



Centers for Medicare & Medicaid
Services
CMS eXpedited Life Cycle (XLC)

Medicare Part B Drug Average Sales Price (ASP)

User Manual

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1. Introduction

1.1 What is the Medicare Part B Drug Average Sales Price (ASP) Application?

Section 303 (b) and (c) of the Medicare Modernization Act (MMA) of 2003 revised the payment methodology for the vast majority of Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs). Per the MMA, beginning January 01, 2005, the ASP methodology is used to determine the payment limit for these drugs. Pricing for compounded drugs is performed by the local contractor. Additionally, beginning in 2006, the ASP methodology is used to determine the payment limit for all End Stage Renal Disease (ESRD) drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS). The ASP methodology is based on quarterly data submitted to the Centers for Medicare and Medicaid Services (CMS) by drug manufacturers. CMS supplies the Medicare Fee-for-Service (FFS) claims processing contractors with the drug pricing files for Medicare Part B drugs on a quarterly basis.

In general, under the ASP methodology, the payment limits are based on the volume-weighted average of the manufacturers' ASP. However, in certain instances, the payment limits are based on the Wholesale Acquisition Cost (WAC). Further, the payment limits for some drugs continue to be based on the Average Wholesale Price (AWP) methodology. These data (WAC and AWP) are published in drug pricing compendia, such as Redbook, Medi-span and First Databank. A Medicare Contractor retrieves the data from drug pricing compendia and provides the pricing data to CMS on a quarterly basis.

In addition, other considerations impact the ASP methodology. Under certain circumstances, the ASP-based payment limits for certain drugs may be replaced with a payment limit identified by the Office of the Inspector General (OIG). If errors in either the ASP data or the payment limit calculation occur, revised drug pricing files may be implemented. If drug manufacturers do not report ASP data or do not report timely, the accuracy of the payment limits may be impacted.

1.2 Purpose of the ASP Application

The purpose of the ASP Application is to:

- Provide users with an Internet-based software application for automating the collection, editing and processing of drug product pricing data received from drug manufacturers on a quarterly basis
- Eliminate data entry errors, data formatting errors, incomplete submitted data and to greatly reduce the process cycle time and resource time needed to provide the pricing to contractors through automation of the manually intensive processes currently used
- Establish a relationship between the manufacturers' reported data and the billing codes used by Medicare providers to calculate a weighted average price for each billing code; prices established for billing codes are used for payment of Part B drugs on certain Medicare claims
- Accept, store, validate, and calculate drug pricing on Medicare Part B drug data received for the Center for Medicare Management (CM) stakeholders

1.3 ASP Business Process

Drug Manufacturers report ASPs by National Drug Codes (NDC), which are 11-digit identifiers that indicate the manufacturer of the drug, the product dosage form, and package size. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis in one of two methods. Drug product data may be submitted either by uploading a file or keying data into a predefined data entry screen. In both instances, data are edited and saved awaiting the manufacturer to certify the accuracy of the data. During the 30-day submission period after the end of the quarter, users will communicate the days remaining in the submission period to each manufacturer and whether the manufacturer is in compliance with the data submission requirements.

Thirty days after the beginning of each quarter (calendar year), manufacturers are required to submit pricing of their Medicare Part B (not paid on a cost or perspective payment basis) qualifying drugs. Once drug manufacturers are registered with the Medicare Part B ASP drug submission application, they need to choose either to submit their data online or upload the data via file transfer. A majority of the drugs are injectable drugs furnished by physicians and other qualified practitioners.

If the drug manufacturer decides to enter their Medicare Part B ASP drug information online, then they log on to the secure website and enter the required drug information into the online application. Validations and error messages ensure that the drug manufacturer is entering data in adherence to the application requirements.

If the drug manufacturer has a large amount of drug data to report to Medicare, they may decide to submit their Medicare Part B ASP drug information by uploading their data via file transfer. In this case, the ASP drug data are entered into a formatted file that is in compliance with Medicare's specifications and it is uploaded. Along with the submission, the user can submit any pertinent information to share with CM regarding their drug product data submissions. CM reviews the assumptions and may respond to the user if necessary. The user can view and check their submitted file and resubmit, if necessary. If the file records do not meet the file transfer validations and edits, then they are rejected, and the drug manufacturer can resubmit the drug data through file transfer or enter it online. With both submission options, the drug manufacturer must certify the accuracy of the data at the time of submission in order for it to be accepted. Regardless, every instance a drug manufacturer submits data they must submit a drug certification along with their submission and they may submit multiple times within a submission time period. Once data have been submitted, the drug manufacturer can view all drug data certified in the current reporting period and view whether current and previous drug submissions are in compliance with the reporting requirements. With drug data corrections within the current reporting period, the user can correct the drug data via data entry or upload. If data needs to be reported after the quarter has ended, the drug manufacturer has the capability to report restated ASP data via upload or online for any reporting period (greater than or equal to Quarter 3 2004) to CM at any time.

CM assigns each drug to one or more billing codes and determine the billing units per billing code. The ASP for each billing code is calculated based on the weighted average of all ASPs within a billing code. Where a billing code does not exist, users submit a request for one to be established.

Updated ASP data are shared with each drug manufacturer. Either users, through quality review or drug manufacturers, may identify errors in the data. The drug manufacturer submits any corrected data so that users can re-calculate the ASP for any affected billing code.

Once the drug manufacturer submits the Reporting Manufacturer data and it is successfully received by CM/Division of Ambulatory Services (DAS), they process and prepare the data accordingly for the ASP calculation. If the ASP Reporting Manufacturer Data submission falls within the 30-day deadline, then, thereafter, the CM/DAS runs drug submission reports. These reports include Impact Analysis Report, Management Reports and Manufacturer Reports. A Drug Manufacturer also has the option to mail Medicare Part B drug data and restated drug data to CM. CM Personnel may key the data online or upload the data on behalf of the manufacturer. Along with the file sent by the manufacturer a letter of certification is sent to CMS. In this case, CMS confirms the written certification received with the file.

The user creates an output file to share with OIG, so they can complete ASP comparison studies. Updates with the Average Manufacturer Price (AMP) provided by OIG are added to the drug pricing file to replace the ASP for some billing codes. After pricing updates are completed, the application creates the following output:

- An impact analysis comparing price changes in support of briefing documents for the clearance process,
- Crosswalk of NDCs to billing codes,
- Part B pricing files for mainframe application for the fee for service contractors,
- Part B pricing files for the internet for CMS website,
- File of AMPs for not otherwise classified billing codes,
- File of Competitive Acquisition Pricing (CAP) data, and
- File of Outpatient and ASC Drug Pricing Data

1.4 ASP User Roles

The ASP Application is a role-based application. This means that certain application functions have been linked to specific “user role profiles.” The ASP Application user roles are as follows:

- Drug Manufacturers: Drug manufacturers can be either Submitters and Certifiers of data
- CM Personnel: Responsible for the calculation and quality of the Part B drug prices
- Center for Medicaid and Children’s Health Insurance Program (CHIP) Services (CMCS): Future participant to provide AMP data for comparative analyses of the ASP to the AMP

1.5 ASP Reference Materials

The following additional reference materials are utilized in order to successfully submit and certify applicable data into the ASP data collection application:

- [EIDM User Guide](#)
- [ASP Data Reporting Templates](#)
- Contextual Help

Click on [EIDM Links](#) for any assistance with using the application and to view applicable videos

2. ASP Application Access

Users are required to access the CMS Portal at <https://portal.cms.gov> to begin the registration and role assignment process.

CMS has established the Enterprise Identity Management (EIDM) system to provide our Business Partners with a means to apply for, obtain approval, and receive a single User ID they can use to access one or more CMS applications. The EIDM Authentication System prompts the user to create a username and password that conforms to the system's policies; this user ID and password is not affiliated with the user's CMS User ID (Enterprise User Administration [EUA]) and password. After the user successfully creates a username and password, the user must create security questions and answers. The user must then re-log in with the new credentials and request the specific Fee-for-Service Data Collection System (FFSDCS) ASP Submitter or ASP Certifier role as applicable. FFSDCS is a system umbrella that houses various Fee-for-Schedule modules. ASP is one of the modules under the FFSDCS system.

As part of the role request process the EIDM Authentication System begins the Remote Identity Proofing (RIPD) process. RIDP is the process of validating sufficient information about the user (e.g., credit history, personal demographic information, and other indicators) to uniquely identify an individual. After the user's identity is verified, the CMS Portal pushes the user's data to CM to review the role request and approve it.

The registration process also involves Multi-Factor Authentication (MFA). This allows the user to authenticate their phone/tablet/PC/laptop, text message Short Message Service (SMS), Interactive Voice Response (IVR), E-mail, and One-Time Security Code.

For additional details on EIDM, review the EIDM User Guide.

2.1 ASP Data Collection Application Access Process

ASP users with an existing CMS Portal username and password can skip Section 2.1.1 and continue on to Section 2.1.2 Requesting ASP Application Access.

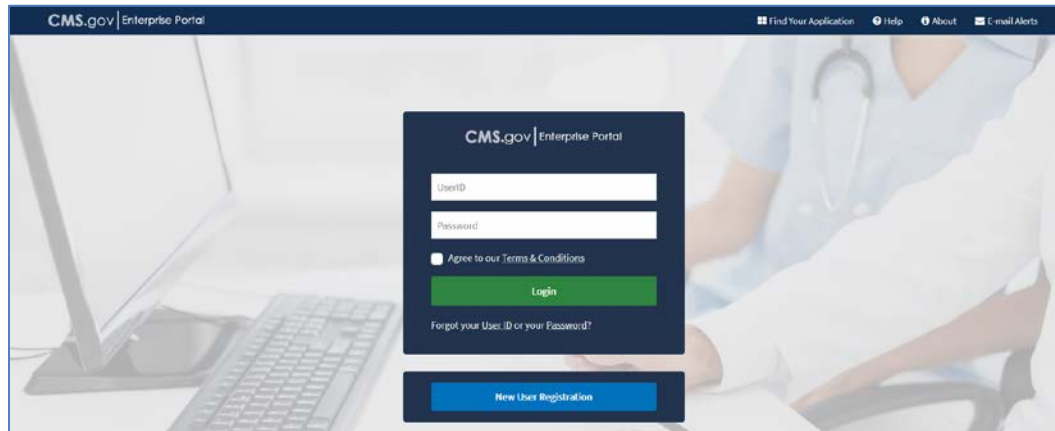
2.1.1 Obtaining a CMS EIDM Username and Password

A CMS EIDM username and password are required in order to access the ASP Application. Perform the following steps in order to receive the required credentials:

1. Access the CMS Portal by entering the following Uniform Resource Locator (URL) in your browser: <https://portal.cms.gov>.

The CMS Enterprise Portal Home Page is shown in Figure 2-1.

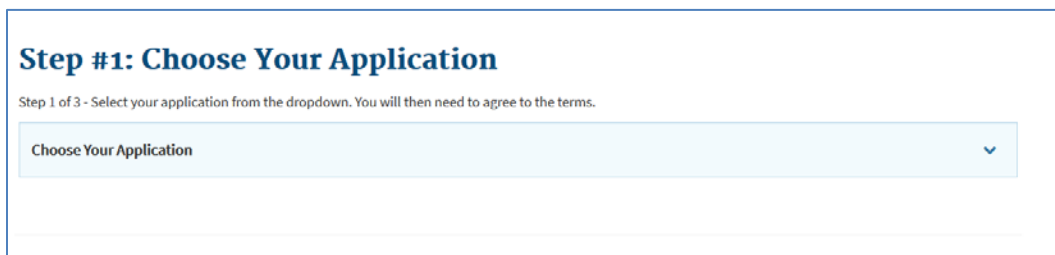
Figure 2-1: CMS Enterprise Portal Home Page



2. Click on the **New User Registration** button.

The “Step #1: Choose Your Application” page opens, as shown in Figure 2-2.

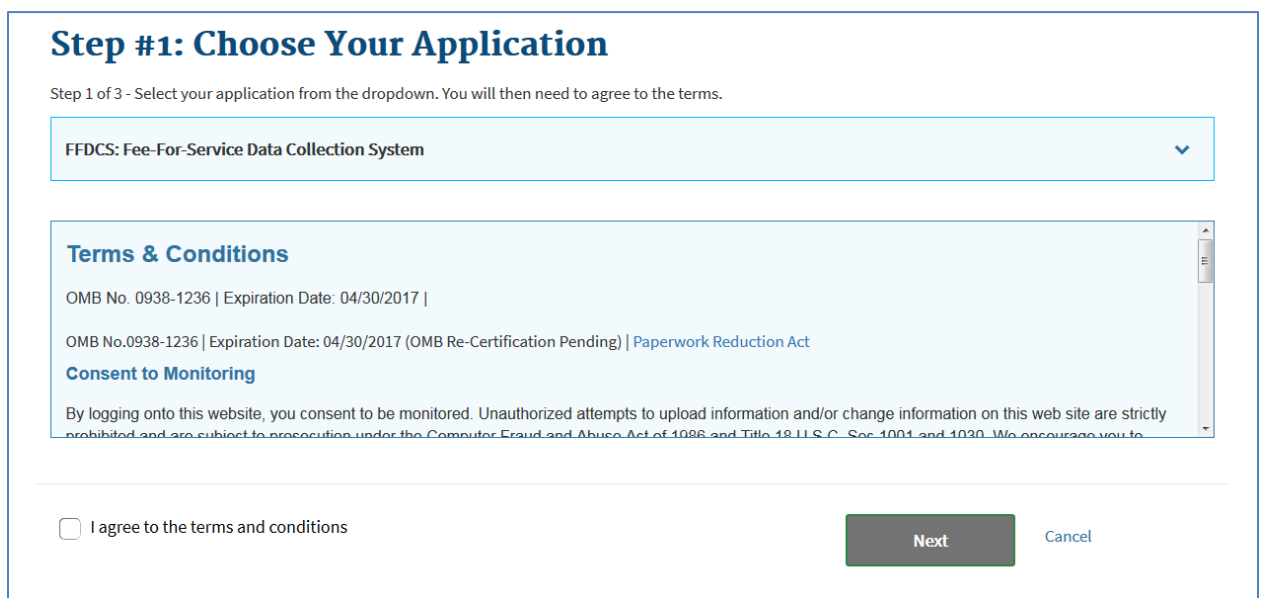
Figure 2-2: Step #1: Choose Your Application Page



3. Select “FFSDCS: Fee-For-Service Data Collection System” from the dropdown list.

The “Terms and Conditions” page opens, as shown in Figure 2-3.

Figure 2-3: Terms and Conditions Page



Note: Read through the Terms and Conditions on the page. The page states that you consent to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it is only used to uniquely identify the new user who is registering with the application. The page provides links to the *HHS Rules of Behavior* and the *CMS Privacy Act Statement*.

- If you agree to the terms and conditions, click the corresponding check box and click on the **Next** button.

Note: Users must agree to the terms and conditions to continue the registration process.

The “Step #2: Register Your Information” page opens, as shown in Figure 2-4.

Figure 2-4: Step #2: Register Your Information Page

Step #2: Register Your Information

Step 2 of 3 - Please enter your personal and contact information.

All fields are required unless marked 'Optional'.

Enter First Name Enter Middle Name (optional) Enter Last Name Suffix (optional) ▼

Enter Social Security Number (optional) Birth Month ▼ Birth Date ▼ Birth Year ▼

Is Your Address US Based?

Yes No

Enter Home Address #1 Enter Home Address #2 (optional)

Enter City State ▼ Enter Zip Code Enter Zip+4 (optional)

Enter E-mail Address Confirm E-mail Address

Enter Phone Number

Back Next Cancel

- Enter your personal information in the required fields which are indicated by an asterisk (the additional fields are optional but may be required for further identity verification) and click on the **Next** button.

The “Step 3: Create User ID, Password & Challenge Questions” page displays as shown in Figure 2-5.

Figure 2-5: Step #3: Create User ID, Password & Challenge Questions Page

Step #3: Create User ID, Password & Challenge Questions

Step 3 of 3 - Please create User ID and Password, Select Challenge questions and provide answers.

Enter User ID

Enter Password

Enter Confirm Password

Select Challenge Question #1 ▼

Enter Challenge Question #1 Answer

Select Challenge Question #2 ▼

Enter Challenge Question #2 Answer

Select Challenge Question #3 ▼

Enter Challenge Question #3 Answer

Back

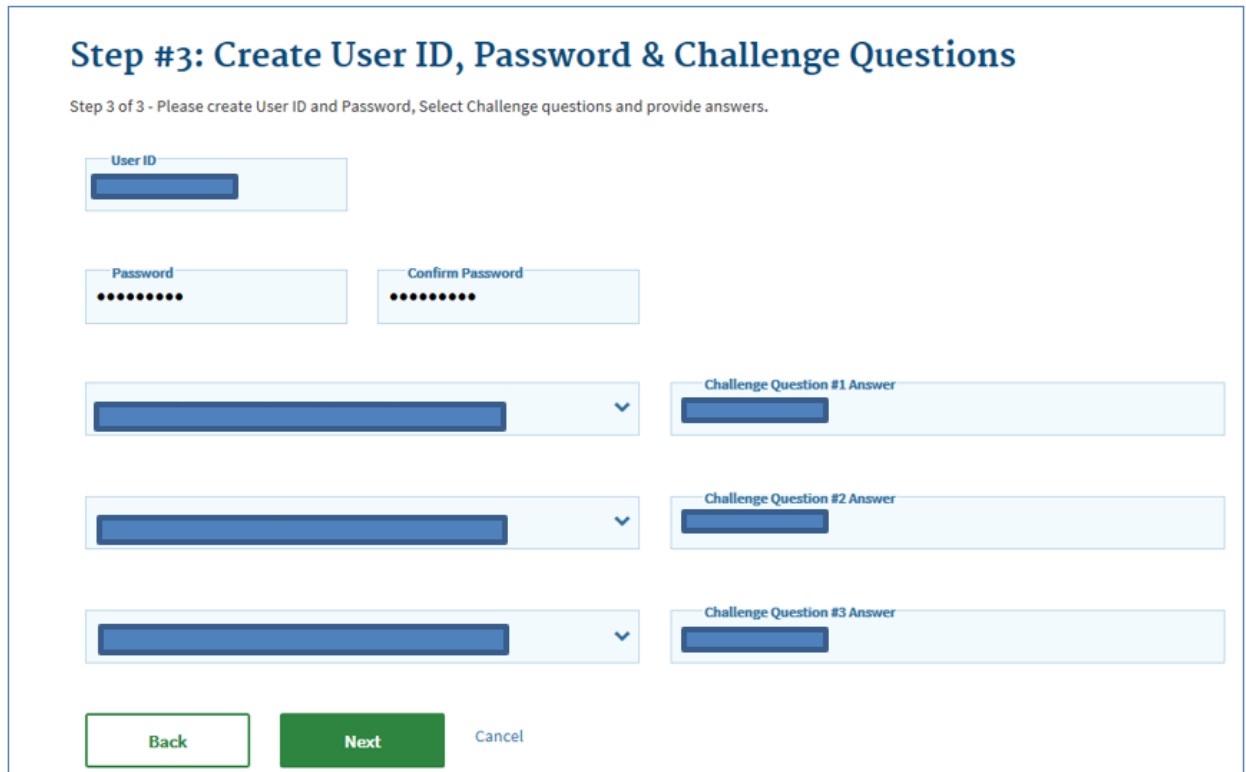
Next

Cancel

6. Enter your desired User ID in the “User ID” field. The User ID must be a minimum of 6 and a maximum of 74 alphanumeric characters. Allowed special characters are dashes (-), underscores (_), apostrophes (’), @ and periods (.).
 7. Enter your desired password in the “Password” field. The CMS Portal password must conform to the following CMS Acceptable Risk Safeguards (ARS) Password Policy:
 - a. Be changed at least every sixty (60) days;
 - b. Be a minimum of eight (8) and a maximum of twenty (20) characters;
 - c. Be changed only once every 24 hours;
 - d. Contain at least one (1) letter, one (1) number, and (1) special character;
 - e. Contain at least one (1) uppercase and one (1) lowercase letter;
 - f. Not contain your User ID;
 - g. Be different from your previous six (6) passwords.
 - h. Not contain commonly used words; and
 - i. The following special characters may not be used: ? < > () ‘ “ / \ &
 8. Re-enter your desired password in the “Confirm Password” field.
- Note:** The passwords must match before you can continue.

9. Select a Security Question from each of the three (3) dropdown lists for which the answer is known.
10. Enter the answers to the Security Questions in the corresponding “Answer” fields.
The fields populate as shown in Figure 2-6.

Figure 2-6: Step #3: Create User ID, Password & Challenge Questions Page Populated



Step #3: Create User ID, Password & Challenge Questions

Step 3 of 3 - Please create User ID and Password, Select Challenge questions and provide answers.

User ID

Password

Confirm Password

Challenge Question #1 Answer

Challenge Question #2 Answer

Challenge Question #3 Answer

Back Next Cancel

11. Click on the **Next** button to complete the registration process.

Note: You may click on the **Cancel** button to exit out of the registration process. New information or changes entered will not be saved.

The “Registration Summary” screen displays as shown in Figure 2-7.

Figure 2-7: Registration Summary Page

Registration Summary

Please review your information and make any necessary changes before submitting.

Y12002: For The Current Data Collection System

All fields are required unless marked 'Optional'.

