Centers for Medicare & Medicaid Services
Center for Medicare Management (CM)
7500 Security Blvd
Baltimore, MD 21244-1850

Center for Medicare Management (CM)
Part B Drug Average Sale Price (ASP)
User Manual for Drug Manufacturers

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APPROVALS

Submitting Organization's Approving Authority:

	Ray Lee		410-992-3760
Signature	Printed Name	Date	Phone Number
DCCA			

CMS' Approving Authority:

	Dona Coffman		410-786-0260
Signature	Printed Name	Date	Phone Number
Project Officer			

CMS Business Owner:

	Sarah Harding		410-786-4001
Signature	Printed Name	Date	Phone Number
Government Task Leader			

REVISION HISTORY

Version	Date	Point of Contact/Organization	Description of Changes
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1.5	5/30/2014	Richard E. McCarthy/DCCA	Revised screen captures throughout the document
2.0	7/21/2014	Richard E. McCarthy/DCCA	Revised screen captures throughout the document

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1 Introduction

1.1 What is the Medicaid Part B 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 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.
The business purpose of the project is to comply with the Sections 303(b) and (c) of the Medicare Modernization Act (MMA) of 2003. Section 303 (b) and (c) of the MMA amended Title XVIII of the Act by revising section 1842(o), the pricing methodology for Part B drugs and biologicals, and adding section 1847A, the new average sale price drug payment methodology.

1.2 Purpose of the ASP Application

The purpose of the ASP Application is to:

- Provide CMS 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.

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 is 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, CMS will communicate the days remaining in the submission period to each manufacturer and whether or not 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 system, they need to choose either to submit their data on line 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 system. Validations and error messages will ensure that the drug manufacturer is entering data in adherence to the system 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 ADP drug data is 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 is able to 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 will be 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 has been submitted, the drug manufacturer can view all drug data certified in the current reporting period and view whether or not current and previous drug submissions is 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 will assign each drug to one or more billing codes and determine the billing units per billing code. The ASP for each billing code will be calculated based on the weighted average of all ASPs within a billing code. Where a billing code does not exist, CMS will submit a request for one to be established.

Updated ASP data is shared with each drug manufacturer. Either CMS through quality review or drug manufacturers may identify errors in the data. The drug manufacturer submits any corrected data so that CMS 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/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 will confirm the written certification received with the file.

CMS creates an output file to share with OIG so they can complete ASP comparison studies. Updates with the 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 system 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 ASPs for not otherwise classified billing codes,
- File of Competitive Acquisition Pricing (CAP) data, and
- File of Outpatient and ASC Drug Pricing Data.

1.3 ASP User Roles

The ASP Application is a role-based system. This means that certain system functions have been linked to specific "user role profiles." When a new user is given access to the ASP Application, system administrators link the user's ID to the profile that provides access to the specific functions they need. The ASP Application user roles are as follows:

- Drug Manufacturers: Responsible for the calculation and quality of the Part B drug prices. Drug manufacturers can be both Submitters and Certifiers.
- CM Personnel: Responsible for the calculation and quality of the Part B drug prices.

- Drug Compendium Contractors: Responsible for submitting drug pricing compendia data for new drugs.
- Fee For Service Contractors: Responsible for submitting new drug data to CM for pricing calculations and billing code assignment
- CMCS: Future participant to provide AMP data for comparative analyses of the ASP to the AMP.

2 ASP Application Access

A CMS User ID is required to access the ASP Application. To obtain a CMS User ID, you must complete the *Application for Access to the Centers for Medicare & Medicaid Services (CMS) Computer Systems* (Form CMS-20037). If you already have a CMS User ID, then you must submit a request to access the ASP Application. The *Application for Access to the Centers for Medicare & Medicaid Services (CMS) Computer Systems* (Form CMS-20037) can be downloaded from the CMS Website at: http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Downloads/EUAaccessform.pdf Users that have been approved for access to the ASP application are assigned a CMS user ID and a password. Users are required to access the CMS Portal to begin the authentication and role assignment process. Users enter their assigned user ID in the User ID field and enter **ASP User** in the Request field in the CMS portal. Users are then directed to the EIdM Authentication System. The EIdM Authentication System performs identity proofing on the user. The EIdM Authentication System will prompt 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 and password. After the user successfully creates a username and password, the EIdM Authentication System will begin the identity proofing process. After the user's identity is verified, the CMS Portal will push the user's data to the ASP application. Users are assigned a role, assigned organization codes, and the NDCI contact is applied to the user.

2.1 ASP Application Access Process

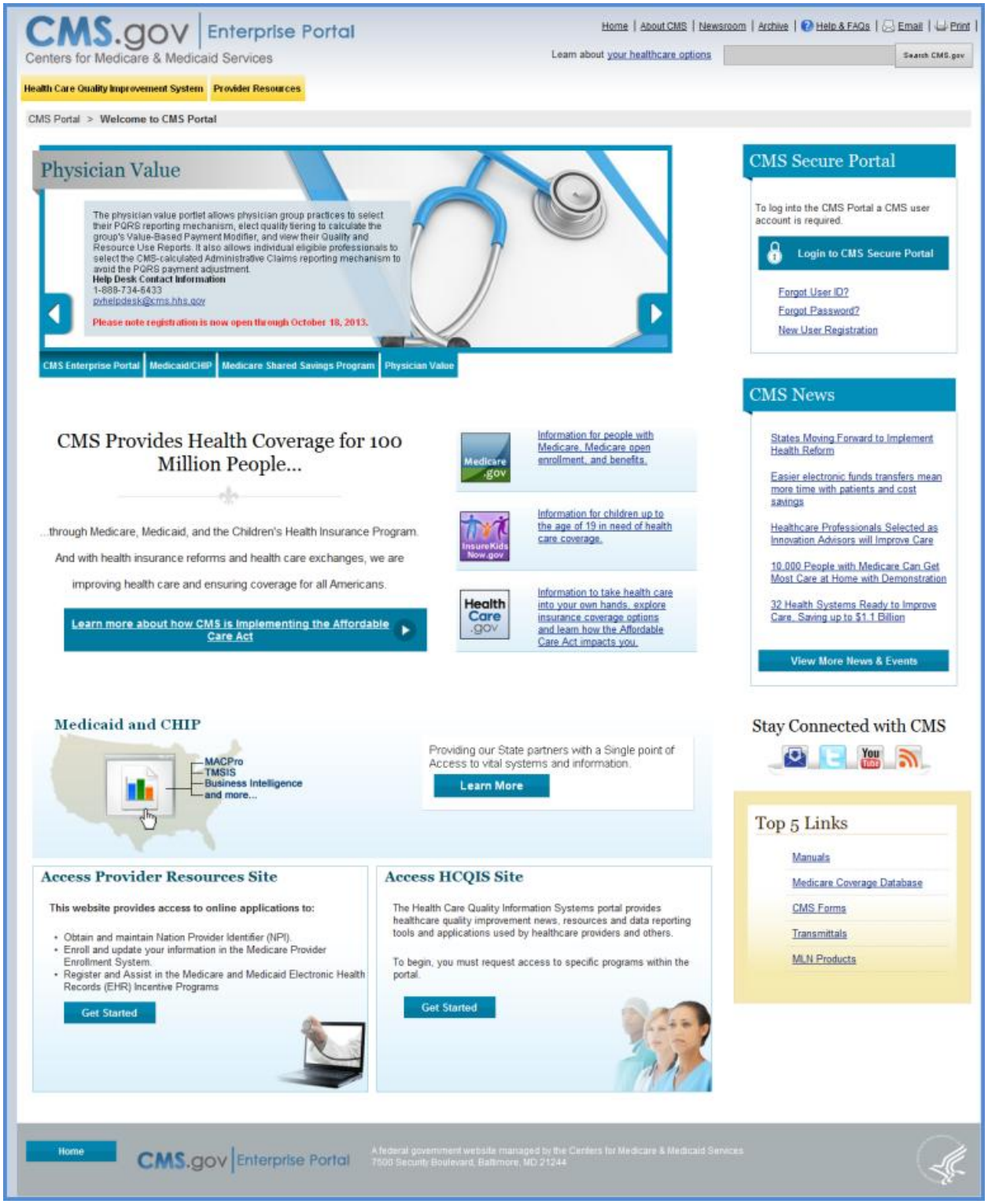
ASP users with an existing CMS Portal username and password can skip Section 2.1.1 and continue on to Section 2.1.2, Requesting ASP Application Access.

2.1.1 Obtaining a CMS Portal Username and Password

A CMS Portal 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 URL in your browser: https:\\portal.cms.gov. The CMS Portal Home Page is shown in Figure 2-1.

Figure 2-1: CMS Portal Home Page

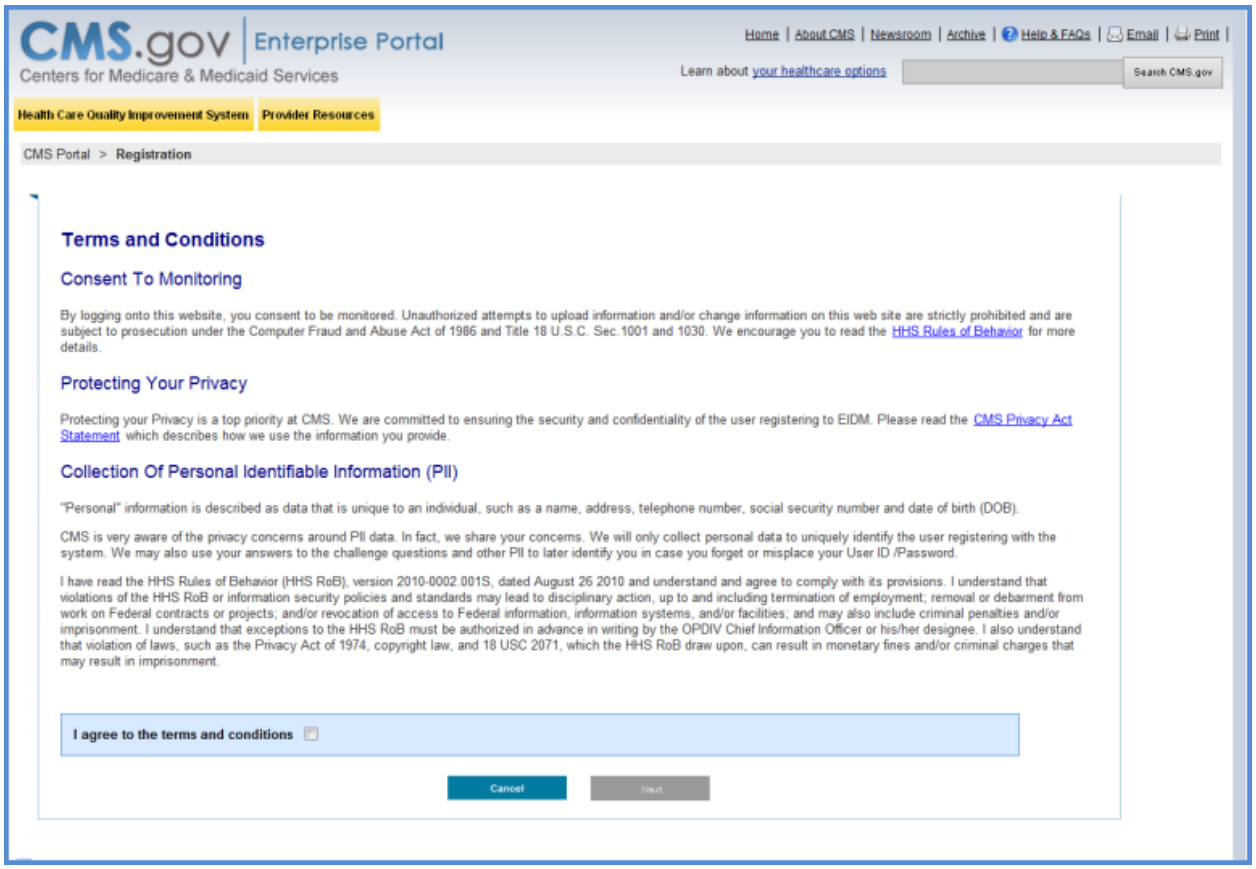


2. Click the **New User Registration** link in the CMS Secure Portal section located in the top-right section of the CMS Portal home page. The CMS Secure Portal section of the page is shown in Figure 2-2.

Figure 2-2: CMS Secure Portal Section

3. The Terms and Conditions Page will open, as shown in Figure 2-3.

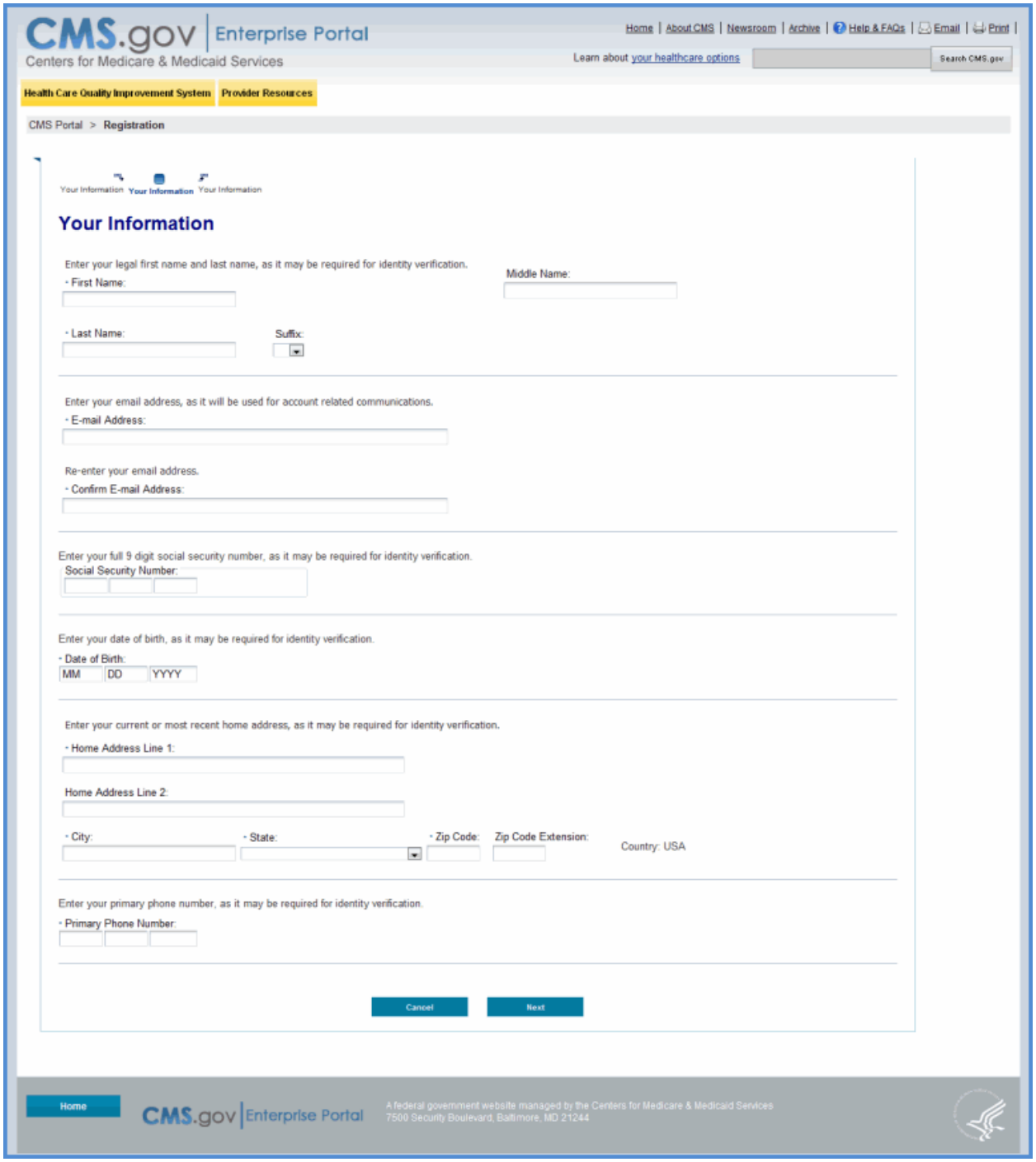
Figure 2-3: CMS Portal Terms and Conditions Page



4. Read through the Terms and Conditions on the page. The page states that you content to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it will only be used to uniquely identify the new user who is registering with the system. 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 the **Next** button. Users must agree to the terms and conditions to continue the registration process. The CMS Portal Registration page opens, as shown in Figure 2-4.

