
# Average Sales Price (ASP) Data Collection System Training

July 7, 2026

# Welcome


Thank you for joining our training for the ASP Data Collection System.

- This session will be recorded and posted.
- Participants can submit questions via the Q&A feature only (do not chat or raise hands).
- There will be time for questions at the end of our 30-minute presentation.

# Agenda

| Topic | Presenter |
| --- | --- |
| Introductory Remarks | Mark Bremer, CMS |
| How to Prepare | Katie Wilder, Contractor |
| System Overview and Data Entry | Brian Edwards, Contractor |
| What to Expect | Katie Wilder, Contractor |
| Q&A Session | Suzanne Bromley, Contractor |
| Closing Remarks | Mark Bremer, CMS |

# Purpose

- Section 1927(b)(3)(A)(iii)(I) of the Social Security Act (SSA) requires manufacturers with a Medicaid drug rebate agreement to report Average Sales Price (ASP) data as specified in section 1847A of the SSA.
- Section 1847A(f)(2) of the SSA 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.
- At the completion of this webinar, manufacturers should:

  - ✓ Have the tools to prepare to submit accurate data to CMS
  - ✓ Be familiar with the system and the resources available
  - ✓ Have the opportunity to ask questions directly to CMS

# How to Prepare

1

## Deadlines

Remember the deadlines associated with the requirement to report ASP data.

2

## Access

Register and ensure the correct individuals have access to the system and data.

3

## New Products

Take an inventory of your products: add new products and update existing products.

4

## Calculations

Gather financial reporting data and calculate the required ASP information.

5

## Enter Data

Submit and Certify your quarterly data to CMS in the ASP Data Collection System.

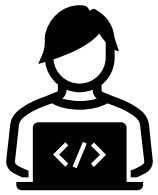
# Quarterly Deadlines

Manufacturers are required to report ASP data within 30 days after the end of each quarter. Information on the penalties associated with misrepresentation and the failure to submit timely and accurate ASP data can be found at 42 CFR § 414.806.

| Quarter | Sales Dates | Manufacturer Data Submission Window | Medicare Payment Effective Date |
|---|---|---|---|
| 1 | January 1 to March 31 | April 1 to April 30 | July 1 |
| 2 | April 1 to June 30 | July 1 to July 30 | October 1 |
| 3 | July 1 to September 30 | October 1 to October 30 | January 1 |
| 4 | October 1 to December 31 | January 1 to January 30 | April 1 |

# System Access

The ASP Data Collection System is a role-based system. When completing registration, users must select from the following roles. The Submitter and Certifier should be two different people.



A **Submitter** account is designated for an individual with authority to provide and submit Average Sales Price (ASP) financial data to CMS. A Submitter can be any individual the manufacturer chooses, including a third-party contractor.

A **Certifier** verifies the submission of the reported data. A Certifier account is reserved for the manufacturer's Chief Executive Officer (CEO) or Chief Financial Officer (CFO) or an individual who has been delegated the authority to sign for, and reports directly to, the manufacturer. 42 CFR § 414.804(a)(7)

# Quarterly Planning Tips

## New Users

Allow enough time for new users to register for the system, preferably before the submission window.

## Out of Office

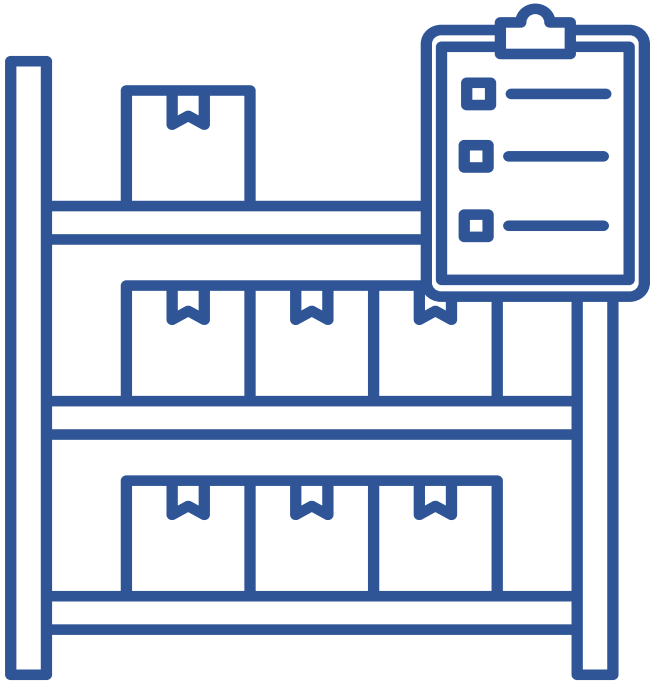
Assign a backup and make sure they have access to the data. Data are associated with the user, not the manufacturer.

## Contact Info

Use personal contact information during registration; update to business contact information after registration is complete.

For assistance, contact the ASP Helpdesk.

# Product Inventory



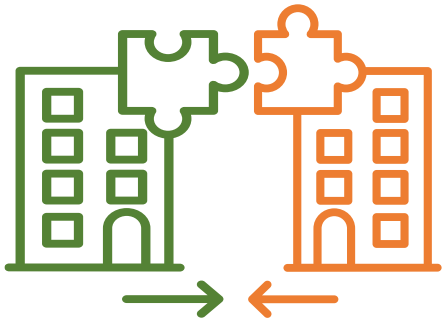
**Request to Add/Update NDC/ALT ID**

- New products marketed since last quarter
- Updates to existing products
- Products no longer marketed
- Products acquired/sold

# Sales and Acquisitions

**When there is a transfer of NDC/ALT ID both the previous and new owners must:**

- Maintain detailed documentation of the transfer of ownership.
- Submit separate ASP data for sales occurring under each respective ownership period.
- Only report sales occurring during each respective ownership period.
- Ensure all required fields are completed for their respective reporting periods.
- Ensure there is no gap or overlap in reporting periods and the sum of both reports from each owner during the quarter represents the quarter's complete data.
- Each product must be reported at the NDC level. If both selling and acquiring entities are using the same NDC they must report separately. No blending is allowed.



Email the CMS ASP Mailbox for additional guidance.

# Calculations

| Field | Description |
|---|---|
| Manufacturer's Average Sales Price (ASP) | A manufacturer average sales price for all NDC/Alt IDs assigned to the drug or biological product. |
| Number of ASP Units | Units are equivalent to the product represented by the NDC, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by an NDC/Alt ID varies. |
| Wholesale Acquisition Cost (WAC) | The manufacturer's list price for the drug or biological to wholesalers or direct purchasers as reported in wholesale price guides or other publications of drug or biological pricing data. For more on the definition of WAC, refer to 42 U.S.C. 1395w-3a. |
| Average Wholesale Price (AWP) | Average price paid for a drug from a manufacturer for a corresponding ASP unit. |

# Reasonable Assumptions

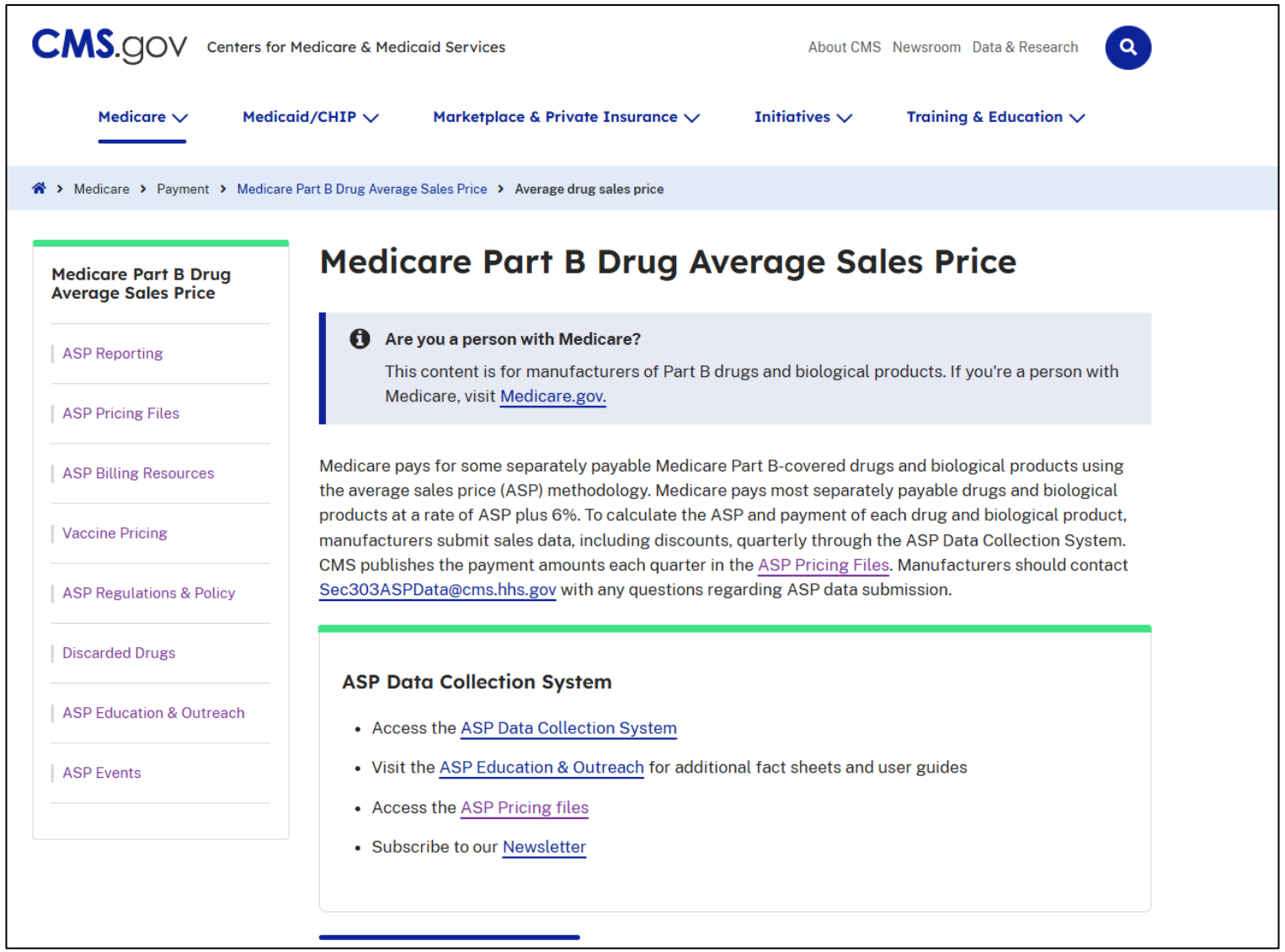
- Now **required** as part of the quarterly data submission
- New form with new fields
- Either the Submitter or Certifier can submit data, but the form must be complete prior to certification

# Bona Fide Service Fees

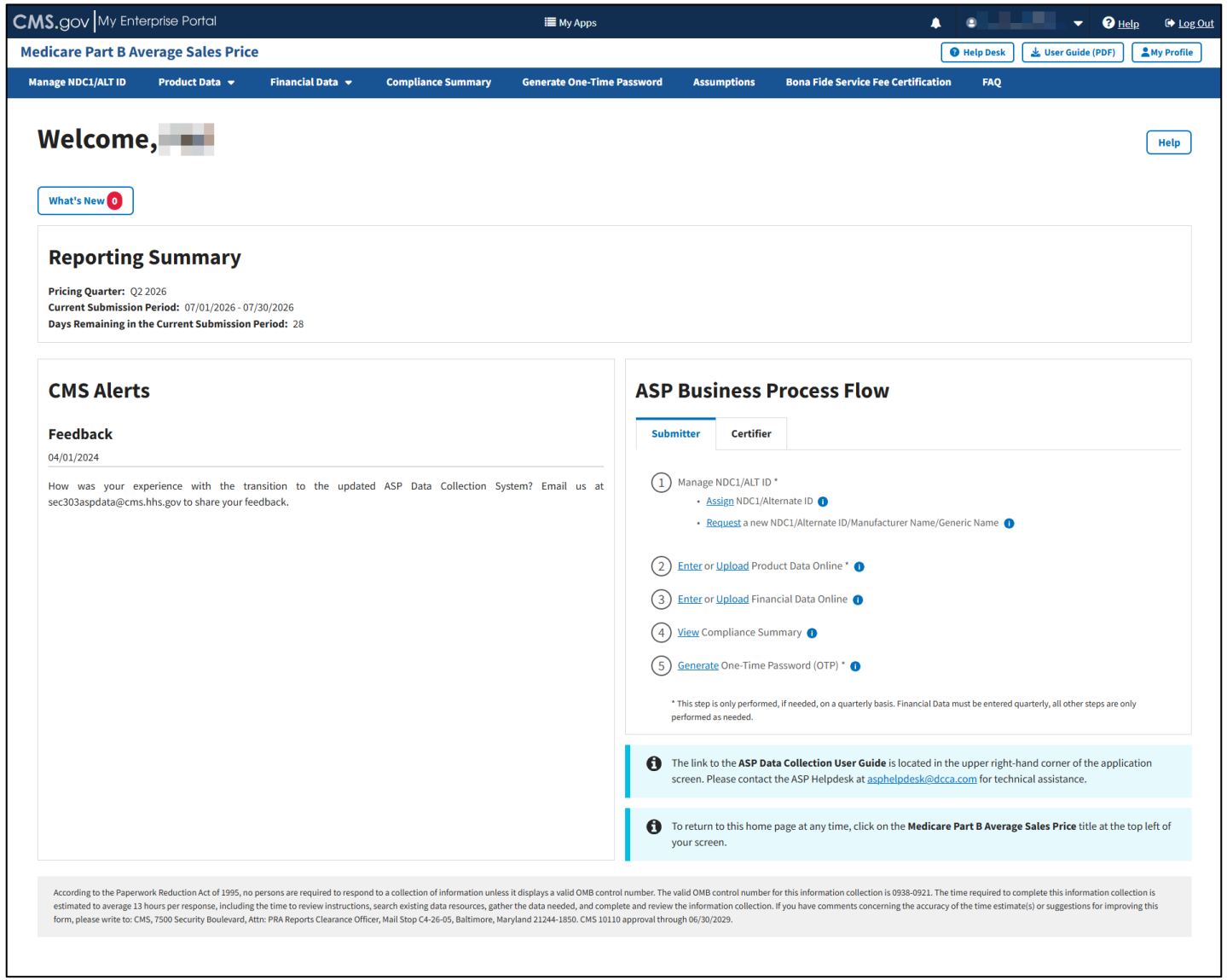

- Both Submitters and Certifiers are now able to download, complete, upload, and submit the bona fide service fee (BFSF) certification form
- New and renewed contracts as of April 1, 2026
- More specific information about this new requirement can be found in the FY26 PFS Final Rule