First Name
 Enter Middle Name (optional)
 Last Name
 Suffix (optional)

Enter Social Security Number (optional)
 Birth Month
 Birth Date
 Birth Year

Home Address #1
 Enter Home Address #2 (optional)

City
 State
 Zip Code
 Enter Zip+4 (optional)

E-mail Address
 Confirm E-mail Address

Phone Number

User ID

Password
 Confirm Password

Challenge Question #1 Answer
 Challenge Question #2 Answer

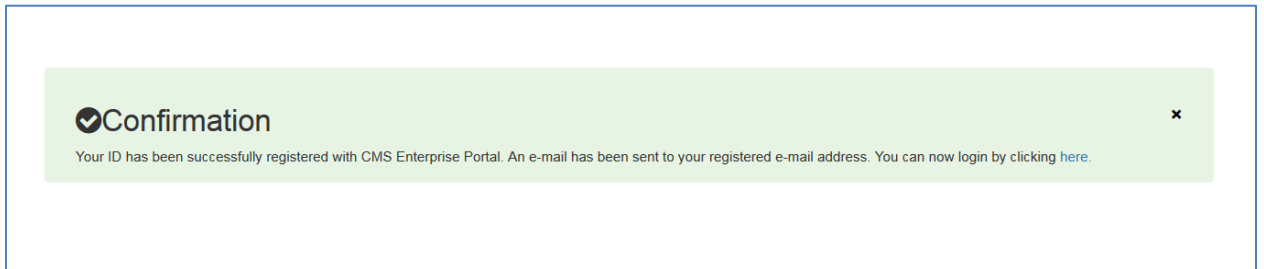
Challenge Question #3 Answer

Challenge Question #4 Answer

12. Review your information, make any necessary changes, and click on the **Submit User** button to complete the registration process.

A "Confirmation" message displays as shown in Figure 2-8.

Figure 2-8: Confirmation Message



13. Please wait at least 5 minutes before logging on to the CMS Portal with your new EIDM user ID and password.

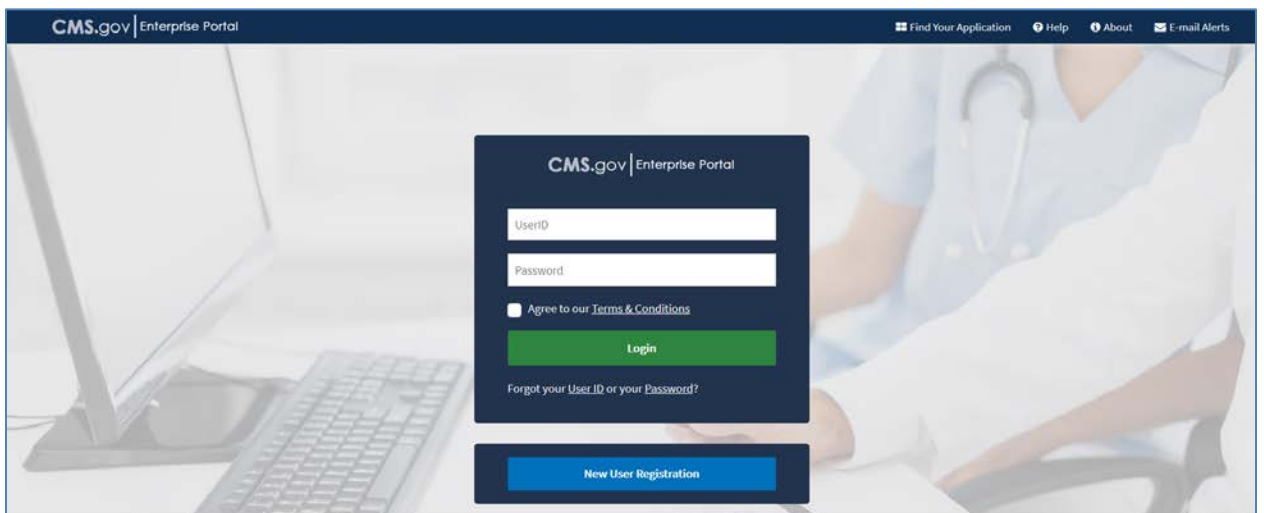
2.1.2 Requesting ASP Application Access

Perform the following steps to request access to the ASP Application:

1. Enter the address for the CMS portal (<https://portal.cms.gov/wps/portal/unauthportal/home/>) into your web browser and click on the **Enter** button.

The CMS Enterprise Portal Home Page is shown in Figure 2-9.

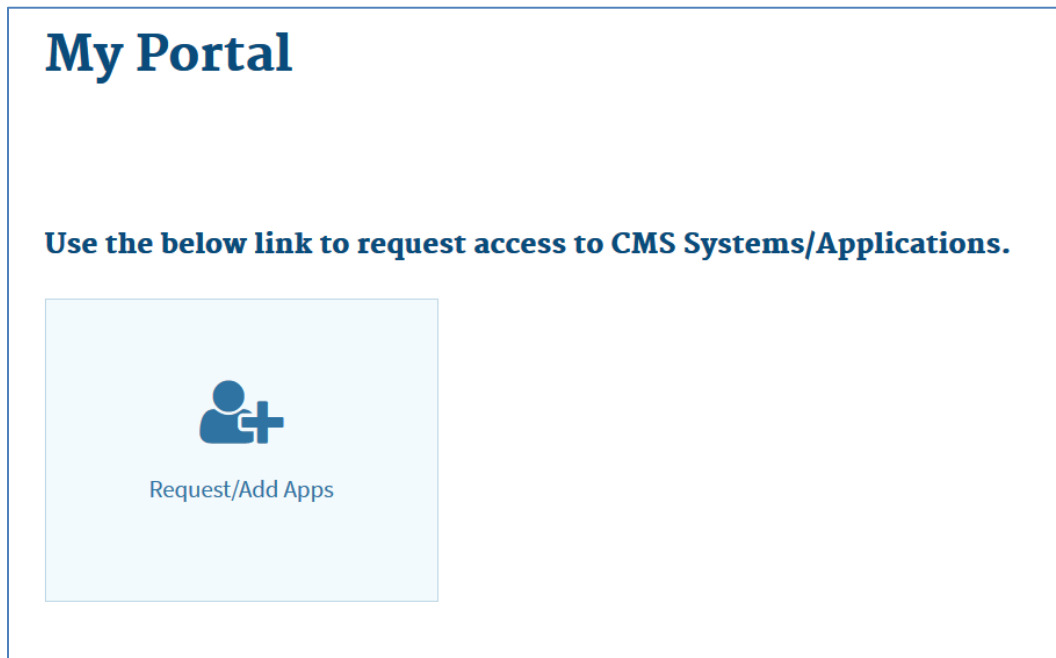
Figure 2-9: CMS Enterprise Portal Home Page



2. Enter your UserID and Password and click on the **Login** button.

The "My Portal" page displays as shown in Figure 2-10.

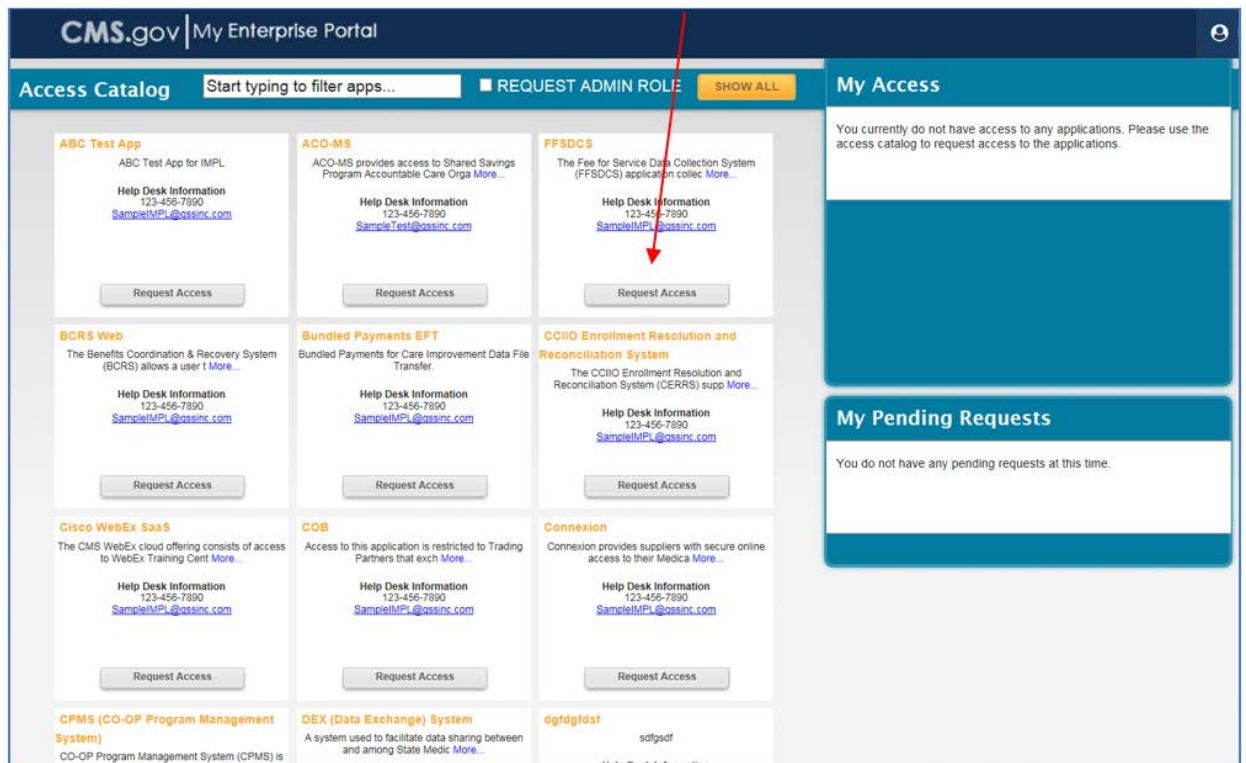
Figure 2-10: My Portal Page



3. Click on **Request/Add Apps**.

The “Access Catalog” page displays as shown in Figure 2-11.

Figure 2-11: Access Catalog Page



4. Click on the **Request Access** button in the “FFSDCS” section.

The “Request New System Access” page displays as shown in Figure 2-12.

Figure 2-12: Request New System Access Page

5. There are two roles that are applicable for ASP quarterly data submission:
 - a. ASP Submitter (who can only submit data; if you are the Submitter, select the “ASP End User” role).
 - b. ASP Certifier (who can only certify data)

If your role is to submit data, click on the “Role” dropdown list and select **ASP End User**.

If your role is to certify, click on the “Role” dropdown list and select **ASP Certifier**.

6. If desired, enter any notes to the approver, and click on the **Submit** button.

The “Identify Verification” page displays as shown in Figure 2-13.

Figure 2-13: Identify Verification Page

7. Review the information and click on the **Next** button.

The “Terms and Conditions” page displays as shown in Figure 2-14.

Figure 2-14: Terms and Conditions Page

My Access
[Request New System Access](#)
[View and Manage My Access](#)
[Annual Certification](#)

Terms and Conditions
 OMB No. 0938-1236 | Expiration Date: 04/30/2017 (OMB Re-Certification Pending) | [Paperwork Reduction Act](#)

Protecting Your Privacy
 Protecting your Privacy is a top priority at CMS. We are committed to ensuring the security and confidentiality of the user registering to EIDM. Please read the [CMS Privacy Act Statement](#), which describes how we use the information you provide.
 "Personal" information is described as data that is unique to an individual, such as a name, address, telephone number, social security number, and date of birth (DOB). CMS is very aware of the privacy concerns around PII data. In fact, we share your concerns. We will only collect personal information to verify your identity. Your information will be disclosed to Experian, an external authentication service provider, to help us verify your identity. If collected, we will validate your Social Security number with Experian only for the purposes of verifying your identity. Experian verifies the information you give us against their records. We may also use your answers to the challenge questions and other PII to later identify you in case you forget or misplace your User ID /Password.

HHS Rules Of Behavior
 We encourage you to read the [HHS Rules of Behavior](#), which provides the appropriate use of all HHS information technology resources for Department users, including Federal employees, contractors, and other system users.
 I have read the HHS Rules of Behavior for Privileged User Accounts (addendum to the HHS Rules of Behavior (HHS RoB), document number HHS-OCIO-2013-0003S and dated July 24, 2013), and understand and agree to comply with its provisions. I understand that violations of the HHS Rules of Behavior for Privileged User Accounts or information security policies and standards may lead to disciplinary action and that these actions may include termination of employment, removal or disbarment from work on federal contracts or projects, revocation of access to federal information, information systems, and/or facilities, criminal penalties, and/or imprisonment. I understand that exceptions to the HHS Rules of Behavior for Privileged User Accounts must be authorized in advance in writing by the OpDiv Chief Information Officer or his/her designee. I also understand that violation of certain laws, such as the Privacy Act of 1974, copyright law, and 18 USC 2071, which the HHS Rules of Behavior for Privileged User Accounts draw upon, can result in monetary fines and/or criminal charges that may result in imprisonment.

Identity Verification
 I understand that the identity proofing services being requested are regulated by the Fair Credit Reporting Act and that my explicit consent is required to use these services. I understand that any special procedures established by CMS for identity proofing using Experian have been met and the services requested by CMS to Experian will be used solely to confirm the applicant's identity to avoid fraudulent transactions in the applicant's name.

I agree to the terms and conditions

Next Cancel

- Review the information, click in the box next to "I agree to the terms and conditions," and click on the **Next** button.

The "Your Information" page displays as shown in Figure 2-15.

Figure 2-15: Your Information Page

My Access
[Request New System Access](#)
[View and Manage My Access](#)
[Annual Certification](#)

Your Information

Enter your legal first name and last name, as it may be required for Identity Verification.

First Name: [Text Field] Middle Name: [Text Field]

Last Name: [Text Field] Suffix: [Dropdown]

Enter your E-mail address, as it will be used for account related communications.

E-mail Address: [Text Field]

Re-enter your E-mail address.

Confirm E-mail Address: [Text Field]

Enter your full 9-digit social security number, as it may be required for Identity Verification.

Social Security Number: [Text Field]

Enter your date of birth in MM/DD/YYYY format, as it may be required for Identity Verification.

Date of Birth: [Dropdown] [Dropdown] [Dropdown]

U.S. Home Address Foreign address

Enter your current or most recent home address, as it may be required for Identity Verification.

Address Address Line 1: [Text Field]

Address Address Line 2: [Text Field]

City: [Text Field] State: [Dropdown] Zip Code: [Text Field] Zip Code Extension: [Text Field] Country: USA

Enter your primary phone number, as it may be required for Identity Verification.

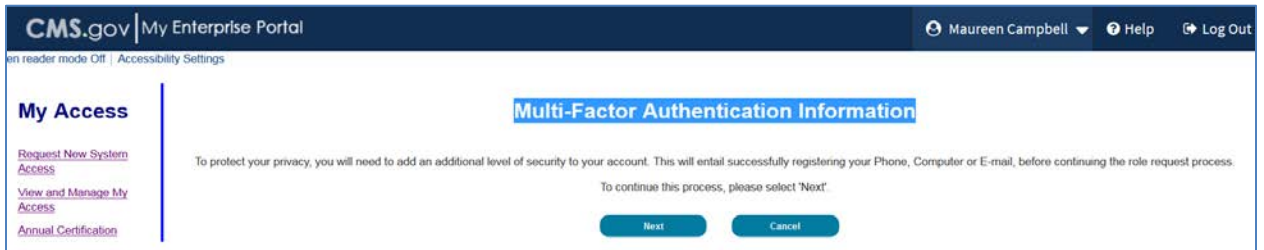
Primary Phone Number: [Text Field]

Next Cancel

- Review your information, complete any additional required fields, and click on the **Next** button.

The "Multi-Factor Authentication Information" page displays as shown in Figure 2-16.

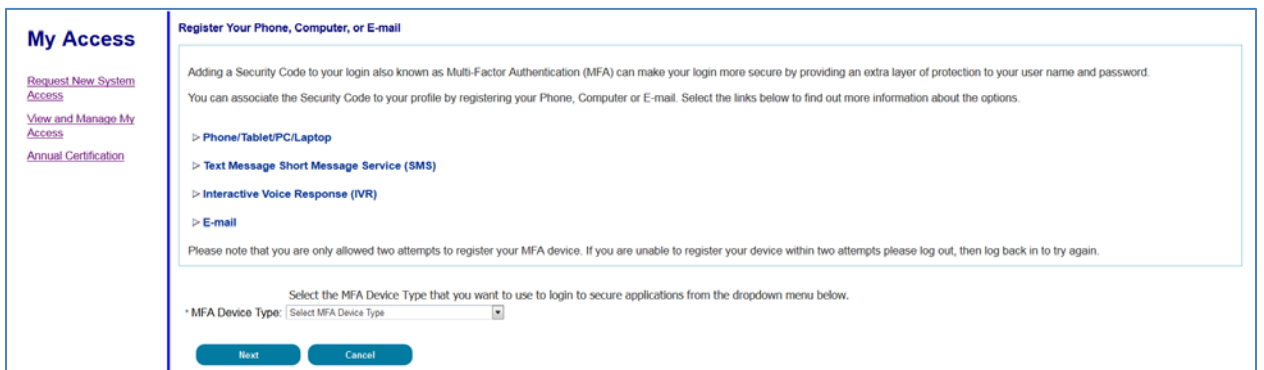
Figure 2-16: Multi-Factor Authentication Information



10. Click on the **Next** button.

The “Register Your Phone, Computer, or Email” page displays as shown in Figure 2-17.

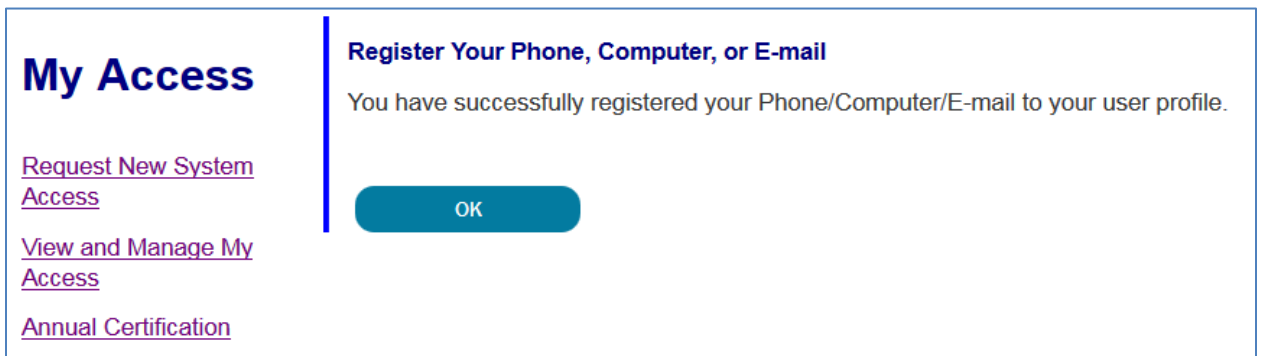
Figure 2-17: Register Your Phone, Computer, or Email Page



11. Select a device from the “MFA Device Type” dropdown list, enter any required information requested for the selected device, and click on the **Next** button.

A message displays that your device has been registered successfully displays, as shown in Figure 2-18.

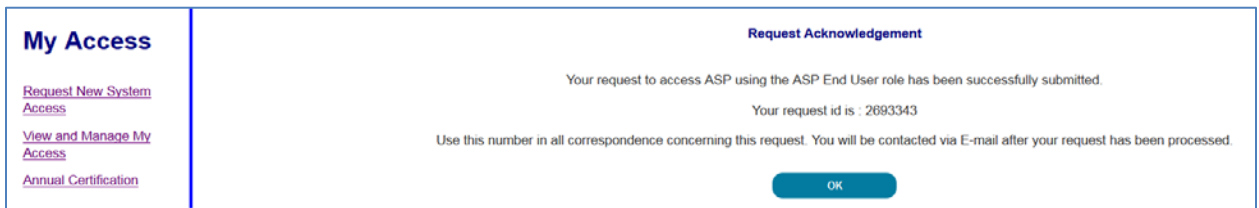
Figure 2-18: Successful MFA Registration Message



12. Click on the **OK** button.

A “Request Acknowledgement” screen displays as shown in Figure 2-19.

Figure 2-19: Request Acknowledgement Page



13. Click on the **OK** button.

Note: After role submission, please wait up to 72 hours to receive an e-mail notification.

2.2 Points of Contact

2.2.1 Tier 1 Support – FFSDCS (ASP) Application Helpdesk

- Email: ASPHelpDesk@dcca.com
- Phone: 844-876-0765
 - 9AM-6PM Eastern, Non-Peak
 - 9AM-9PM Eastern, Peak
 - Jan 1st – Jan 31st
 - Apr 1st – Apr 30th
 - Jul 1st – Jul 31st
 - Oct 1st - Oct 31st
- Tier 1 Issue examples:
 - Account Unlock
 - Password Reset
 - Registration process questions
 - Policy Question escalations
 - System Availability escalations
 - Other

2.2.2 Tier 2 Support – CM Policy Support

- sec303aspdata@cms.hhs.gov
- Remedy/Service Now (SNOW) Service Tickets

2.2.3 Tier 3 Application/System Support (Data Computer Corporation of America [DCCA])

- Remedy/SNOW Service Tickets

2.2.4 Tier 4 Support

- Data Center SR Workflow

3. ASP Application Home Page

The ASP Application is comprised of numerous pages and pop-up windows to allow drug manufacturers to add, update, and view data entries (product data, financial data, certifications, re-statements, and compliance). The ASP Application uses a consistent layout across pages. The fields displayed on each page differ based on the type of user logged in and the privileges assigned to the user role for the logged in user. You can enter data into fields in the ASP Application unless the field displays with a gray background.

If the user is new to the application, the user is placed directly into the Home page (for Submitter [Figure 3-1] or Certifier [Figure 3-2]).