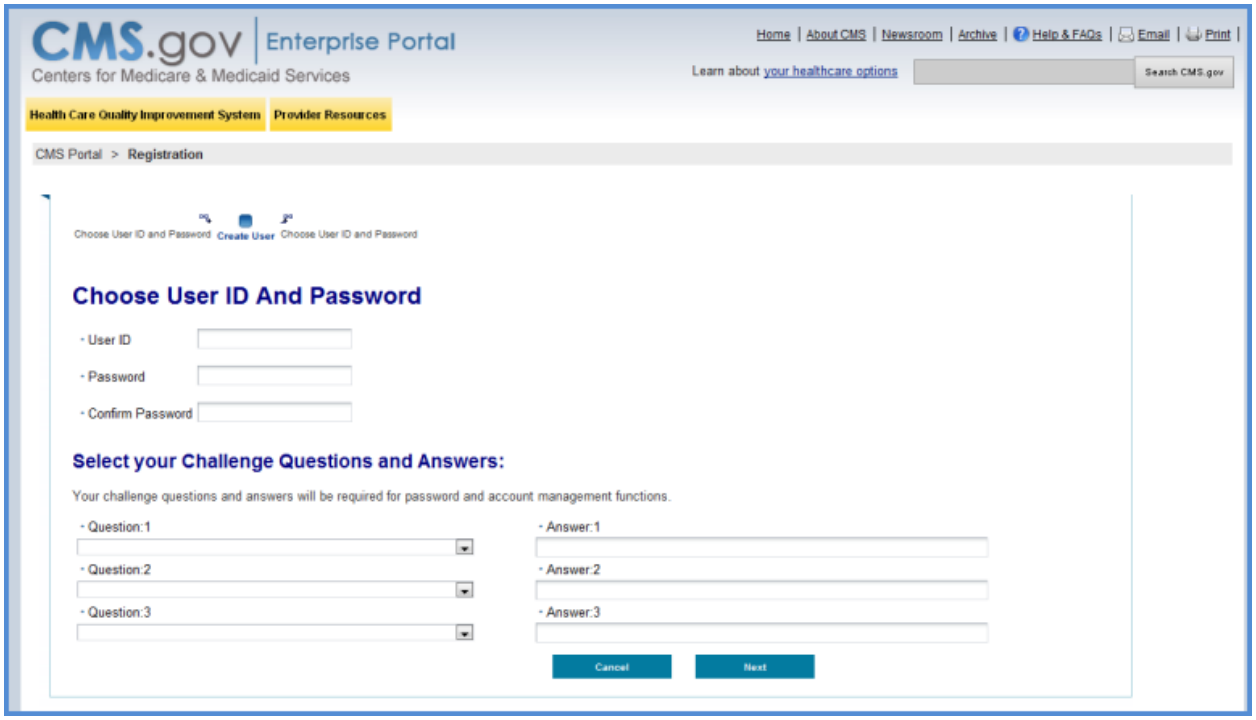
Figure 2-4: CMS Portal Registration Page



5. 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.

6. Click **Next** when completed. The screen shown in Figure 2-5will be displayed.

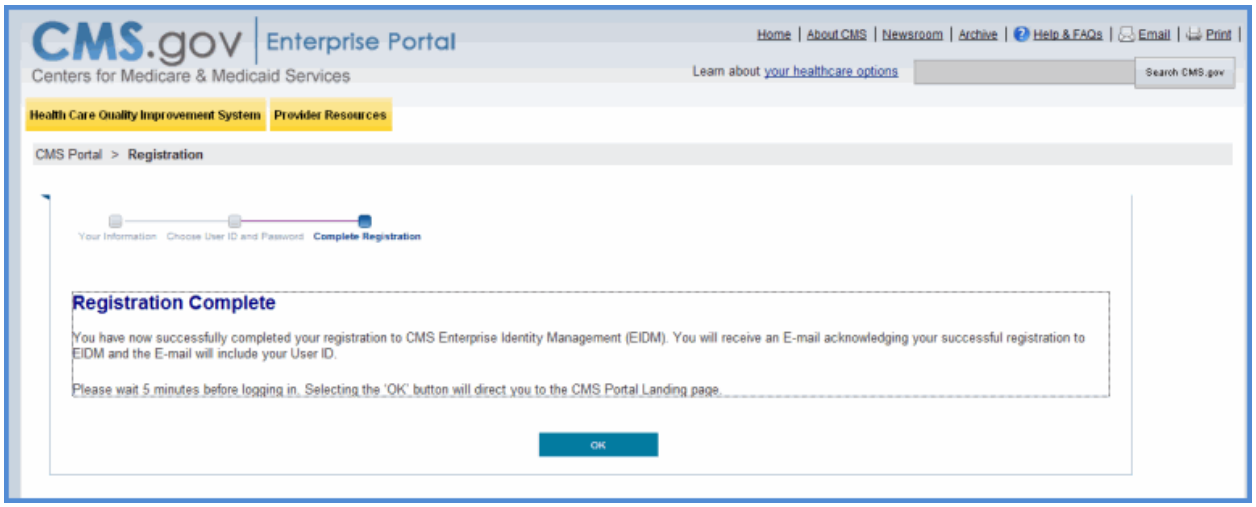
Figure 2-5: CMS Portal User ID and Password Selection



7. 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 (.).
8. Enter your desired password in the **Password** field. The CMS Portal password must conform to the following CMS 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 a day;
   d. Contain at least one (1) letter and one (1) number;
   e. Contain at least one (1) uppercase and one (1) lowercase letter;
   f. Not contain your User ID; and
   g. Be different from your previous six (6) passwords.
9. Re-enter your desired password in the **Confirm Password** field.
10. Select a Challenge Question from each of the three (3) drop-down lists for which the answer is known.
11. Enter the answers to the Challenge Questions in the corresponding **Answer** fields. The special characters that are allowed are apostrophes (‘), hyphens (-), and spaces followed by alphanumeric characters.

12. Click the **Next** button to complete the registration process. The Registration Complete screen is displayed as shown in Figure 2-6.

Figure 2-6: CMS Portal Registration Complete



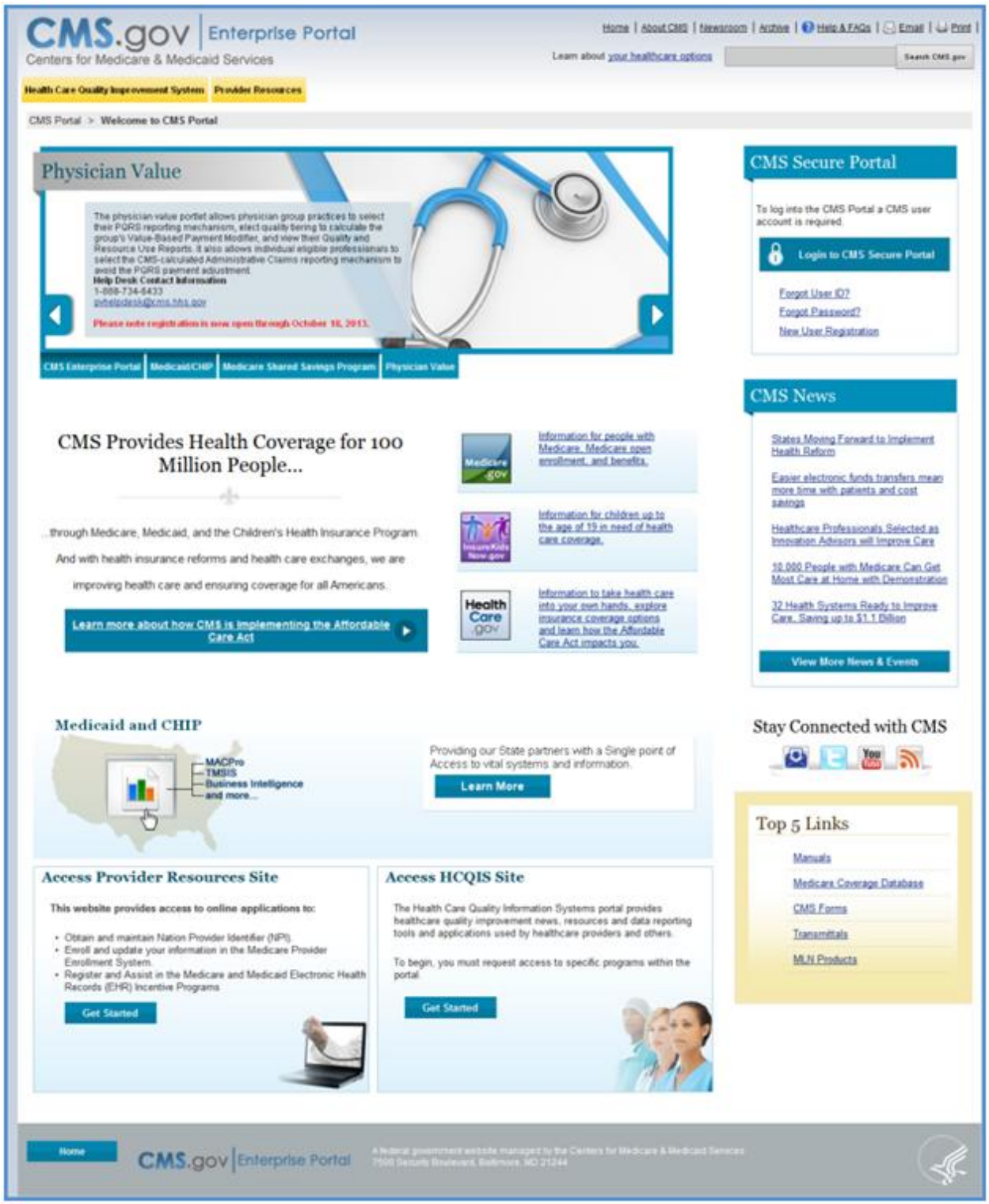
13. Click **OK** to return to the CMS Portal Landing page. Please wait at least five (5) minutes before logging on to the CMS Portal with your new user ID and password.

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) into your web browser and press **Enter**. The CMS Portal Home Page will open as shown in Figure 2-7.

Figure 2-7: CMS Portal Home Page

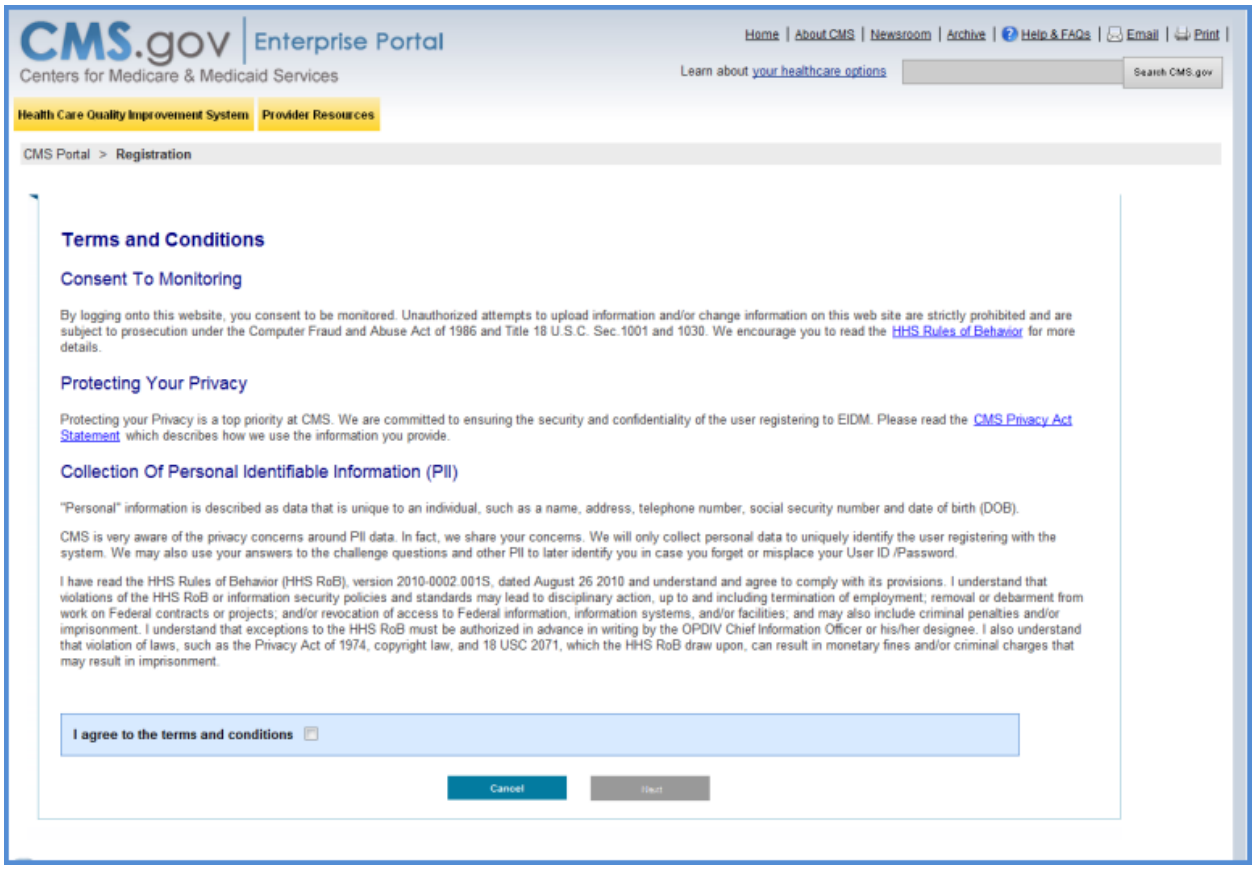


2. Click the **Login to CMS Secure Portal** button in the CMS Secure Portal section located in the top-right section of the CMS Portal home page. The CMS Secure Portal section of the page is shown in Figure 2-2.