# System Demonstration

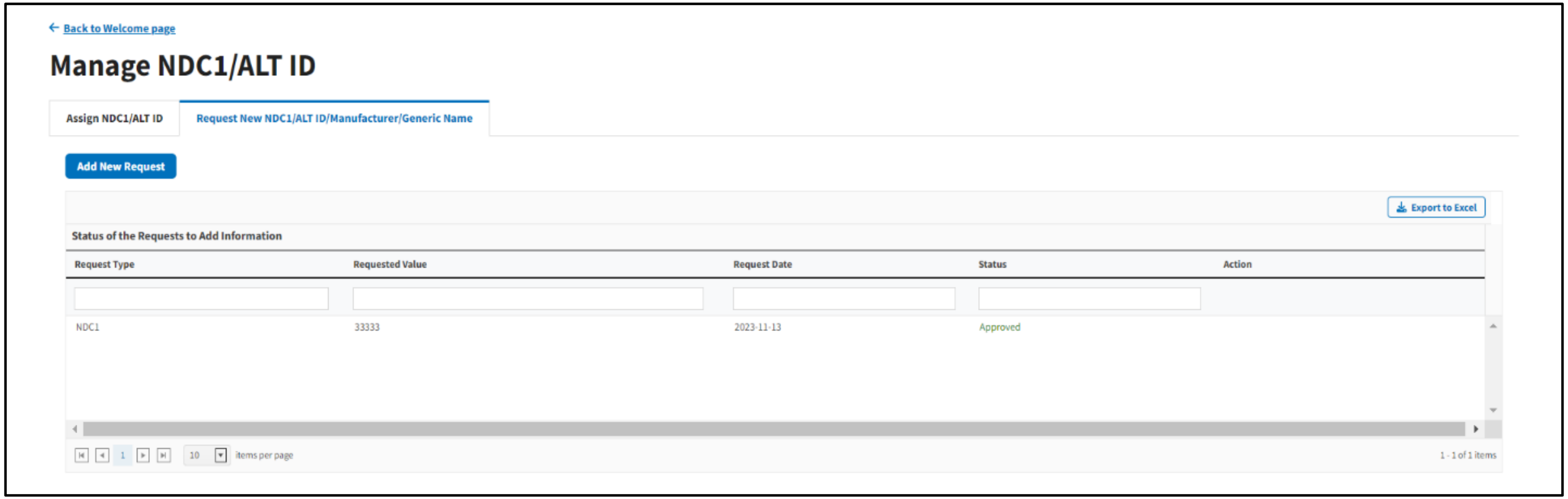
# Accessing the ASP Data Collection System



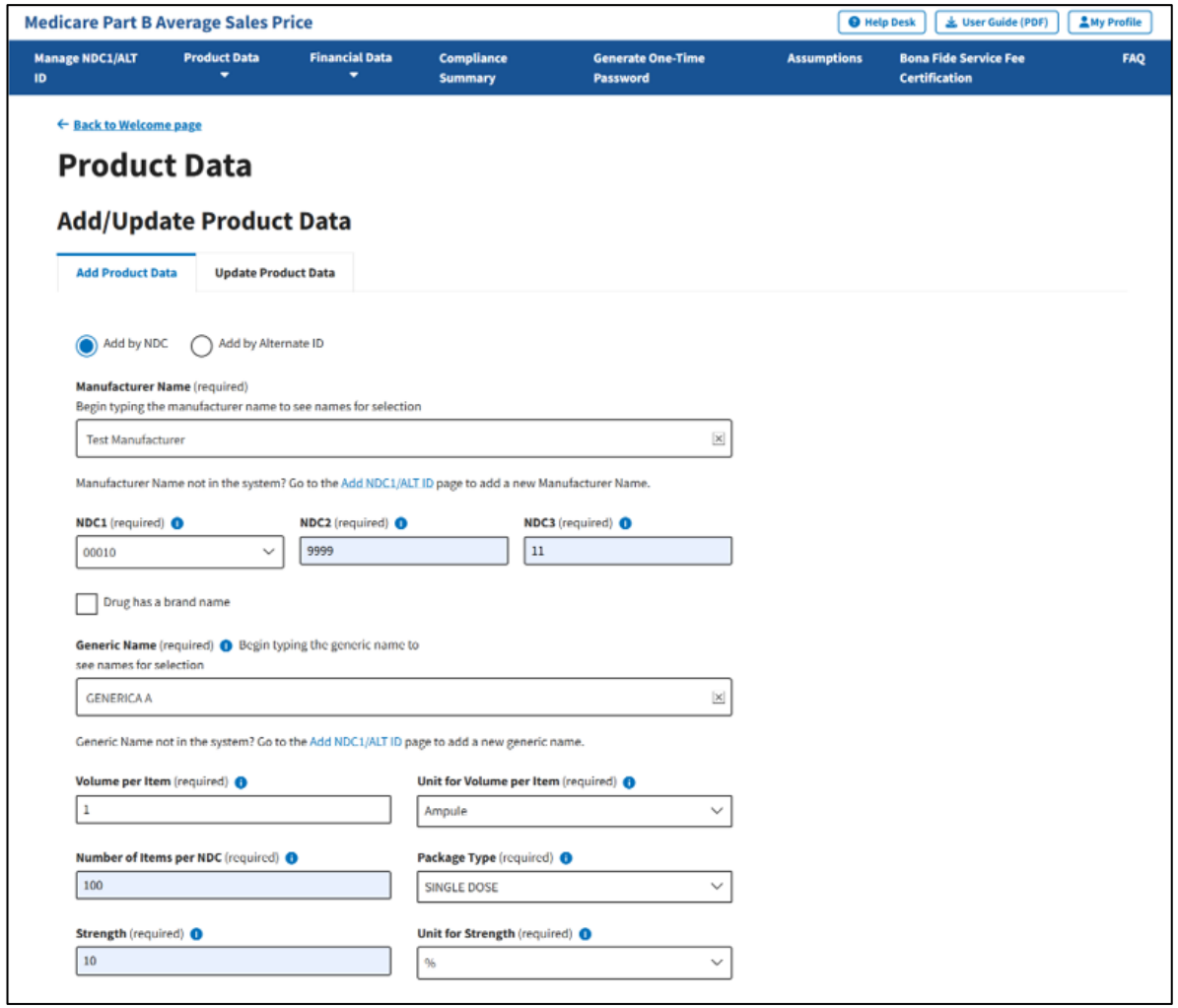
# Home Page

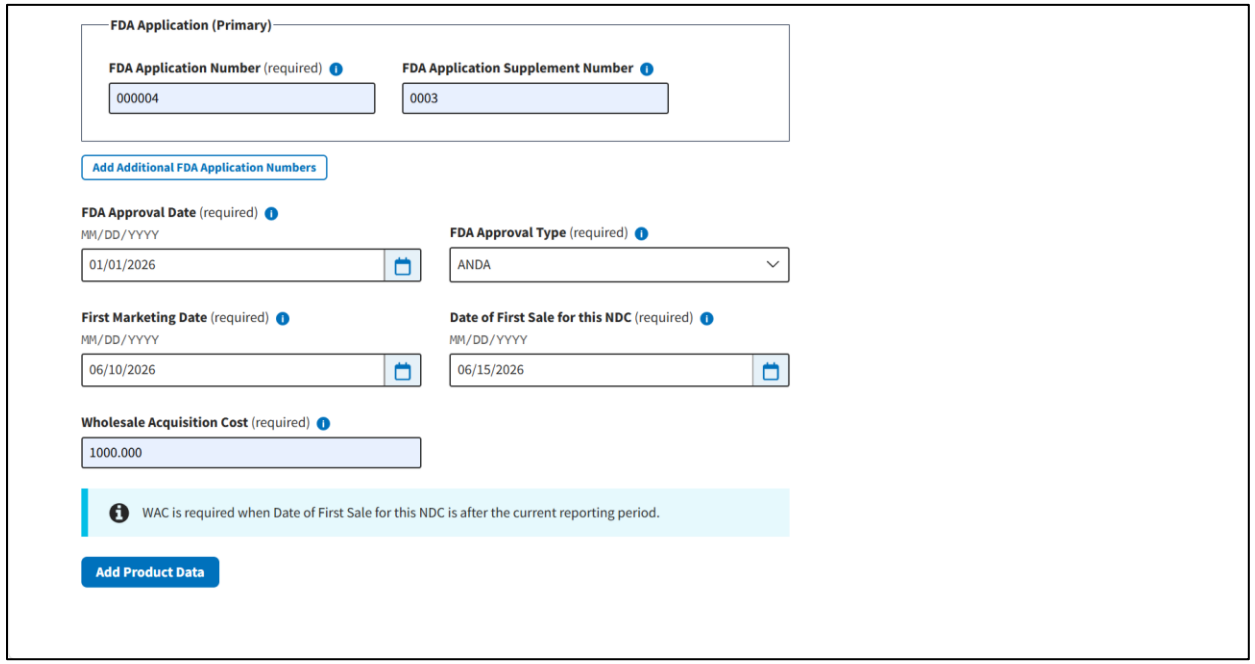

CMS.gov | My Enterprise Portal
My Apps
Help
Log Out
Medicare Part B Average Sales Price
Help Desk
User Guide (PDF)
My Profile
Manage NDC1/ALT ID
Product Data
Financial Data
Compliance Summary
Generate One-Time Password
Assumptions
Bona Fide Service Fee Certification
FAQ
Welcome,
Help
What's New 0
Reporting Summary
Pricing Quarter: Q2 2026
Current Submission Period: 07/01/2026 - 07/30/2026
Days Remaining in the Current Submission Period: 28
CMS Alerts
Feedback
04/01/2024
How was your experience with the transition to the updated ASP Data Collection System? Email us at sec303aspdata@cms.hhs.gov to share your feedback.
ASP Business Process Flow
Submitter
Certifier
1 Manage NDC1/ALT ID *
Assign NDC1/Alternate ID
Request a new NDC1/Alternate ID/Manufacturer Name/Generic Name
2 Enter or Upload Product Data Online *
3 Enter or Upload Financial Data Online
4 View Compliance Summary
5 Generate One-Time Password (OTP) *
* This step is only performed, if needed, on a quarterly basis. Financial Data must be entered quarterly, all other steps are only performed as needed.
The link to the ASP Data Collection User Guide is located in the upper right-hand corner of the application screen. Please contact the ASP Helpdesk at asphelpdesk@dcca.com for technical assistance.
To return to this home page at any time, click on the Medicare Part B Average Sales Price title at the top left of your screen.
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0921. 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 through 06/30/2029.

