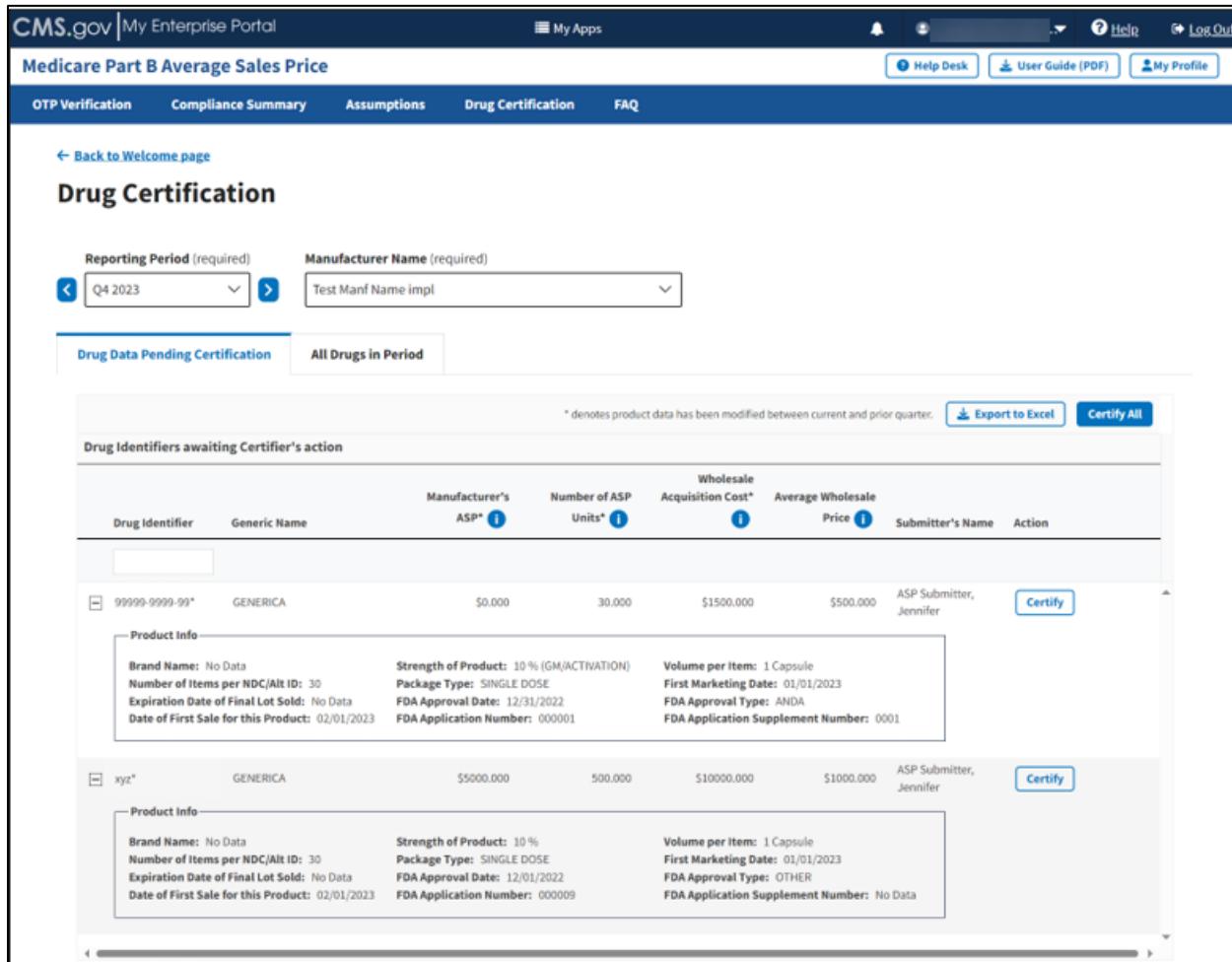
Follow these steps to complete the drug data certification process and certify your products:

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

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

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

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



Reporting Period (required): Q4 2023

Manufacturer Name (required): Test Manf Name impl

Drug Data Pending Certification | All Drugs in Period

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

Export to Excel | Certify All

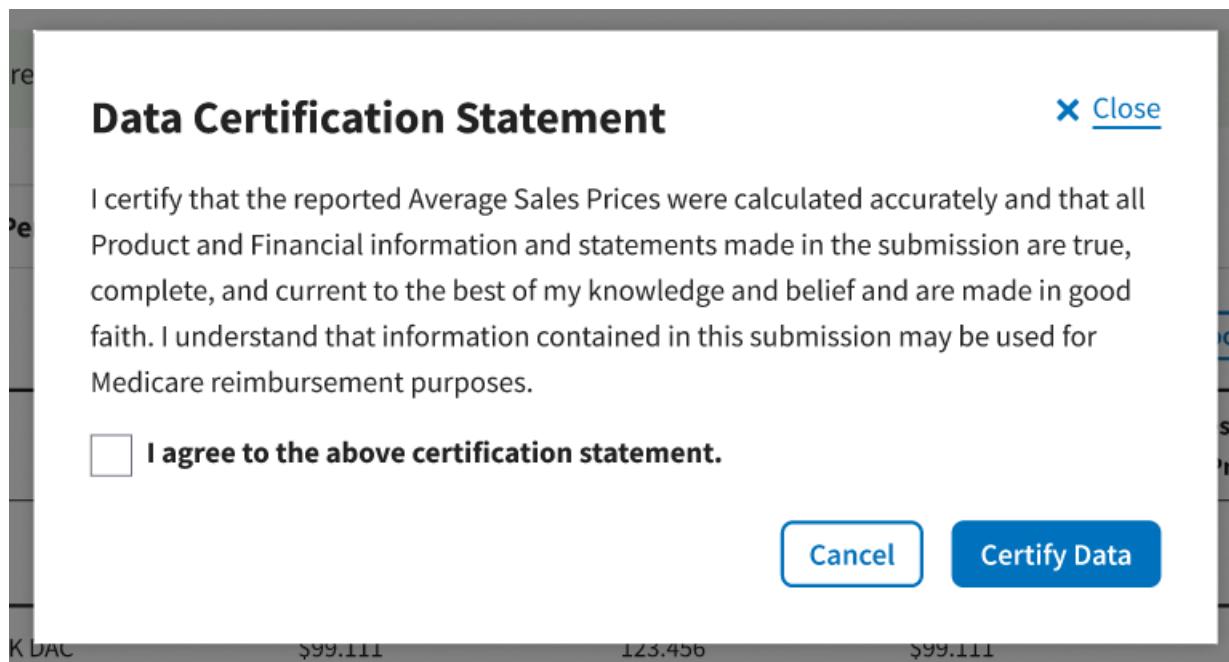
Drug Identifiers awaiting Certifier's action