Figure 2-8: CMS Secure Portal Section

3. The Terms and Conditions Page will open, as shown in Figure 2-3.

Figure 2-9: CMS Portal Terms and Conditions Page

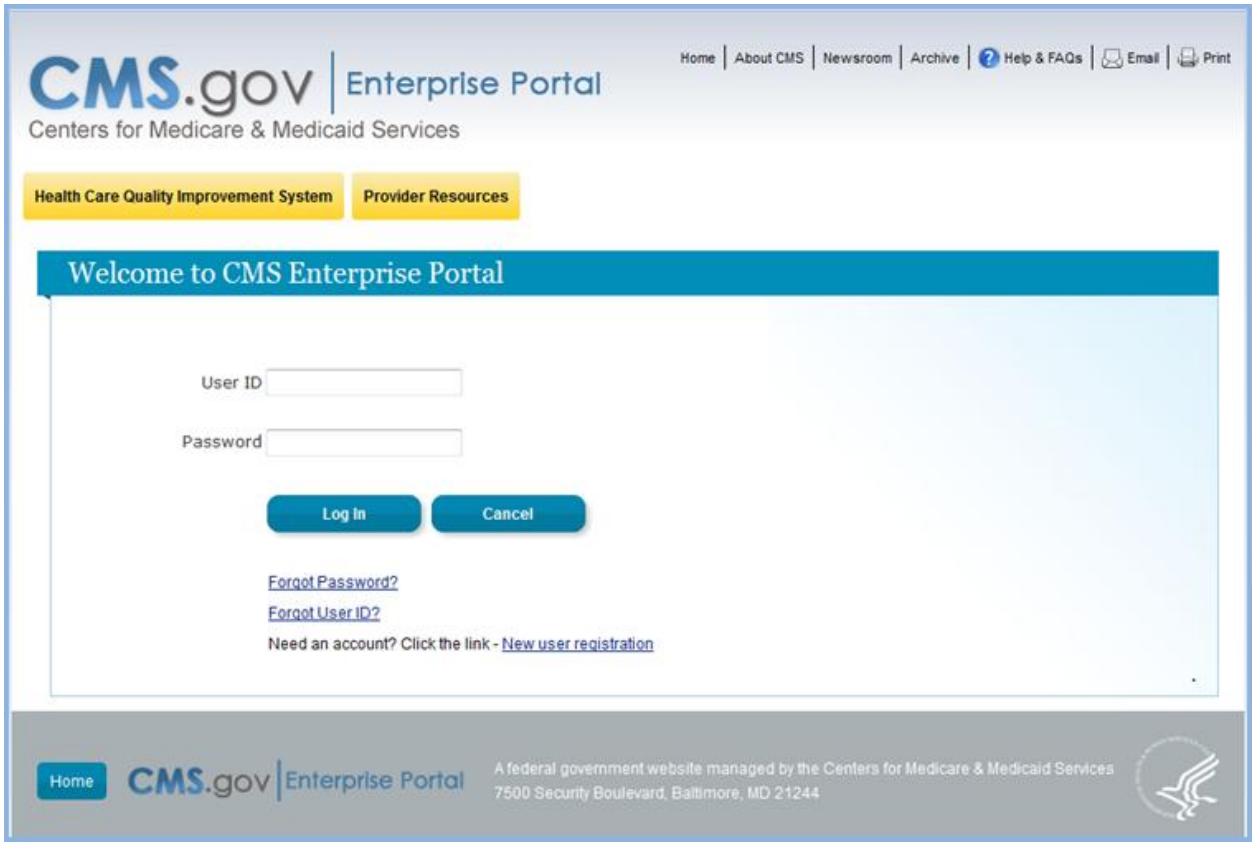


4. Read through the Terms and Conditions on the page. The page states that you content to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it will only be used to uniquely identify the new user who is registering with the system. 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 the **Next** button. Users must agree to the terms and conditions to continue the log-in process.

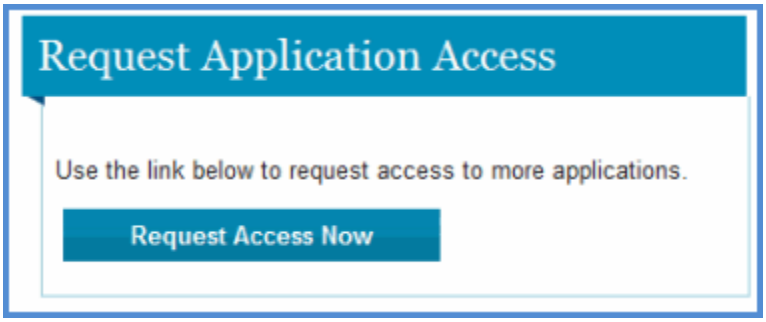
5. The CMS Portal Log In page opens as shown in Figure 2-10.

Figure 2-10: CMS Portal Log In Page



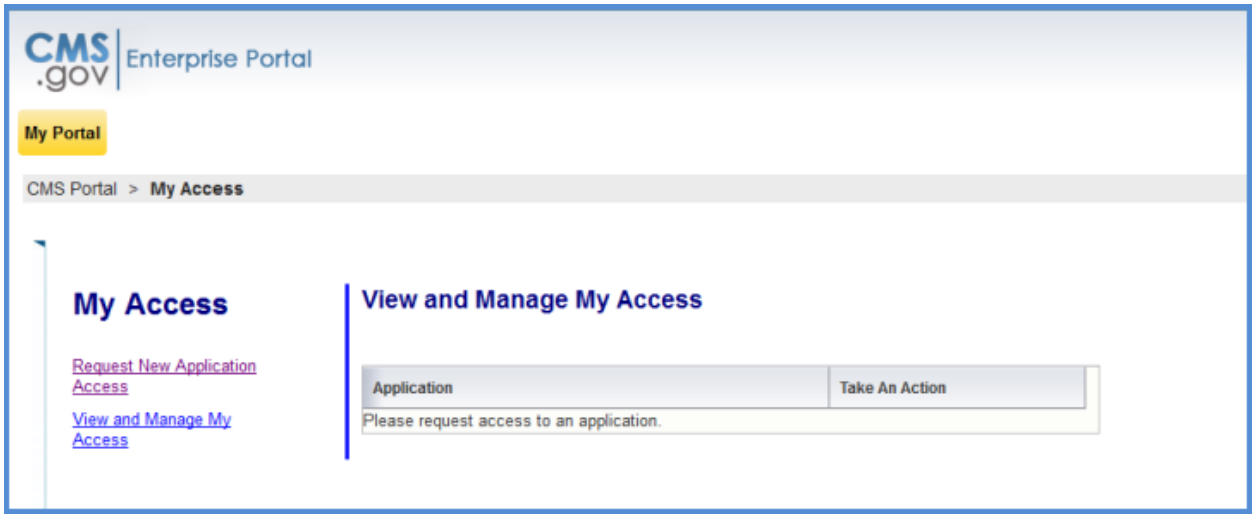
6. Enter your user ID and password and click **Log In**. The CMS Portal Home Page will open. Click the Request Access Now button on the on the CMS Portal home page, as shown in Figure 2-11.

Figure 2-11: Request Application Access Button



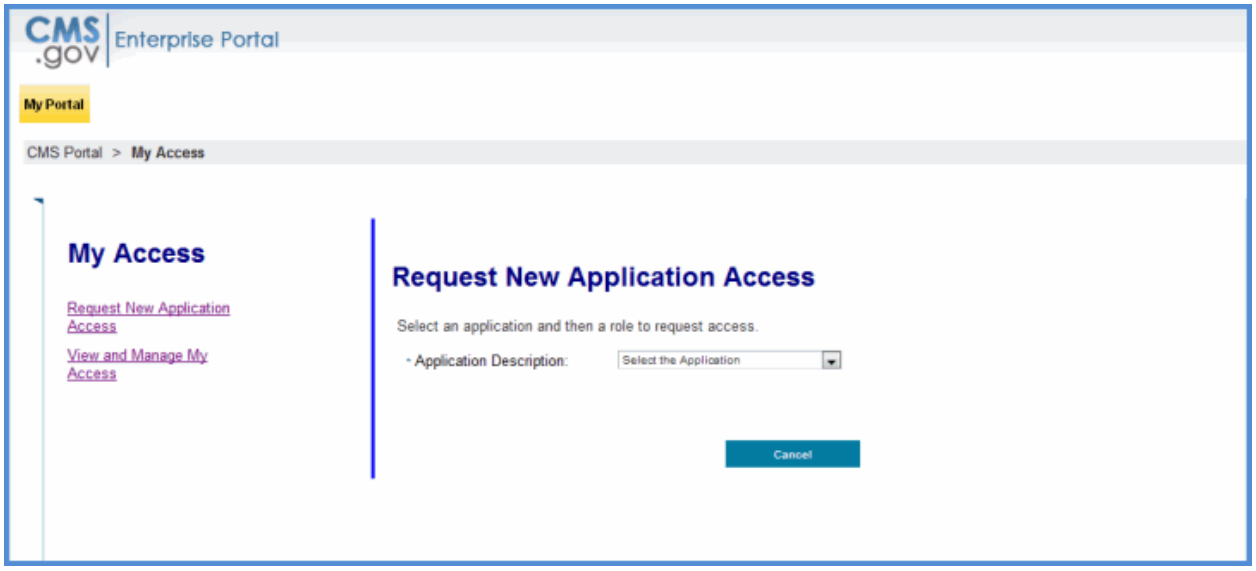
7. The View and Manage My Access page opens after clicking the Request Access Now button, as shown in Figure 2-12.

Figure 2-12: View and Manage My Access Page



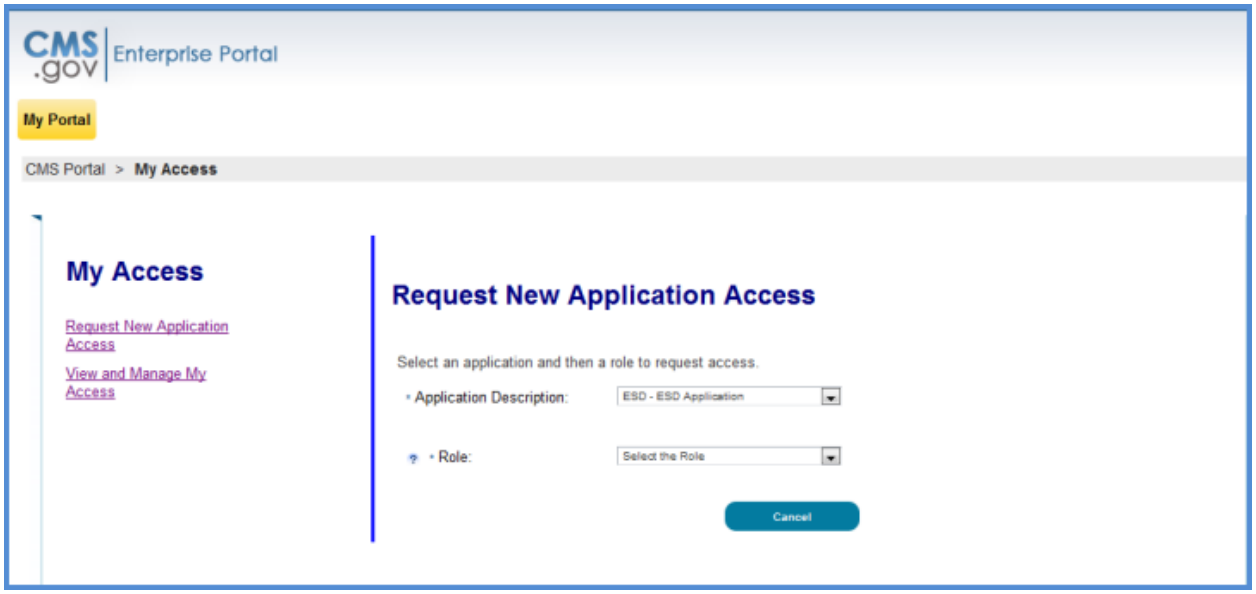
8. Click the **Request New Application Access** link in the My Access section. The request New Application Access Page opens as shown in Figure 2-13.

Figure 2-13: Request New Application Access Page



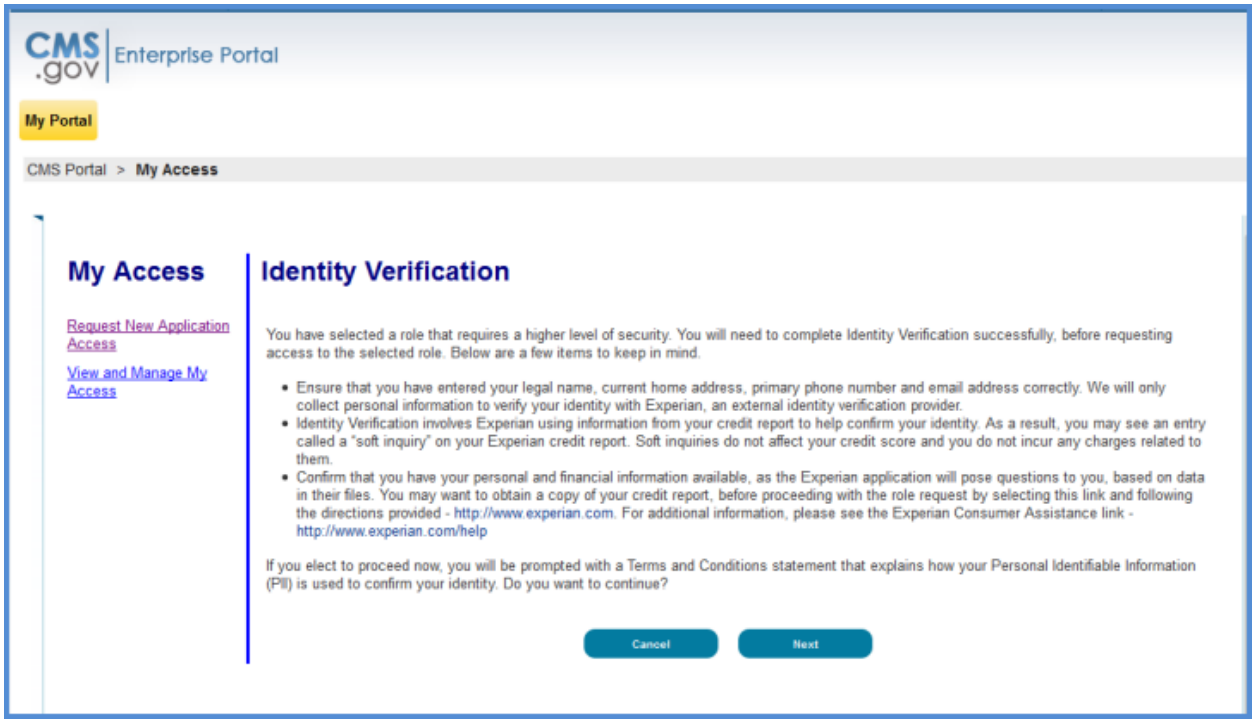
9. Click the **Application Description** drop-down box and select ASP Application.
10. A Role drop-down box will appear as shown in Figure 2-14.

Figure 2-14: Request New Application Access Page – Select Role



11. Select the appropriate role for the **Role** drop-down box and click **Submit**. The Identity Verification page opens, as shown in Figure 2-15.