# Requesting a New Product

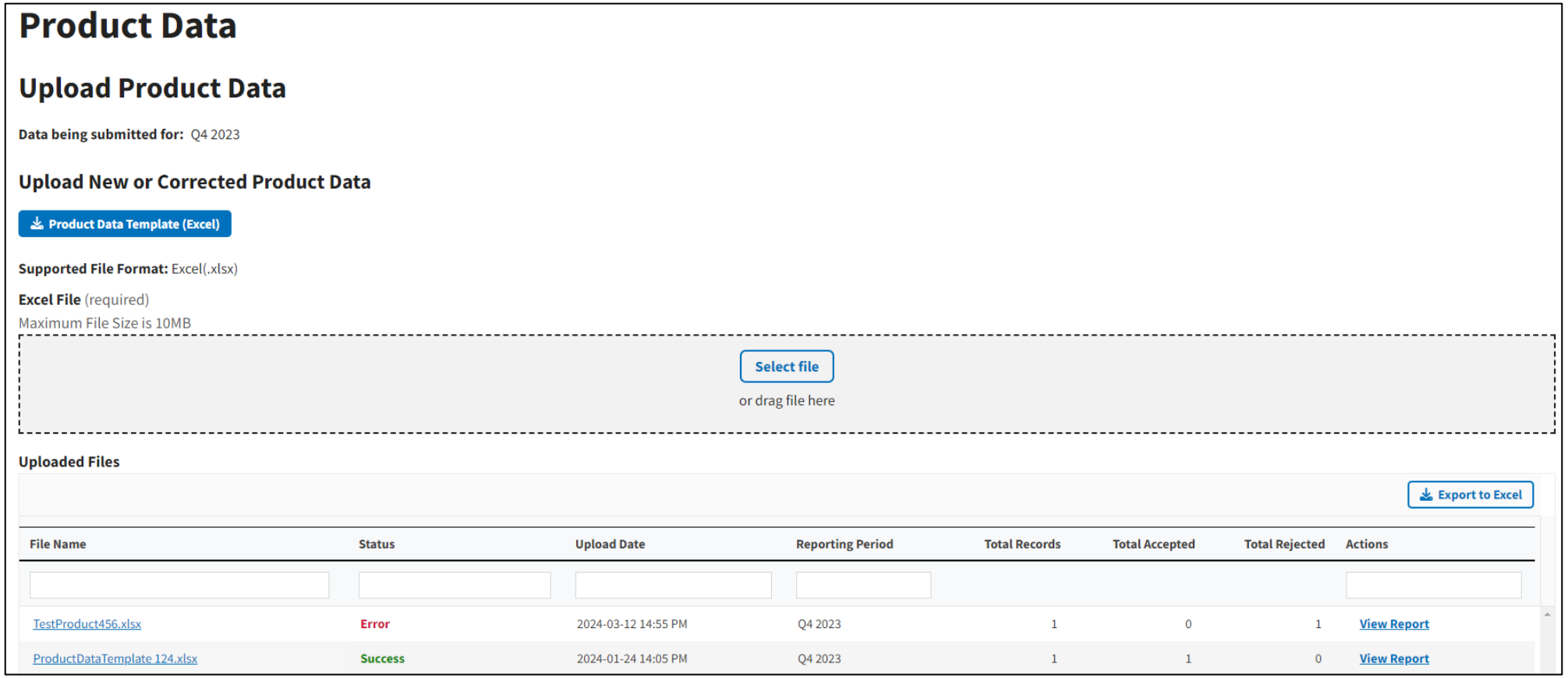


# Add Product Data

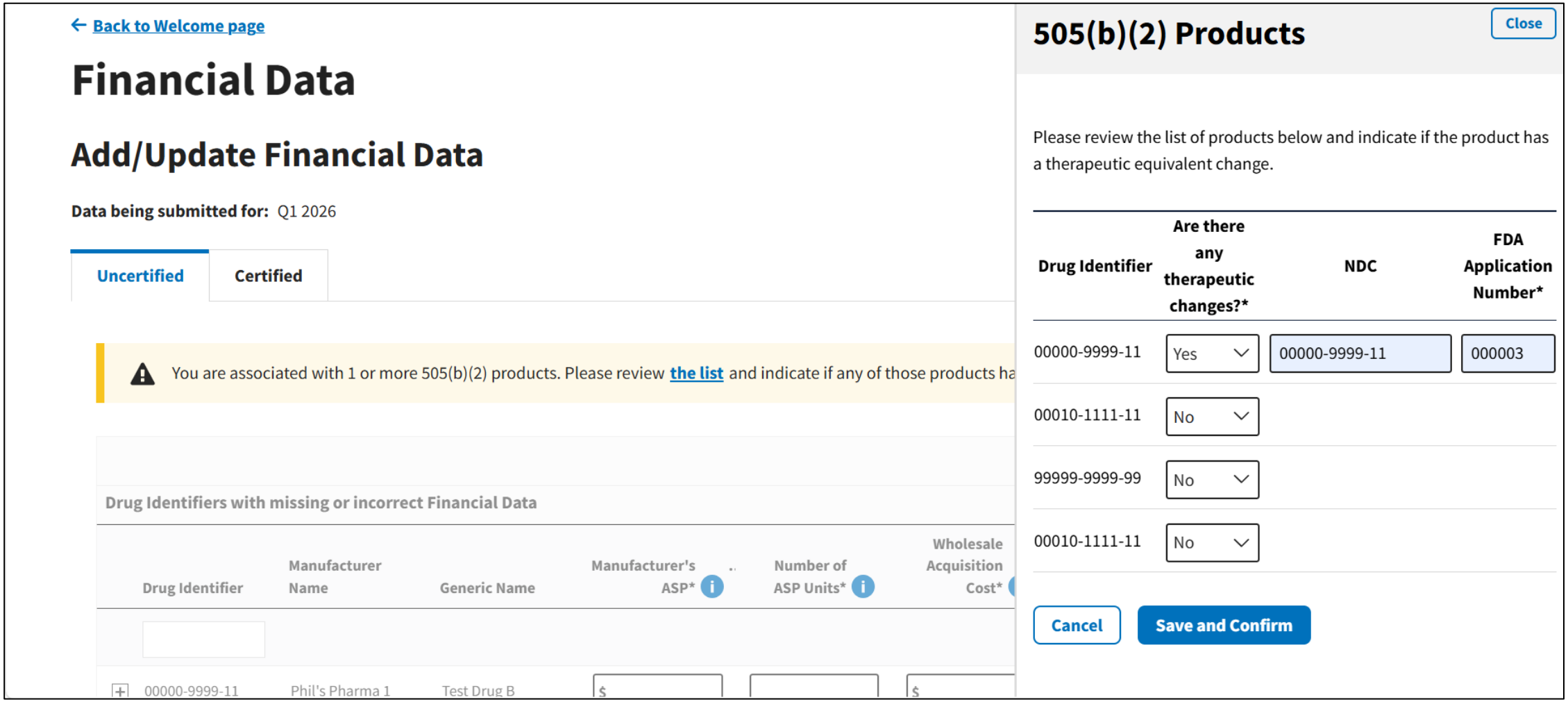


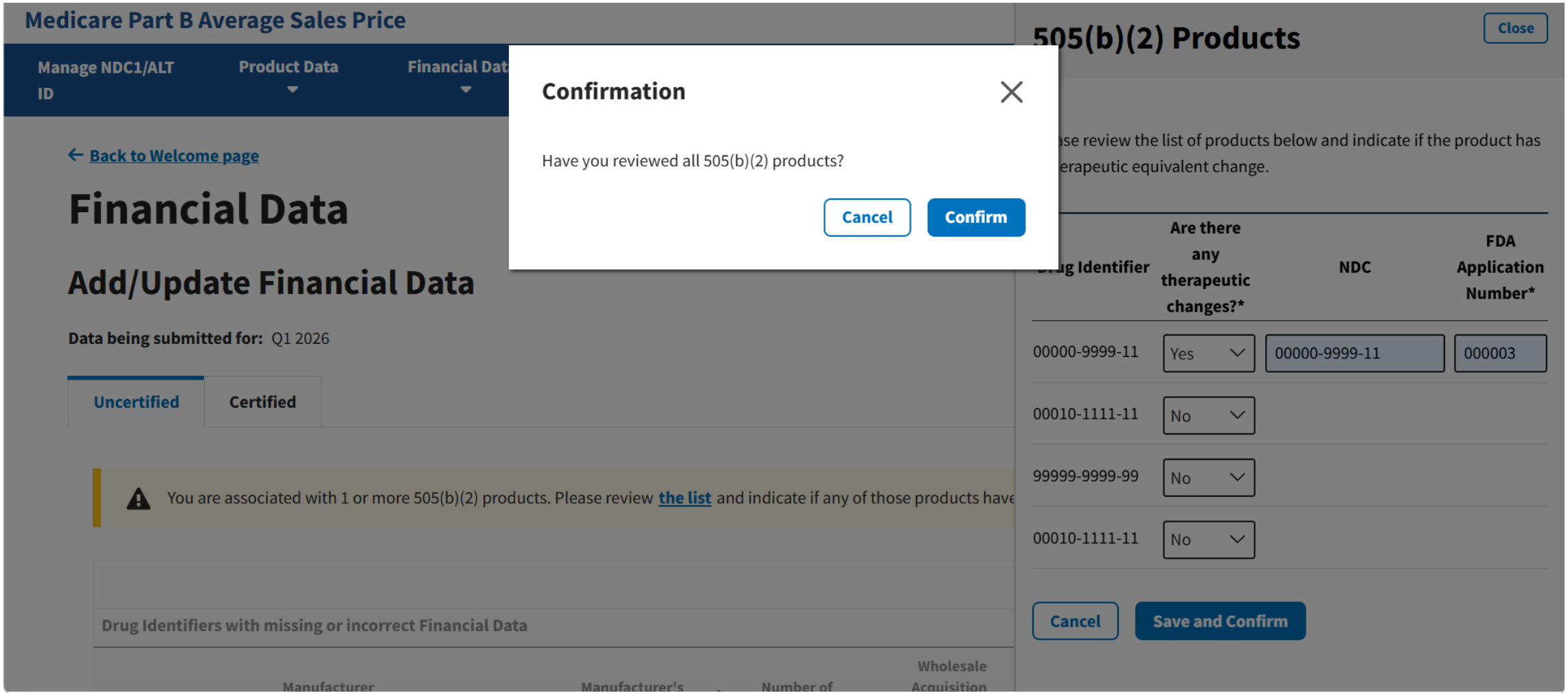
# Upload Product Data



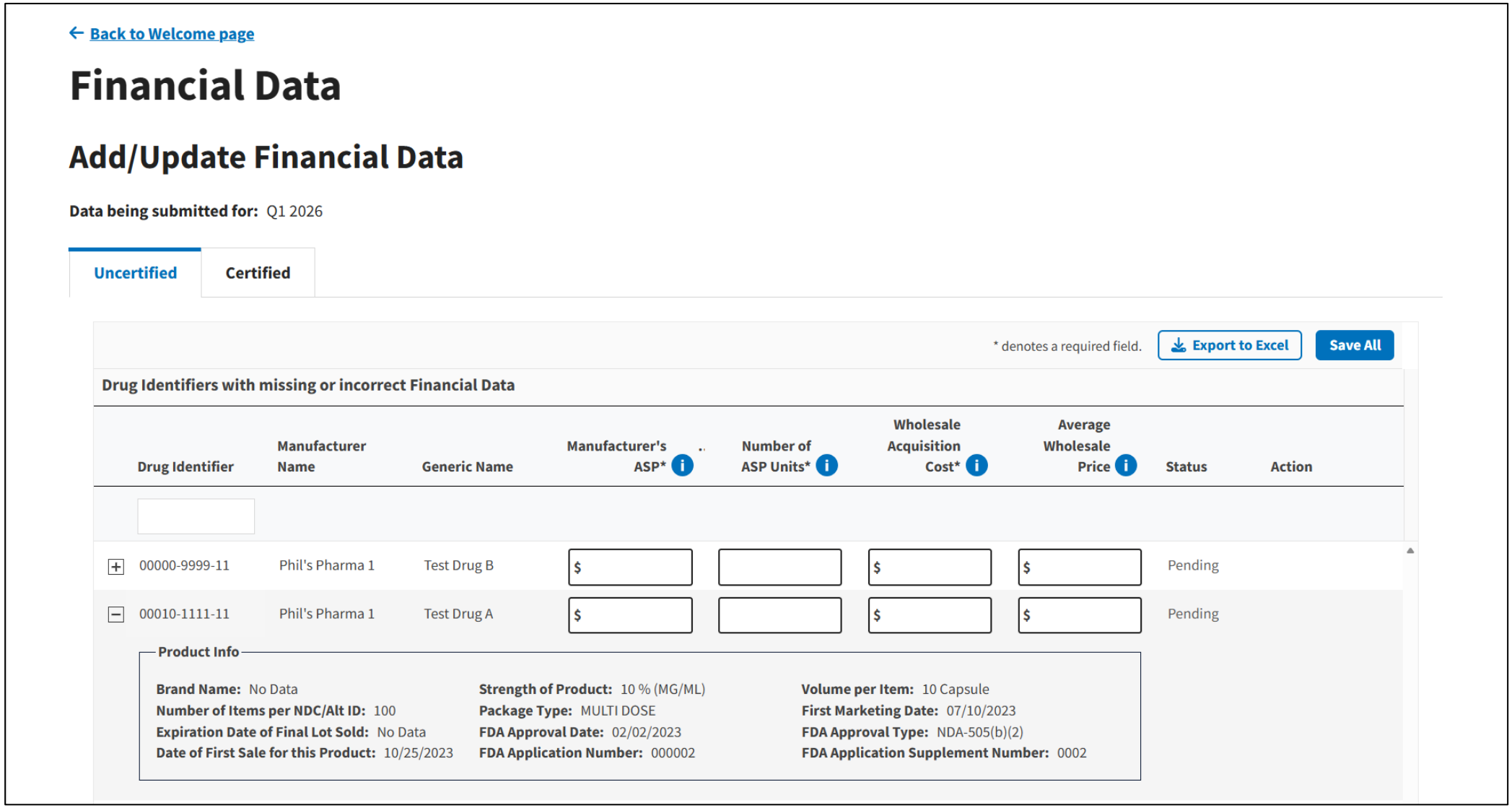
# 505(b)(2)


Back to Welcome page
Financial Data
Add/Update Financial Data
Data being submitted for: Q1 2026
Uncertified
Certified
You are associated with 1 or more 505(b)(2) products. Please review the list and indicate if any of those products ha
Drug Identifiers with missing or incorrect Financial Data
Drug Identifier
Manufacturer Name
Generic Name
Manufacturer's ASP*
Number of ASP Units*
Wholesale Acquisition Cost*
00000-9999-11
Phil's Pharma 1
Test Drug B
505(b)(2) Products
Close
Please review the list of products below and indicate if the product has a therapeutic equivalent change.
Drug Identifier
Are there any therapeutic changes?*
NDC
FDA Application Number*
00000-9999-11
Yes
00000-9999-11
000003
00010-1111-11
No
99999-9999-99
No
00010-1111-11
No
Cancel
Save and Confirm