Figure 3-1: ASP Application Home Page – ASP Submitter

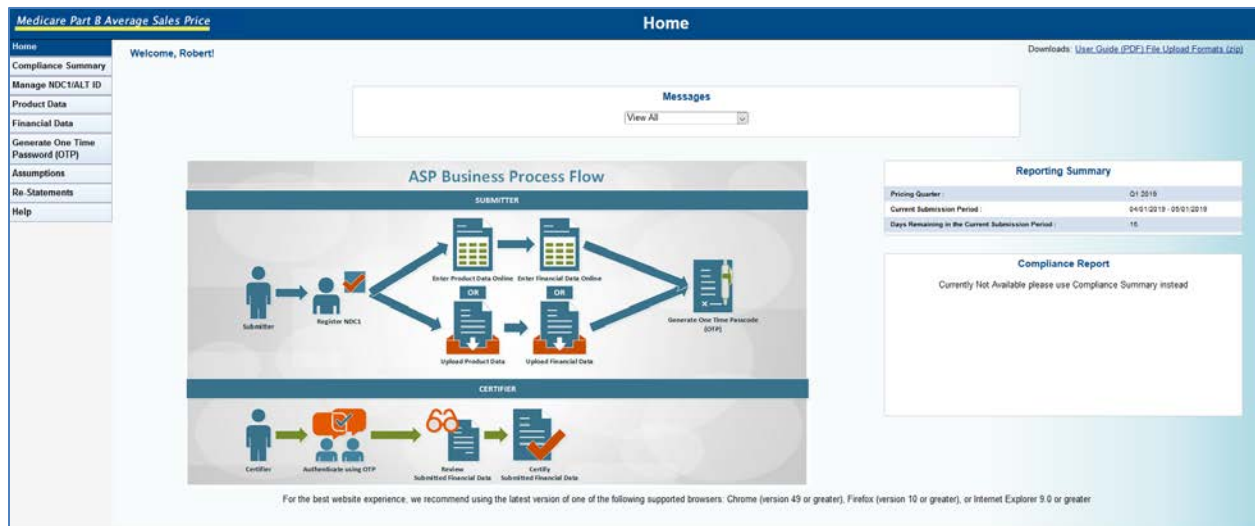
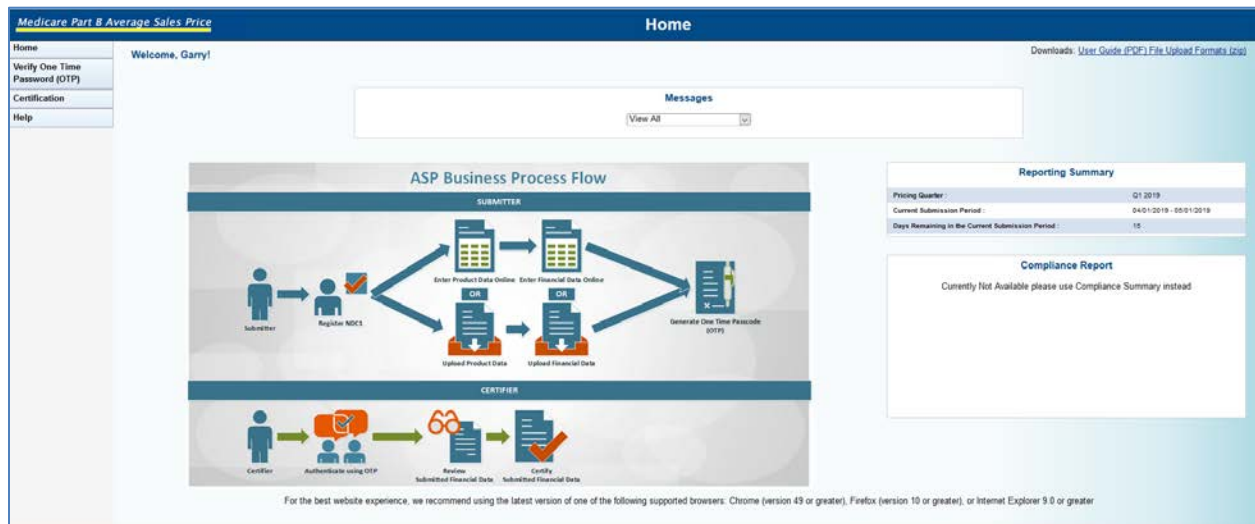


Figure 3-2: ASP Application Home Page – ASP Certifier



4. Manage NDC1/ALT ID - Submitter

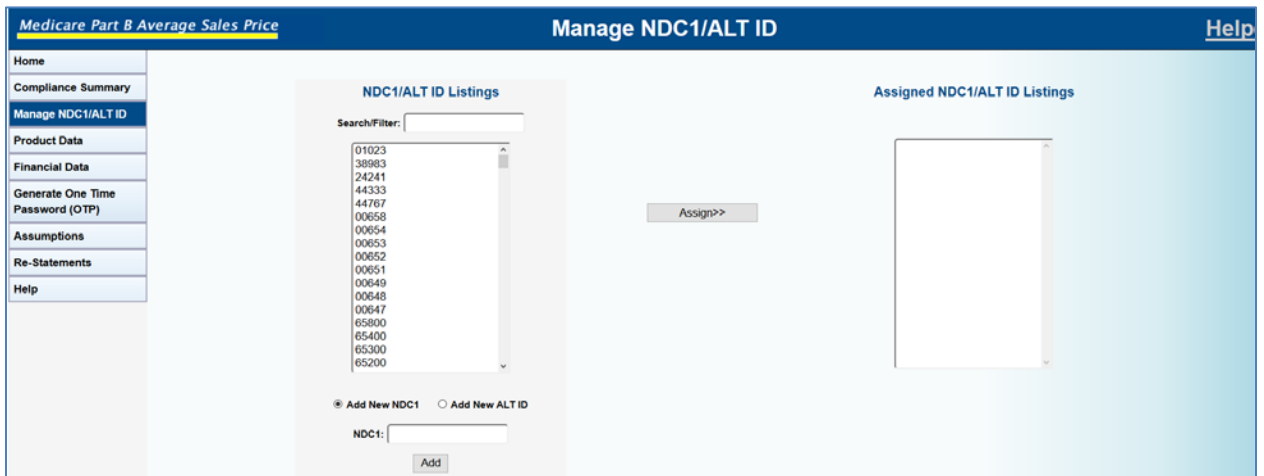
Before a labeler (Submitter) can begin submitting Product and Financial data for their respective labeler codes (NDC1/ALT ID), they are required to assign those labeler codes to their unique user account.

To assign NDC1 or Alternate ID codes, they must first be listed in the “NDC1/ALT ID Listings” list. If the NDC1 or Alternate ID is not on the list, you must add them to the list. Once on the list, they can then be assigned. Perform the following steps to manage NDC1s and Alternate IDs.

1. Click on **Manage NDC1/ALT ID** from the menu on the left side of the screen.

The “Manage NDC1/ALT ID” screen displays with the global list visible, as shown in Figure 4-1.

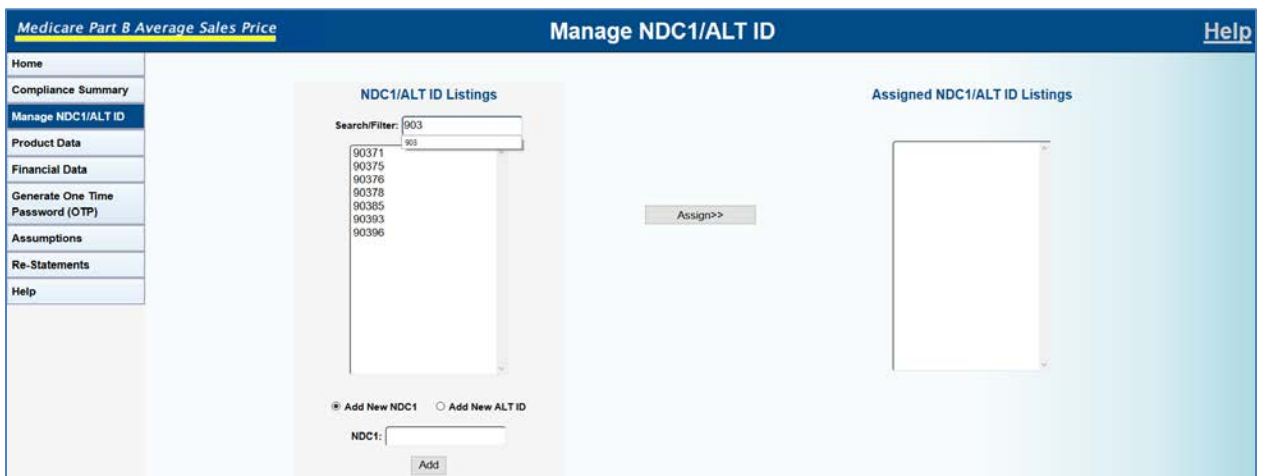
Figure 4-1: Manage NDC1/ALT ID Screen



2. To search for an NDC1, enter the partial or full NDC1 in the “Search/Filter:” field.

The application filters the entered NDC1, as shown in Figure 4-2.

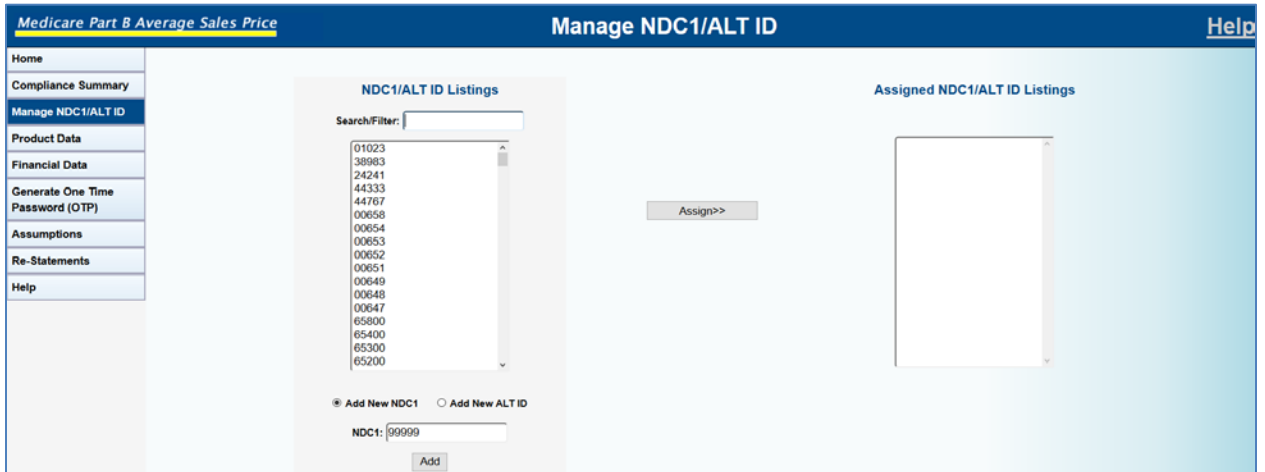
Figure 4-2: Manage NDC/ALT ID - Filter



- To add an NDC1 to the global list, click on the “Add New NDC1” radio button and enter your new NDC1 in the “NDC1:” field.

The “NDC1:” field is populated, as shown in Figure 4-3.

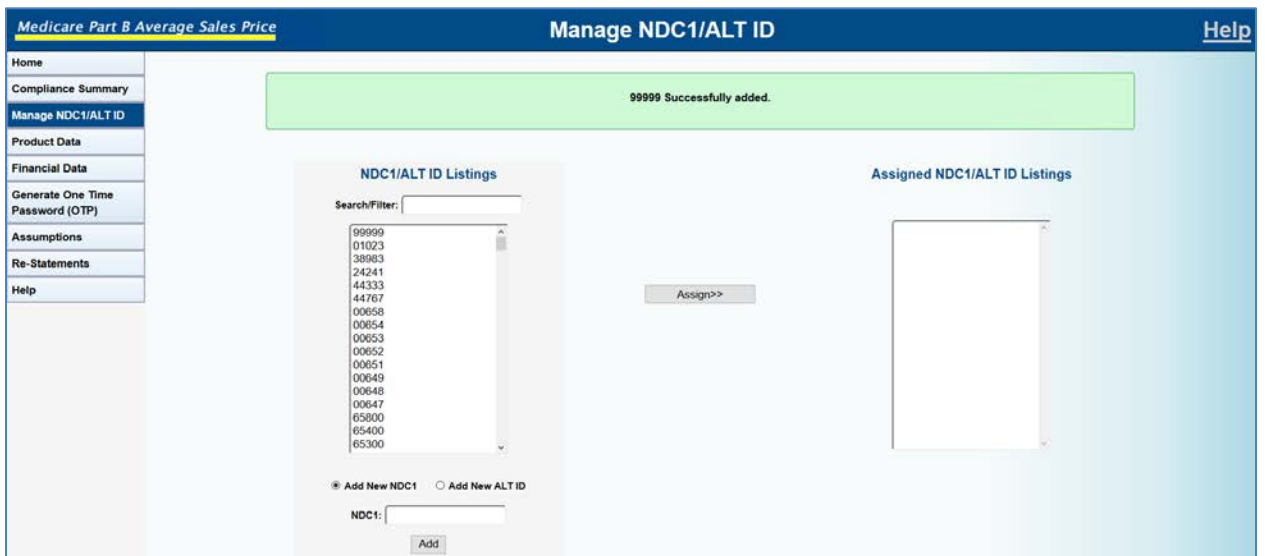
Figure 4-3: Manage NDC/ALT ID – NDC1 Field Populated



- Click on the **Add** button.

A message displays confirming that the new NDC1 was added successfully and the new NDC1 is listed at the top of the global list, as shown in Figure 4-4.

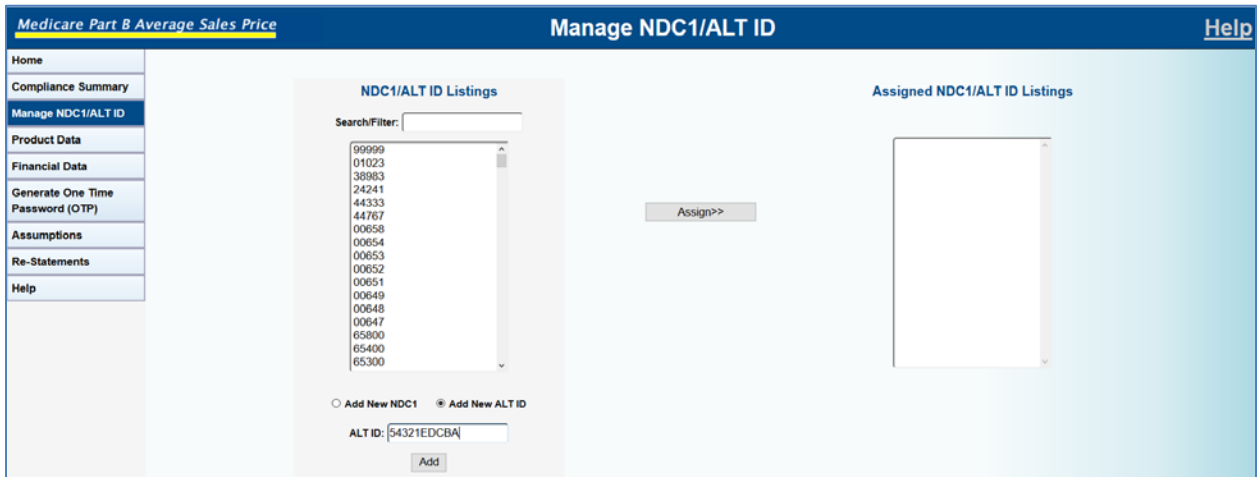
Figure 4-4: Manage NDC/ALT ID – NDC1 Saved Successfully



- To add an Alternate ID to the global list, click on the “Add New ALT ID” radio button

The “ALT ID:” field is populated, as shown in Figure 4-5.

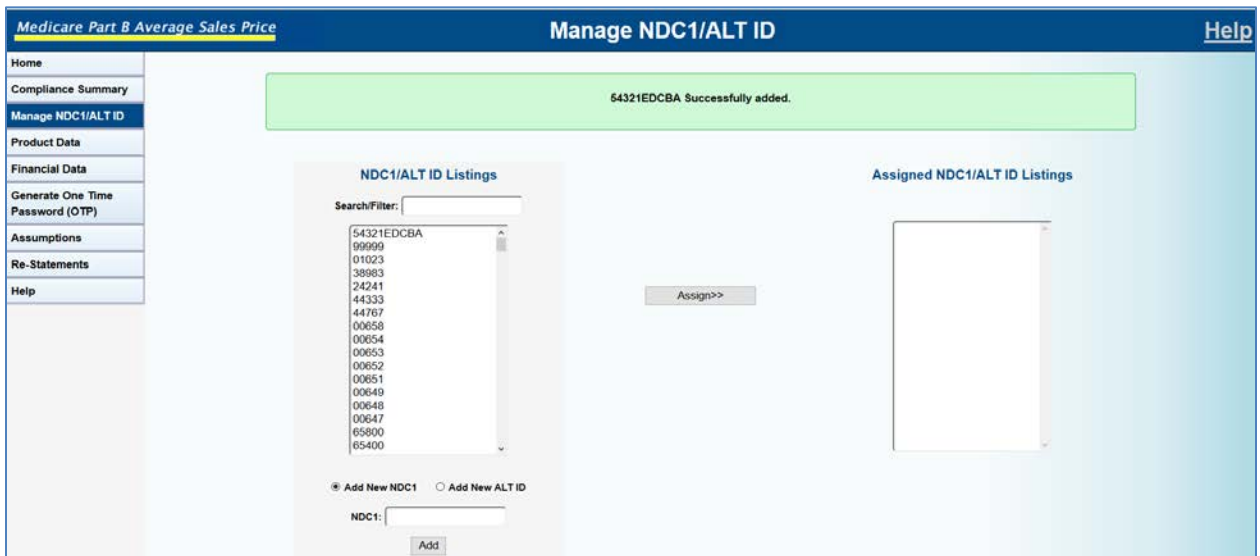
Figure 4-5: Manage NDC/ALT ID – ALT ID Field Populated



6. Click on the **Add** button.

A message displays confirming that the new ALT ID was added successfully, and the new Alternate ID is listed at the top of the global list, as shown in Figure 4-6.

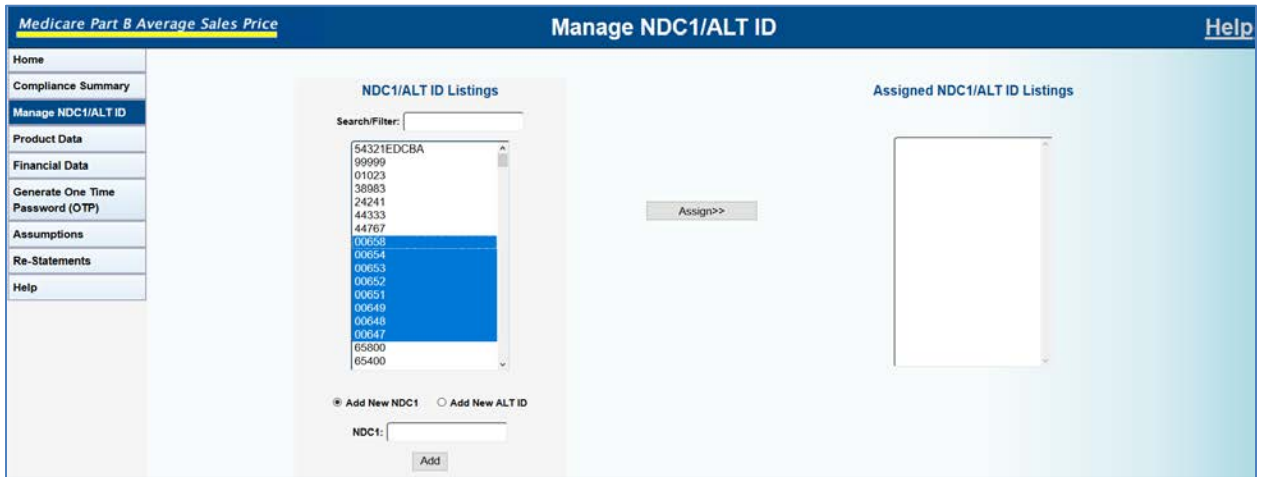
Figure 4-6: Manage NDC/ALT ID – ALT ID Saved Successfully



7. To assign NDC1s and ALT IDs, select one or more items from the “NDC1/ALT ID Listings” field.

The selected item(s) are highlighted, as shown in Figure 4-7.

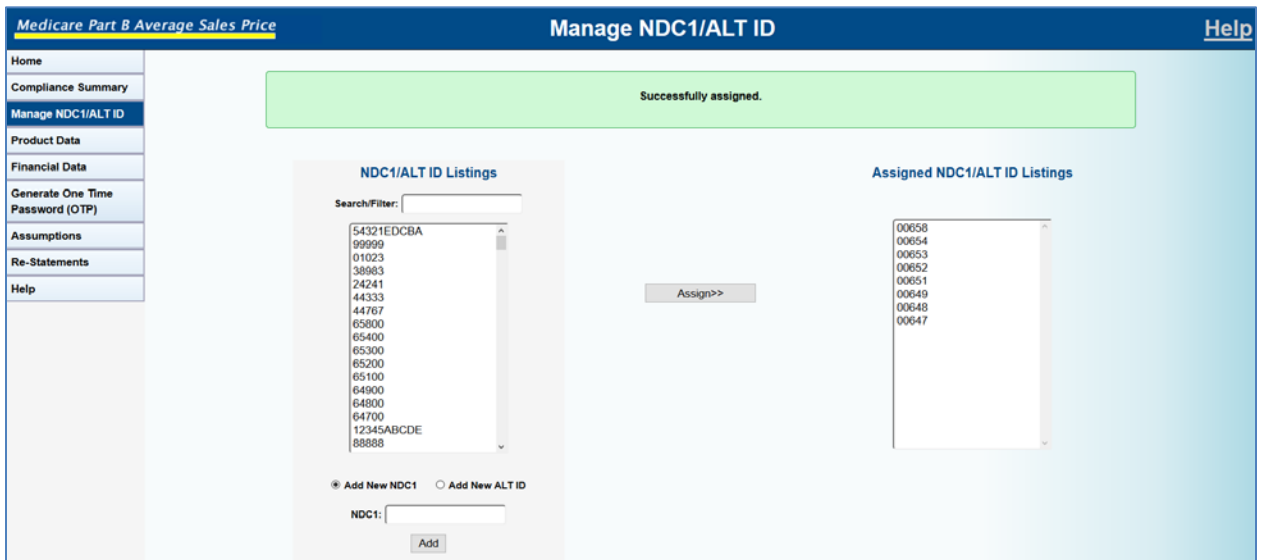
Figure 4-7: Manage NDC/ALT ID – Select NDCs/ALT IDs for Assignment



8. Click on the **Assign>>** button.

A message displays stating that the items were successfully assigned. The selected item(s) appear in the “Assigned NDC1/ALT ID Listings” field, as shown in Figure 4-8.