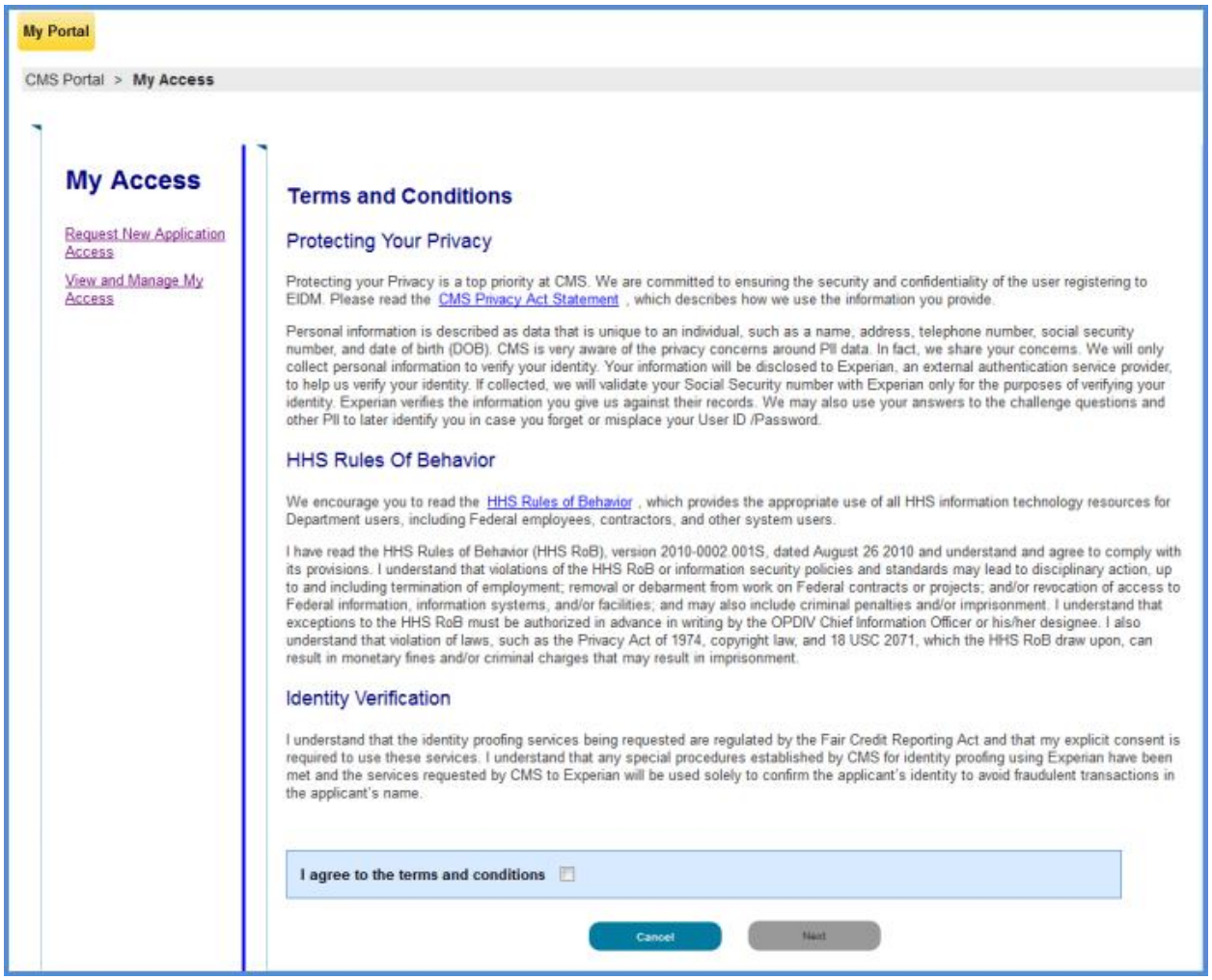
Figure 2-15: Identity Verification Page



12. The Identity Verification page describes how your personal information will be used to verify your identity before being assigned to the selected role. CMS uses Experian as an external identity provider. Experian uses information from your credit report to assist with confirming your identity. The Experian application will pose questions to you based

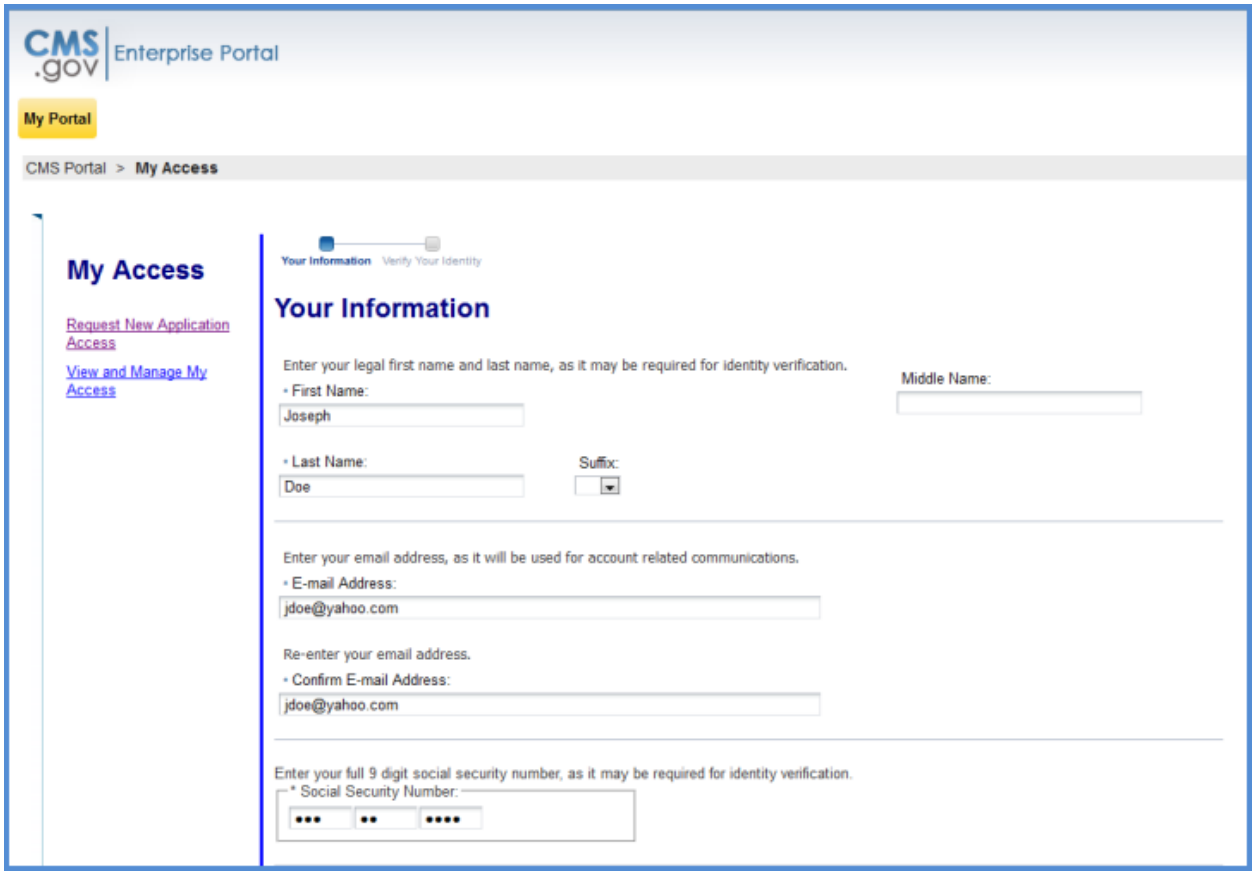
on the data in your report. Read the Identity Verification page carefully, and click the **Next** button to proceed. The Terms and Conditions page opens, as shown in Figure 2-16.

Figure 2-16: Terms and Conditions



13. Read through the Terms and Conditions on the page. The page states that you content to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it will only be used to uniquely identify the new user who is registering with the system. 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 the **Next** button. The Your Information page opens, as shown in Figure 2-17.

Figure 2-17: Your Information Page



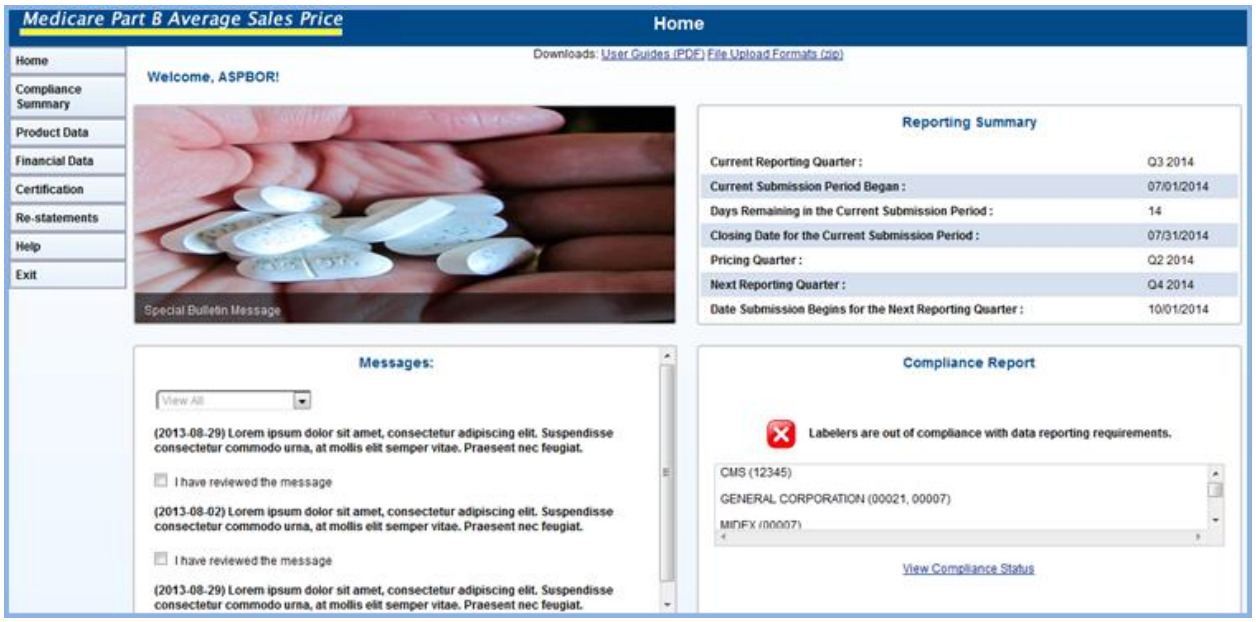
14. Much of the information on this page will be pre-populated in the corresponding fields. Enter any missing information in the fields and click the **Next** button. A page will open that will ask you a series of questions to verify your identity. These questions are generated from the information in your credit report. Answer the questions and click the **Next** button. Your identity will be verified based on your answers, and access to your requested role will be granted.
15. You will now be able to access the ASP Application using the CMS Portal. The ASP Application is accessed using a link that is displayed on you My Access page.

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 compliances). 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 is displayed with a gray background.

The ASP Application Home Page displays content based on your user role and the privileges assigned to the user role. The user roles in the ASP Application are dynamic and are maintained by the central system administrator. The ASP Application Home Page is shown in Figure 3-1.

Figure 3-1: ASP Application Home Page



4 Data Submission

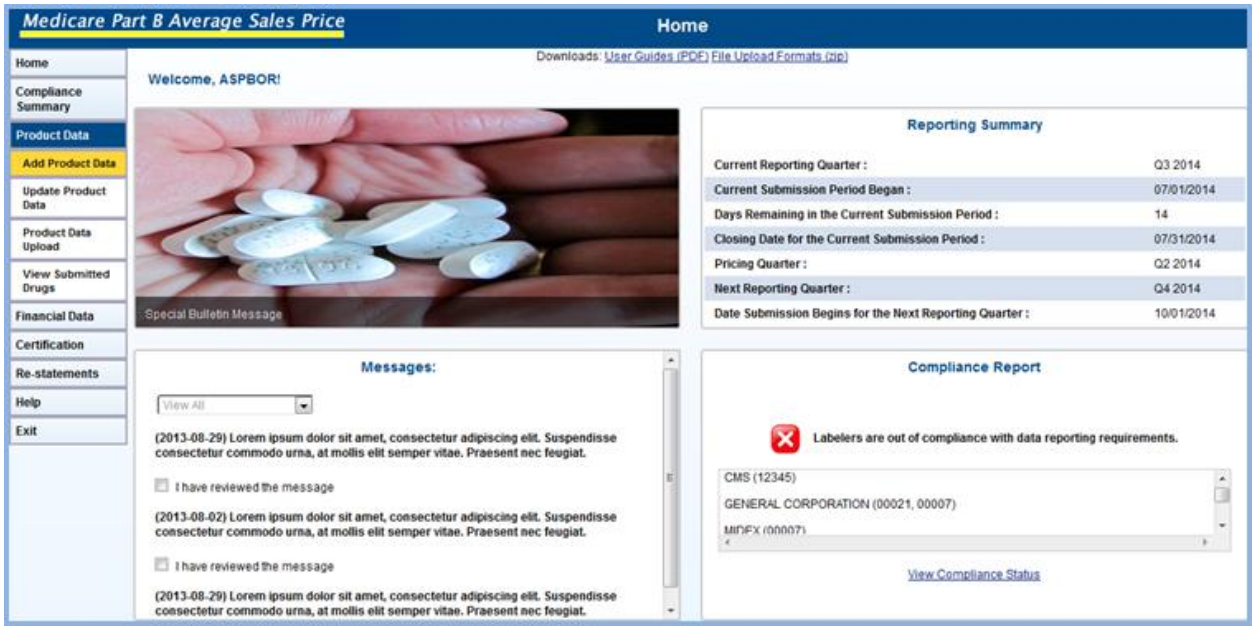
Drug manufacturers are required to submit quarterly drug data to the ASP application database for ASP pricing using a file transfer process or through online data entry. Drug data consists of product data and financial data. The following subsections detail the steps required to submit drug and product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

4.1 Online Product Data

The ASP database provides drug manufacturers the ability submit Medicaid Part B drug product data to CMS. Perform the following steps to enter drug product data using the online data entry process:

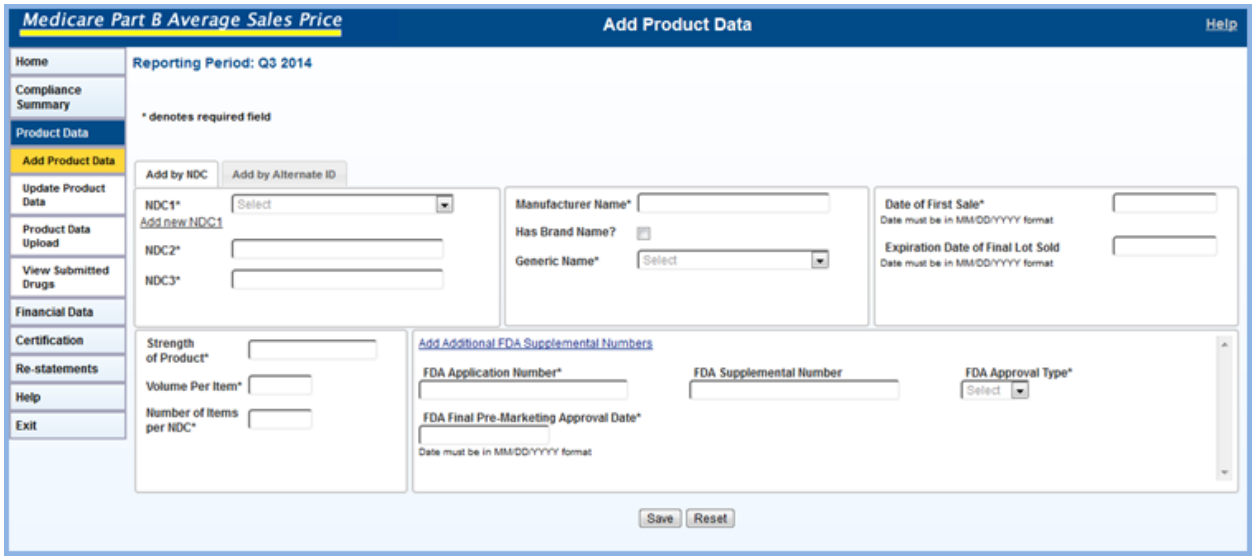
1. Click the **Product Data** button on the left side menu on the ASP Application Home Page and select **Add Product Data** from the drop-down list. The Add Product Data Selection on the ASP Application home page is shown in Figure 4-1.