# 505(b)(2) Confirmation



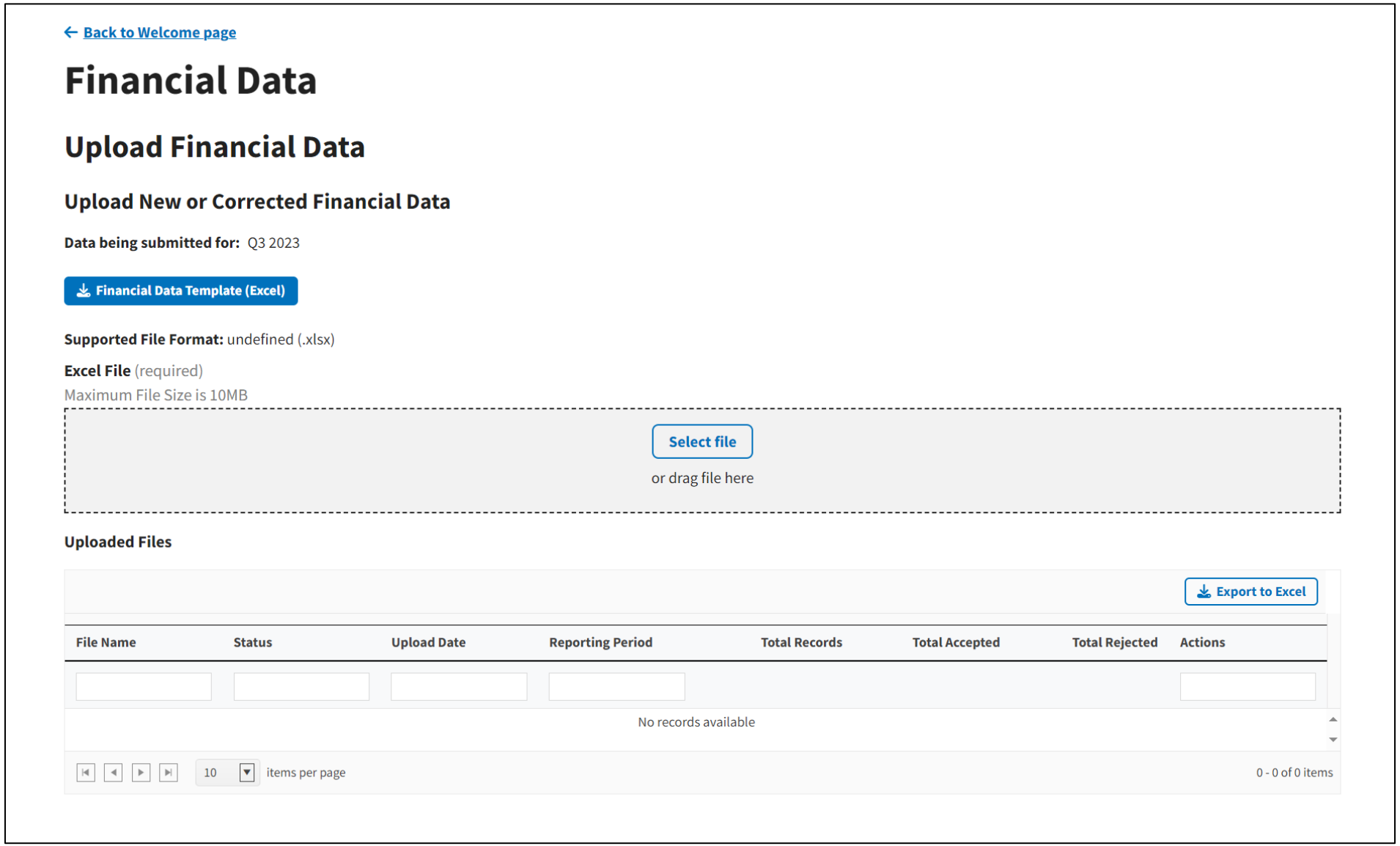
# Add/Update Financial Data



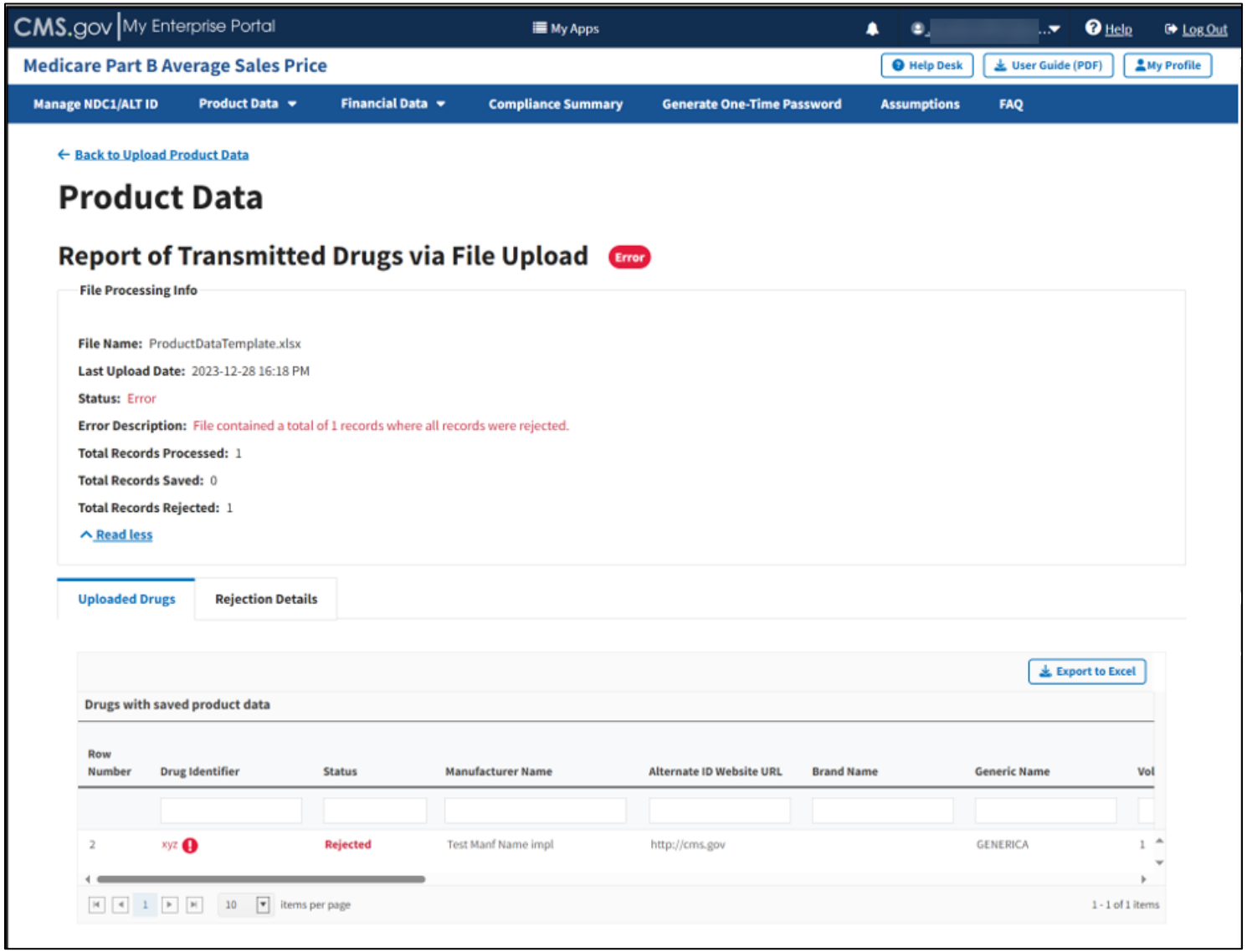
# Financial Data Tips

1. Enter numbers with 3 decimal places.
2. For ASP Units Sold, enter sales based on the product info packaging reported during product data entry.
3. The WAC and AWP should be positive numbers.
4. If there is no AWP, leave the field blank.
5. Manufacturer's ASP and ASP Units Sold can be zero or negative values.
6. For skin substitute products, financial data should be entered individually for each Alternate ID sold by the manufacturer, and not grouped or blended in any way, such as at a HCPCS code level.

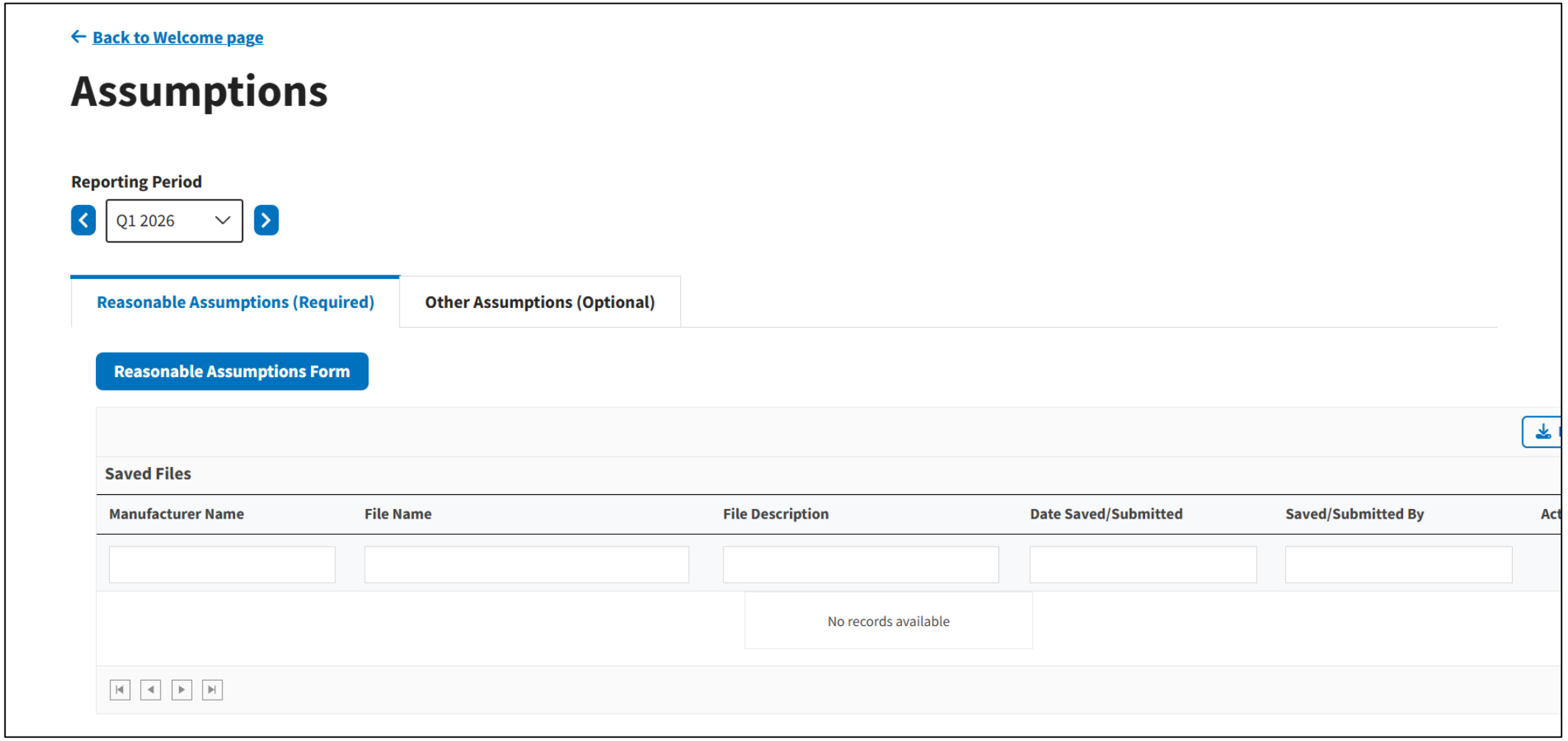
# Upload Financial Data



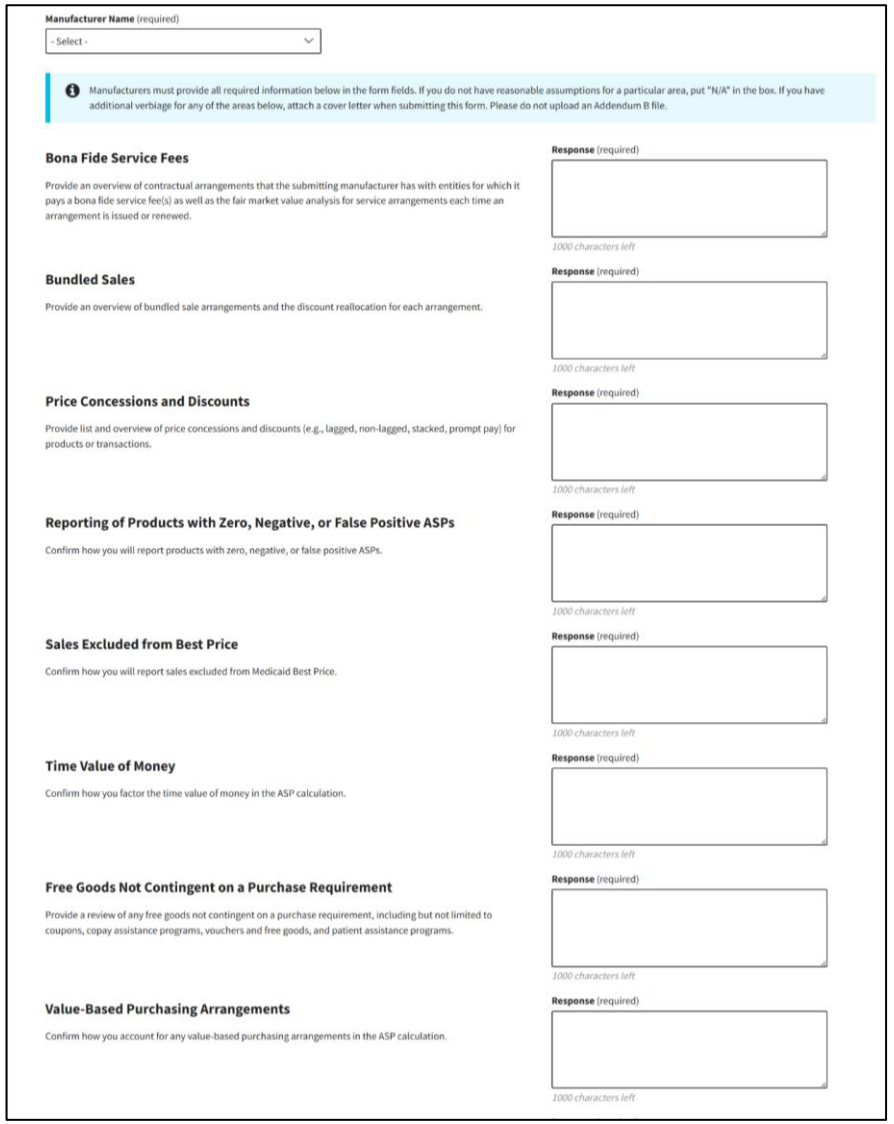
# Error Reports



# Assumptions



# Reasonable Assumptions Form



**Manufacturer Name** (required)

- Select -

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

**Bona Fide Service Fees**

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

**Response** (required)

*1000 characters left*

**Bundled Sales**

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

**Response** (required)

*1000 characters left*

**Price Concessions and Discounts**

Provide list and overview of price concessions and discounts (e.g., lagged, non-lagged, stacked, prompt pay) for products or transactions.

**Response** (required)

*1000 characters left*

**Reporting of Products with Zero, Negative, or False Positive ASPs**

Confirm how you will report products with zero, negative, or false positive ASPs.

**Response** (required)

*1000 characters left*

**Sales Excluded from Best Price**

Confirm how you will report sales excluded from Medicaid Best Price.

**Response** (required)

*1000 characters left*

**Time Value of Money**

Confirm how you factor the time value of money in the ASP calculation.

**Response** (required)

*1000 characters left*

**Free Goods Not Contingent on a Purchase Requirement**

Provide a review of any free goods not contingent on a purchase requirement, including but not limited to coupons, copay assistance programs, vouchers and free goods, and patient assistance programs.

**Response** (required)

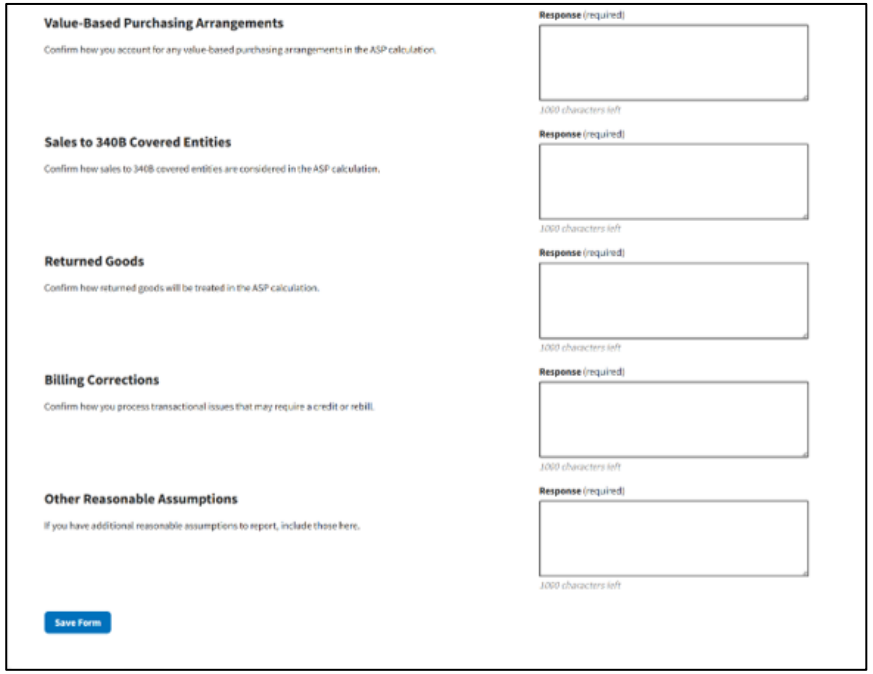
*1000 characters left*

**Value-Based Purchasing Arrangements**

Confirm how you account for any value-based purchasing arrangements in the ASP calculation.

**Response** (required)

*1000 characters left*



**Value-Based Purchasing Arrangements**

Confirm how you account for any value-based purchasing arrangements in the ASP calculation.

**Response** (required)

*1000 characters left*

**Sales to 340B Covered Entities**

Confirm how sales to 340B covered entities are considered in the ASP calculation.