Figure 4-8: Manage NDC/ALT ID – NDC1/ALT ID Assigned Successfully



5. Compliance Summary - Submitter

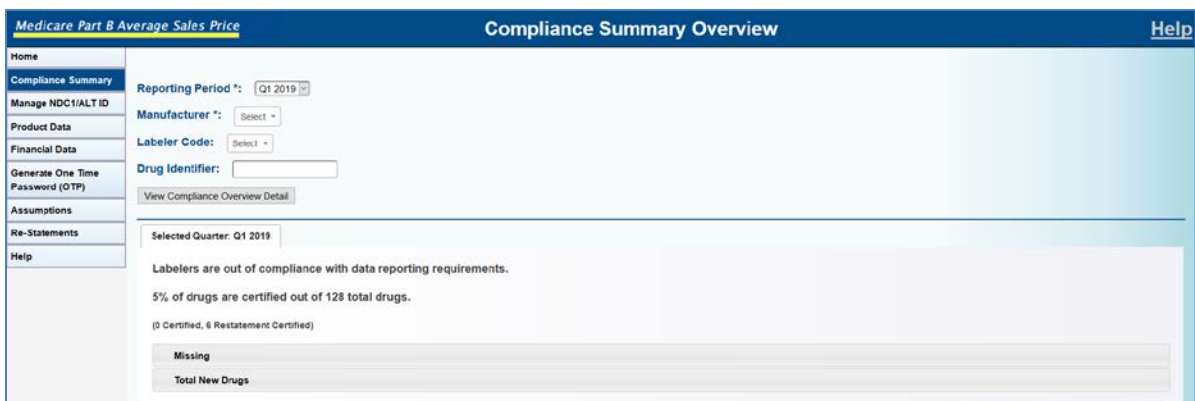
The Compliance Summary features allow Drug Manufacturers to view whether their drugs are in compliance with the drug submission reporting requirements. Drug Manufacturers can access a compliance summary for all drugs using the Compliance Summary menu tab.

1. From the menu on the left side of the page, click on **Compliance Summary**.

The “Compliance Summary Overview” page displays with the current reporting period as the default, as shown in Figure 5-1.

Note: The “Compliance Summary Overview” screen lists the compliance summary for all manufacturers assigned to a Submitter by default.

Figure 5-1: Compliance Summary Overview Page: Submitter



2. Select the desired reporting period from the “Reporting Period” dropdown list, the desired manufacturer from the “Manufacturer” dropdown list (optional), either a full or partial drug identifier (optional), and click on the **View Compliance Overview Detail** button to display the summary report.

The drug information displays for the selected manufacturer for the selected reporting period as shown in Figure 5-2.

Figure 5-2: Manufacturer’s Compliance Summary Report

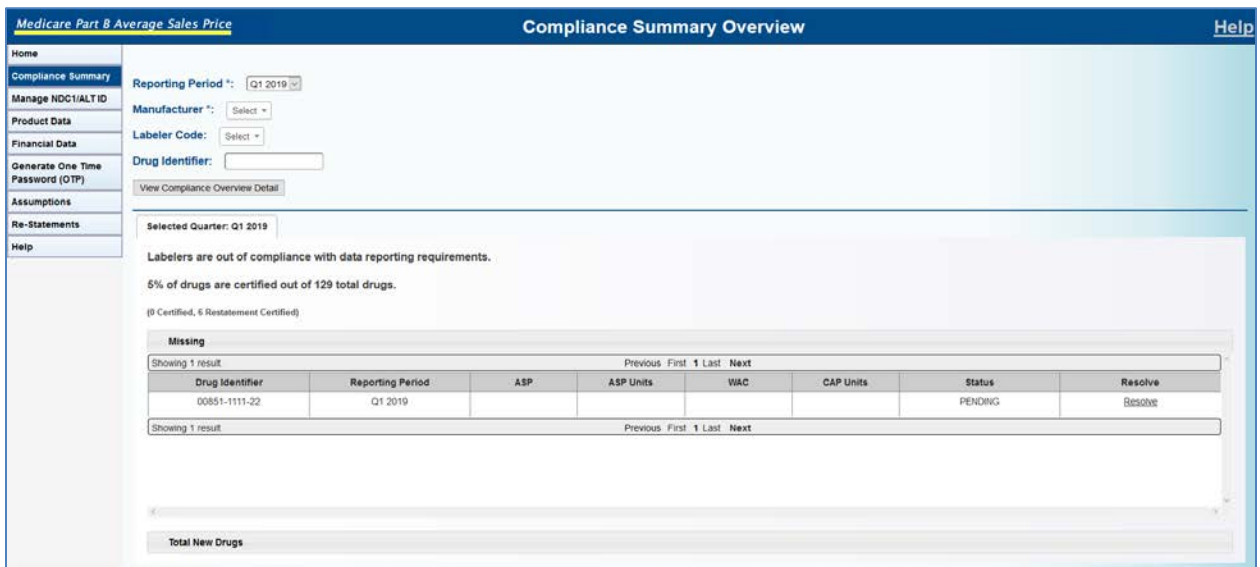


The Compliance Summary Overview screen displays statements whether or not the Drug Manufacturer is within compliance for the reporting period. Also listed is the percentage of drugs assigned to the user that are certified for the selected reporting period:

- Missing (go to step 3)
 - Total New Drugs (go to step 6)
3. To view drugs that are not compliant because the financial data for the drug has not been submitted, click on the **Missing** panel.

The “Missing” report displays, as shown in Figure 5-3.

Figure 5-3: Compliance Summary: Submitter - Missing

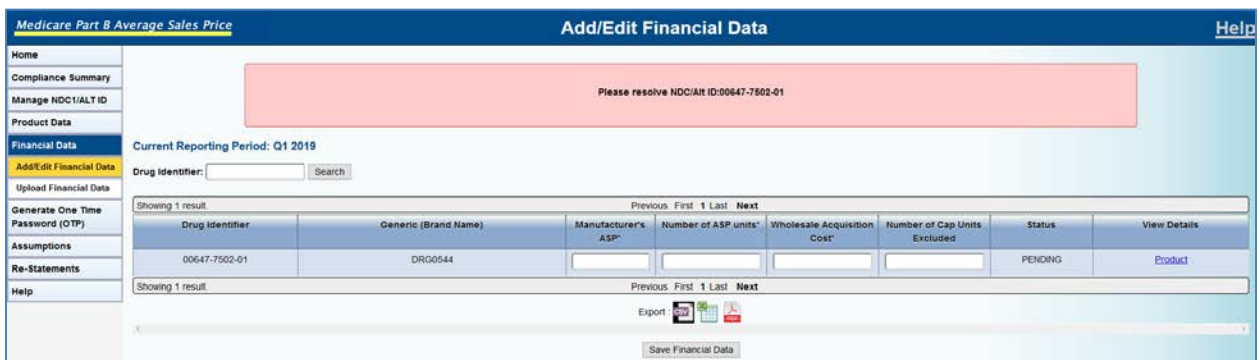


Drug Manufacturers have the ability to enter financial data by clicking on the “Resolve” link for the specific drug identifier.

4. Click on the **Resolve** link.

The “Add/Edit Financial Data” screen displays for the drug identifier selected from the “Compliance Summary” screen, as shown in Figure 5-4.

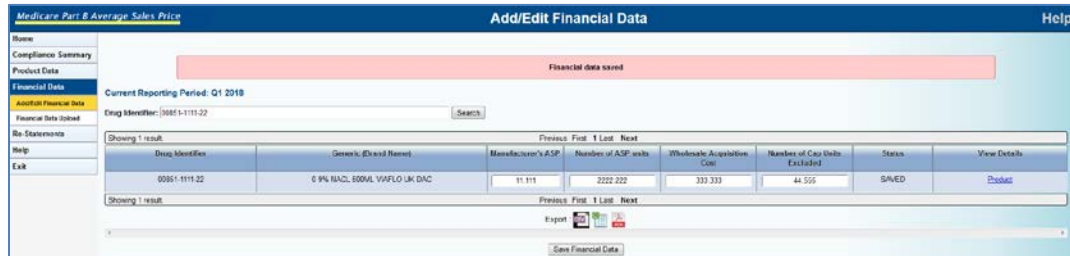
Figure 5-4: Compliance Summary: Submitter – Add/Edit Financial Data



5. Enter the missing financial data and click on the **Save Financial Data** button.

A message displays stating that the financial data were saved successfully, as shown in Figure 5-5. The drug identifier status will now be “SAVED”.

Figure 5-5: Compliance Summary: Submitter – Financial Data Saved Successfully



6. To view the product and financial information for new drugs that have been certified or saved, click on the **Total New Drugs** panel.

The “Total New Drugs” report displays, as shown in Figure 5-6.

Figure 5-6: Compliance Summary: Submitter – Total New Drugs



6. Product Data

Drug manufacturers are required to submit quarterly drug data to the ASP application for ASP pricing using a file transfer process or through online data entry. Drug data consists of product data and financial data. The following subsections detail the steps required to submit drug product data using online data entry and through approved file uploads.

6.1 Add Product Data

Add Product Data allows drug manufacturers the ability to manually submit drug product data one at a time to CMS. To upload product data for multiple drugs at once from a file, skip to section 6.2.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Add Product Data**.

The “Add Product Data” screen displays with the current reporting period as shown in Figure 6-1.

Figure 6-1: Add Product Data Screen

2. To add fields by NDC, select the “Add by NDC” tab and use the following requirements:

Note: To add fields by Alternate ID, go to step 4.

NDC1: dropdown

Note: if the NDC1 desired is not in the dropdown list, click on **Manage NDC1/ALT ID** from the menu on the left side of the screen, and add and assign your NDC1.

NDC2: numeric
required
4-digit entry

NDC3: numeric
required
2-digit entry

Manufacturer Name: required
limited to 250 characters

Note: When entering Product Data for the same Manufacturer more than once, be sure that the spelling is the same each time for that Manufacturer. If data were entered through “Upload Product Data,” the spelling must match that as well.

Has Brand Name?: checkbox
optional

Brand Name: field is only displayed if the “Has Brand Name?” box is checked
required if “Has Brand Name?” box is checked
limited to 250 characters

Generic Name: dropdown list
required

New Generic Name: displayed only if selecting “Add New Generic Name” from the
“Generic Name” dropdown list
required
limited to 250 characters

Date of First Sale: MM/DD/YYYY format
required
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per NDC: numeric
required
limited to 9 digits

FDA Approval Date: required
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: required
 alphanumeric
 up to 9 characters
 can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

FDA Approval Type: required
 dropdown list

FDA Application Supplement Number: alphanumeric
 optional
 up to 9 characters
 can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The field windows populate with the entered data, as shown in Figure 6-2.

Figure 6-2: Add Product Data – Fields Populated

The screenshot shows the 'Add Product Data' form with the following populated fields:

- Current Reporting Period:** Q4 2018
- NDC1*:** 05585
- NDC2*:** 2222
- NDC3*:** 44
- Manufacturer Name*:** TEST - New Manufacturer
- Has Brand Name?:**
- Generic Name*:** 0.9% NAACL 250ML VAFLO LR
- Date of First Sale*:** 06/01/2018
- Strength of the Product*:** 100
- Volume per Item*:** 10
- Number of Items per NDC*:** 1
- FDA Approval Date*:** 05/01/2018
- FDA Approval Type*:** 510(K)
- FDA Application Number/Registration Number*:** 444444
- FDA Application Supplement Number:** (empty)
- Additional FDA Application Number/Registration Number #1:** (empty)
- Additional FDA Application Supplement Number #1:** (empty)

- Click on the **Save** button.

The screen displays the confirmation that the product submission has been successfully saved, as shown in Figure 6-3.

Figure 6-3: Add Product Data – Product Submission Saved Successfully

The screenshot shows the 'Add Product Data' form in the Medicare Part B Average Sales Price (ASP) system. The form is titled 'Add Product Data' and includes a navigation menu on the left with options like Home, Compliance Summary, Manage NDC1/ALT ID, Product Data, Add Product Data, Update Product Data, Upload Product Data, View Submitted Drugs, Financial Data, Generate One Time Password (OTP), Assumptions, Re-Statements, and Help. The main content area displays a green success message: '8888-2222-44 product data have been saved successfully.' Below the message, there are two tabs: 'Add by NDC' and 'Add by Alternate ID'. The 'Add by Alternate ID' tab is selected. The form contains several required fields (marked with an asterisk): NDC1 (dropdown), NDC2 (text), NDC3 (text), Manufacturer Name (text, limited to 250 characters), Date of First Sale (text, MMDDYYYY format), Expiration Date of Final Lot Sold (text, MMDDYYYY format), Strength of the Product (text), Volume per Item (text), Number of Items per NDC (text), FDA Approval Date (text, MMDDYYYY format), FDA Approval Type (dropdown), FDA Application Number/Registration Number (text), and FDA Application Supplement Number (text). There is also a checkbox for 'Has Brand Name?' and a dropdown for 'Generic Name'. A 'Save' button is located at the bottom right of the form.

4. To add fields by Alternate ID, select the “Add by Alternate ID” tab, and use the following requirements:

Alternate ID: required
dropdown

Note: if the Alternate ID you want to use is not in the dropdown list, you must click on **Manage NDC1/ALT ID** from the menu on the left side of the screen, and add and assign the Alternate ID.

Manufacturer Name: required
limited to 250 characters

Note: When entering Product Data for the same Manufacturer more than once, be sure that the spelling is the same each time for that Manufacturer. If data were entered through “Upload Product Data,” the spelling must match that as well.

Has Brand Name?: checkbox
optional

Brand Name: field is only displayed if the “Has Brand Name?” box is checked
required if “Has Brand Name?” box is checked
limited to 250 characters

Generic Name: dropdown list
required

New Generic Name: only displayed when selecting “Add New Generic Name” from the “Generic Name” dropdown list
required
limited to 250 characters

Date of First Sale: MM/DD/YYYY format
numeric
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per Alternate ID: numeric
required
up to 9 digits allowed

FDA Approval Date: optional
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: optional
alphanumeric
up to 9 characters
can have up to 2 more optional
entries by clicking on the “Add New
Application Numbers” link

FDA Approval Type: optional
dropdown list

FDA Application Supplement Number: alphanumeric
optional
up to 9 characters
can have up to 2 more optional entries by
clicking on the “Add New Application
Numbers” link

The fields populate with the entered data, as shown in Figure 6-4.

Figure 6-4: Add Product Data – Add Fields by Alternate ID

The screenshot shows the 'Add Product Data' form with the following fields and values:

- Current Reporting Period:** Q4 2018
- Alternate ID*:** 54321EDCBA
- Manufacturer Name*:** TEST - Manufacturer Name by ALT ID
- Date of First Sale*:** 06/01/2018
- Expiration Date of Final Lot Sold:** (empty)
- Generic Name*:** 0.9% NACL 250ML VAFLO LR NP
- Strength of the Product*:** 200
- Volume per Item*:** 100
- Number of Items per Alternate ID*:** 1
- FDA Approval Date:** 05/01/2018
- FDA Approval Type:** 510(k)
- FDA Application Number:** 1111122
- FDA Application Supplement Number:** (empty)

5. Click on the **Save** button.

The screen displays the confirmation that the product submission has been successfully saved, as shown in Figure 6-5.

Figure 6-5: Add Product Data – Product Submission Saved Successfully

The screenshot shows the 'Add Product Data' form with a green confirmation message at the top: "54321EDCBA product data have been saved successfully." The form fields are now empty or in a selection state:

- Alternate ID*:** (empty)
- Manufacturer Name*:** (empty)
- Date of First Sale*:** (empty)
- Expiration Date of Final Lot Sold:** (empty)
- Generic Name*:** Select Generic Name
- Strength of the Product*:** (empty)
- Volume per Item*:** (empty)
- Number of Items per NDC*:** (empty)
- FDA Approval Date*:** (empty)
- FDA Approval Type*:** Select
- FDA Application Number/Registration Number*:** (empty)
- FDA Application Supplement Number:** (empty)

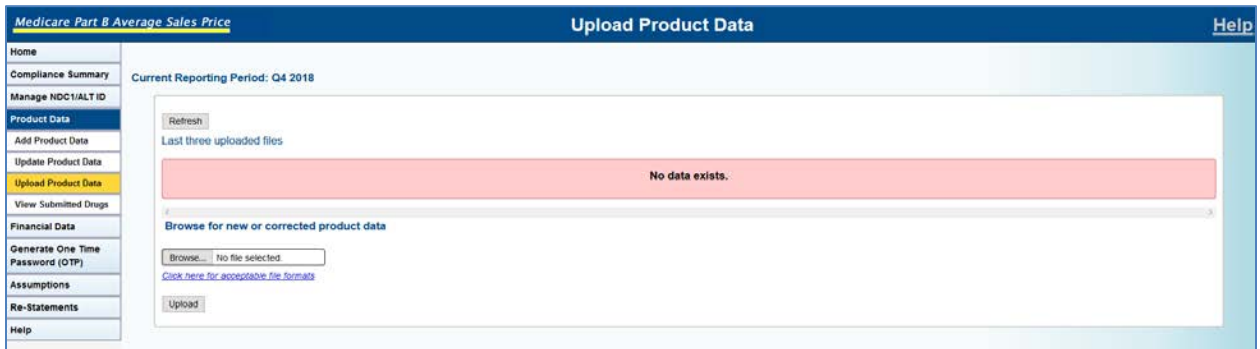
6.2 Upload Product Data

ASP provides drug manufacturers the ability to submit Medicaid Part B drug data to CMS. Perform the following steps to upload drug product data using the file transfer process.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Upload Product Data**.

The “Upload Product Data” screen displays with the current reporting period showing, as shown in Figure 6-6.

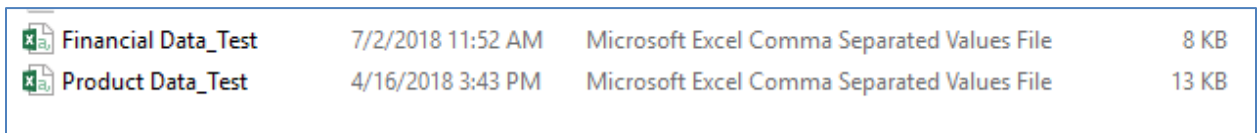
Figure 6-6: Upload Product Data Screen



- To upload data, click on the **Browse...** button.

The file directory opens, as shown in Figure 6-7.

Figure 6-7: File Directory Window



- Select a file and double-click on it.

The “Browse...” field is populated, as shown in Figure 6-8.

Figure 6-8: Upload Product Data Browse Field Populated



- Click on the **Upload** button.

A message displays confirming that the product data were saved successfully, and the drug data are listed, as shown in Figure 6-9.

Figure 6-9: Upload Product Data Saved Successfully

Note: Errors will be displayed in the “Status” column detailing what you will have to change in the Upload File.

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 5. To be certain of file column formatting, click on the “Click here for acceptable file formats” link, or follow the criteria below.