Figure 4-1: Add Product Data Selection



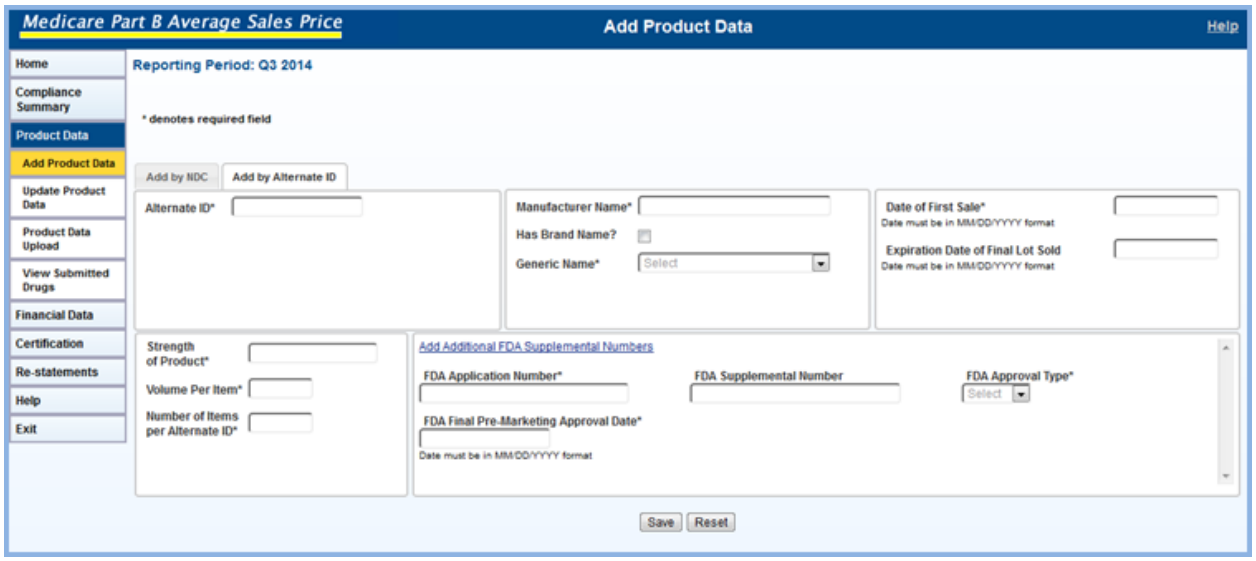
2. Click **Add Product Data**. The Add Product Data page opens, as shown in Figure 4-2.

Figure 4-2: Add Product Data



3. The Add Product Data pages defaults to the Add by NDC tab. Click the **Add by Alternate ID** tab to open the Add Product Data page with the Add by Alternate ID view which is displayed in Figure 4-3.

Figure 4-3: Add Product Data – Alternate ID



The following table describes the fields and the user actions on the Add Product Data screens.

Table 4-1 Add Product Data Page Information

Name	User Action	Comments
– NDC1	– Click the arrow on drop-down box and select the desired National Drug Code (NDC).	• NDC1 is a required field if Alternate ID is missing. • NDC1 is a 5-digit numeric entry.

Name	User Action	Comments
– Add new NDC1 (link)	– Click the link to add a New NDC1.	• Link displayed when the “Add by NDC” tab is selected.
– Add by Existing NDC1	– Click the link to enter an existing NDC1.	• Link is displayed when Add new NDC1 link is selected.
– NDC2	– Enter the NDC2 in the field.	• NDC2 is a required field if Alternate ID is missing. • NDC2 is a 4-digit numeric entry.
– NDC3	– Enter the NDC3 in the field.	• NDC3 is a required field if Alternate ID is missing. • NDC3 is a 2-digit numeric entry.
– Alternate ID	– Enter the Alternate Product ID	• Alt ID is required if NDC is missing.
– Manufacturer Name	– Enter the name of the drug’s manufacturer.	• If a new manufacturer is entered, the ASP Application, the manufacturer’s name will be marked ‘Pending.’
– Brand Name	– Enter the brand name of the drug in the field.	• The Brand Name field is only displayed when the Has Brand Name? box is checked. • Brand Name is required if the Has Brand Name? box is checked. • The Brand Name is limited to 250 characters. • The Brand Name field is optional.
– Generic Name	– Select the Generic Name from the drop-down list.	• The Generic Name is required.
– Date of First Sale	– Enter the date when the drug was first available for sale.	• The Date of First Sale is required. • The date format is MM/DD/YYYY. • Date of First Sale cannot occur before the FDA Final Pre-Marketing/Approval Date. • Date of First Sale must occur prior to the reporting period start date.
– Expiration Date of Final Lot Sold	– Enter the expiration date of the final lot that was sold. Scroll through the pop-up calendar for the desired date, or enter the date directly into the field.	• The date format is MM/DD/YYYY. • The Expiration Date of Final Lot Sold field is optional.
– Strength of Product	– Enter the Strength of product in the field.	• The Strength of Product is required. • The Strength of Product has a limit of 250 characters.
– Volume Per Item	– Enter the Volume per Item in the field.	• The Volume per Item is required. • The Volume per Item has a limit of 250 characters.

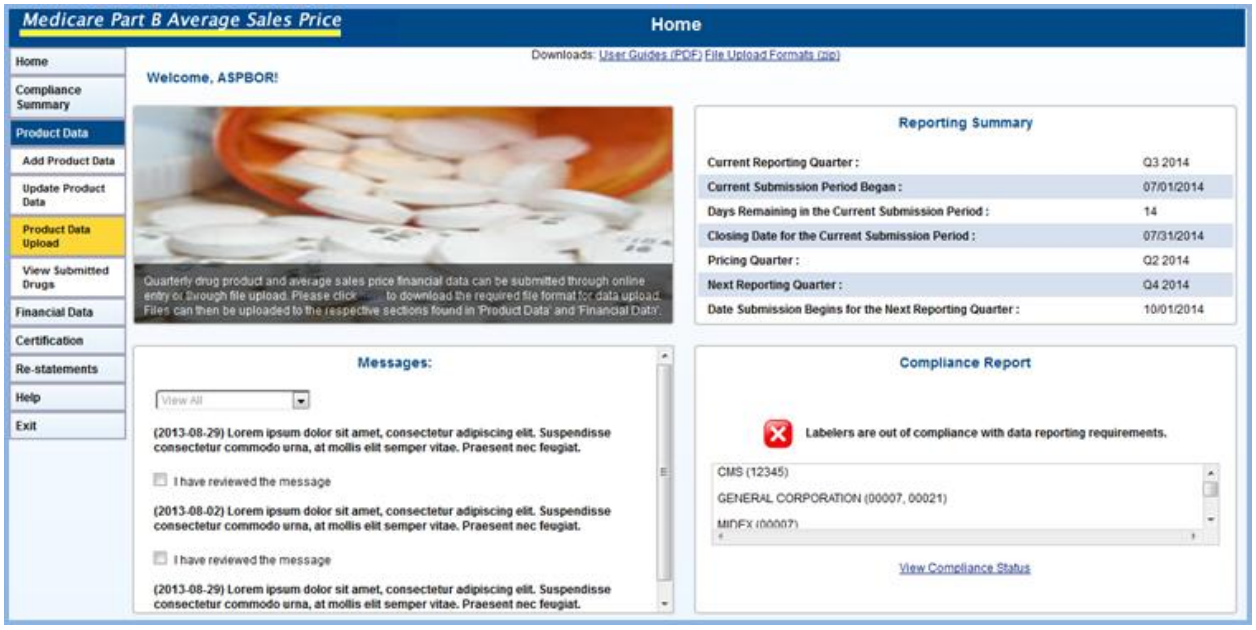
Name	User Action	Comments
– Number of Items per NDC	– Enter the Number of Items per NDC in the field.	• The Number of Items per NDC is required.
– FDA Application Number	– Enter the FDA Application Number in the field.	• The FDA Application Number is required. • The FDA Application Number format is alphanumeric.
– FDA Final Pre-Marketing Approval Date	– Enter the FDA Final Pre-Marketing Approval Date. Scroll through the pop-up calendar for the desired date, or enter the date directly into the field.	• The FDA Final Pre-Marketing Approval Date is required. • The date format is MM/DD/YYYY. • The FDA Final Pre-marketing Approval Date cannot be after the entered date of the data.
– FDA Supplemental Number	– Enter the FDA Supplemental Number in the field.	• The FDA Supplemental Number format must be alphanumeric. • The FDA Supplemental Number field is optional
– FDA Approval Type	– Select the FDA Approval Type from the drop-down list.	• The FDA Approval Type is required.

4.2 Upload Product Data – File Transfer

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

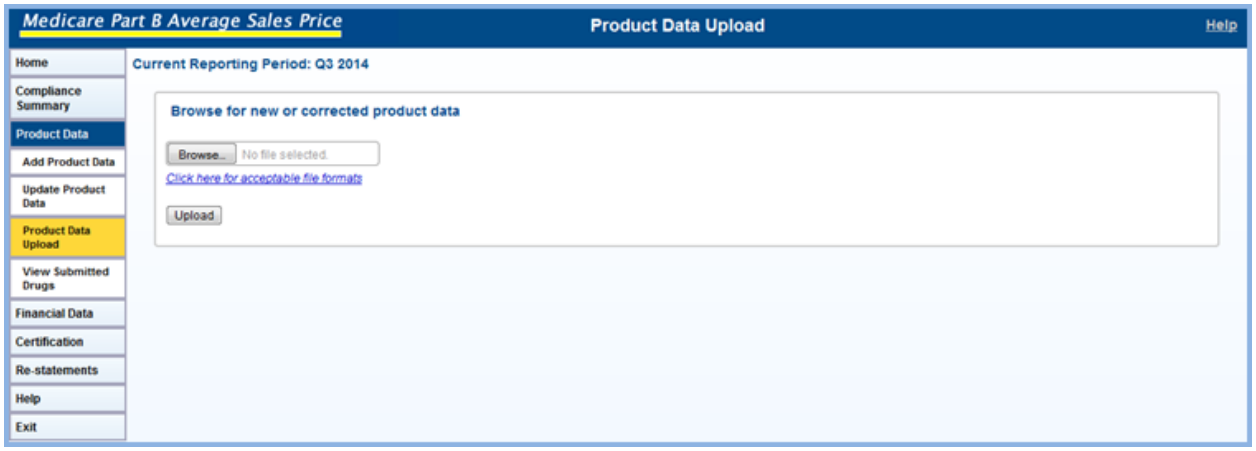
1. Click the **Product Data** button on the left side menu on the ASP Application Home Page and select **Product Data Upload** from the drop-down list. The Product Data Upload Selection on the ASP Application home page is shown in Figure 4-4.

Figure 4-4: Product Data Upload Selection



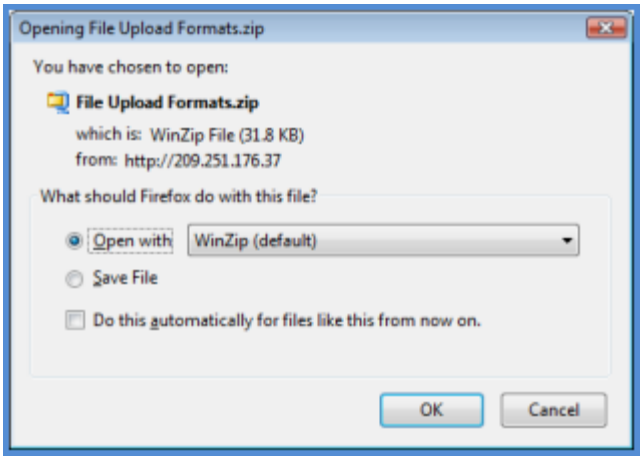
2. Click **Product Data Upload**. The Product Data Upload page opens, as shown in Figure 4-5.

Figure 4-5: Product Data Upload



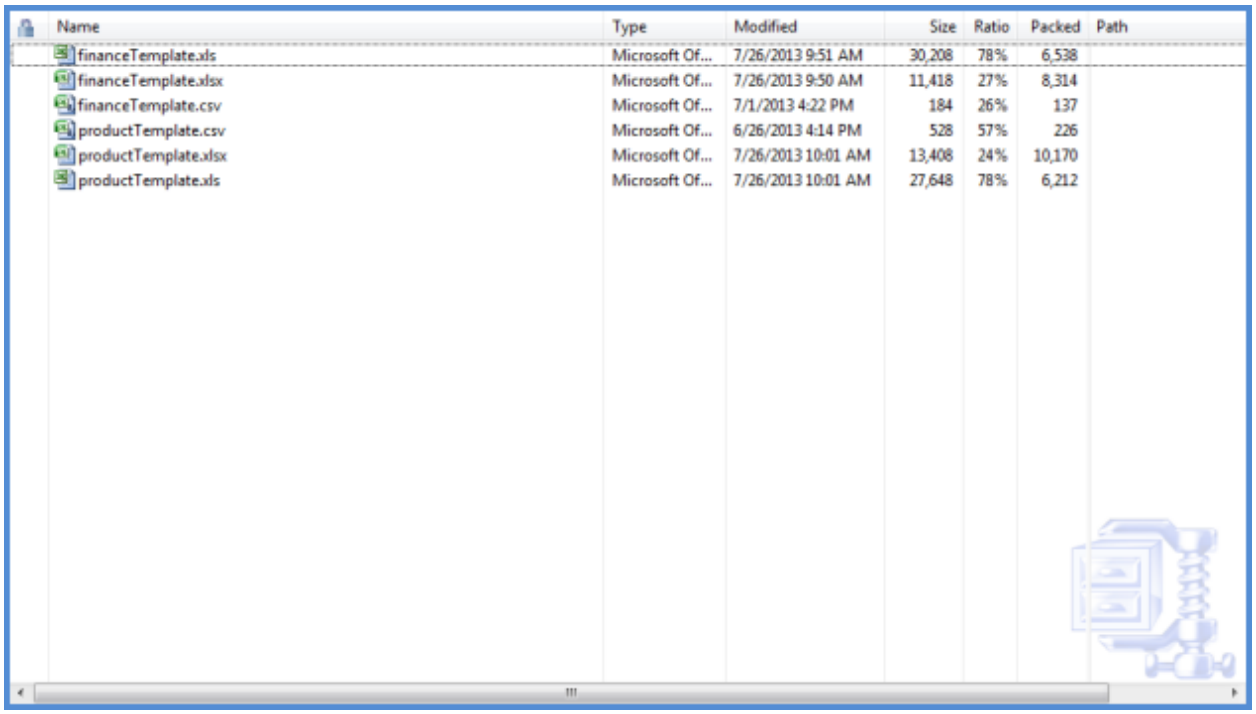
3. If the drug product data has been entered and saved to a file of an acceptable file format, click **Browse** to locate the file path and name of the file to be uploaded.
4. If the drug product data has not been entered and saved to a file of an acceptable file format, click the **Click here of acceptable file formats** link. A pop-up window opens asking for authorization to upload a .zip file containing the file formats, as shown in Figure 4-6.