**Response** (required)

*1000 characters left*

**Returned Goods**

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

**Response** (required)

*1000 characters left*

**Billing Corrections**

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

**Response** (required)

*1000 characters left*

**Other Reasonable Assumptions**

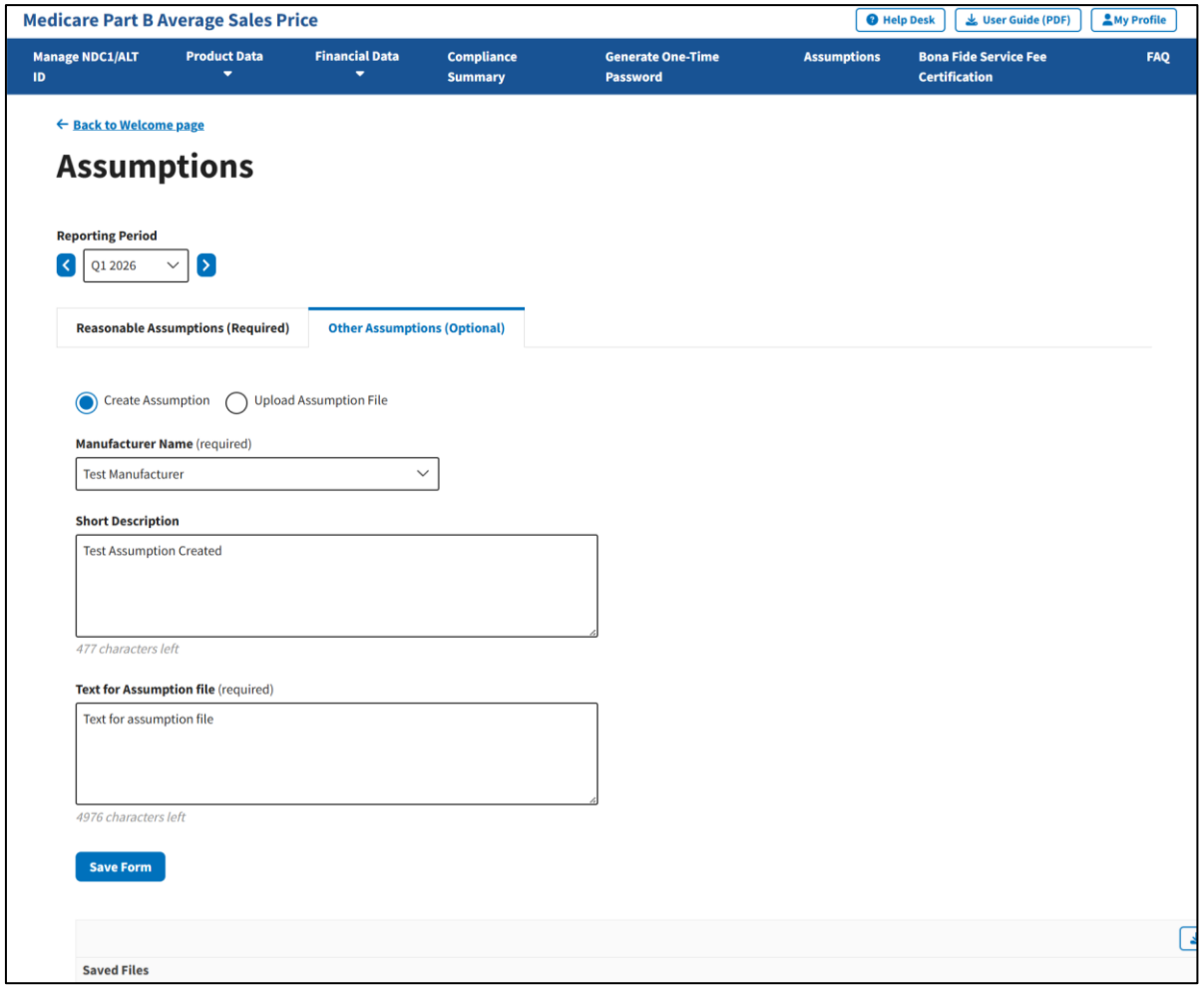
If you have additional reasonable assumptions to report, include those here.

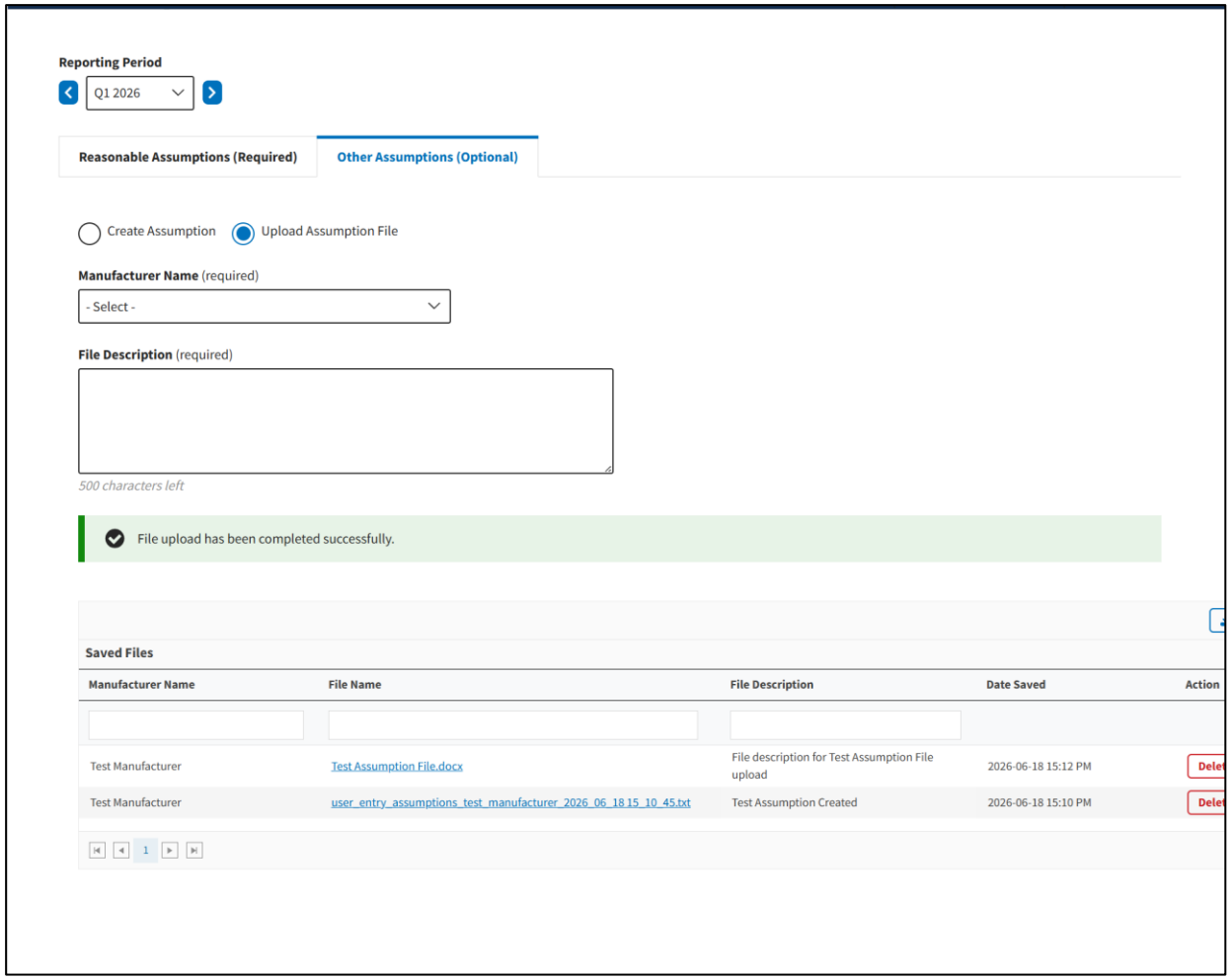
**Response** (required)