Drug Identifier	Generic Name	Manufacturer's ASP*	Number of ASP Units*	Wholesale Acquisition Cost*	Average Wholesale Price	Submitter's Name	Action												
99999-9999-99*	GENERICA	\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter, Jennifer	<button>Certify</button>												
<b>Product Info</b> <table border="1"> <tr> <td>Brand Name: No Data</td> <td>Strength of Product: 10 % (GM/ACT/NIVATION)</td> <td>Volume per Item: 1 Capsule</td> </tr> <tr> <td>Number of Items per NDC/Alt ID: 30</td> <td>Package Type: SINGLE DOSE</td> <td>First Marketing Date: 01/01/2023</td> </tr> <tr> <td>Expiration Date of Final Lot Sold: No Data</td> <td>FDA Approval Date: 12/31/2022</td> <td>FDA Approval Type: ANDA</td> </tr> <tr> <td>Date of First Sale for this Product: 02/01/2023</td> <td>FDA Application Number: 000001</td> <td>FDA Application Supplement Number: 0001</td> </tr> </table>								Brand Name: No Data	Strength of Product: 10 % (GM/ACT/NIVATION)	Volume per Item: 1 Capsule	Number of Items per NDC/Alt ID: 30	Package Type: SINGLE DOSE	First Marketing Date: 01/01/2023	Expiration Date of Final Lot Sold: No Data	FDA Approval Date: 12/31/2022	FDA Approval Type: ANDA	Date of First Sale for this Product: 02/01/2023	FDA Application Number: 000001	FDA Application Supplement Number: 0001
Brand Name: No Data	Strength of Product: 10 % (GM/ACT/NIVATION)	Volume per Item: 1 Capsule																	
Number of Items per NDC/Alt ID: 30	Package Type: SINGLE DOSE	First Marketing Date: 01/01/2023																	
Expiration Date of Final Lot Sold: No Data	FDA Approval Date: 12/31/2022	FDA Approval Type: ANDA																	
Date of First Sale for this Product: 02/01/2023	FDA Application Number: 000001	FDA Application Supplement Number: 0001																	
xyz*	GENERICA	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, Jennifer	<button>Certify</button>												
<b>Product Info</b> <table border="1"> <tr> <td>Brand Name: No Data</td> <td>Strength of Product: 10 %</td> <td>Volume per Item: 1 Capsule</td> </tr> <tr> <td>Number of Items per NDC/Alt ID: 30</td> <td>Package Type: SINGLE DOSE</td> <td>First Marketing Date: 01/01/2023</td> </tr> <tr> <td>Expiration Date of Final Lot Sold: No Data</td> <td>FDA Approval Date: 12/01/2022</td> <td>FDA Approval Type: OTHER</td> </tr> <tr> <td>Date of First Sale for this Product: 02/01/2023</td> <td>FDA Application Number: 000009</td> <td>FDA Application Supplement Number: No Data</td> </tr> </table>								Brand Name: No Data	Strength of Product: 10 %	Volume per Item: 1 Capsule	Number of Items per NDC/Alt ID: 30	Package Type: SINGLE DOSE	First Marketing Date: 01/01/2023	Expiration Date of Final Lot Sold: No Data	FDA Approval Date: 12/01/2022	FDA Approval Type: OTHER	Date of First Sale for this Product: 02/01/2023	FDA Application Number: 000009	FDA Application Supplement Number: No Data
Brand Name: No Data	Strength of Product: 10 %	Volume per Item: 1 Capsule																	
Number of Items per NDC/Alt ID: 30	Package Type: SINGLE DOSE	First Marketing Date: 01/01/2023																	
Expiration Date of Final Lot Sold: No Data	FDA Approval Date: 12/01/2022	FDA Approval Type: OTHER																	
Date of First Sale for this Product: 02/01/2023	FDA Application Number: 000009	FDA Application Supplement Number: No Data																	