Figure 4-6: Attachment Upload -- .zip File



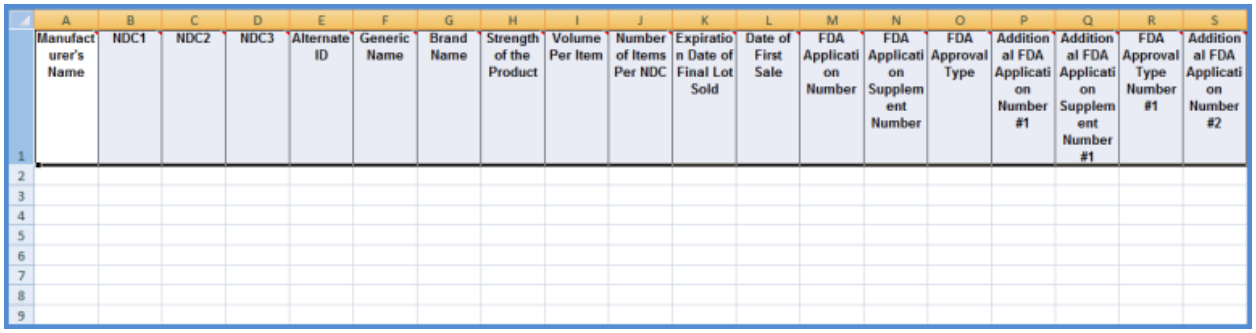
5. Click **OK** to upload the .zip file. The .zip file opens displaying the acceptable file format templates, as shown in Figure 4-7.

Figure 4-7: Acceptable File Format Templates



6. Click any one of the Product Template files to open a product data template. There are three options: productTemplate.csv, productTemplate.xlsx and productTemplate.xls. A sample template is shown in Figure 4-8.

Figure 4-8: Sample Product Data Template

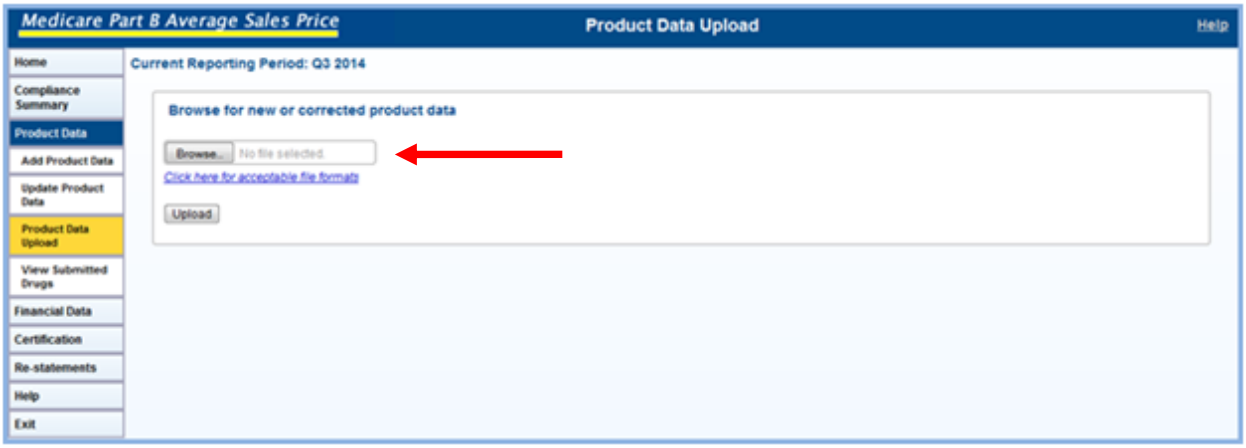


	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	Manufacturer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Strength of the Product	Volume Per Item	Number of Items Per NDC	Expiration Date of Final Lot Sold	Date of First Sale	FDA Application Number	FDA Application Supplement Number	FDA Approval Type	Additional FDA Application Number #1	Additional FDA Application Supplement Number #1	FDA Approval Type Number #1	Additional FDA Application Number #2
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			

* Please note that not all rows of the template are displayed in Figure 4-8.

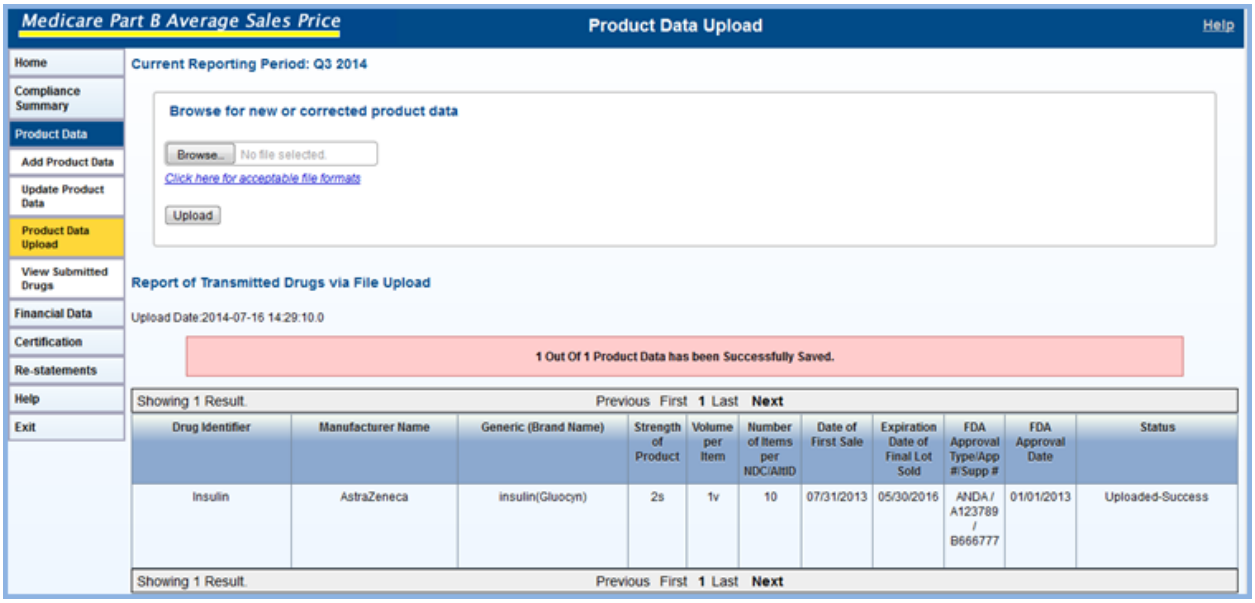
7. Enter the drug product information on the template. The entries on the template consist of the same fields that are described in Section 2.2, Upload Product Data – Online Data Entry. Refer to Table 2-1 for a description of the fields and which fields are required. Save the file using a different name and to an easily accessible location on your computer. Close the file and return to the Upload Product Data page.
8. Click **Browse** to locate the file path and name of the file to be uploaded. A file upload window will open.
9. Locate the file and click **Open**. The File Upload window will close, and the file to be uploaded will be displayed on the Upload Product Data page, as shown in Figure 4-9.

Figure 4-9: Upload Product Data – File to be Uploaded



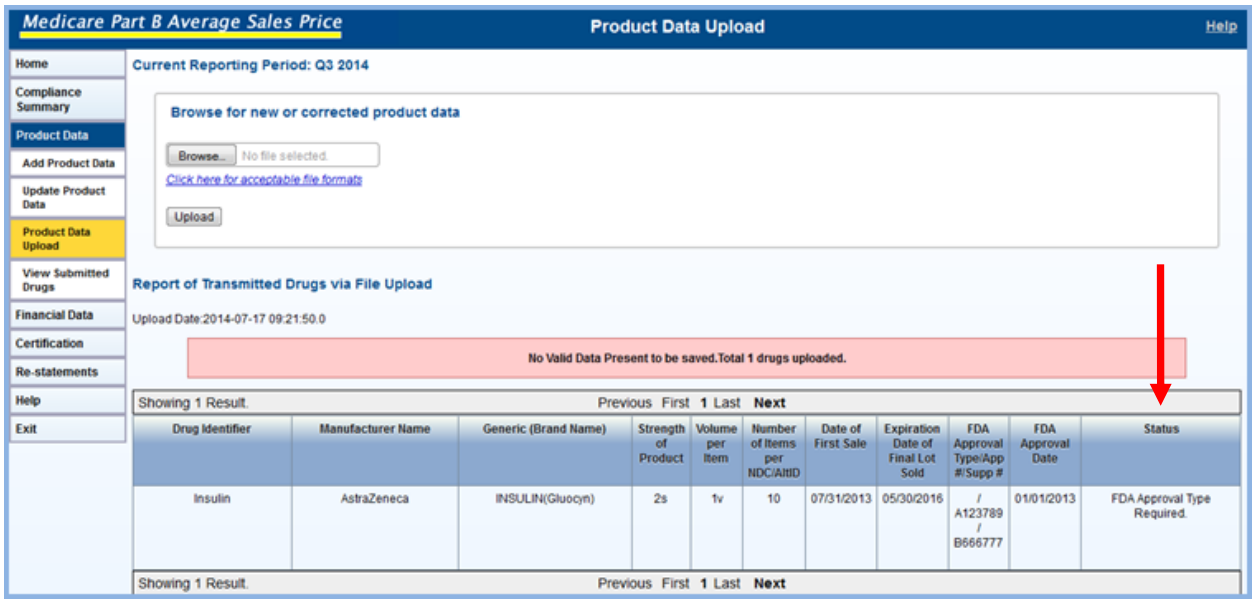
10. Click **Upload**. The Product Data Upload result screen will be displayed, along with a message that the product data has been successfully saved, as shown in Figure 4-10.

Figure 4-10: Product Data Upload Result



11. The Product Data Upload result screen will display a report of the drug product data that was just uploaded using the file transfer process. Review the data on the screen. Data that may be missing will be shown in the Status column. A sample upload with missing data is shown in Figure 4-11.

Figure 4-11: Product Data Upload – Error



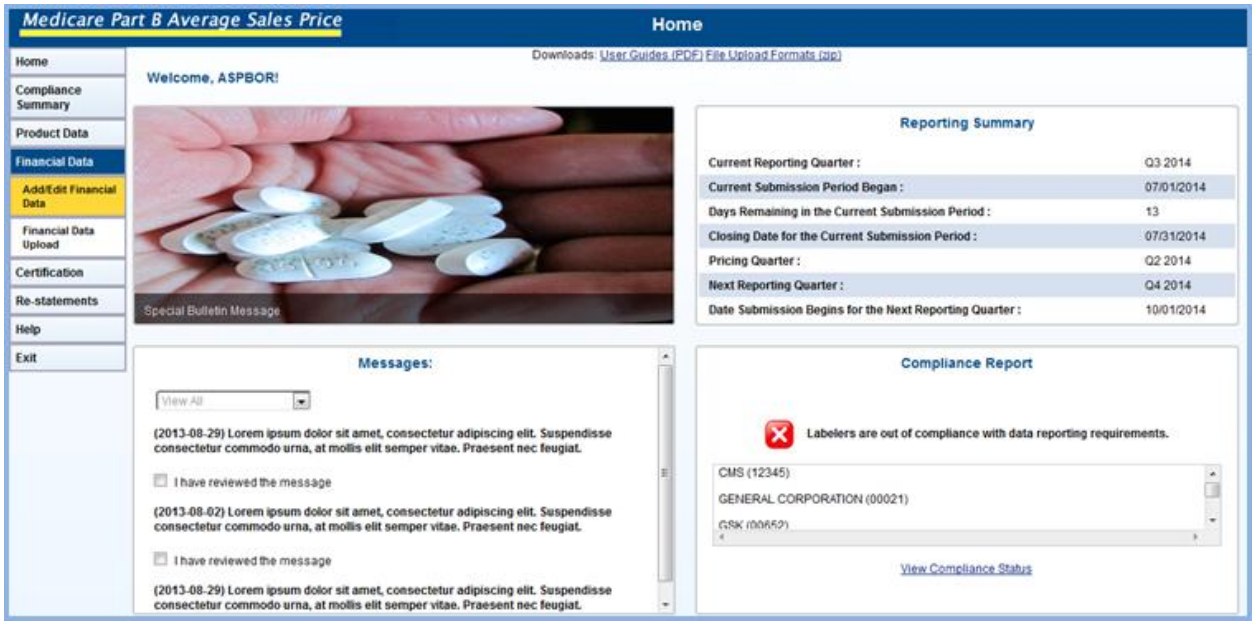
12. Reopen the file that was uploaded and make the necessary corrections. Save the file, and repeat Step 8 through Step 10.

4.3 Add Financial Data – Online Data Entry

The ASP database provides drug manufacturers the ability submit Medicaid Part B drug financial data to CMS. Perform the following steps to add drug financial data using the online data entry process:

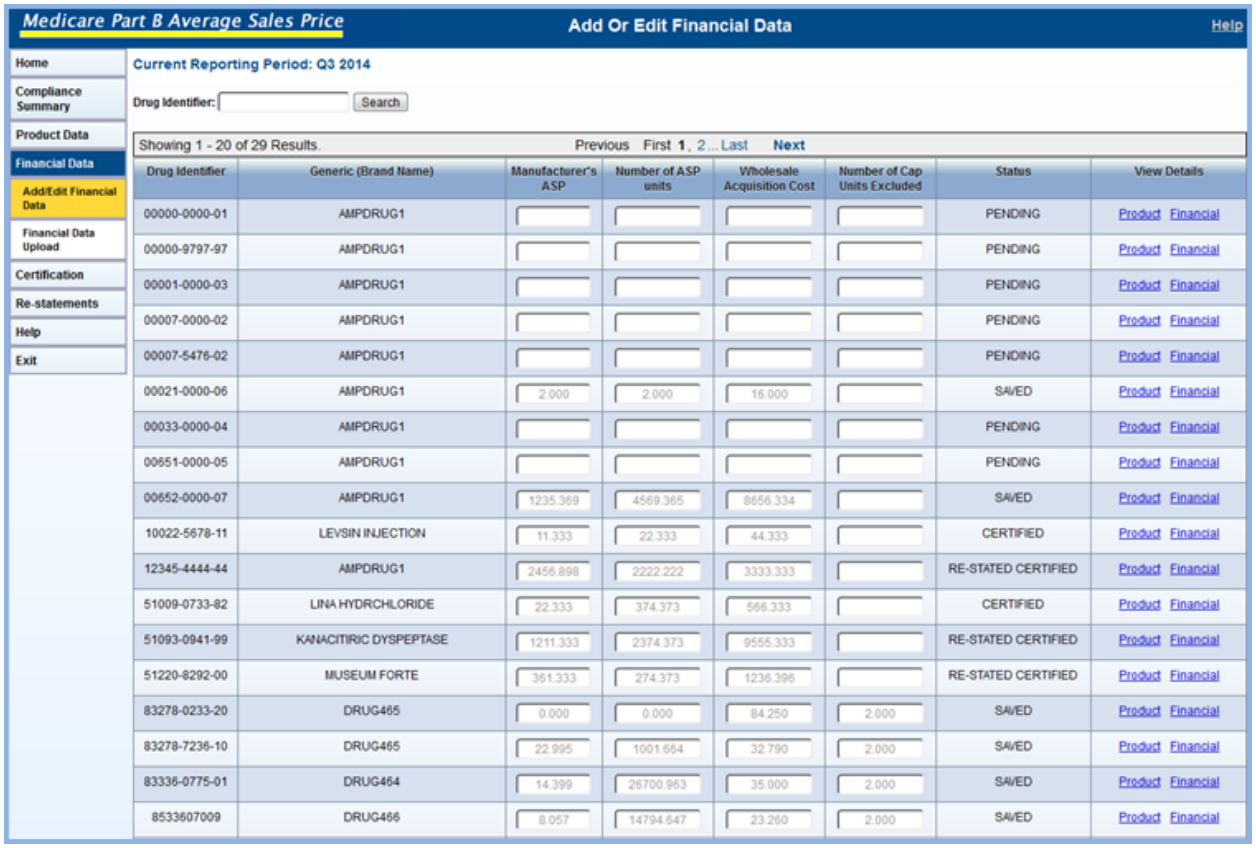
1. Click the **Financial Data** button on the left side menu on the ASP Application Home Page and select **Add/Edit Financial Data** from the drop-down list. The Add/Edit Financial Data Selection on the ASP Application home page is shown in Figure 4-12.