*1000 characters left*

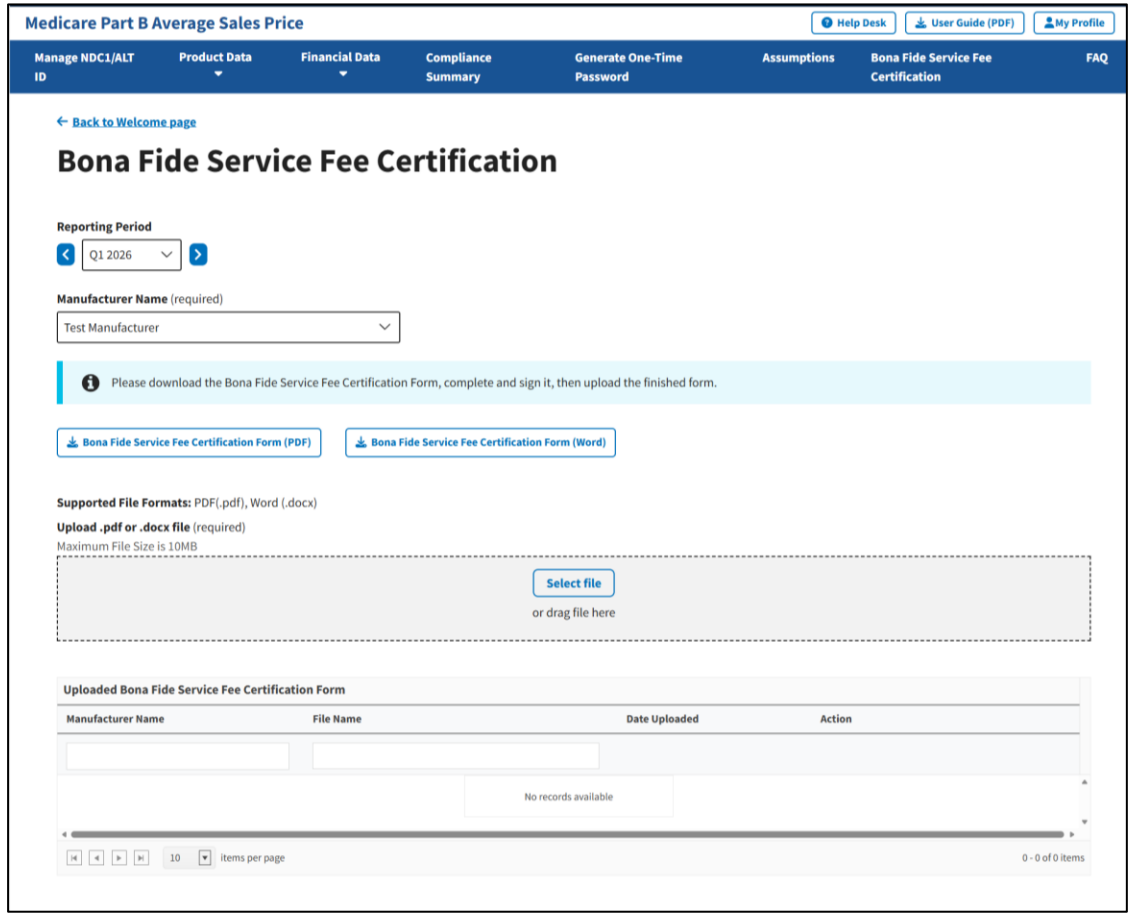
Save Form

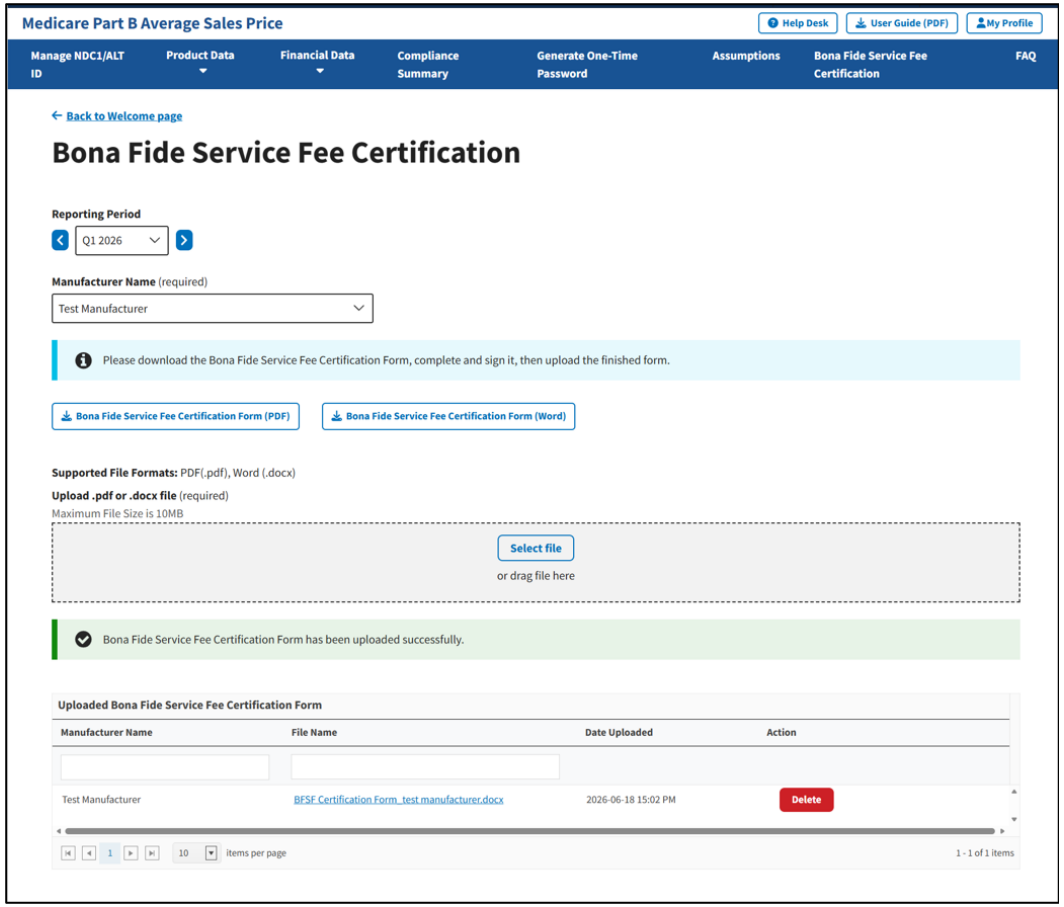
# Create/Upload Other Assumptions Form



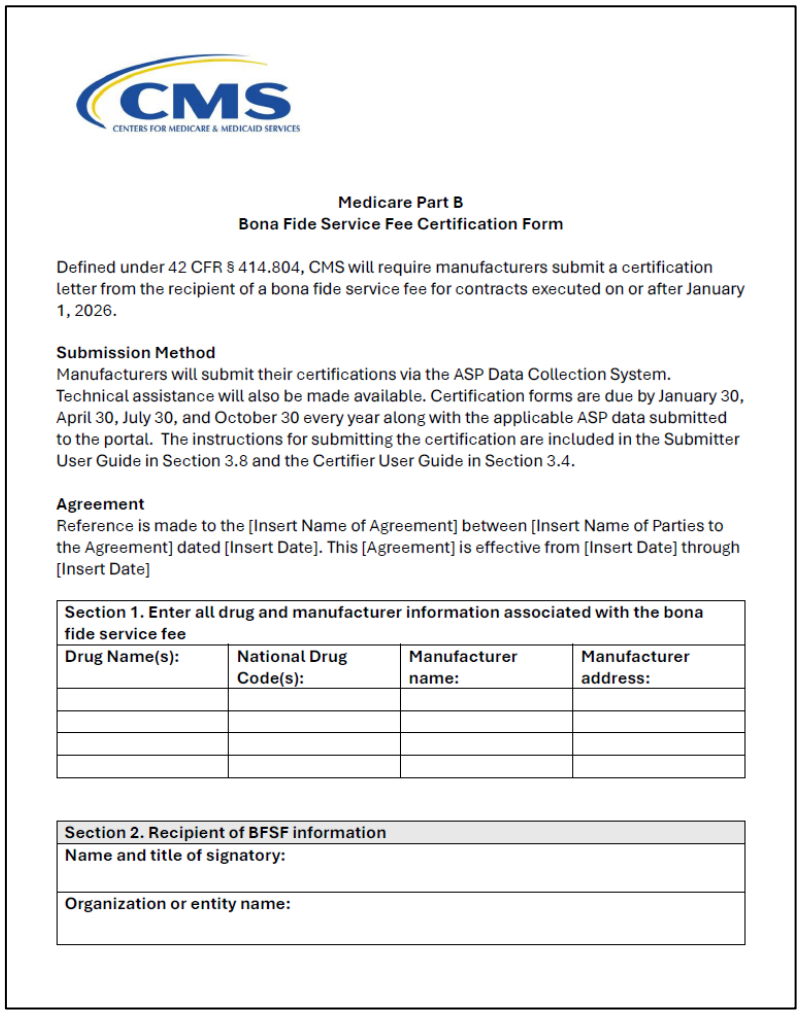



# Bona Fide Service Fee Form



# Bona Fide Service Fee Form (Word)



**Medicare Part B**
**Bona Fide Service Fee Certification Form**

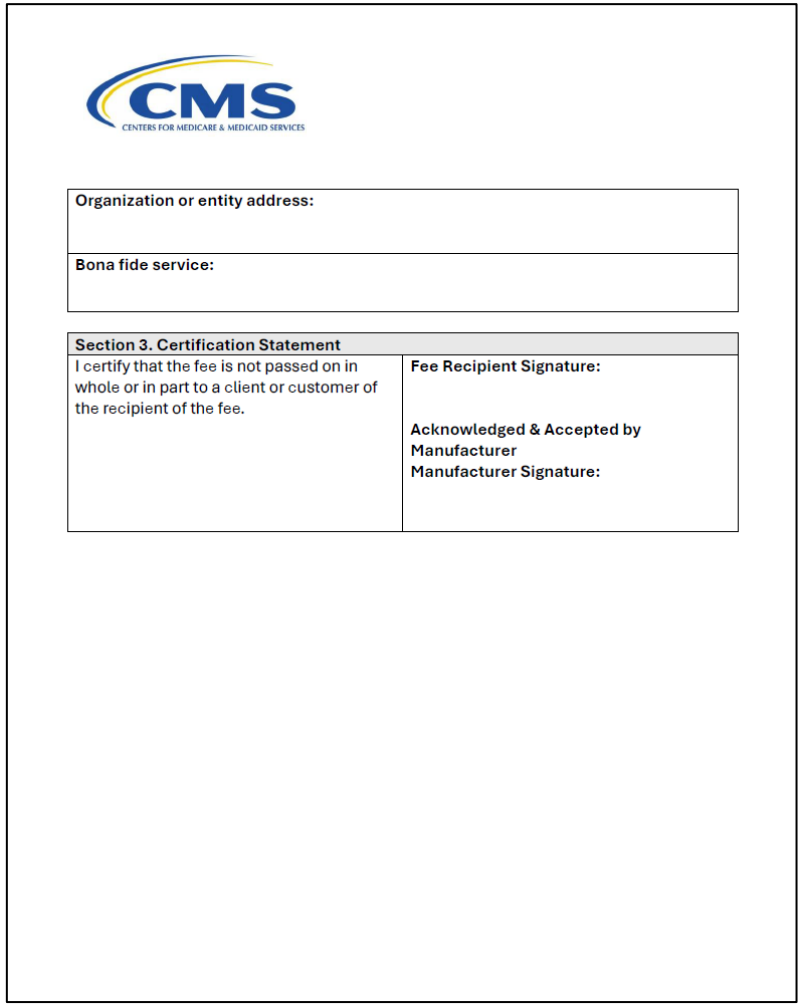
Defined under 42 CFR § 414.804, CMS will require manufacturers submit a certification letter from the recipient of a bona fide service fee for contracts executed on or after January 1, 2026.

**Submission Method**
Manufacturers will submit their certifications via the ASP Data Collection System. Technical assistance will also be made available. Certification forms are due by January 30, April 30, July 30, and October 30 every year along with the applicable ASP data submitted to the portal. The instructions for submitting the certification are included in the Submitter User Guide in Section 3.8 and the Certifier User Guide in Section 3.4.

**Agreement**
Reference is made to the [Insert Name of Agreement] between [Insert Name of Parties to the Agreement] dated [Insert Date]. This [Agreement] is effective from [Insert Date] through [Insert Date]

| Section 1. Enter all drug and manufacturer information associated with the bona fide service fee | | | |
|---|---|---|---|
| **Drug Name(s):** | **National Drug Code(s):** | **Manufacturer name:** | **Manufacturer address:** |
| | | | |
| | | | |
| | | | |
| | | | |

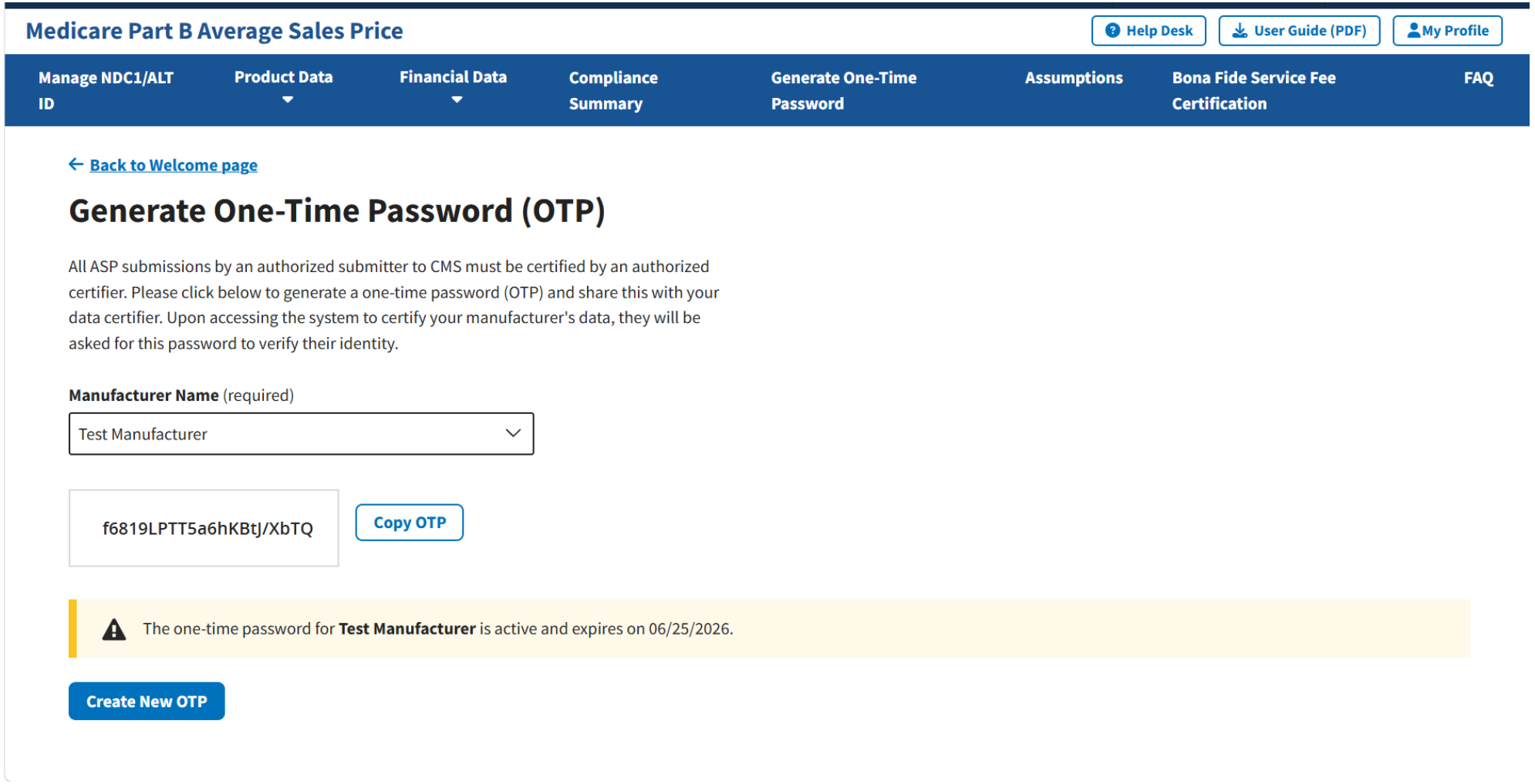
| Section 2. Recipient of BFSF information |
|---|
| **Name and title of signatory:** |
| **Organization or entity name:** |



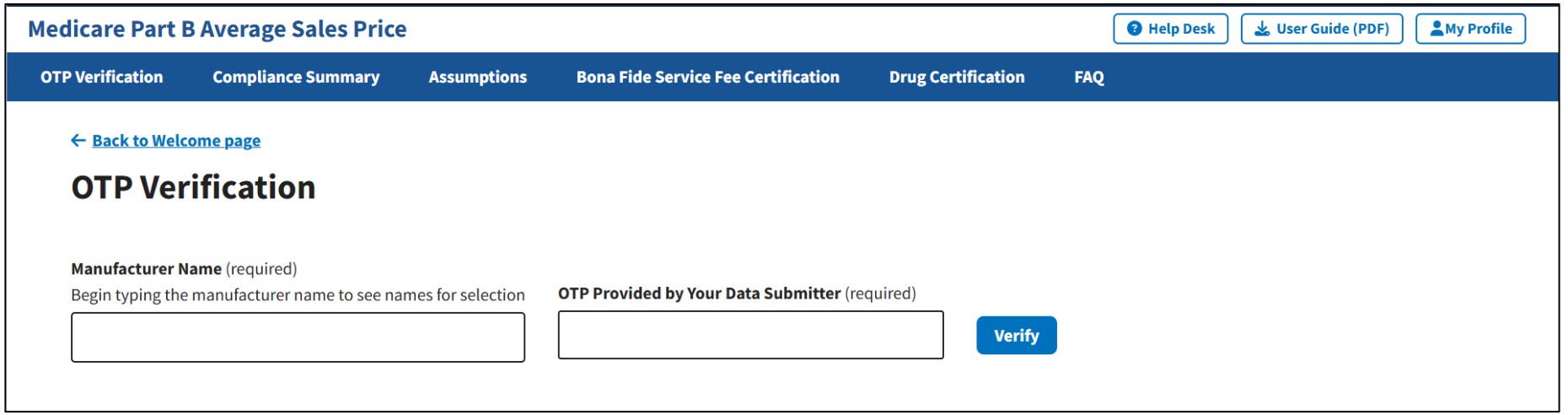
| **Organization or entity address:** |
|---|
| **Bona fide service:** |

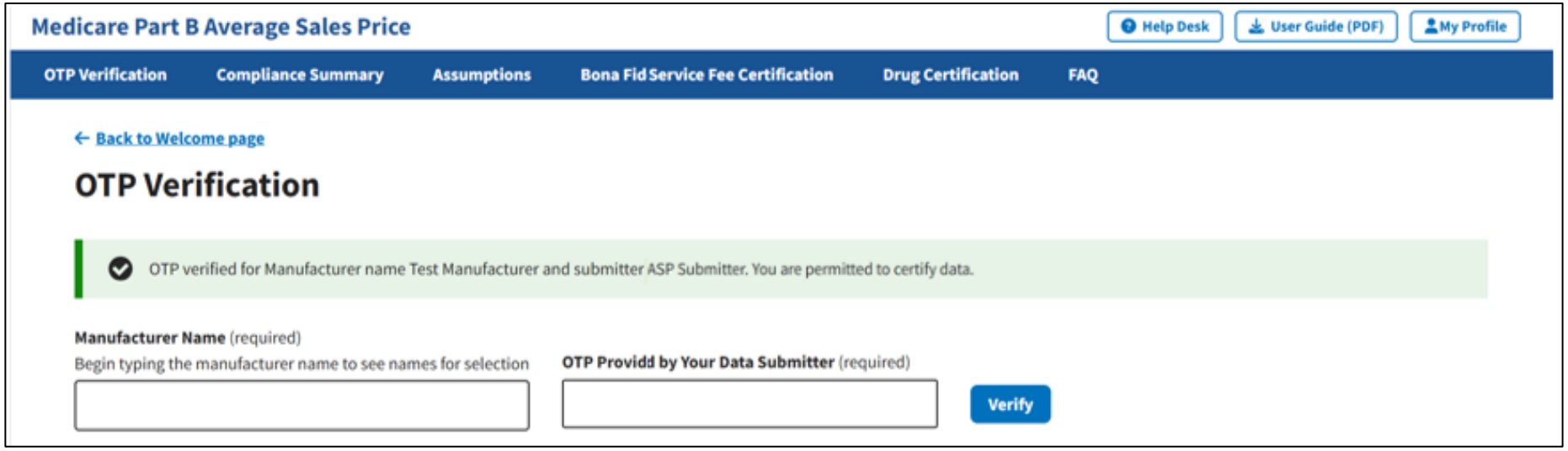
| Section 3. Certification Statement | |
|---|---|
| I certify that the fee is not passed on in whole or in part to a client or customer of the recipient of the fee. | **Fee Recipient Signature:**<br><br>**Acknowledged & Accepted by Manufacturer**<br>**Manufacturer Signature:** |