5. Open the “Upload Product” file, as shown in Figure 6-10.

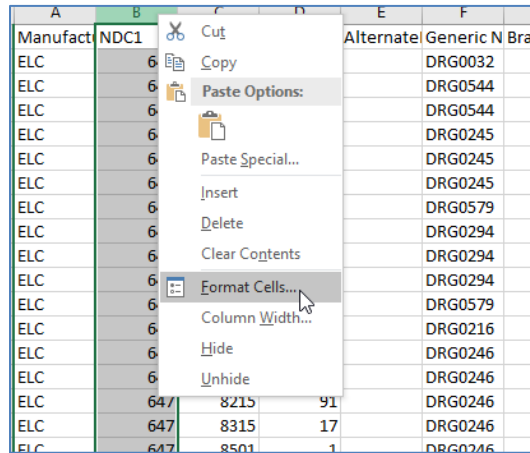
Figure 6-10: Upload Product File

A1	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V		
	Manufact	NDC1	NDC2	NDC3	Alternat	Generic N	Brand Nar	Strength	c	Volume	P	Number	o	Expiration	Date of Firs	FDA Appli	FDA Appli	FDA Appri	Additional	Additional	Additional	Additional	FDA Approval	Date
1	ELC	647	7140	1	DRG0032	2 mg/ml	5 ml	1	1	2/1/2005	103575	5110	BLA										12/16/2003	
2	ELC	647	7501	1	DRG0544	200 MG		1	1	5/16/1996	20509	70	NDA										5/15/1996	
3	ELC	647	7502	1	DRG0544	1 GM		1	1	5/16/1996	20509	70	NDA										5/15/1996	
4	ELC	647	7510	1	DRG0245	100units/	10 ml	1	1	7/15/1996	20563	126	NDA										6/14/1996	
5	ELC	647	7510	17	DRG0245	100units/	3 ml	1	1	1/4/2010	20563	126	NDA										6/14/1996	
6	ELC	647	7516	59	DRG0245	100units/	3 ml	5	1	8/2/2000	20563	126	NDA										6/14/1996	
7	ELC	647	7623	1	DRG0579	500 mg		1	1	2/13/2004	21462	40	NDA										2/4/2004	
8	ELC	647	7635	11	DRG0294	210 MG		1	1	3/1/2010	22173	14	NDA										12/11/2009	
9	ELC	647	7636	11	DRG0294	300 MG		1	1	3/1/2010	22173	14	NDA										12/11/2009	
10	ELC	647	7637	11	DRG0294	405 MG		1	1	3/1/2010	22173	14	NDA										12/11/2009	
11	ELC	647	7640	1	DRG0579	100 mg		1	1	1/10/2008	21462	40	NDA										2/4/2004	
12	ELC	647	8031	1	DRG0216	1 mg		1	1	2/22/1999	20928	44	NDA										9/11/1998	
13	ELC	647	8215	1	DRG0246	100units/	10 ml	1	1	7/1/1983	18780	138	NDA										10/28/1982	
14	ELC	647	8215	17	DRG0246	100units/	3 ml	1	1	4/4/2010	18780	138	NDA										10/28/1982	
15	ELC	647	8215	91	DRG0246	100units/	10 ml	1	1	8/16/2010	18780	138	NDA										10/28/1982	
16	ELC	647	8315	17	DRG0246	100units/	3 ml	1	1	7/12/2010	18781	124	NDA										7/1/1983	
17	ELC	647	8501	1	DRG0246	500 units/	20 ml	1	1	12/11/1996	18780	138	NDA										10/28/1982	
18	ELC	647	8725	59	DRG0245	100units/	3 ml	5	1	11/9/1998	20563	126	NDA										6/14/1996	
19	BMSC	648	293	5	DRG0384	40mg/ml		1	1	9/30/1990	14901		NDA										2/1/1965	
20	BMSC	648	293	20	DRG0384	40mg/ml		5	1	9/30/1990	14901		NDA										2/1/1965	
21	BMSC	648	293	28	DRG0384	40mg/ml		10	1	9/30/1990	14901		NDA										2/1/1965	
22	BMSC	648	371	13	DRG0074	250mg		1	1	6/27/2011	125288		BLA										6/15/2011	
23	BMSC	648	494	20	DRG0384	10mg/ml		5	1	9/30/1990	12041		NDA										1/4/1960	
24	BMSC	648	2187	10	DRG0031	250mg		1	1	2/9/2006	125118		BLA										12/23/2005	
25	BMSC	648	2327	11	DRG0563	5mg/ml		10	1	4/6/2011	125377		BLA										3/25/2011	
26	BMSC	648	2328	22	DRG0563	5mg/ml		40	1	4/6/2011	125377		BLA										3/25/2011	
27	GNTHI	649	188	9	DRG0232	3MG/3ML		0	1	3/2/2006	21858		NDA										1/6/2006	
28	GNTHI	649	191	9	DRG0233	3MG/3ML		0	1	3/2/2006	21859		NDA										1/6/2006	
29	GNTHI	649	259	1	DRG0465	250 MG. C		0	100	6/12/1995	50722		NDA										5/3/1995	
30	GNTHI	649	259	5	DRG0465	250 MG. C		0	1440	6/12/1995	50722		NDA										5/3/1995	
31	GNTHI	649	259	43	DRG0465	250 MG. C		0	500	6/12/1995	50722		NDA										5/3/1995	
32	GNTHI	649	260	1	DRG0465	500MG TA		0	100	8/12/1997	50723		NDA										6/19/1997	
33	GNTHI	649	260	43	DRG0465	500MG TA		0	500	8/12/1997	50723		NDA										6/19/1997	
34	GNTHI	649	261	29	DRG0465	175ML ML		0	175	5/10/1999	50759		NDA										10/1/1998	
35	GNTHI	649	1100	20	DRG0489	150 MG TA		0	60	5/15/1998	20896		NDA										4/30/1998	
36	GNTHI	649	1101	50	DRG0489	500MG TA		0	120	5/15/1998	20896		NDA										4/30/1998	

- To reformat a column, right-click on a column header.

The “Column Editing” dropdown displays, as shown in Figure 6-11.

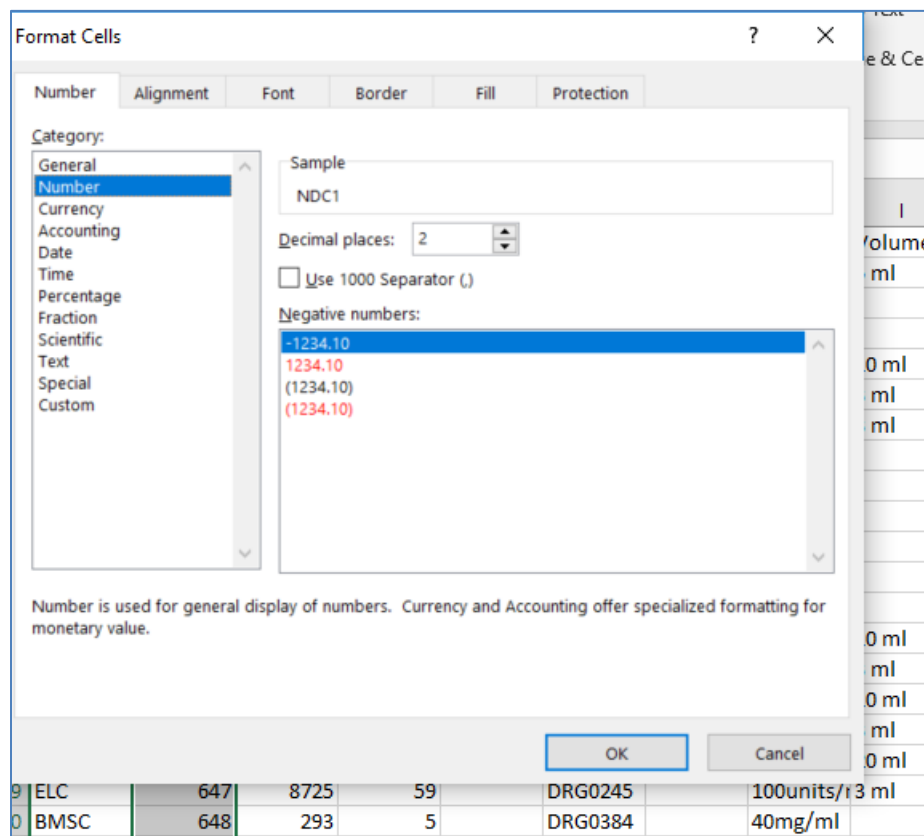
Figure 6-11: Upload Product Data Column Editing Dropdown



- Select “Format Cells.”

The “Format Cells” window displays, as shown in Figure 6-12.

Figure 6-12: Upload Product Data Format Cells Window

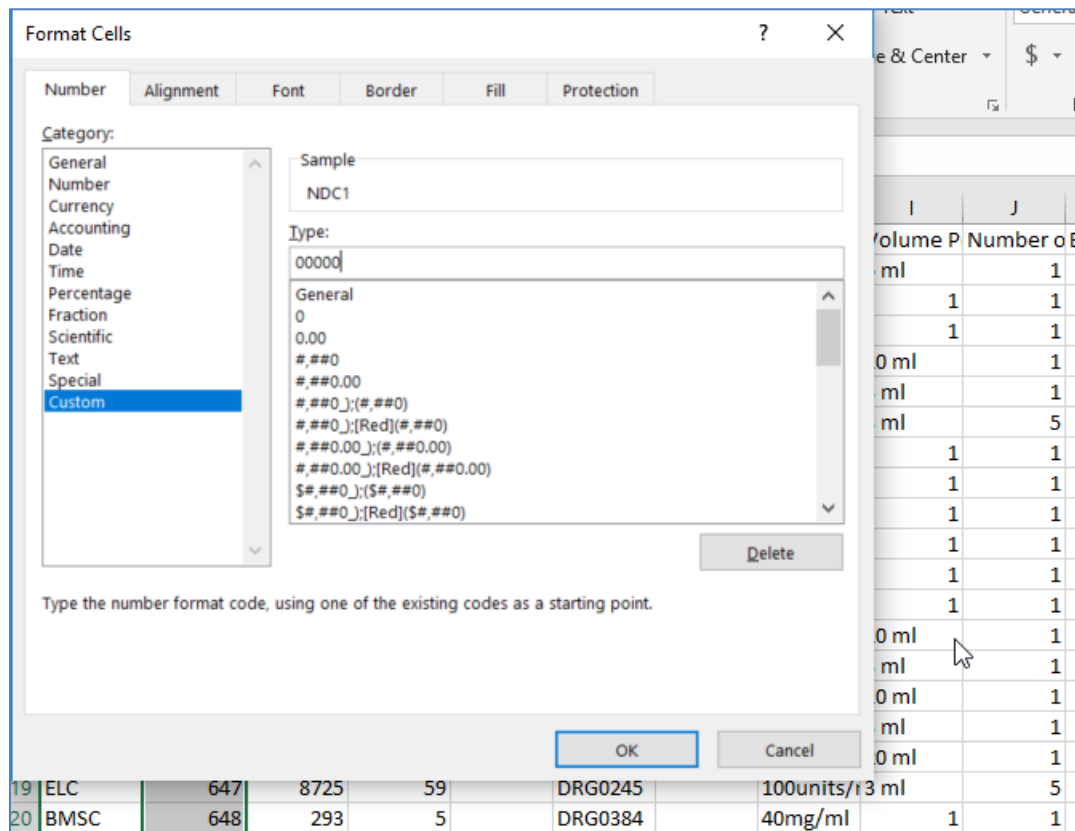


8. Make the following changes according to the below criteria:

Note: For NDC1, NDC2, and NDC3 columns, select “Number” and then “Custom.”

- NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 6 for any other column changes
- NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 6 for any other column changes
- NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 6 for any other column changes

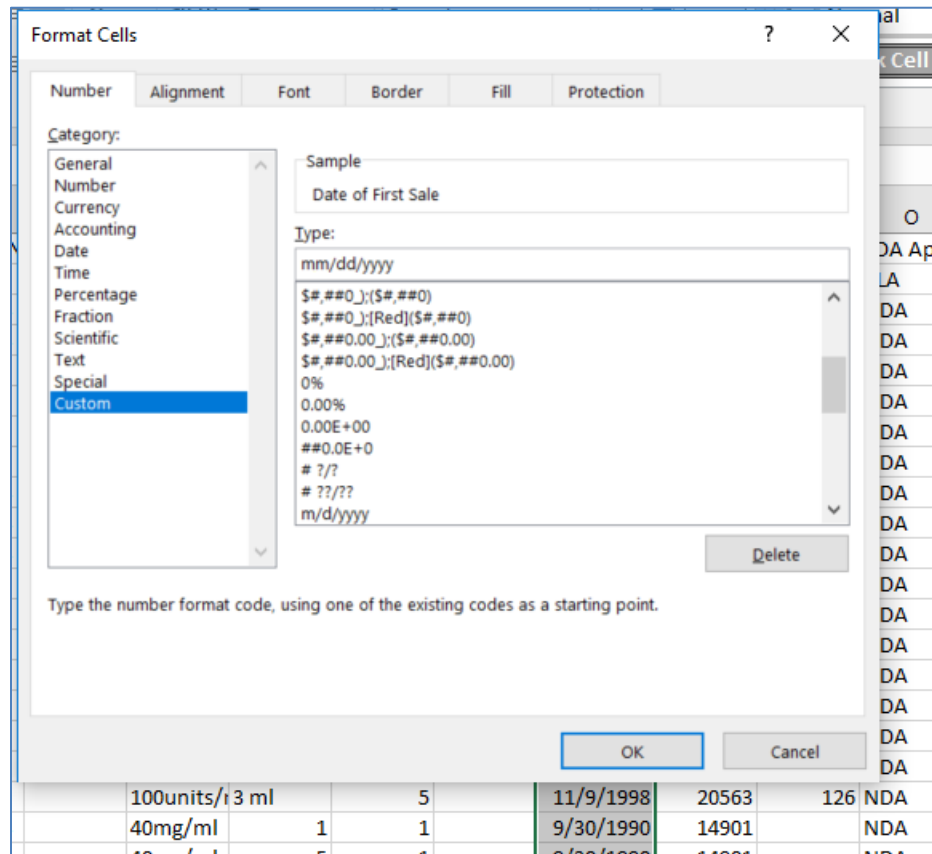
Figure 6-13: Upload Product Data Format Cells Custom Editing Example



Note: For the Expiration Date, Date of First Sale, and FDA Approval Date columns, select “Date” and then “Custom.”

- Expiration Date: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes
- Date of First Sale: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes
- FDA Final Pre-Marketing Approval Date: Type MM/DD/YYYY, click on the **OK** button, and repeat from Step 6 for any other column changes

Figure 6-14: Upload Product Data Format Cells Date Custom Editing Example



9. Save the file and go back to Step 2.

Note: Be sure that you do NOT change any of the column headers, as that will invalidate the upload.

Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 5 through 7 again, before you resave the file.

6.3 Update Product Data

Update Product Data allows drug manufacturers the ability to update drug product data to CMS.

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **Update Product Data**.

The “Update Product Data” screen displays with the current reporting period showing, as shown in Figure 6-15.

Figure 6-15: Update Product Data Screen

2. To update fields by NDC, select the “Update by NDC” tab.

Note: To update fields by Alternate ID, go to step 6.

3. Select Drug Identifier: dropdown menu required

All of the fields automatically populate, as shown in Figure 6-16.

Figure 6-16: Update Product Data Screen, Update by NDC Tab Fields Populated

4. Make any updates using the following criteria.

Has Brand Name?: checkbox
optional

Brand Name: field is only displayed if the “Has Brand Name?” box is checked
required if “Has Brand Name?” box is checked
limited to 250 characters

Generic Name: dropdown list
required

New Generic Name: displayed only if selecting “Add New Generic Name” from the
“Generic Name” dropdown list
required
limited to 250 characters

Date of First Sale: MM/DD/YYYY format
required
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per NDC: numeric
required
limited to 9 digits

FDA Approval Date: required
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: required
alphanumeric
up to 9 characters
can have up to 2 more optional
entries by clicking on the “Add New
Application Numbers” link

FDA Approval Type: required
dropdown list

FDA Application Supplement Number: optional
 alphanumeric
 up to 9 characters
 can have up to 2 more optional entries by clicking on the “Add New Application Numbers” link

The fields populate with the entered data.

5. Click on the **UPDATE** button.

The screen displays the confirmation that the product submission has been saved, as shown in Figure 6-17.

Figure 6-17: Update Product Data Screen – Update by NDC Saved Successfully

6. To update fields by Alternate ID, select the “Update by Alternate ID” tab, select an alternate ID from the dropdown list, and use the following requirements:

Has Brand Name?: checkbox
 optional

Brand Name: field is only displayed if “Has Brand Name?” box is checked
 required if “Has Brand Name?” box is checked
 limited to 250 characters

Generic Name: dropdown list
 required

New Generic Name: only displayed when selecting “Add New Generic Name” from the “Generic Name” dropdown list
 required
 limited to 250 characters

Date of First Sale: MM/DD/YYYY format
required
cannot occur before the FDA approval date
must occur prior to the “Current Reporting Period” start date

Expiration Date of Final Lot Sold: MM/DD/YYYY format
optional

Strength of the Product: required
limited to 500 characters

Volume Per Item: required
limited to 250 characters

Number of Items per NDC: numeric
required
up to 9 digits

FDA Approval Date: optional
MM/DD/YYYY format
must be prior to “Current Reporting Period” start date

FDA Application Number/Registration Number: optional
alphanumeric
up to 9 characters
can have up to 2 more optional
entries by clicking on the “Add New
Application Numbers” link

FDA Approval Type: optional
dropdown list

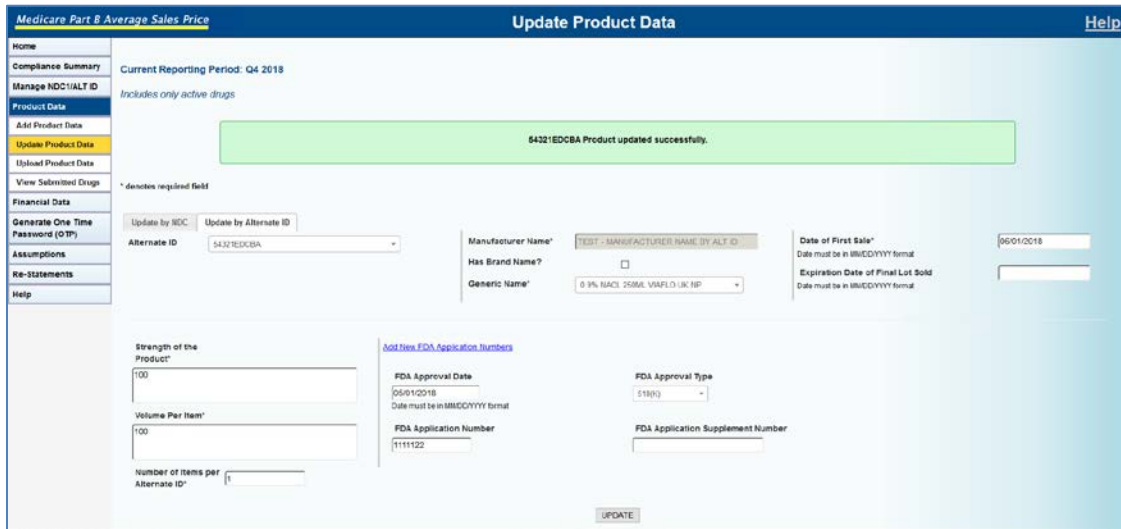
FDA Application Supplement Number: optional
alphanumeric
up to 9 characters
can have up to 2 more optional entries by
clicking on the “Add New Application
Numbers” link

The fields populate with the entered data.

7. Click on the **UPDATE** button.

The screen displays the confirmation that the product submission has been saved, as shown in Figure 6-18.

Figure 6-18: Update Product Data Screen – Update by Alternate ID Updated Successfully



6.4 View Submitted Drugs

Drug manufacturers have the ability to view drug data that has been submitted during the current reporting period. Drug manufacturers cannot update or edit drug data using this feature.

Perform the following steps to view submitted drug data:

1. Click on **Product Data** from the menu on the left side of the screen, and then click on **View Submitted Drugs**.

The “View Submitted Drugs” window displays, as shown in Figure 6-19.

Figure 6-19: View Submitted Drugs Screen

The screenshot shows the 'View Submitted Drugs' interface. At the top, it says 'Current Reporting Period: Q4 2018'. Below this is a search bar for 'Drug Identifier' with a 'Search' button. The main area is a table with columns: 'Drug Identifier', 'Generic (Brand Name)', 'Manufacturer's ASP', 'Number of ASP units', 'Wholesale Acquisition Cost', 'Number of Cap Units Excluded', and 'Status'. The table contains 20 rows of data. At the bottom, there are pagination controls showing 'Showing 1 - 20 of 192 results' and 'Export' options.

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status
09047-7149-01	DRG0002					PENDING
09047-7350-01	DRG0044	145.230	80.100	145.198		SAVED
09047-7350-01	DRG0044					PENDING
09047-7319-01	DRG0045					PENDING
09047-7319-17	DRG0045	17.028	320769.240	36.800		SAVED
09047-7319-05	DRG0045					PENDING
09047-7623-01	DRG0076	2789.260	76487.640	2818.750		SAVED
09047-7626-11	DRG0034	546.370	224.880	656.608	6.000	SAVED
09047-7626-11	DRG0034					PENDING
09047-7637-11	DRG0034	1081.930	1812.280	1073.200	3.000	SAVED
09047-7148-01	DRG0076					PENDING
09047-8031-01	DRG0048	136.750	211267.300	136.688		SAVED
09047-8215-01	DRG0048	46.128	23948.640	70.400		SAVED
09047-8215-17	DRG0048					PENDING
09047-8215-01	DRG0048	17.698	0.800	18.110		SAVED
09047-8215-17	DRG0048					PENDING
09047-8201-01	DRG0048					PENDING
09047-8225-09	DRG0045	0.000	0.000	207.858		SAVED
09049-0200-05	DRG0034	0.942	397847.741	6.000		SAVED
09049-0200-20	DRG0034					PENDING

This can be used to scroll through the list of drugs displayed on the “View Submitted Drugs” page in order to view submitted drug data and status. This can also be used to enter the “Drug Identifier” field and click on the **Search** button to filter the results to view a particular drug’s data, using either a full or partial search of the drug identifier.

7. Financial Data

Drug manufacturers are required to submit quarterly drug data to the ASP application for ASP pricing using a file transfer process or through online data entry. Drug data consists of product data and financial data. The following subsections detail the steps required to submit drug financial data using online data entry and through approved file uploads

7.1 Add/Edit Financial Data

The ASP application provides drug manufacturers the ability to submit Medicaid Part B drug financial data to CMS. Perform the following steps to add drug financial data manually using the online data entry process. To upload financial data for multiple drugs at once from a file, skip to section 7.2.

1. Click on **Financial Data** from the menu on the left side of the screen, and then click on **Add/Edit Financial Data**.

The “Add/Edit Financial Data” page displays a listing all of the drugs that are assigned for the current reporting period, as shown in Figure 7-1.

Figure 7-1: Add/Edit Financial Data Screen

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP*	Number of ASP units*	Wholesale Acquisition Cost*	Number of Cap Units Excluded	Status	View Details
54321EDCBA	0.9% NACL 250ML VIAFLO UK NP					PENDING	Product
88888-2222-44	0.9% NACL 250ML VIAFLO UK NP					PENDING	Product

2. Scroll through the list of drugs displayed on the “Add/Edit Financial Data” page in order to locate the drug(s) needing financial data added or updated, or enter the drug identifier in the “Drug Identifier” field, and click on the **Search** button to filter the results.
3. Enter the Manufacturer’s ASP, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded in the respective fields, using the following criteria:

Manufacturer’s ASP: numeric

Must have three decimal places (i.e., XXXXXX.XXX).

can be a positive number, a negative number, or be equal to 0.000

Number of ASP units: numeric

must have three decimal places (i.e., XXXXXXXXXXXX.XXX).