Figure 4-12: Add/Edit Financial Data Selection



2. Click **Add/Edit Financial Data**. The Add or Edit Financial Data page opens, as shown in Figure 4-13.

Figure 4-13: Add or Edit Financial Data Home Page



The following table describes the fields and the user actions on the Add or Edit Financial Data screen.

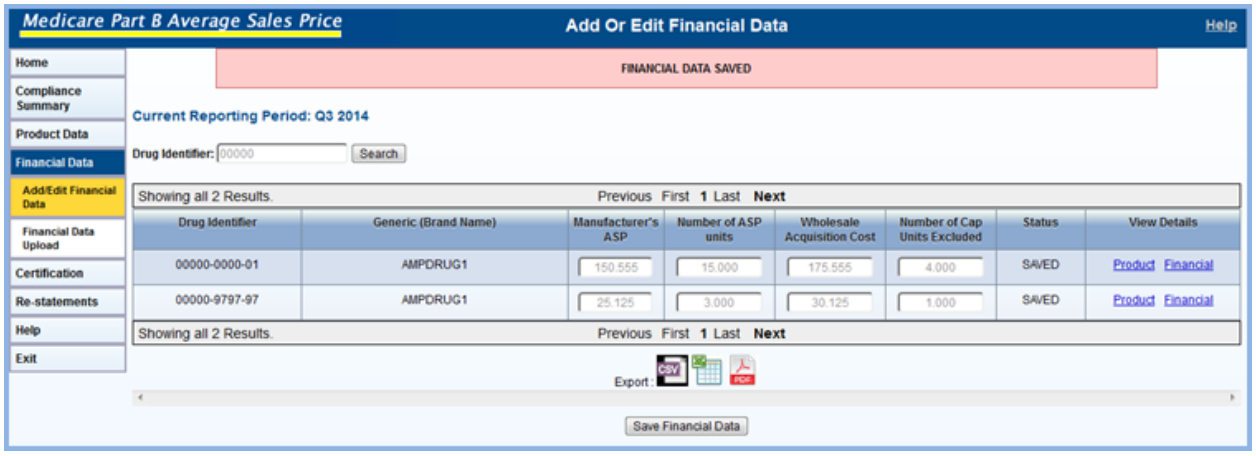
Table 4-2 Add or Edit Financial Data Home Page Information

Name	User Action	Comments
– Manufacturer's ASP	– Enter or update the Manufacturer's Average Sale Price (ASP) in the field.	• The Manufacturer's ASP is a required field. • The Manufacturer's ASP must be in a numeric format. • The Manufacturer's ASP must have three decimal places (i.e., XXXXX.XXX). • The Manufacturer's ASP can be a positive number, a negative number, or be equal to 0.
– Number of ASP Units	– Enter the drug's ASP Units in the field.	• The Number of ASP Units is a required field. • The Number of ASP Units must be in a numeric format. • The Number of ASP Units must have three decimal places (i.e., XXXXXXXXX.XXX). • The Number of ASP Units can be a positive number, a negative number, or equal to zero (0).

Name	User Action	Comments
– Wholesale Acquisition Cost	– Enter the Wholesale Acquisition Cost (WAC) in the field.	• The WAC is a required field. • The WAC must be in a numeric format. • The WAC must have three decimal places (i.e., XXXXX.XX). • The WAC can be a positive number, a negative number, or equal to zero (0).
– Number of CAP Units Excluded	– Enter the Number of CAP Unites Excluded	• The Number of CAP Units Excluded is a required field. • The Number of CAP Units Excluded must have three decimal places (i.e., XXXXXXXXX.XXX). • The Number of CAP Units Excluded can be a positive number, a negative number, or equal to zero (0).

3. The Add or Edit Financial Data home page lists all of the drugs that have been submitted during the current reporting period. Scroll through the list of drugs displayed on the Add or Edit Financial Data home 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 **Search** to filter the results.
4. Enter the **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Number of CAP Units Excluded** in the respective fields.
5. Click the **Save Financial Data** button to add the drug financial data. Figure 4-14 will be displayed, which indicates that the drug financial data has been successfully saved to the ASP application database.

Figure 4-14: Add or Edit Financial Data – Financial Data Saved

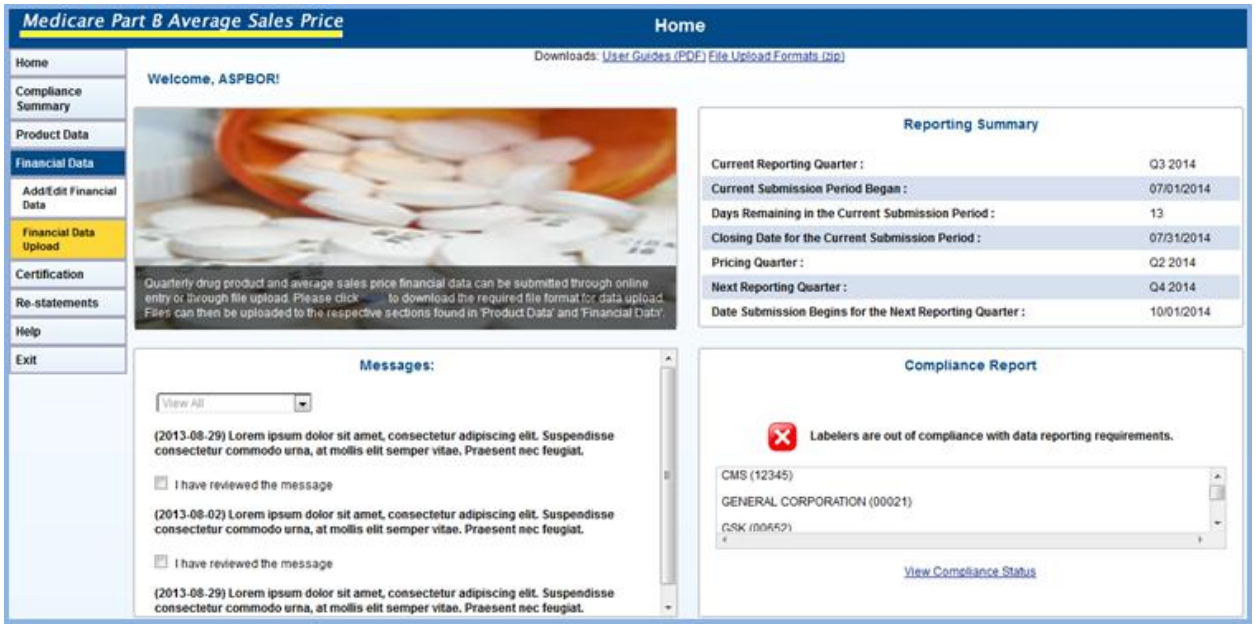


4.4 Upload Financial Data – File Transfer

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

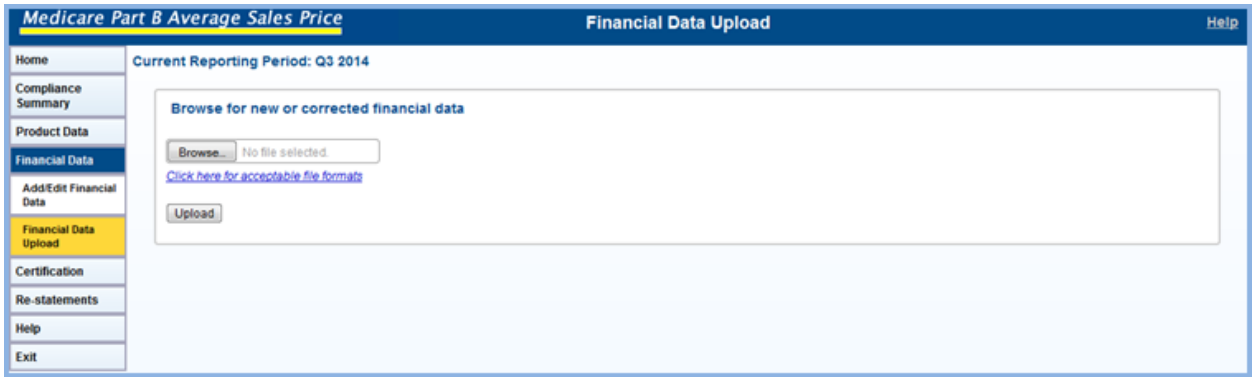
1. Click the **Financial Data** button on the left side menu on the ASP Application Home Page and select **Financial Data Upload** from the drop-down list. The Financial Data Upload selection on the ASP Application home page is shown in Figure 4-15.

Figure 4-15: Financial Data Upload Selection



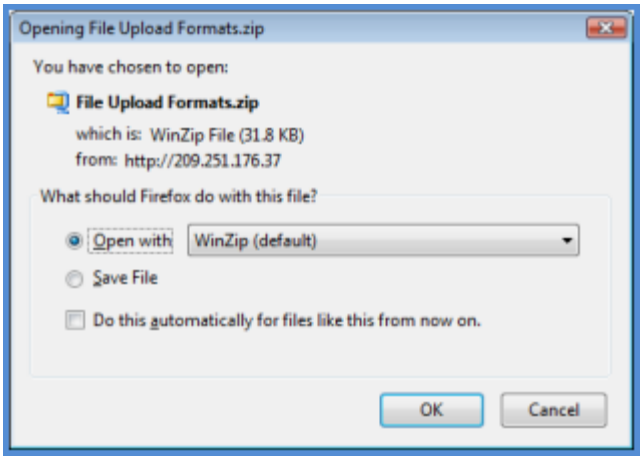
2. Click **Financial Data Upload**. The Financial Data Upload page opens, as shown in Figure 4-16.

Figure 4-16: Financial Data Upload Page



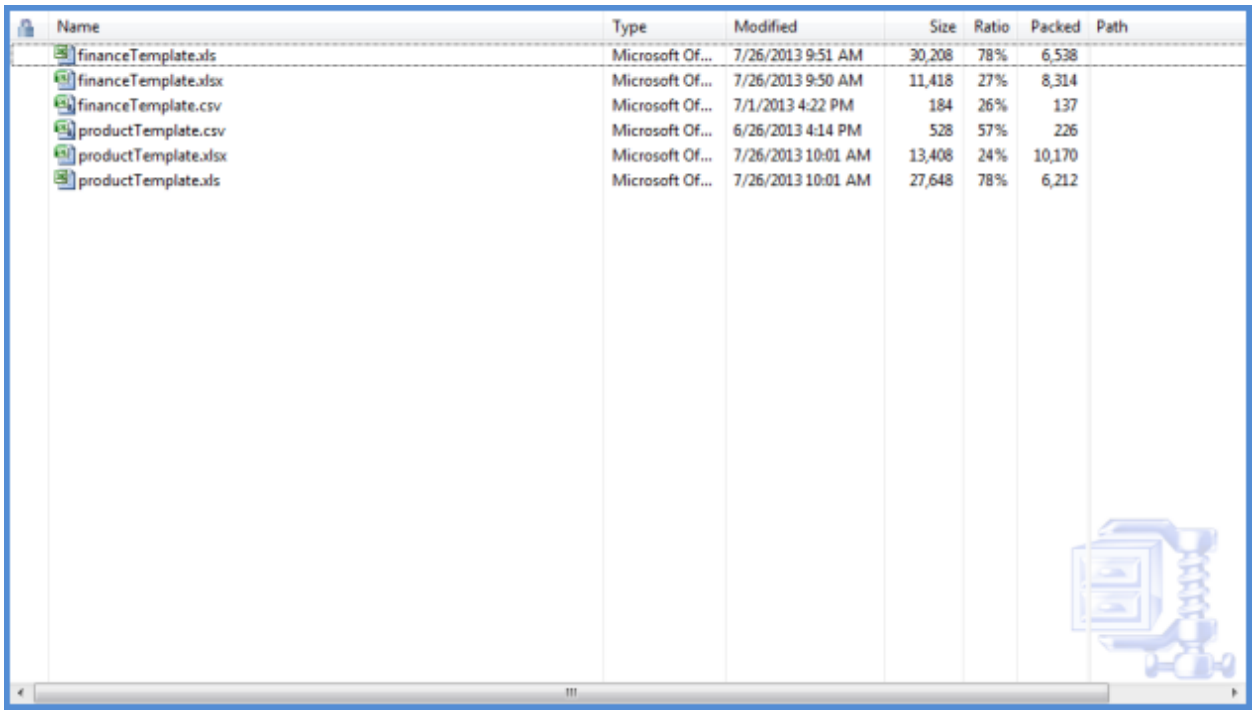
3. If the drug financial data has been entered and saves to a file of an acceptable file format, click **Browse** to locate the file path and name of the file to be uploaded.
4. If the drug financial data has not been entered and saves to a file of an acceptable file format, click the **Click here of acceptable file formats** link. A pop-up window opens asking for authorization to upload a .zip file containing the file formats, as shown in Figure 4-17.

Figure 4-17: Attachment Upload -- .zip File



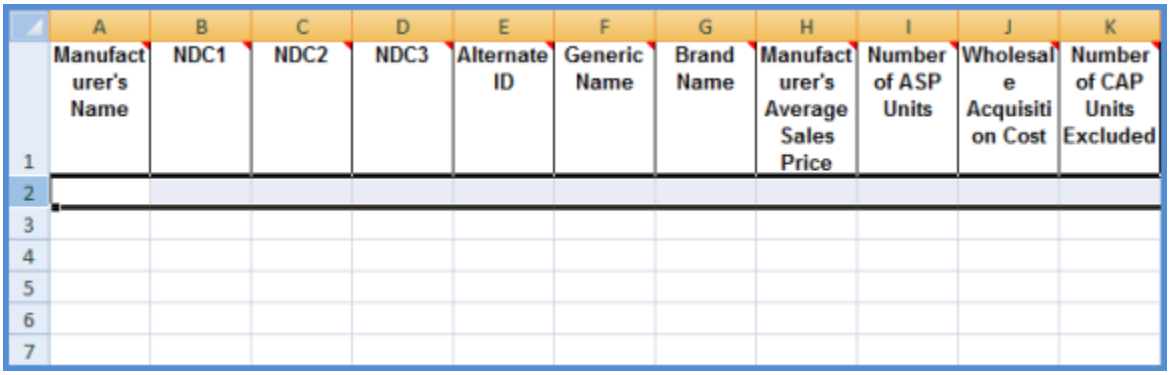
5. Click **OK** to upload the .zip file. The .zip file opens displaying the acceptable file form templates, as shown in Figure 4-18.