Figure 42: Drug Data Pending Certification

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

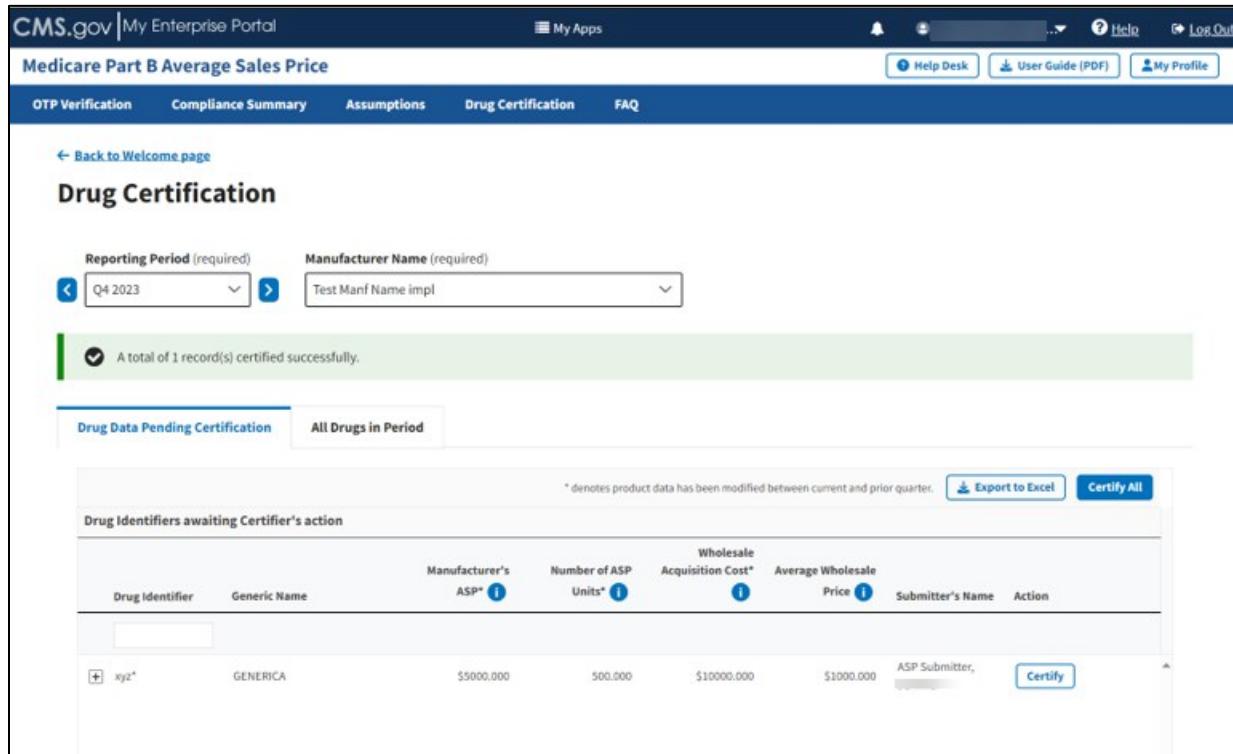
2. Click the plus symbol on each row of the table to expand each product's information and view additional drug product fields, such as **Brand Name**, **First Marketing Date**, **Volume per Item**, and all other information the Submitter previously reported. Refer to *Figure 42*.
3. Select the drug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



**Figure 43: Data Certification Statement**

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

A message displays confirming you have successfully certified the drug data. Refer to *Figure 44*.



Reporting Period (required) **Q4 2023**

Manufacturer Name (required) **Test Manf Name impl**

A total of 1 record(s) certified successfully.

Drug Identifier	Generic Name	Manufacturer's ASP*	Number of ASP Units*	Acquisition Cost*	Average Wholesale Price	Submitter's Name	Action
xyz*	GENERIC A	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter,	<b>Certify</b>

**Figure 44: Data Certification - Confirmation Message**

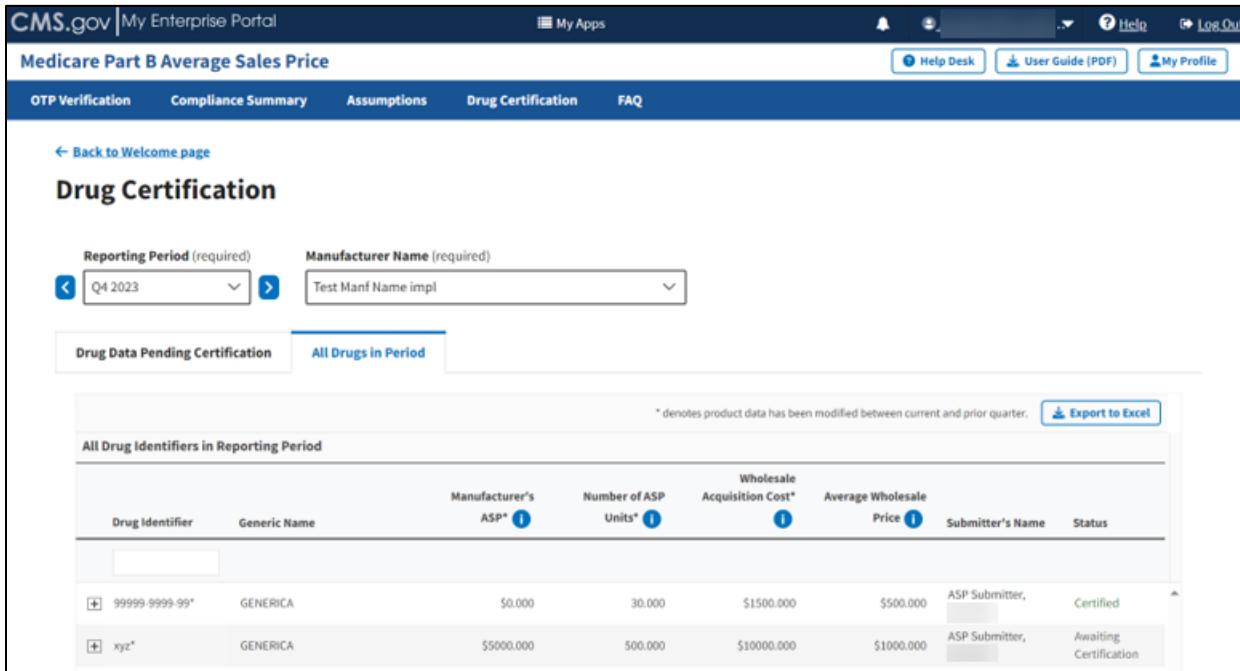
**Note:** Click the **Export to Excel** box to download the information on this page into an Excel file.