# Generate OTP

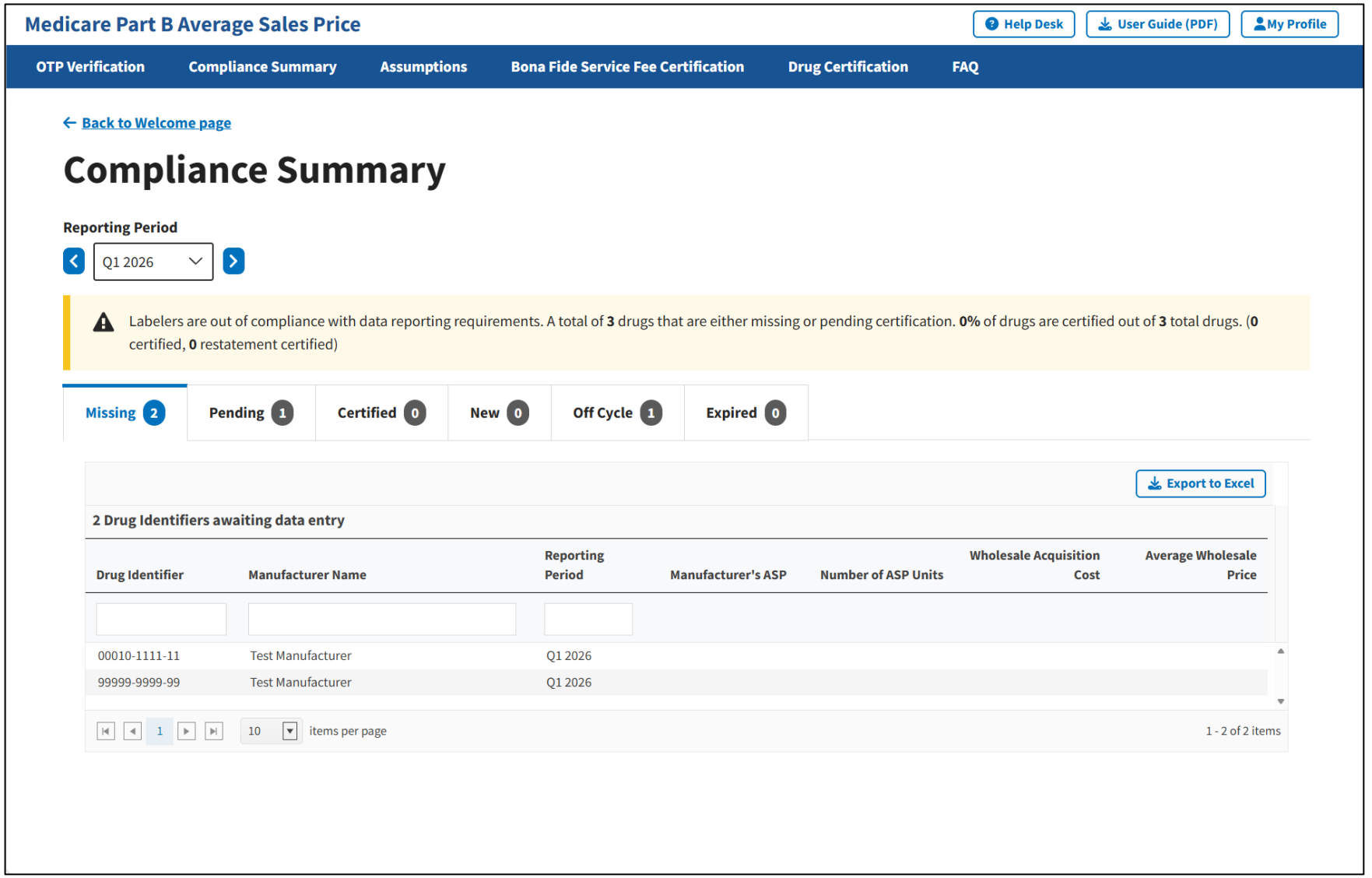


# OTP Verification

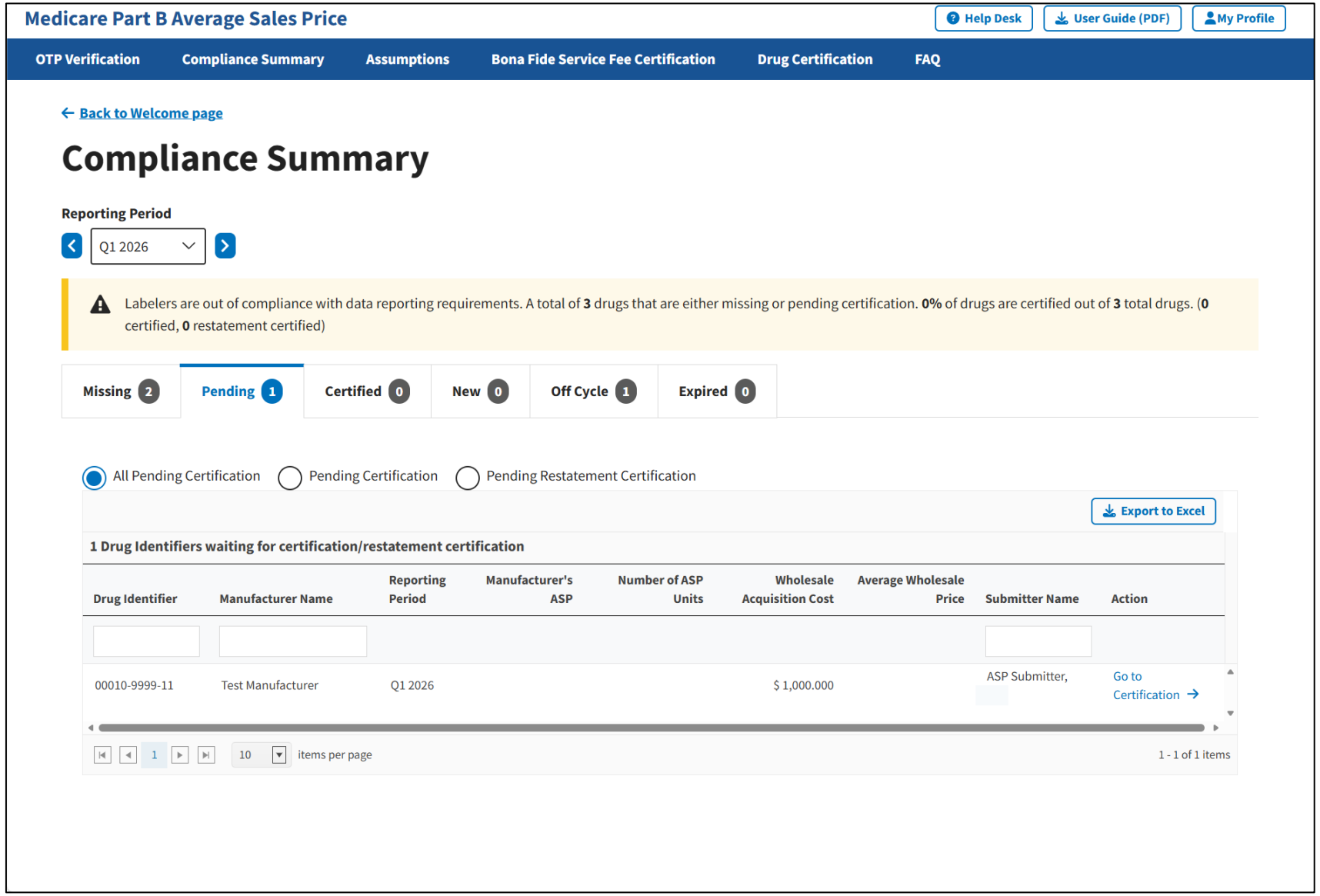


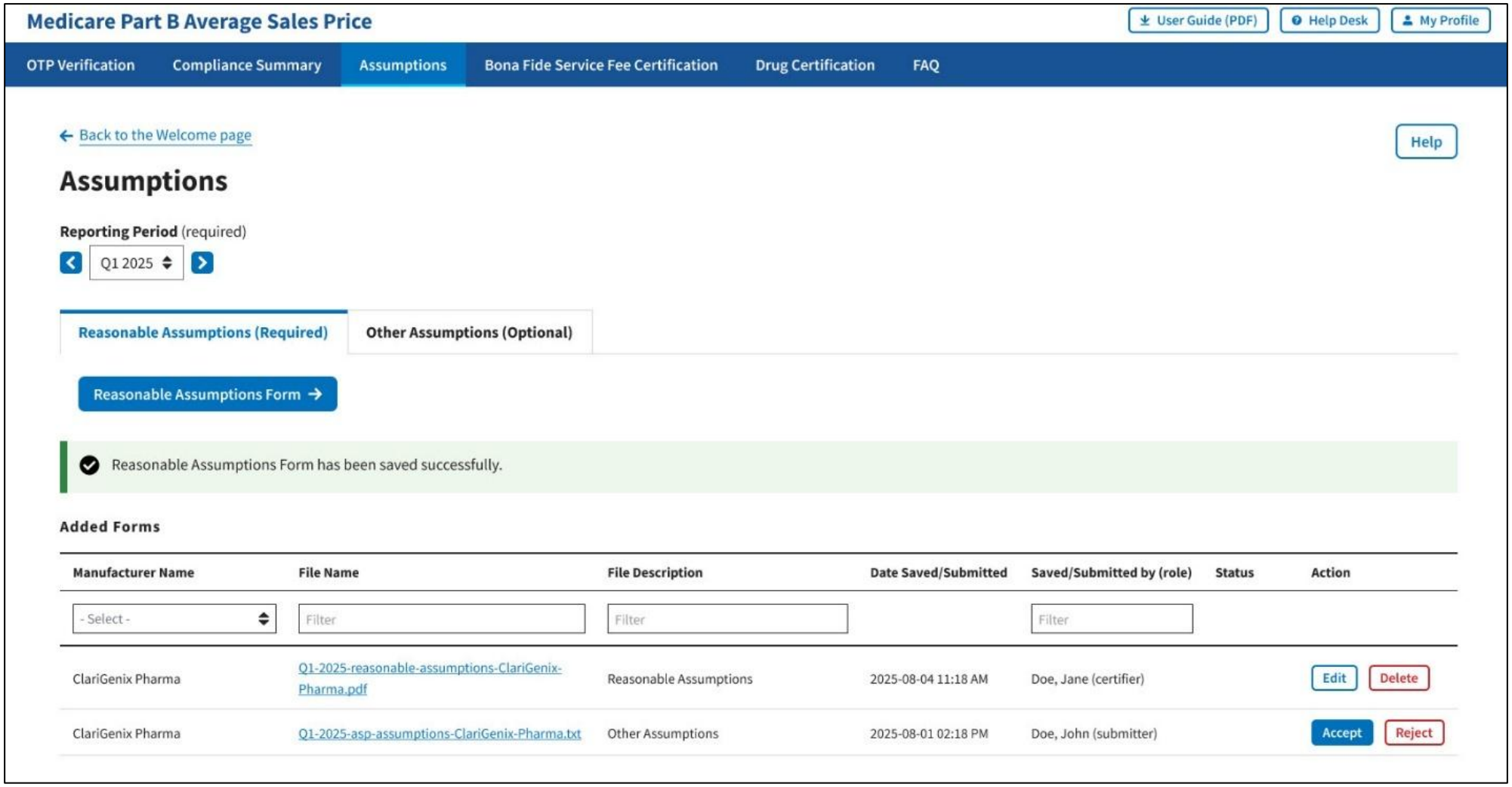
# Compliance Summary - Missing



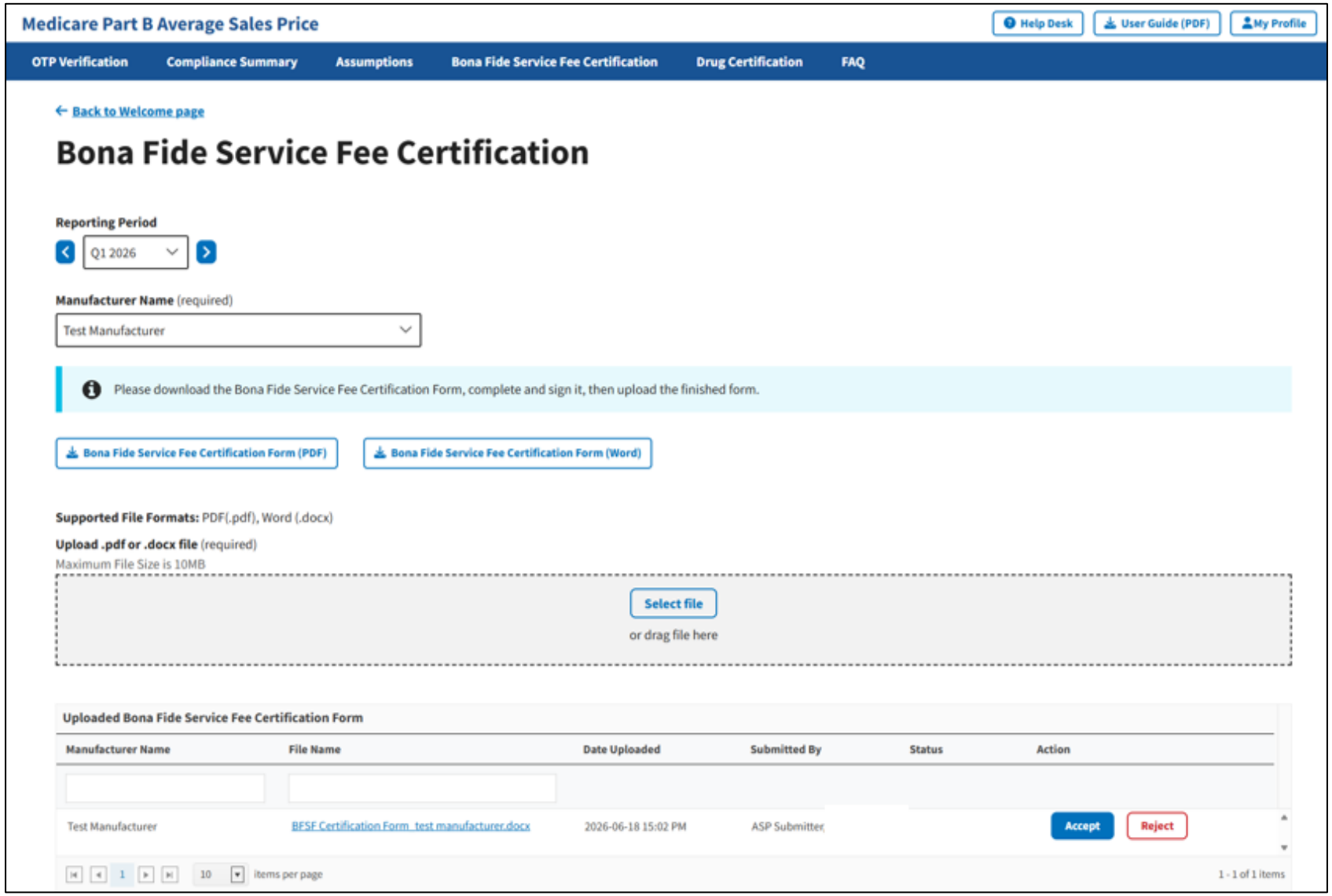
# Compliance Summary - Pending



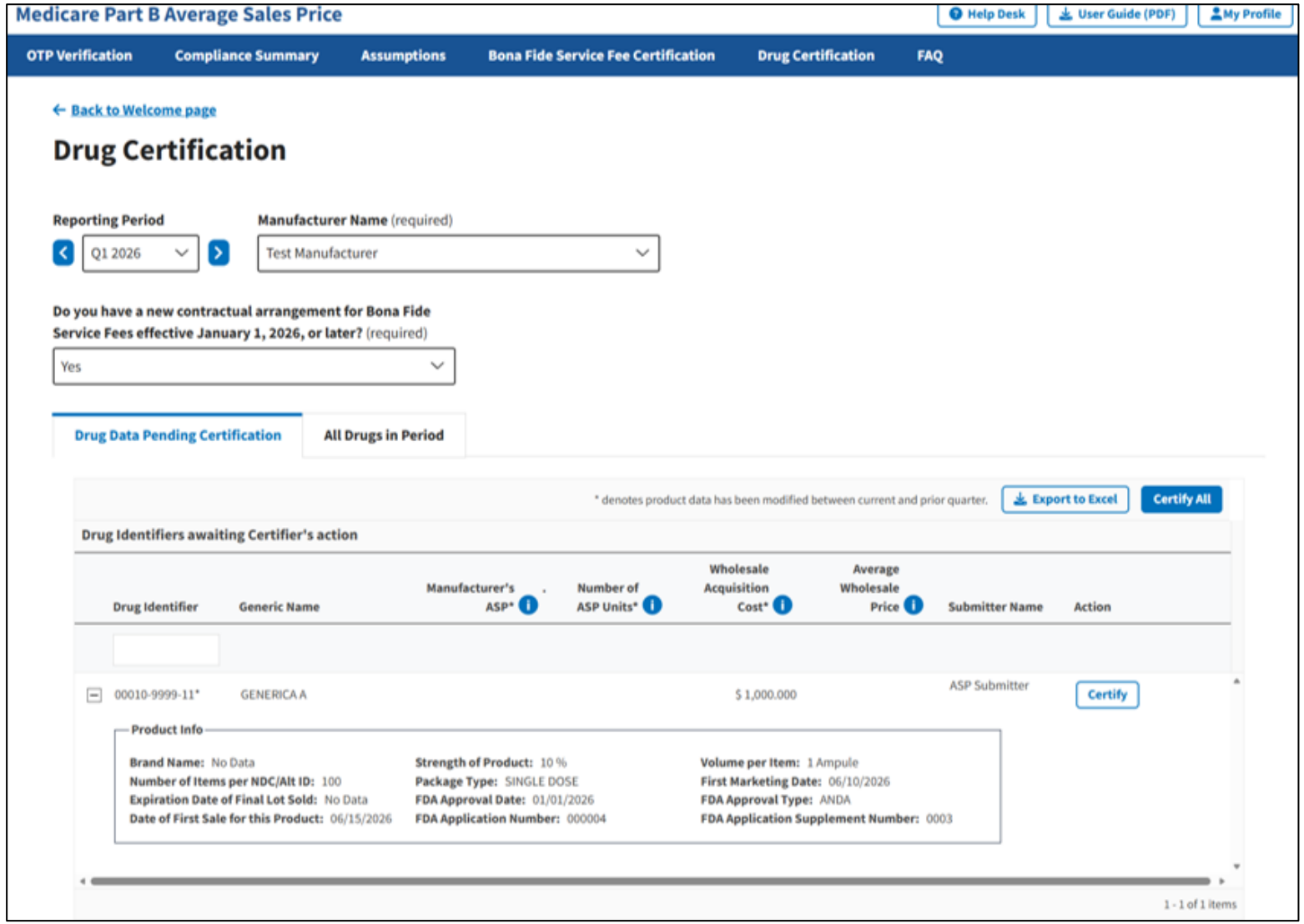
# Verify Assumptions

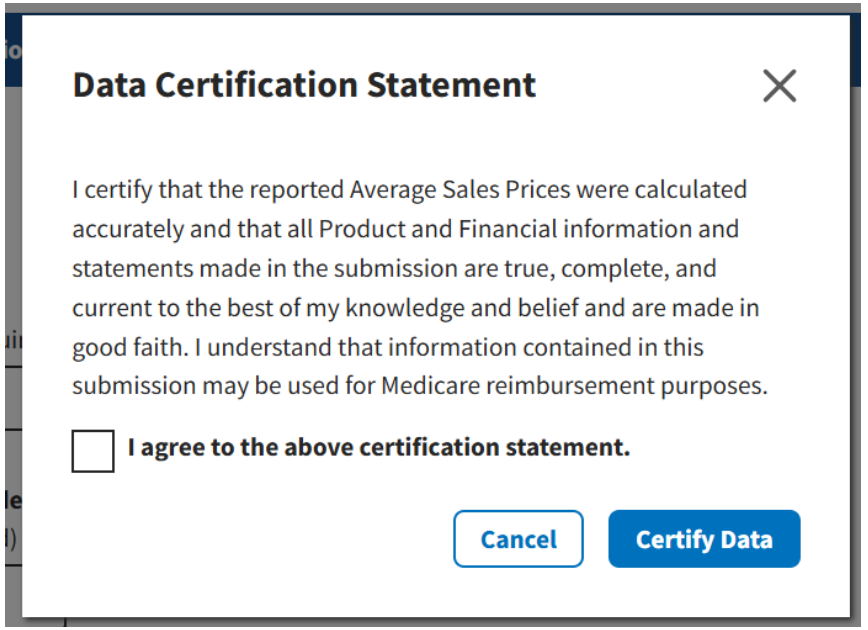


# Review Bona Fide Service Fee Form

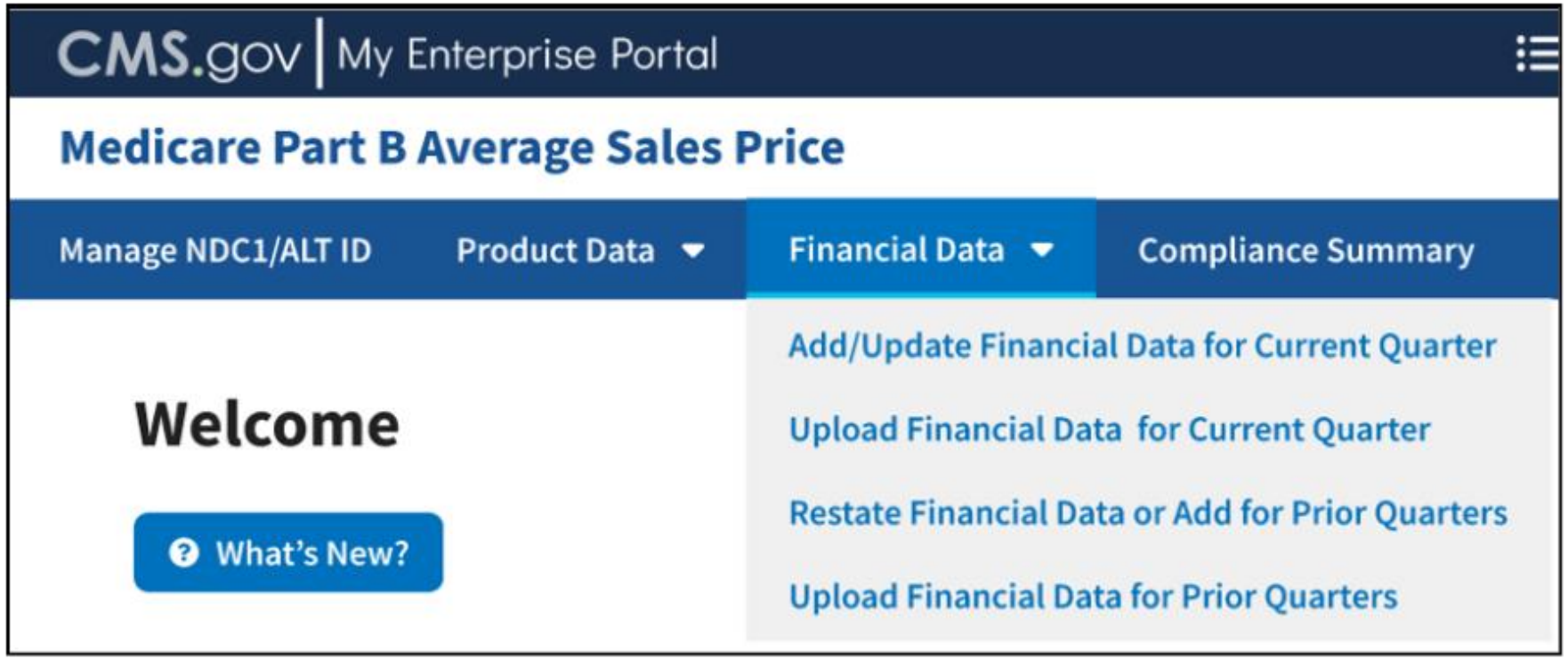


# Drug Certification

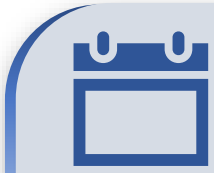


# Restatement



# What to Expect After Submission



The deadline for completed, accurate submissions is the **30th of the month** following the close of the quarter.

CMS conducts validation checks to ensure accuracy and identify any errors in the ASP Data Collection System or within any publicly available information.

CMS will not change or edit submitted manufacturer ASP data. It is the responsibility of manufacturers to report their data accurately.

CMS may communicate with manufacturers to request clarification or additional information; CMS may ask manufacturers to provide documentation or evidence to support the accuracy of the reported data.

If all data submitted or needed is not available or verifiable to CMS during the calculation period, there could be significant delays in the calculation process, potentially causing omission from the Medicare Part B Drug Payment Limit File.