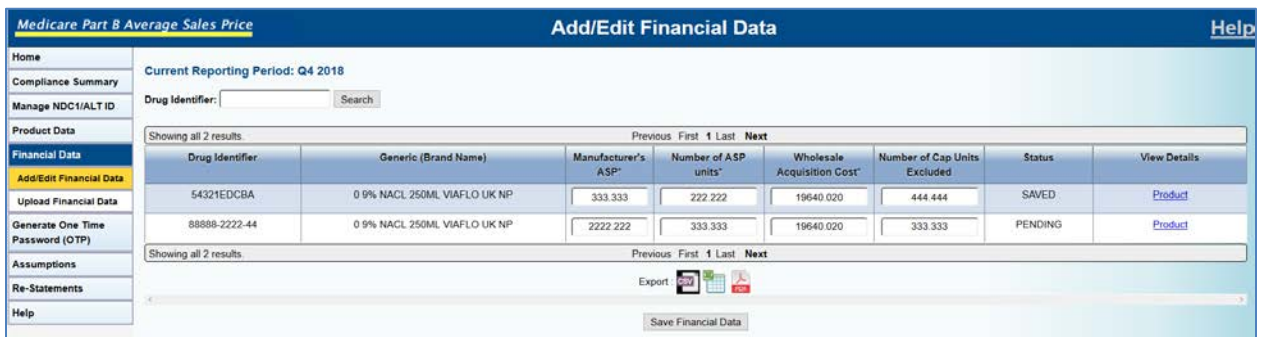
can be a positive number, a negative number, or be equal to 0.000

Wholesale Acquisition Cost: numeric
 must have three decimal places (i.e., XXXXXX.XXX).
 can be a positive number, a negative number, or be equal to 0.000

Number of Cap Units Excluded: optional
 numeric
 must have three decimal places (i.e., XXXXXXXXX.XXX).
 can be a positive number or be equal to 0.000

The fields populate, as shown in Figure 7-2.

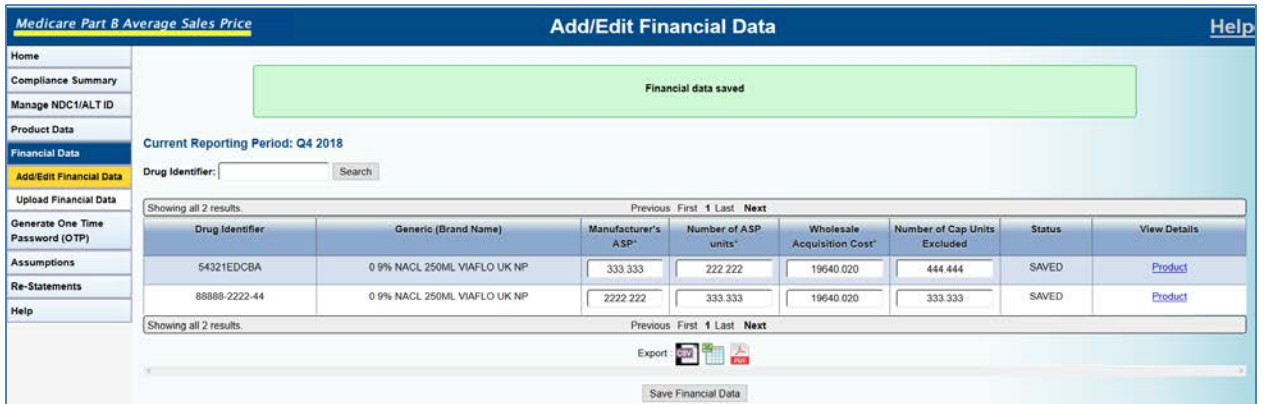
Figure 7-2: Add/Edit Financial Data Screen – Fields Populated



- Click on the **Save Financial Data** button to add/update the Drug Identifier financial data.

A message displays indicating that the Drug Identifier financial data have been saved to the ASP application and the status of the drug changes from “PENDING” to “SAVED,” as shown in Figure 7-3.

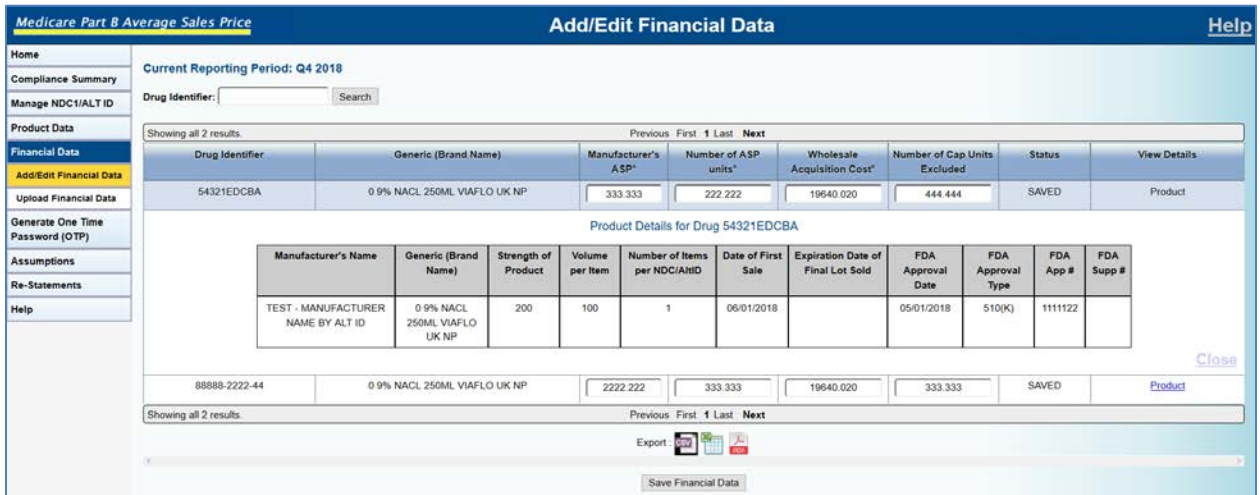
Figure 7-3: Add/Edit Financial Data Screen – Financial Data Saved



- To view the product data for the Drug Identifier, click on the “Product” link in the “View Details” tab.

The product data for the selected financial data displays, as shown in Figure 7-4.

Figure 7-4: Add/Edit Financial Data Screen – Selected Financial Data



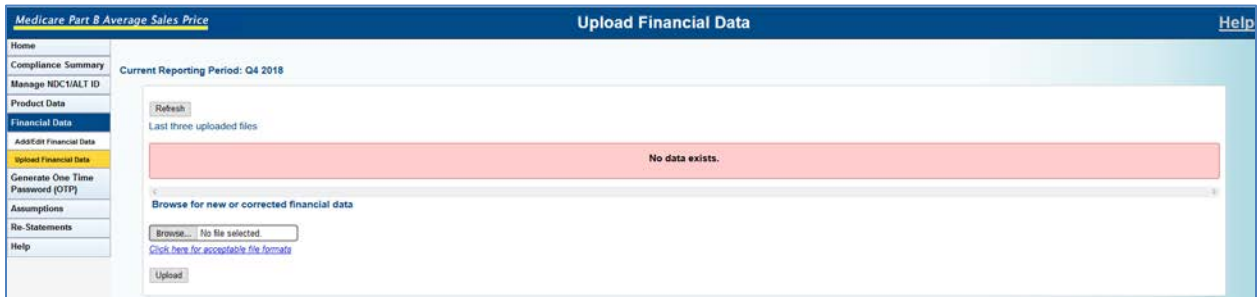
7.2 Upload Financial Data

ASP provides drug manufacturers the ability to submit Medicaid Part B financial data to CMS. Perform the following steps to upload drug financial data using the file transfer process.

1. Click on **Financial Data** from the menu on the left side of the screen, and then click on **Upload Financial Data**.

The “Upload Financial Data” screen displays with the current reporting period showing, as shown in Figure 7-5.

Figure 7-5: Upload Financial Data Screen



2. To upload data, click on the **Browse...** button.

The file directory opens, as shown in Figure 7-6.

Figure 7-6: File Directory Window

	Financial Data_Test	12/23/2016 4:52 PM	Microsoft Excel Comma Separated Values File
	Product Data_Test	4/16/2018 3:43 PM	Microsoft Excel Comma Separated Values File

3. Select a file and double-click on it.

The “Browse...” field is populated, as shown in Figure 7-7.

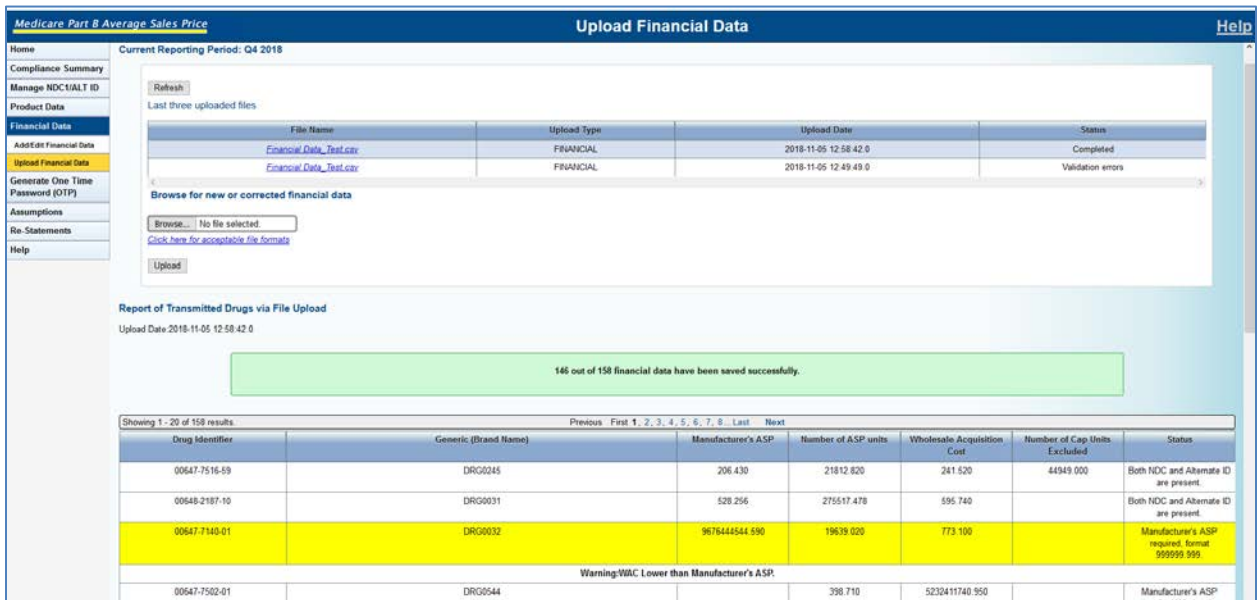
Figure 7-7: Upload Financial Data Browse Field Populated



4. Click on the **Upload** button.

A message displays confirming that the financial data were uploaded successfully, and the drug financial data are listed, as shown in Figure 7-8.

Figure 7-8: Upload Financial Data Saved Successfully



Note: Errors will be displayed in the “Status” column detailing what you will have to change in the Upload File.

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 5. To be certain of file column formatting, click on the “Click here for acceptable file formats” link, or follow the criteria below.

- Open the “Upload Financial” file, as shown in Figure 7-9.

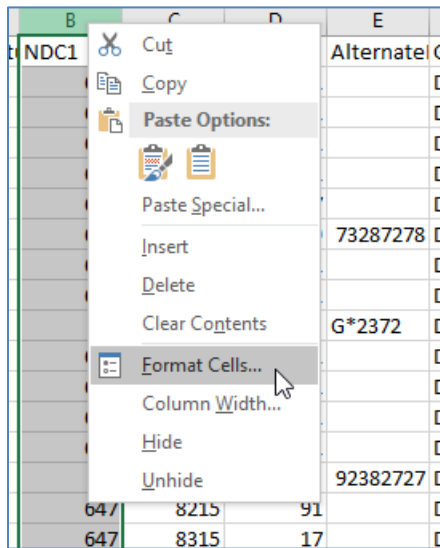
Figure 7-9: Upload Financial Data File

Manufacturer	NDC1	NDC2	NDC3	Alternate	Generic N Brand Name	Manufacture Number	Wholesale Number	Number of Cap Units Excluded
ELC	647	7140	1		DRG0032	967644.6	19639.02	773.1
ELC	647	7501	1		DRG0544	145.23	90.1	148.19
ELC	647	7502	1		DRG0544		398.71	5.23E+09
ELC	647	7510	1		DRG0245	104.65	3.21E+09	130
ELC	647	7510	17		DRG0245	17.18	329708.2	39
ELC	647	7516	59	73287278	DRG0245	206.43	21812.82	241.52 44949
ELC	647	7623	1		DRG0579	2739.25	76487.84	2818.75
ELC	647	7635	11		DRG0294	545.37	224.88	556.5 0
ELC	647	7637	11	G*2372	DRG0294	779.1	2197.76	795 -1
ELC	647	7640	1		DRG0294	1051.13	1512.29	1073.25 2
ELC	647	8031	1		DRG0579	546.94	-7	563.75 hh
ELC	647	8031	1		DRG0216	135.75	213207.3	138.98
ELC	647	8215	1		DRG0246	46.12	229545.6	70.4
ELC	647	8215	91	92382727	DRG0246	4.66	455360.2	21.12 1E+09
ELC	647	8315	17		DRG0246	17.69	0	18.15
ELC	647	8315	17		DRG0246	6.01	76992.82	
ELC	647	8501	1		DRG0246	565.89	79204.13	704
ELC	647	8725	59		DRG0245	0	0	207.85
BMSC	648	293	5		DRG0384	8.042	781947.7	8.55
BMSC	648	293	20		DRG0384	39.447	148675.6	43.39
BMSC	648	293	28		DRG0384	0	236581.5	64.8
BMSC	648	371	13		DRG0074	897.76	2657.74	923
BMSC	648	2187	10	G8329828	DRG0384	9.767	142772.6	11.04
BMSC	648	2327	11		DRG0031	528.256	275517.5	595.74
BMSC	648	2328	22		DRG0563	5904.116	4150.718	6000
BMSC	648	2328	22		DRG0563	23616.52	0	24000
GNTHI	649	188	9		DRG0232	0	0	439.16
GNTHI	649	191	9		DRG0233	428.789	5110	439.16
GNTHI	649	259	1		DRG0465	0	26631	439.16
GNTHI	649	259	5		DRG0465	7648.63	181	7942.81
GNTHI	649	259	43		DRG0465	2647.225	1682	7942.81
GNTHI	649	260	1		DRG0465	1061.597	18168	1103.17
GNTHI	649	260	43		DRG0465	5275.052	1461	5515.84
GNTHI	649	261	29		DRG0465	882.067	11362	908.85
GNTHI	649	1100	20		DRG0489	502.218	6880	527.72
GNTHI	649	1101	50		DRG0489	3341.122	54671	3517.67

- To reformat a column, right-click on a column header.

The “Column Editing” dropdown displays, as shown in Figure 7-10.

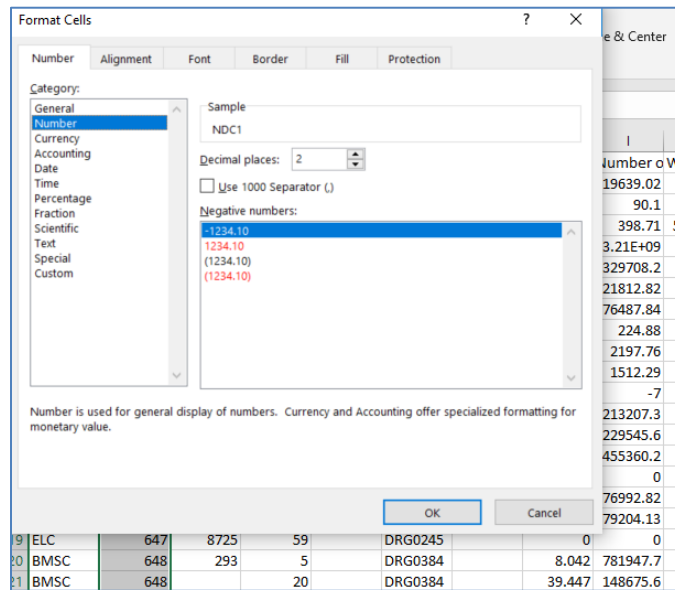
Figure 7-10: Upload Financial Data Column Editing Dropdown



- Select “Format Cells.”

The “Format Cells” window displays, as shown in Figure 7-11.

Figure 7-11: Upload Financial Data Format Cells Number Editing

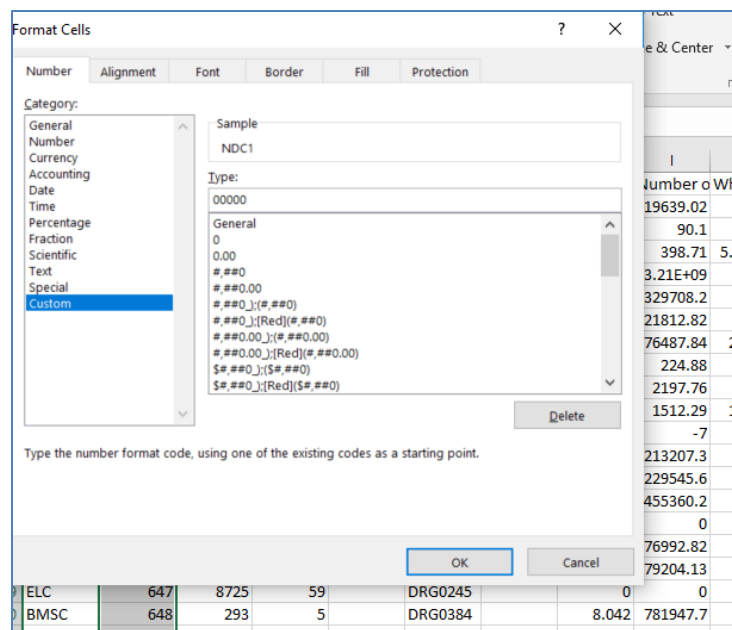


8. Make the following changes in the “Type” field according to the below criteria:

Note: For NDC1, NDC2, and NDC3 columns, select “Number” and then “Custom.”

- NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 7 for any other column changes
- NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 7 for any other column changes
- NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 7 for any other column changes

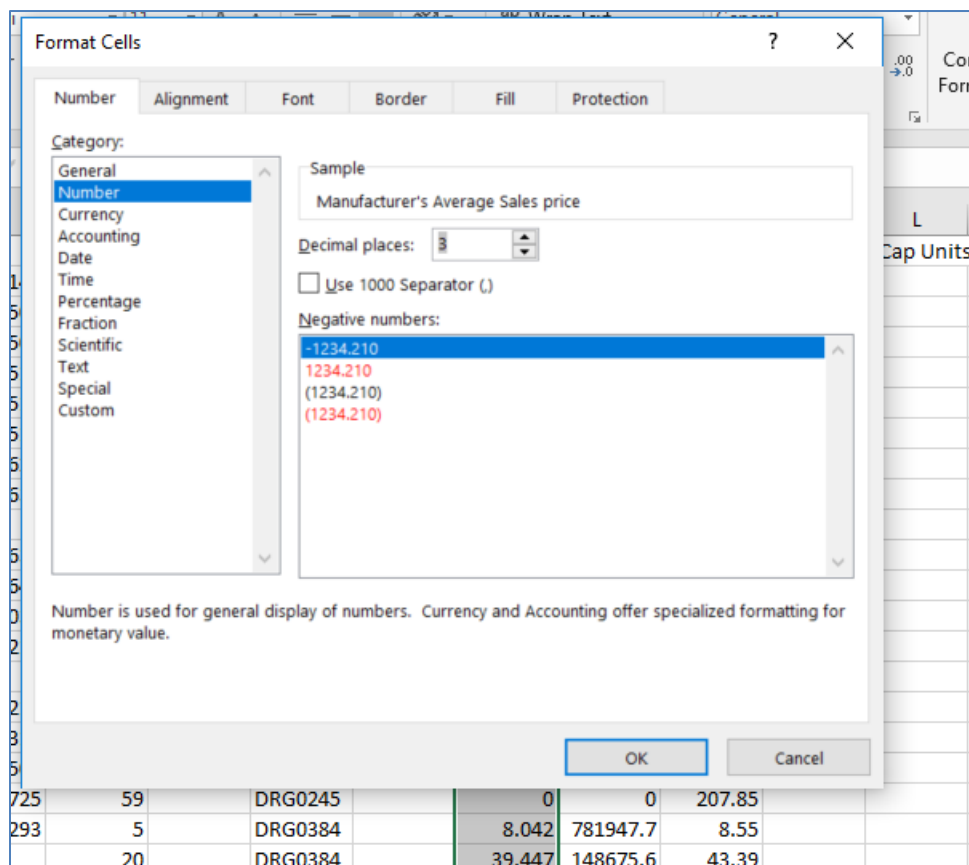
Figure 7-12: Upload Financial Data Format Cells Number Custom Editing Example



Note: For Manufacturer’s Average Sales Price, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded, select “Number.”

- Manufacturer’s Average Sales Price: Change the number of decimal places to “3,” click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of ASP Units: Change the number of decimal places to “3,” click on the **OK** button, and repeat from Step 7 for any other column changes
- Wholesale Acquisition Cost: Change the number of decimal places to “3,” click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of CAP Units Excluded: Change the number of decimal places to “3,” click on the **OK** button, and repeat from Step 7 for any other column changes

Figure 7-13: Upload Financial Data Format Cells Number Editing Example



9. Save the file and go back to Step 2.

Note: Be sure that you do NOT change any of the column headers, as that will invalidate the upload.

Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 6 through 8 again, before you resave the file.

8. Generate One Time Password (OTP) - Submitter

Once the ASP Submitter successfully enters all the Product and Financial Data for the first time into the ASP application, the ASP Submitter can generate a One Time Password (OTP) for each Manufacturer Name. Once the OTP is generated, the ASP Submitter can provide the OTP to the Certifier. The OTP expires after 7 days of being generated. If the OTP expires, the ASP Submitter can generate another OTP and once again provide the OTP to the ASP Certifier. There can only be one active Certifier for a manufacturer. If the Certifier changes, the Submitter has to share a new OTP with the new Certifier.

1. Click on **Generate One Time Password (OTP)** from the menu on the left side of the screen.

The “Generate One Time Password (OTP)” screen displays, as shown in Figure 8-1.

Figure 8-1: Generate One Time Password (OTP) Screen

2. Select a Manufacturer name from the “Please select the Manufacturer Name*.” dropdown list.

The selected Manufacturer populates in the field, as shown in Figure 8-2.

Figure 8-2: Generate OTP – Please select the Manufacturer name*: Field Populated

3. Click on the **Generate One Time Password (OTP)** button.

The OTP displays and is available for 7 days, as shown in Figure 8-3.