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

### 3.5.4 All Drugs in Period

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

1. From the **Drug Certification** homepage, click the **All Drugs in Period** tab.  
The **All Drugs in Period** page opens. Refer to *Figure 45*.


 A screenshot of the CMS.gov Drug Certification interface. The top navigation bar includes 'My Enterprise Portal', 'My Apps', 'Help', 'User Guide (PDF)', and 'Log Out'. Below the navigation is a blue header bar with tabs: 'OTP Verification', 'Compliance Summary', 'Assumptions', 'Drug Certification', and 'FAQ'. A 'Back to Welcome page' link is on the left. The main section is titled 'Drug Certification' and shows a reporting period of 'Q4 2023' and a manufacturer name of 'Test Manf Name impl'. It includes a 'Drug Data Pending Certification' button and a 'All Drugs in Period' button. A note indicates that an asterisk (\*) denotes product data has been modified between current and prior quarter. An 'Export to Excel' button is in the top right of the data table. The table lists drug identifiers, generic names, manufacturer's ASP, number of units, wholesale acquisition cost, average wholesale price, submitter's name, and status. Two rows are shown: one for '99999-9999-99\*' with status 'Certified' and one for 'xyz\*' with status 'Awaiting Certification'.
 

Drug Identifier	Generic Name	Manufacturer's ASP*	Number of ASP Units*	Wholesale Acquisition Cost*	Average Wholesale Price*	Submitter's Name	Status
99999-9999-99*	GENERICA	\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter, [REDACTED]	Certified
xyz*	GENERICA	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, [REDACTED]	Awaiting Certification

**Figure 45: Drug Certification - All Drugs in Period**

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

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

2. Click the plus symbol on each row of the table to expand each product's information and view additional Drug Product data fields, such as **Brand Name, First Marketing Date, Volume per Item**, and all other information the Submitter previously reported.
3. Review the information for accuracy.
4. 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: Field Definitions

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

**Table 2: Field Definitions**

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

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

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

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

## Appendix B: Revision History

Table 3 provides a revision history for this document.

**Table 3: Revision History**

Version Number	Date	Author/Editor	Description of Change
1.0	03/15/2024	Index Analytics/DCCA	Initial version of ASP Data Collection System Certifier User Guide
2.0	08/08/2025	Index Analytics/DCCA	<ul style="list-style-type: none"><li>Updated <i>Figure 9</i> and <i>Figure 12</i> based on updates to the ASP Data Collection System.</li><li>Made various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections.</li></ul>
2.1	08/29/2025	Index Analytics/DCCA	<ul style="list-style-type: none"><li>Updated <i>Sections 3.3 and 3.4</i>.</li><li>Made various font, grammatical, punctuation, shading, formatting, date, version, pagination, glossary, and alignment corrections.</li></ul>

## Appendix C: Glossary

Table 4 presents a list of terms, acronyms, and definitions in this document.

**Table 4: Glossary**

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

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

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