# Emailing CMS

CMS will:

- Respond as appropriate within a reasonable timeframe
- Confirm receipt of data submission
- Direct you to official guidance with examples

CMS will not:

- Offer specific instruction outside of published guidance
- Confirm or deny accuracy of data
- Tell you how to calculate your specific data
- Incorporate any late submissions

CMS will only respond to messages received via CMS ASP Mailbox.

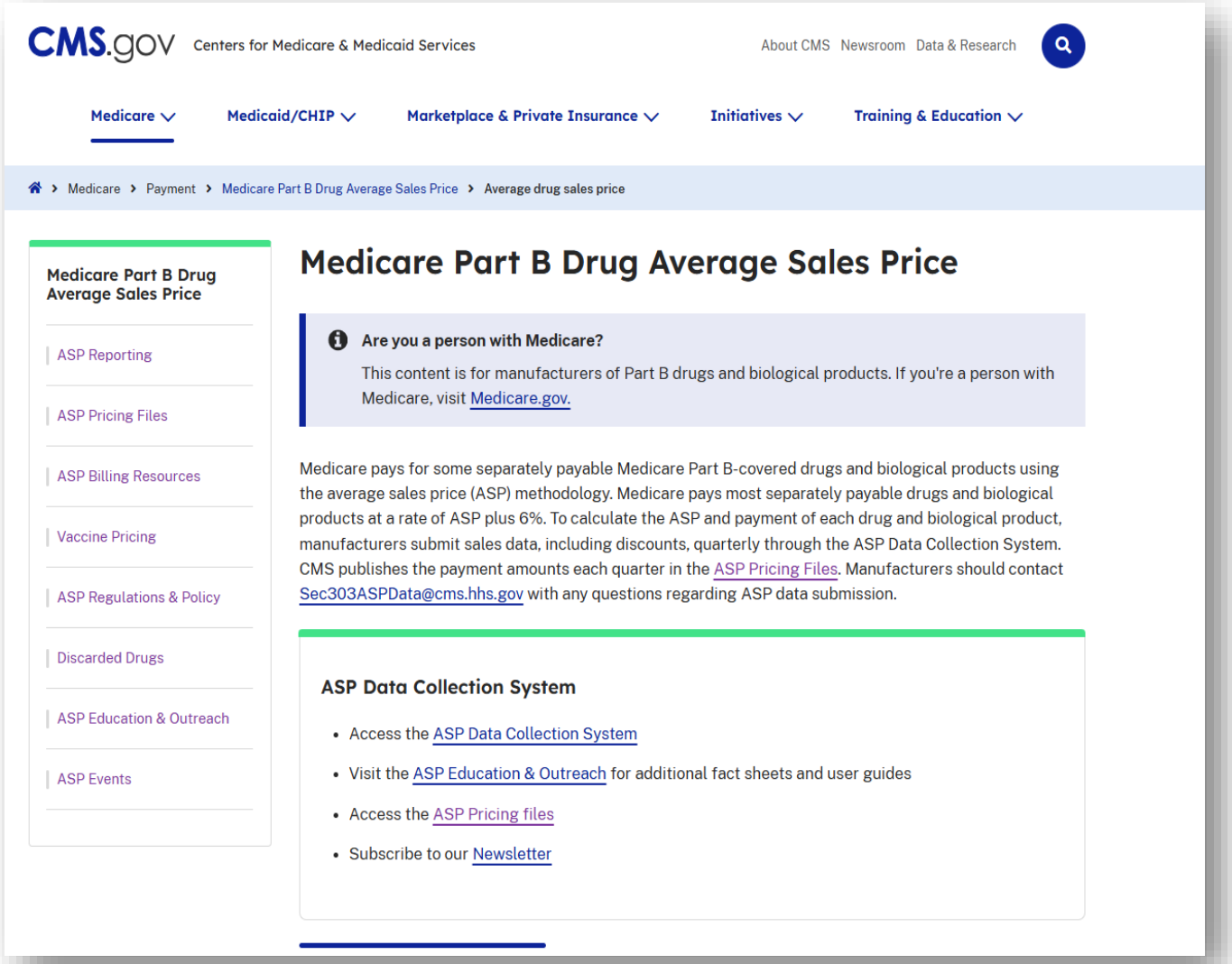
# Why Is My Product Not Listed?

- If a drug product's NDC or HCPCS code does not appear on a quarter's crosswalk file or payment limit file, it may still be paid by the local contractor that processes the Part B drug claim, provided that the claim is reasonable and necessary and meets all necessary requirements for payment.
- Also, please note that the absence or presence of an NDC in the payment limit or crosswalk files does not indicate whether Medicare covers the drug.

# ASP Website

Manufacturers, and other interested parties, can visit the ASP website to find all available information and resources, including:

- Medicare Part B Payment Limit File
- Reporting
- Regulations and Policy
- Education and Outreach
- Events



# Resources

- Education and Outreach page

- **Technical Support**
  - ASP Helpdesk
  - 1-844-876-0765
  - 9:00 a.m. through 6:00 p.m., Eastern Standard Time (EST), Monday through Friday

- **Feedback and Other Questions**
  - CMS ASP Mailbox

# Q&A