Figure 8-3: OTP Generated Successfully

Medicare Part B Average Sales Price **Generate One Time Password (OTP)** [Help](#)

Home
Compliance Summary
Manage NDC1/ALT ID
Product Data
Financial Data
Generate One Time Password (OTP)
Assumptions
Re-Statements
Help

Generated OTP successfully. Expires 11/12/2018.

Please select the Manufacturer Name* : ELC

[Generate One Time Password \(OTP\)](#)

All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier. Please click below to generate a one-time password (OTP) and share this with your data certifier. Upon accessing the system to certify your manufacturer's data, they will be asked for this password to verify their identity.

[Generate One Time Password \(OTP\)](#)

irtj1t8MSzy1iQz4xecr7A

One Time Password expires on 11/12/2018

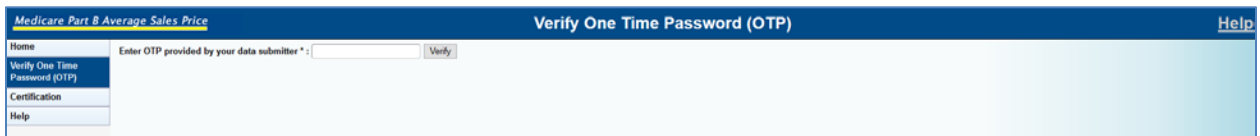
9. Verify OTP - Certifier

Once the ASP Submitter generates and provides an OTP for each Manufacturer Name to the Certifier, the Certifier must verify the OTP. The one-time password expires after 7 days of being generated. If the OTP expires, the ASP Submitter can generate another OTP and once again provide the OTP to the ASP Certifier.

1. Click on **Verify One Time Password (OTP)** from the menu on the left side of the screen.

The “Verify One Time Password (OTP)” screen displays, as shown in Figure 9-1.

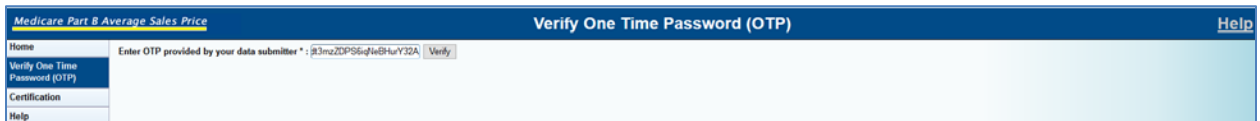
Figure 9-1: **Verify One Time Password (OTP)** Screen



2. Enter the OTP in the “Enter OTP provided by your data submitter*” field.

The “Enter OTP provided by your data submitter*” field populates, as shown in Figure 9-2.

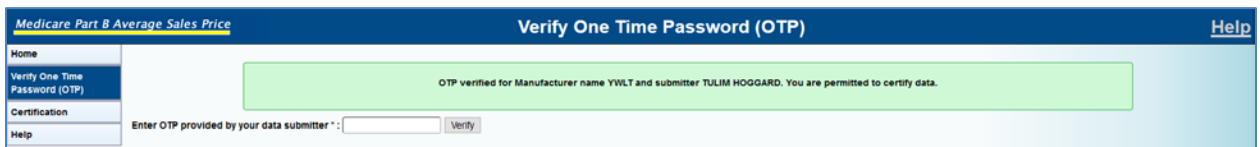
Figure 9-2: Verify OTP – Enter OTP provided by your data submitter*: Field Populated



3. Click on the **Verify** button.

A message displays that the OTP has been verified and the data for that manufacturer is ready for certification, as shown in Figure 9-3.

Figure 9-3: Verify OTP – OTP Verified Message



10. Assumptions

10.1 Assumptions - Submitter

Drug Manufacturers can submit comments regarding their certifications to CMS. These comments may be submitted for either the current or prior reporting periods. Perform the following steps to submit certification assumptions to CMS.

1. Begin by clicking on **Assumptions** button on the left side menu.

The “Assumptions” page displays showing the current report period, as shown in Figure 10-1.

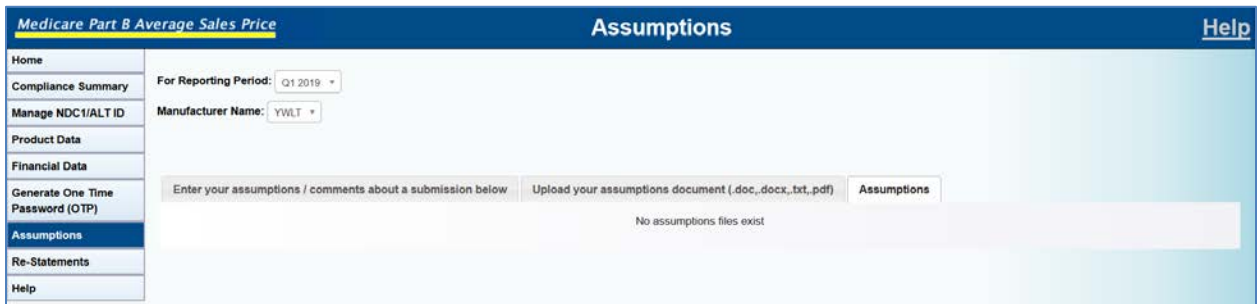
Figure 10-1: Assumptions Screen - Submitter



2. Select the desired reporting period from the “For Reporting Period” dropdown list and select the desired manufacturer name from the “Manufacturer Name” dropdown list.

The “Assumptions” page is shown with the Manufacturer name populated, as shown in Figure 10-2.

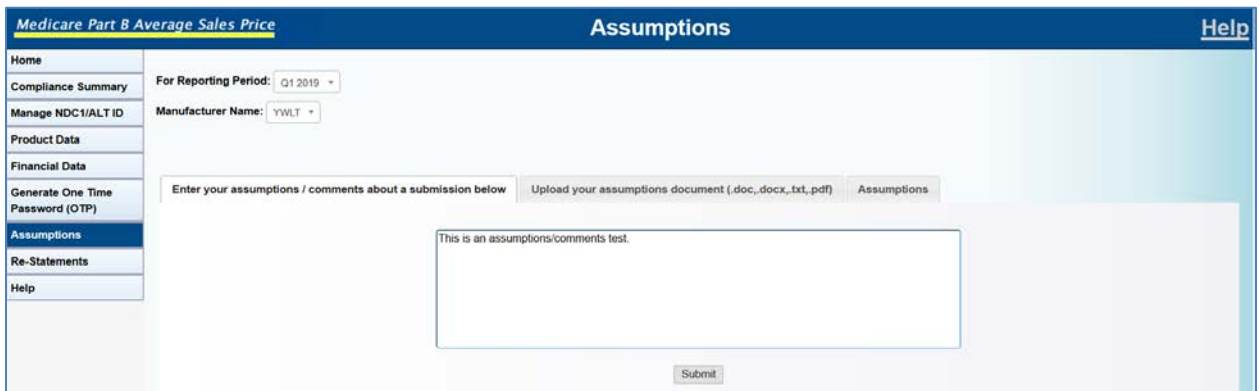
Figure 10-2: Assumptions – For Reporting Period Field Populated



3. Select the “Enter your assumptions / comments about a submission below” tab and enter your comment in the text field.

The text field is populated, as shown in Figure 10-3.

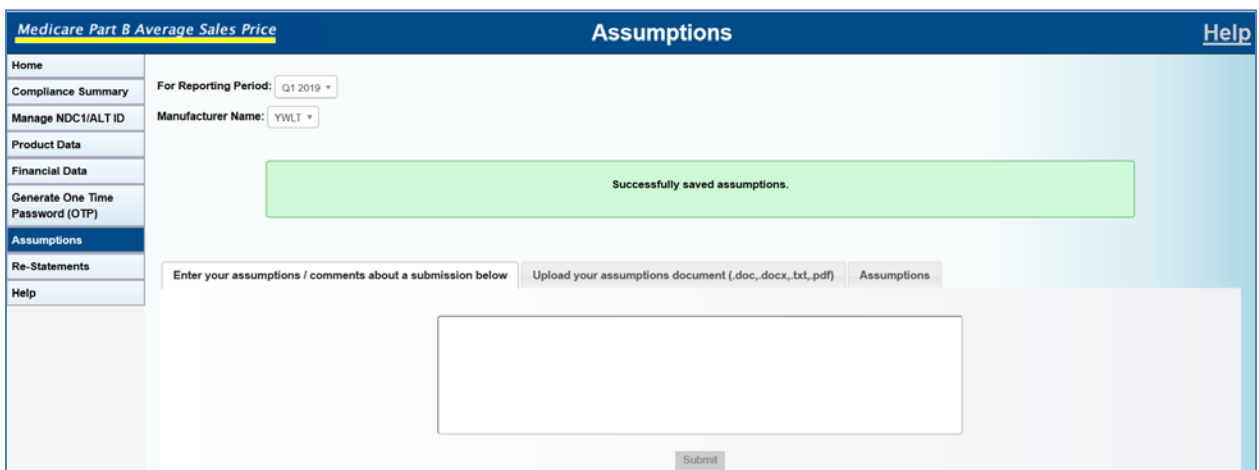
Figure 10-3: Assumptions – Comments Field Populated



4. Click on the **Submit** button.

A message displays that the assumption has been successfully saved, as shown in Figure 10-4.

Figure 10-4: Assumptions Saved Successfully



5. To upload an assumption, select a Manufacturer Name, select the “Upload your assumptions document (.doc,.docx,.txt,.pdf)” tab, and click on the **Browse** button.

The file directory window opens, as shown in Figure 10-5.

Figure 10-5: File Directory Window

Test Upload Files	11/8/2017 10:59 AM	File folder	
Assumptions.docx	2/2/2018 10:39 AM	Microsoft Word D...	12 KB
FinanceTest1.csv	2/17/2017 11:59 AM	Microsoft Excel C...	7 KB
FinanceTest2.csv	2/17/2017 12:03 PM	Microsoft Excel C...	7 KB
FinanceTest3.csv	9/19/2017 3:35 PM	Microsoft Excel C...	8 KB
NewProductTest1.csv	9/18/2017 11:01 AM	Microsoft Excel C...	11 KB
NewProductTest2.csv	9/18/2017 10:50 AM	Microsoft Excel C...	11 KB
NewProductTest3.csv	9/18/2017 10:54 AM	Microsoft Excel C...	12 KB

6. Select the document to upload, and click on the **Submit** button.

A message displays that the assumption has been successfully saved, as shown in Figure 10-6.

Figure 10-6: Assumptions Saved Successfully

The screenshot shows the 'Assumptions' page with a green message box stating 'Successfully saved assumptions.' The page includes a sidebar with navigation options like 'Home', 'Compliance Summary', and 'Assumptions'. The main content area has fields for 'For Reporting Period' (Q1 2019) and 'Manufacturer Name' (YWLT), along with a 'Submit' button and a file upload section.

7. To view assumptions that have been added, select a Manufacturer Name and click on the “Assumptions” tab.

The added assumptions are listed, as shown in Figure 10-7.

Figure 10-7: Assumptions Listed

The screenshot shows the 'Assumptions' page with a table listing saved assumptions. The table has columns for 'File Name', 'Upload Date', and 'File Uploaded User'.

File Name	Upload Date	File Uploaded User
USER ENTRY ASSUMPTIONS_2019-03-28_11:53:23.493	03/28/2019 11:53:24	TULIM HOGGARD
Assumptions.docx	03/28/2019 11:54:07	TULIM HOGGARD

The Assumptions can be viewed and opened by clicking the file link in the “File Name” column.

10.2 Assumptions – Certifier

Drug Manufacturers can submit comments regarding their certifications to CMS. These comments may be submitted for either the current or prior reporting periods. Perform the following steps to submit certification assumptions to CMS.

1. Begin by clicking on **Certification** from the menu on the left side of the screen, and then click on **Assumptions**.

The “Assumptions” page displays showing the current report period, as shown in Figure 10-8.

Figure 10-8: Assumptions Screen - Certifier



2. Select the desired reporting period from the “For Reporting Period” dropdown list and select the desired manufacturer name from the “Manufacturer Name” dropdown list.

The “Assumptions” page is shown with the Manufacturer name populated, as shown in Figure 10-9.

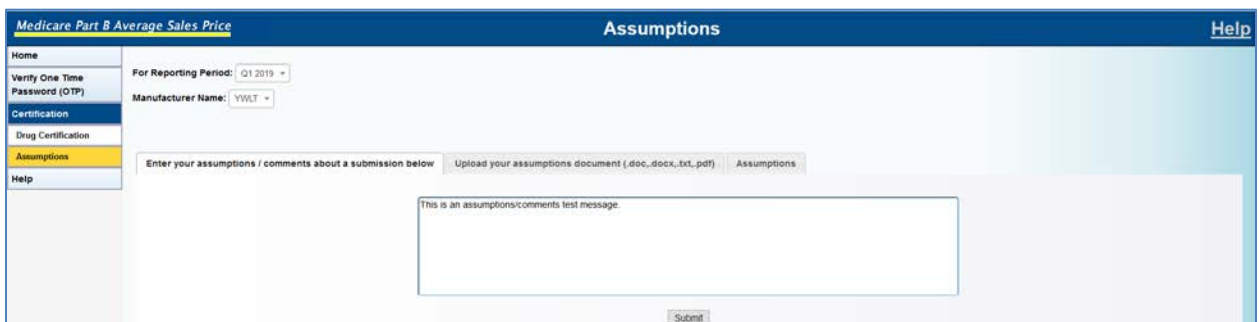
Figure 10-9: Assumptions – For Reporting Period Field Populated



3. Select the “Enter your assumptions / comments about a submission below” tab and enter your comment in the text field.

The text field is populated, as shown in Figure 10-10.

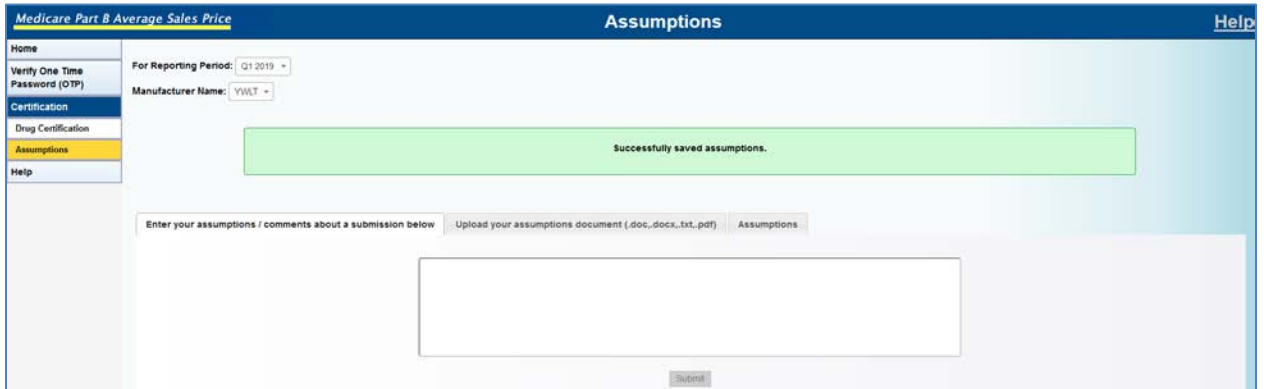
Figure 10-10: Assumptions – Comments Field Populated



- Click on the **Submit** button.

A message displays that the assumption has been successfully saved, as shown in Figure 10-11.

Figure 10-11: Assumptions Saved Successfully



- To upload an assumption, select the “Upload your assumptions document (.doc,.docx,.txt,.pdf)” tab, and click on the **Browse** button.

The file directory opens, as shown in Figure 10-12.

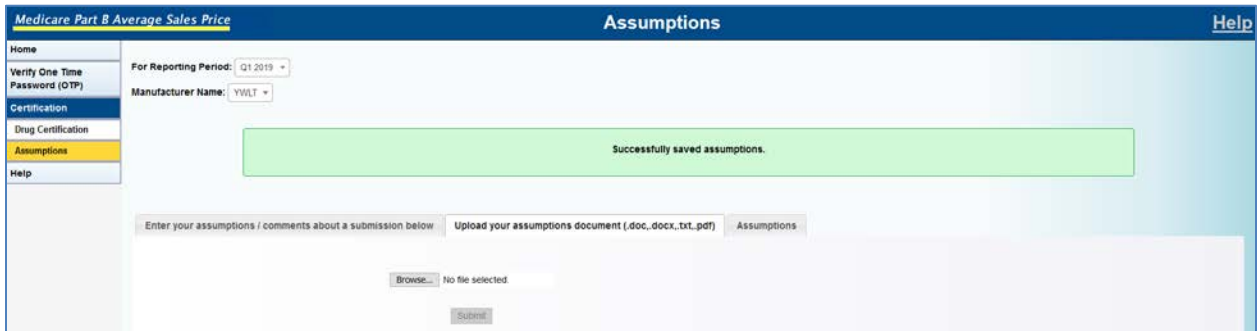
Figure 10-12: File Directory Window

File Name	Date and Time	File Type	Size
Test Upload Files	11/8/2017 10:59 AM	File folder	
Assumptions.docx	2/2/2018 10:39 AM	Microsoft Word D...	12 KB
FinanceTest1.csv	2/17/2017 11:59 AM	Microsoft Excel C...	7 KB
FinanceTest2.csv	2/17/2017 12:03 PM	Microsoft Excel C...	7 KB
FinanceTest3.csv	9/19/2017 3:35 PM	Microsoft Excel C...	8 KB
NewProductTest1.csv	9/18/2017 11:01 AM	Microsoft Excel C...	11 KB
NewProductTest2.csv	9/18/2017 10:50 AM	Microsoft Excel C...	11 KB
NewProductTest3.csv	9/18/2017 10:54 AM	Microsoft Excel C...	12 KB

- Select the document to upload, and click on the **Submit** button.

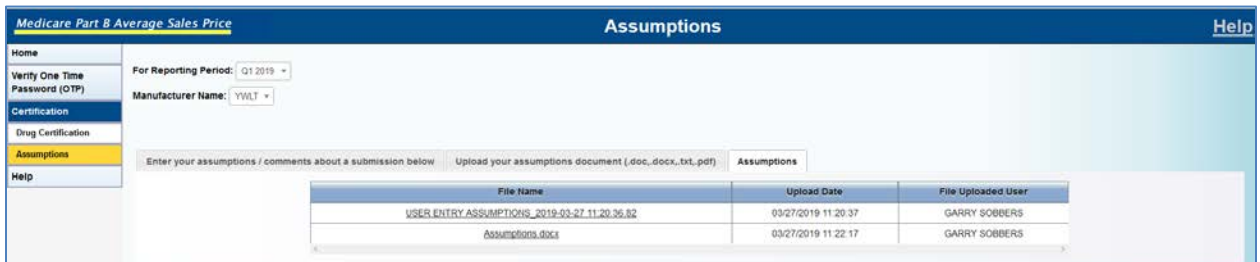
A message displays that the assumption has been successfully saved, as shown in Figure 10-13.

Figure 10-13: Assumptions Saved Successfully



- To view assumptions that have been added select the “Assumptions” tab. The added assumptions are listed, as shown in Figure 10-14.

Figure 10-14: Assumptions Listed



The Assumptions can be viewed and opened by clicking the file link in the “File Name” column.

11. Re-Statements

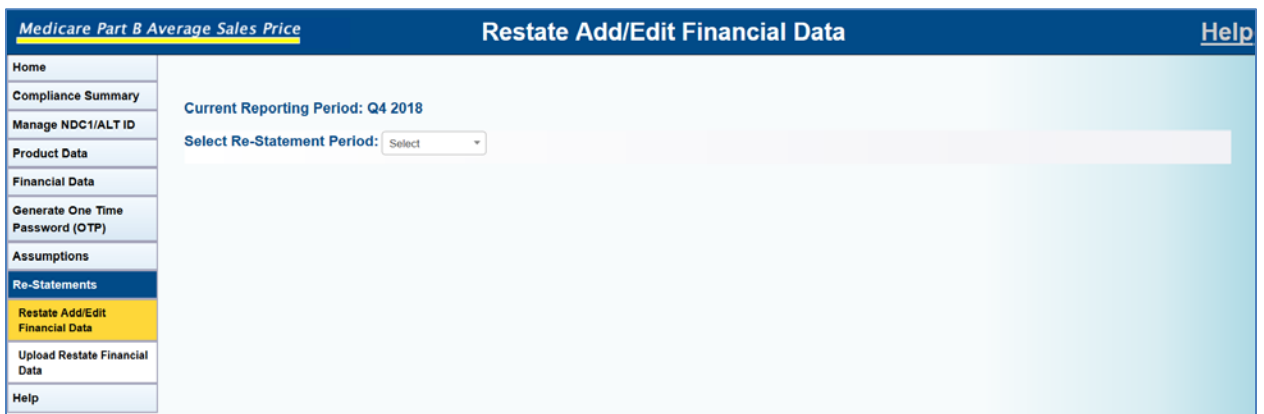
11.1 Add/Edit Restate Financial Data

ASP provides drug manufacturers the ability to restate Medicaid Part B financial data to CMS. Perform the following steps to add or edit financial data.

1. Click on **Re-Statements** from the menu on the left side of the screen, and then click on **Add/Edit Restate Financial Data**.

The “Add/Edit Restate Financial Data” screen displays with the current reporting period showing, as shown in Figure 11-1.

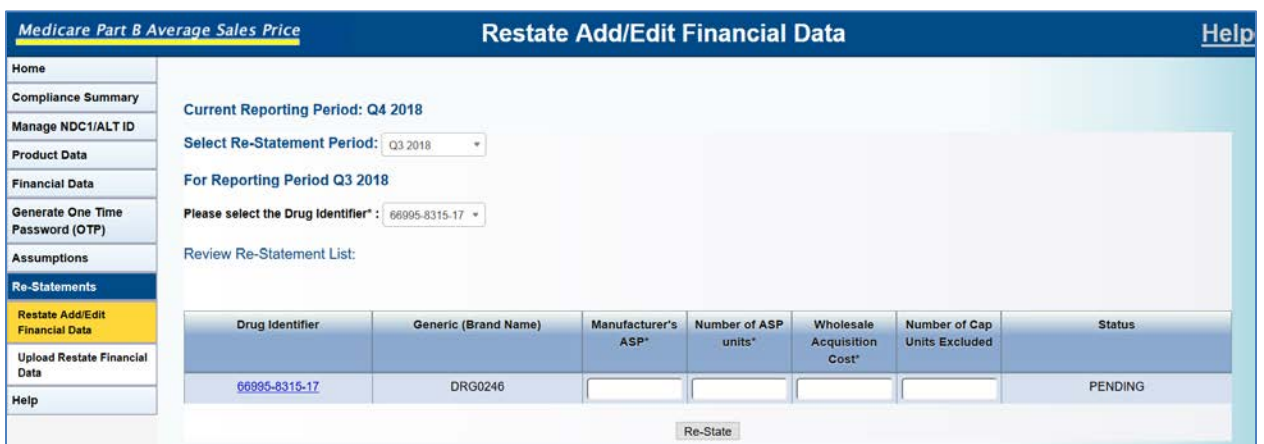
Figure 11-1: Add/Edit Restate Financial Data Screen



2. To add or edit data, select a reporting period from the dropdown menu in the “Select Re-Statement Period:” field and select a drug identifier.

The “Select Re-Statement Period:” and “Please select the Drug Identifier*:” fields populate, as shown in Figure 11-2.

Figure 11-2: Add/Edit Restate Financial Data – Select Re-Statement Period and Drug Identifier



3. Add or edit the Manufacturer’s ASP, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded in the respective fields, using the following criteria:

Manufacturer’s ASP: numeric
 must have three decimal places (i.e., XXXXXX.XXX).
 can be a positive number, a negative number, or be equal to 0.000

Number of ASP units: numeric
 must have three decimal places (i.e., XXXXXXXXX.XXX).
 can be a positive number, a negative number, or be equal to 0.000

Wholesale Acquisition Cost: numeric
 must have three decimal places (i.e., XXXXXX.XXX).
 can be a positive number, a negative number, or be equal to 0.000

Number of Cap Units Excluded: optional
 numeric
 must have three decimal places (i.e., XXXXXXXXX.XXX).
 can be a positive number or be equal to 0.000

The fields populate, as shown in Figure 11-3.

Figure 11-3: Add/Edit Restate Financial Data – Add/Edit Data

The screenshot shows the 'Restate Add/Edit Financial Data' interface. The main content area includes the following information:

- Current Reporting Period: Q4 2018
- Select Re-Statement Period: Q3 2018
- For Reporting Period Q3 2018
- Please select the Drug Identifier*: 66995-8315-17
- Review Re-Statement List:

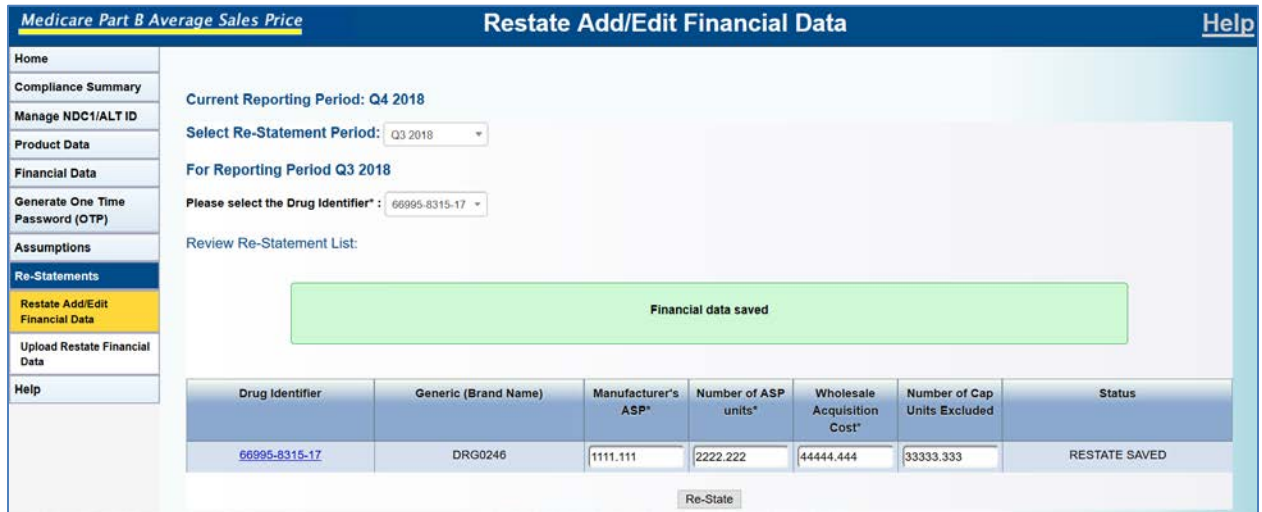
Drug Identifier	Generic (Brand Name)	Manufacturer's ASP*	Number of ASP units*	Wholesale Acquisition Cost*	Number of Cap Units Excluded	Status
66995-8315-17	DRG0246	1111.111	2222.222	44444.444	33333.333	PENDING

Re-State

4. Click on the **Re-State** button.

A message displays stating that the financial data have been saved, as shown in Figure 11-4.

Figure 11-4: Add/Edit Restate Financial Data – Data Saved Successfully



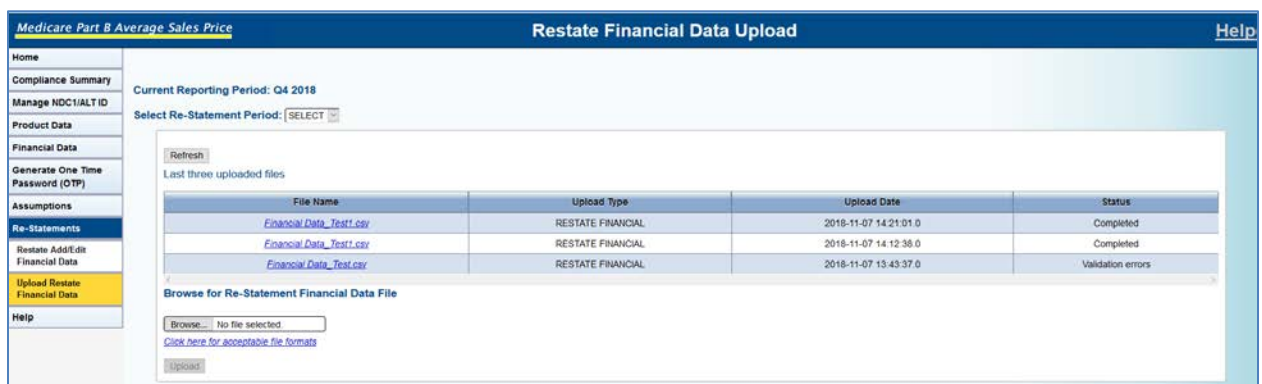
11.2 Upload Re-State Financial Data

ASP provides drug manufacturers the ability to restate Medicaid Part B financial data to CMS. Perform the following steps to upload financial data using the file transfer process.

1. Click on **Re-statements** from the menu on the left side of the screen, and then click on **Upload Restate Financial Data**.

The “Upload Restate Financial Data” screen displays with the current reporting period showing, as shown in Figure 11-5.

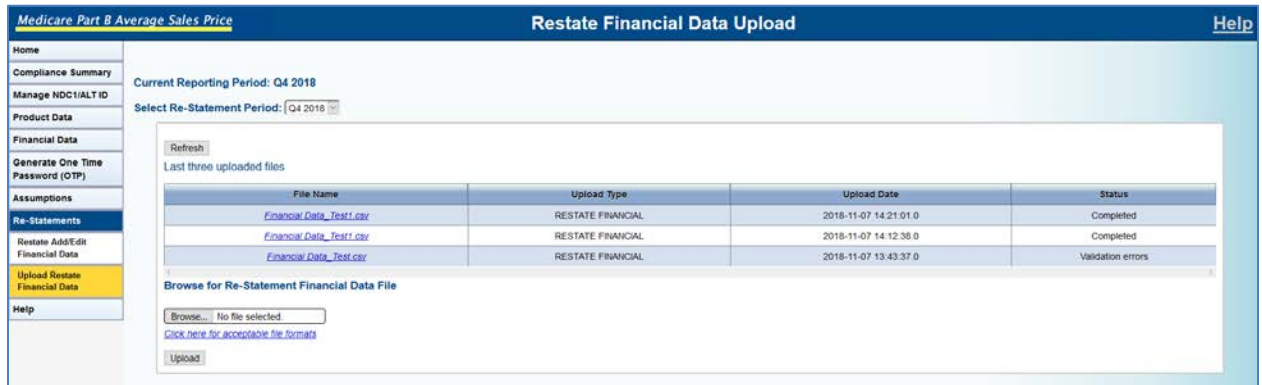
Figure 11-5: Upload Restate Financial Data Screen



2. To upload data, select a reporting period from the dropdown menu in the “Select Re-Statement Period:” field.

The “Select Re-Statement Period:” field populates, as shown in Figure 11-6.

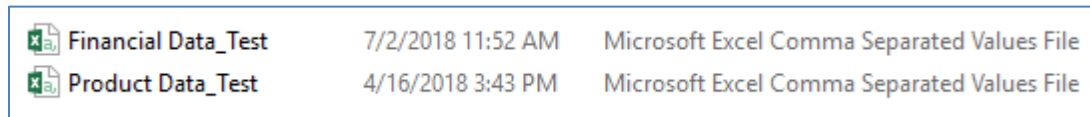
Figure 11-6: Upload Restate Financial Data Screen – Select Re-Statement Field Populated



3. Click on the **Browse** button.

The file directory opens, as shown in Figure 11-7.

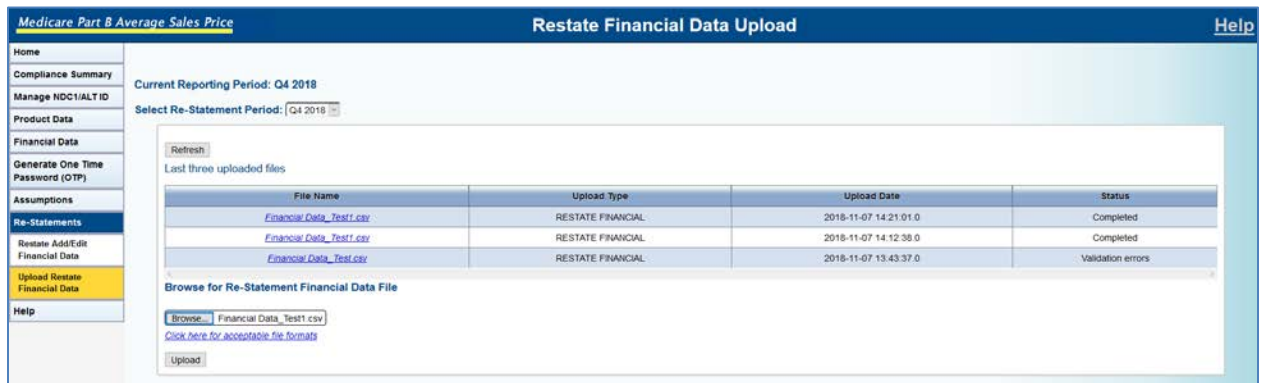
Figure 11-7: File Directory Window



4. Select a file in the appropriate format and double-click on it.

The “Browse” field is populated, as shown in Figure 11-8.

Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated



5. Click on the **Upload** button.

A message displays confirming that the financial data were saved successfully, and the financial data are listed, as shown in Figure 11-9.

Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully

Medicare Part B Average Sales Price **Restate Financial Data Upload** [Help](#)

Home | Compliance Summary | Manage NDC/ALF ID | Product Data | Financial Data | Generate One Time Password (OTFP) | Assumptions | Re-Statements | Revoke Audit | Financial Data | **Upload Restate Financial Data** | Help

Current Reporting Period: Q4 2018
 Select Re-Statement Period: Q3 2018

Last three uploaded files

File Name	Upload Type	Upload Date	Status
Financial Data_Upload.asp	RESTATE FINANCIAL	2018-11-13 11:47:57.0	Completed
Financial Data_Upload.asp	RESTATE FINANCIAL	2018-11-13 11:47:19.0	Validation errors
Financial Data_Upload.asp	RESTATE FINANCIAL	2018-11-07 14:21:01.0	Completed

Browse for Re-Statement Financial Data File

Browse: No file selected.
[Click here for accessible file format](#)
 Upload

Report of Transmitted Drugs via File Upload
 Upload Date: 2018-11-13 11:47:57.0

42 out of 150 financial data have been saved successfully.

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Strips Excluded	Status
8895-3236-11	DRO0228	801.263	1538.468	1196.856		Uploaded-Success
8895-4205-11	DRO0499	795.426	328.254	817.090		Uploaded-Success
8895-4207-11	DRO0499	3177.847	771.749	3268.340		Uploaded-Success
8895-1040-10	DRO0488	583.140	215.296	583.760		Uploaded-Success
8895-1041-10	DRO0488	1184.430	1877.413	1187.520		Uploaded-Success
8895-4995-20	DRO5376	791.600	4530.887	791.600		Uploaded-Success
8895-3073-22	DRO6110	2.700	9094.000	7.530		Uploaded-Success

12. Drug Certification

Drug certification is a process where a drug manufacturer certifies the accuracy of the drug data. In this section, data are selected and marked for immediate certification or later certification. Selection may be one drug product item, a list of drug items or all drug items pending certification for a manufacturer. The Drug Manufacturer gathers required quarterly drug data and submits it to CM for ASP pricing. The Drug Manufacturer certifies that the data reported are correct.

With the appropriate user access, the ASP Application provides drug manufacturers the ability to certify the accuracy of drug data that have been previously submitted. This is for the Certifier to perform the following steps to certify drug data online.

1. Log into the application, click on **Certification** on the left of the screen, and then click on **Drug Certification**.

The “Drug Certification” screen displays showing the current reporting period and “Select Option” is defaulted to “Drug data pending certification.” The “Manufacturer Name” field is defaulted to “View All” and displays all of the drugs for the selected quarterly reporting period in the results, as shown in Figure 12-1.

Figure 12-1: Drug Certification Screen

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Bites Excluded	Status	Drug Details	Certify
0001-2404-02	DRG0317	43.810	7175.937	127.200		SAVED	Product	<input type="checkbox"/>
0001-2405-02	DRG0317	67.190	30211.197	190.830		SAVED	Product	<input type="checkbox"/>
0001-2406-02	DRG0317	112.110	8445.499	241.600		SAVED	Product	<input type="checkbox"/>
0001-2409-02	DRG0317	213.850	2285.139	366.150		SAVED	Product	<input type="checkbox"/>
0001-2411-02	DRG0317	270.460	10004.492	549.350		SAVED	Product	<input type="checkbox"/>
0001-2413-02	DRG0317	158.400	7899.278	348.100		SAVED	Product	<input type="checkbox"/>
0001-2416-01	DRG0317	99.610	13543.368	229.060		SAVED	Product	<input type="checkbox"/>
0001-8802-16	DRG0317	48.130	26447.202	127.200		SAVED	Product	<input type="checkbox"/>
0001-8804-16	DRG0318	79.880	119548.102	190.830		SAVED	Product	<input type="checkbox"/>
0001-8805-16	DRG0318	114.580	35053.884	241.600		SAVED	Product	<input type="checkbox"/>
0001-8809-10	DRG0317	119.470	21464.029	229.060		SAVED	Product	<input type="checkbox"/>
0001-8800-02	DRG0318	231.190	10641.140	366.150		SAVED	Product	<input type="checkbox"/>
0001-8801-02	DRG0318	301.070	45844.610	549.350		SAVED	Product	<input type="checkbox"/>
0001-8802-02	DRG0318	190.460	22088.469	348.100		SAVED	Product	<input type="checkbox"/>

2. Select a Reporting Period from the dropdown list (if not using the current one), select the desired manufacturer from the “Manufacturer Name” dropdown list, and click on the **Submit** button.

The status for the drug information for the selected quarter and manufacturer displays as “SAVED,” as shown in Figure 12-2.

Figure 12-2: Selected Drugs to be Certified

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify
00851-2404-02	DR02317	43.610	7175.637	127.200		SAVED	Product	<input type="checkbox"/>
00851-2405-02	DR02317	67.190	30211.107	190.830		SAVED	Product	<input type="checkbox"/>
00851-2406-02	DR02317	112.110	8448.499	241.880		SAVED	Product	<input type="checkbox"/>
00851-2409-02	DR02317	213.850	3205.139	366.150		SAVED	Product	<input type="checkbox"/>
00851-2411-02	DR02317	279.400	10004.492	549.350		SAVED	Product	<input type="checkbox"/>
00851-2413-02	DR02317	158.400	7695.276	346.100		SAVED	Product	<input type="checkbox"/>
00851-2416-01	DR02317	99.510	13545.360	229.060		SAVED	Product	<input type="checkbox"/>
00851-8802-16	DR02317	46.130	26447.202	127.200		SAVED	Product	<input type="checkbox"/>
00851-8804-16	DR02318	79.800	119548.102	190.830		SAVED	Product	<input type="checkbox"/>
00851-8805-16	DR02318	114.560	33053.884	241.880		SAVED	Product	<input type="checkbox"/>
00851-8809-10	DR02317	110.470	21484.029	229.060		SAVED	Product	<input type="checkbox"/>
00851-8800-02	DR02318	231.180	10641.148	366.150		SAVED	Product	<input type="checkbox"/>
00851-8801-02	DR02318	301.670	45044.610	549.350		SAVED	Product	<input type="checkbox"/>
00851-8802-02	DR02318	190.400	22088.469	346.100		SAVED	Product	<input type="checkbox"/>

3. Select the drugs to be certified by clicking the “Certify” check box of the individual drugs and clicking on the **Certify Selected Data** button, or by clicking on the **Certify All Data** button at the bottom of the page. If a drug is checked inadvertently, click on the **Reset All Checked Drugs** button to clear the drug check boxes.

A “Data Certification Statement” window displays, as shown in Figure 12-3.

Figure 12-3: Data Certification Statement

Data Certification Statement:

I certify that the reported Average Sales Prices were calculated accurately and that all Product and Financial information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

Please agree to data certification statement

I agree to the above certification statement

[Proceed to Certify Data](#)

4. Review the statement, click on the checkbox next to “I agree to the above certification statement,” and click on the **Proceed to Certify Data** button.

A message displays stating that the data have been successfully certified, as shown in Figure 12-4.

Figure 12-4: Drug Information Successfully Certified

Medicare Part B Average Sales Price Drug Certification [Help](#)

Name: _____

Verify One Time Password (OTP): _____

Reporting Period: [Q1 2019] Select Option: [Drug data pending certification] Manufacturer Name: [VLT]

Certification: Drug Identifier: _____ Submit

8 out of 14 drug product data has been successfully certified.

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

Showing all 14 results		Previous		First	Last	Next				
Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify		
0001-2413-02	DR02317	153,400	7895,278	348,100		SAVED	Product	<input type="checkbox"/>		
0001-2416-01	DR02317	99,510	13643,368	229,060		SAVED	Product	<input type="checkbox"/>		
0001-8802-16	DR02317	48,100	26947,202	127,200		SAVED	Product	<input type="checkbox"/>		
0001-8804-16	DR02318	79,800	119248,102	190,830		SAVED	Product	<input type="checkbox"/>		
0001-8805-16	DR02318	114,000	33053,804	241,680		SAVED	Product	<input type="checkbox"/>		
0001-8809-10	DR02317	110,470	21464,029	229,060		SAVED	Product	<input type="checkbox"/>		
0001-8800-02	DR02318	231,190	10641,149	368,150		SAVED	Product	<input type="checkbox"/>		
0001-8801-02	DR02318	351,070	45644,810	549,350		SAVED	Product	<input type="checkbox"/>		
0001-8802-02	DR02318	190,400	22888,469	348,100		SAVED	Product	<input type="checkbox"/>		

Showing all 14 results Previous First Last Next

Appendix A: Record of Changes

Table A-1: Record of Changes

Version Number	Date	Author/Owner	Description of Change
1.0	03/23/2018	Maureen Campbell	Initial Release
1.1	04/26/2018	Maureen Campbell	Section 4.1: Add Product Data - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," "FDA Approval Date," and "Alternate ID."
1.1	04/26/2018	Maureen Campbell	Section 4.3: Update Product Data - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," "FDA Approval Date," and "Alternate ID."
1.1	04/26/2018	Maureen Campbell	Section 7.1: Restate Online - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," and "FDA Approval Date."
2.0	3/28/2019	Maureen Campbell	Globally: Changes to reflect changes in the application for Release 9

Appendix B: Acronyms

Table B-1: Acronyms

Acronym	Definition
ALT ID	Alternate Identification
AMP	Average Manufacturer Price
ARS	Acceptable Risk Safeguards
ASP	Average Sales Price
AWP	Average Wholesale Price
CAP	Competitive Acquisition Pricing
CHIP	Children's Health Insurance Program
CLFS	Clinical Laboratory Fee Schedule
CM	Center for Medicare
CMCS	Center for Medicaid and CHIP Services
CMS	Centers for Medicare & Medicaid Services
CSV	Comma-Separated Values
DAS	Division of Ambulatory Services
DCCA	Data Computer Corporation of America
EIDM	Enterprise Identity Management
ESRD	End Stage Renal Disease
EUA	Enterprise User Administration
FDA	Food and Drug Administration
FFS	Fee-for-Service
FFSDCS	Fee-for-Service Data Collection System
HHS	Health and Human Services
IVR	Interactive Voice Response
MFA	Multi-Factor Authentication
MMA	Medicare Modernization Act

Acronym	Definition
NDC	National Drug Code
OIG	Office of the Inspector General
OPPS	Outpatient Prospective Payment System
OTP	One Time Password
PII	Personally Identifiable Information
RIPD	Remote Identity Proofing
SMS	Short Message Service
SNOW	Service Now
URL	Uniform Resource Locator
WAC	Wholesale Acquisition Cost
XLC	eXpedited Life Cycle