Figure 4-18: Acceptable File Format Templates



6. Click any one of Finance Template files to open a finance data template. There are three finance upload template options: financeTemplate.csv, financeTemplate.xlsx and financeTemplate.xls. A sample template is shown in Figure 4-19.

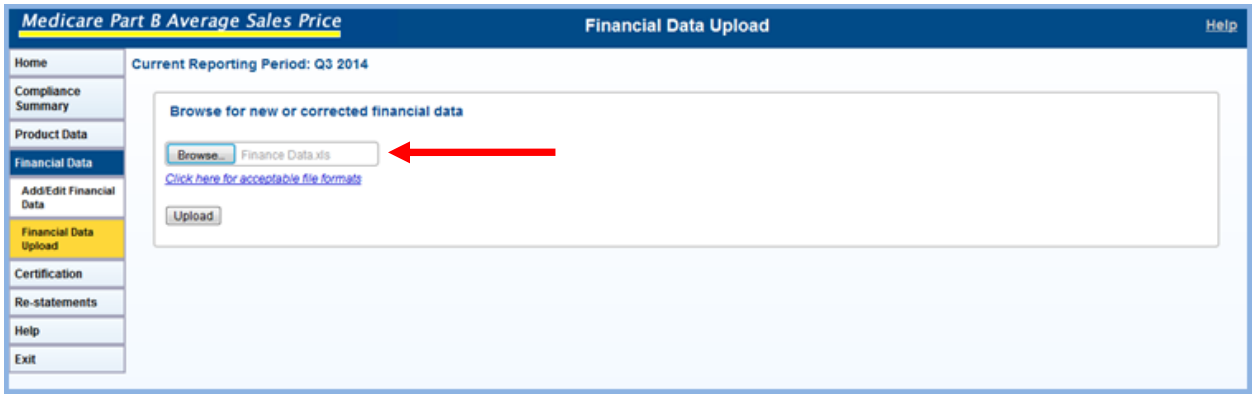
Figure 4-19: Sample Financial Data Template



	A	B	C	D	E	F	G	H	I	J	K
1	Manufacturer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Manufacturer's Average Sales Price	Number of ASP Units	Wholesale Acquisition Cost	Number of CAP Units Excluded
2											
3											
4											
5											
6											
7											

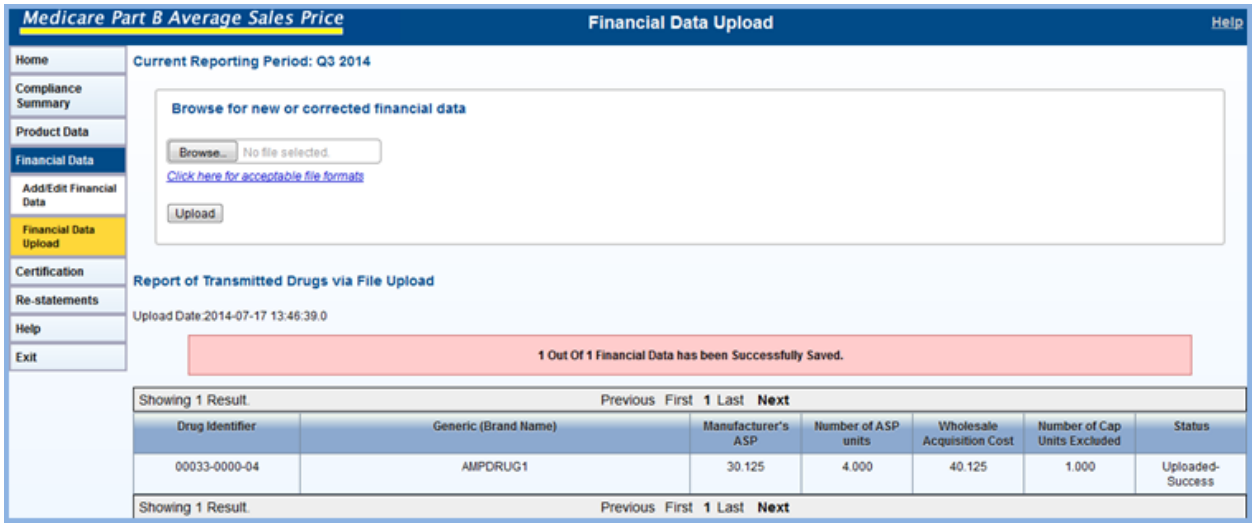
7. Enter the drug financial information on the template. The entries on the template consist of the same fields that are described in Section 2.3, Add Financial Data – Online Entry. Refer to Table 2-2 for a description of the fields and which fields are required. Save the file using a different name and to an easily accessible location on your computer. Close the file and return to the Upload Financial Data page.
8. Click **Browse** to locate the file path and name of the file to be uploaded. A file upload window will open.
9. Locate the file and click **Open**. The File Upload window will close, and the file to be uploaded will be displayed on the Upload Product Data page, as shown in Figure 4-20.

Figure 4-20: Financial Data Upload – File to be Uploaded



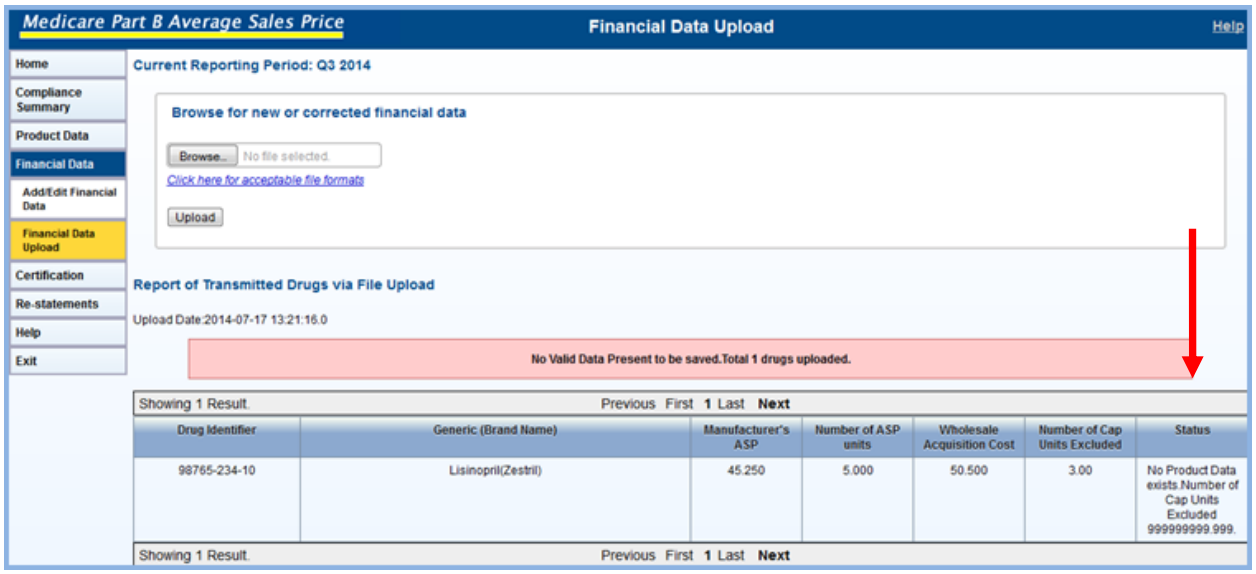
10. Click **Upload**. The Upload Financial Data Result screen will open, as shown in Figure 4-21.

Figure 4-21: Financial Data Upload -- Result



11. The Upload Financial Data Result screen displays a report of the drug financial data that was just uploaded using the file transfer process. Review the data on the screen. Data that may be missing will be shown in the Status column. A sample upload with missing data is shown in Figure 4-22.

Figure 4-22: Financial Data Upload – Error



12. Reopen the file that was uploaded and make the necessary corrections. Save the file, and repeat Step 8 through Step 10.
13. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

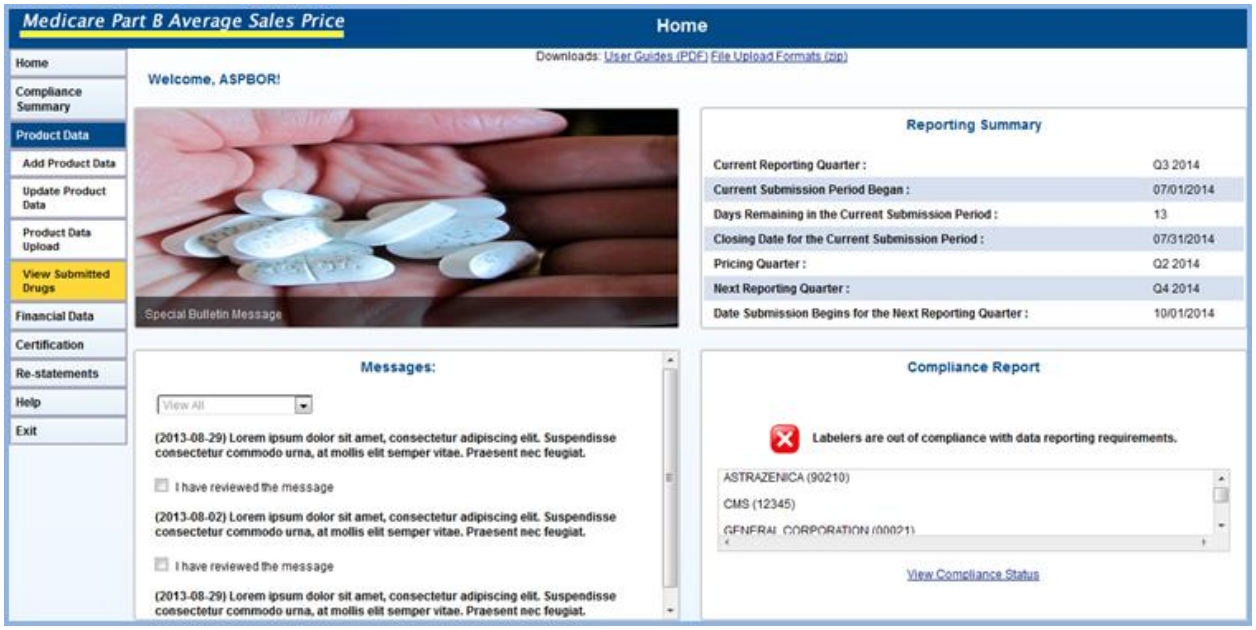
4.5 View Submitted Drug Data

Drug manufacturers have the ability to view drug data that has been submitted and certified 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:

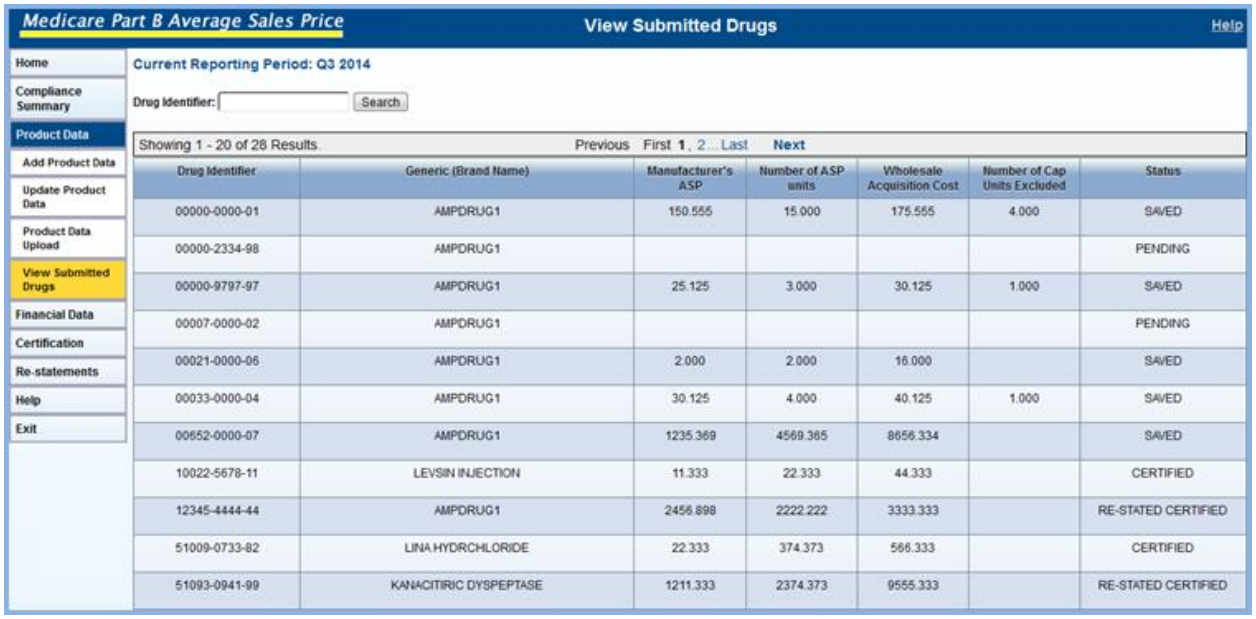
1. Click the **Product Data** button on the left side menu on the ASP Application Home Page and select **View Submitted Drugs** from the drop-down list. The View Submitted Drugs Selection on the ASP Application home page is shown in Figure 4-23.

Figure 4-23: View Submitted Drugs Selection



2. Click **View Submitted Drugs**. The View Submitted Drugs page opens, as shown in Figure 4-24.

Figure 4-24: View Submitted Drugs



Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status
00000-0000-01	AMPDRUG1	150.555	15.000	175.555	4.000	SAVED
00000-2334-98	AMPDRUG1					PENDING
00000-9797-97	AMPDRUG1	25.125	3.000	30.125	1.000	SAVED
00007-0000-02	AMPDRUG1					PENDING
00021-0000-06	AMPDRUG1	2.000	2.000	16.000		SAVED
00033-0000-04	AMPDRUG1	30.125	4.000	40.125	1.000	SAVED
00652-0000-07	AMPDRUG1	1235.369	4569.365	8656.334		SAVED
10022-5678-11	LEVSIN INJECTION	11.333	22.333	44.333		CERTIFIED
12345-4444-44	AMPDRUG1	2456.898	2222.222	3333.333		RE-STATED CERTIFIED
51009-0733-82	LINA HYDRCHLORIDE	22.333	374.373	566.333		CERTIFIED
51093-0941-99	KANACITIRIC DYSPEPTASE	1211.333	2374.373	9555.333		RE-STATED CERTIFIED

3. Drug financial data and drug product data are displayed on this screen. This screen can be used to verify drug data for accuracy. Scroll through the list of drugs displayed on the View Submitted Drugs 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 **Search** to filter the results Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

5 Certifications

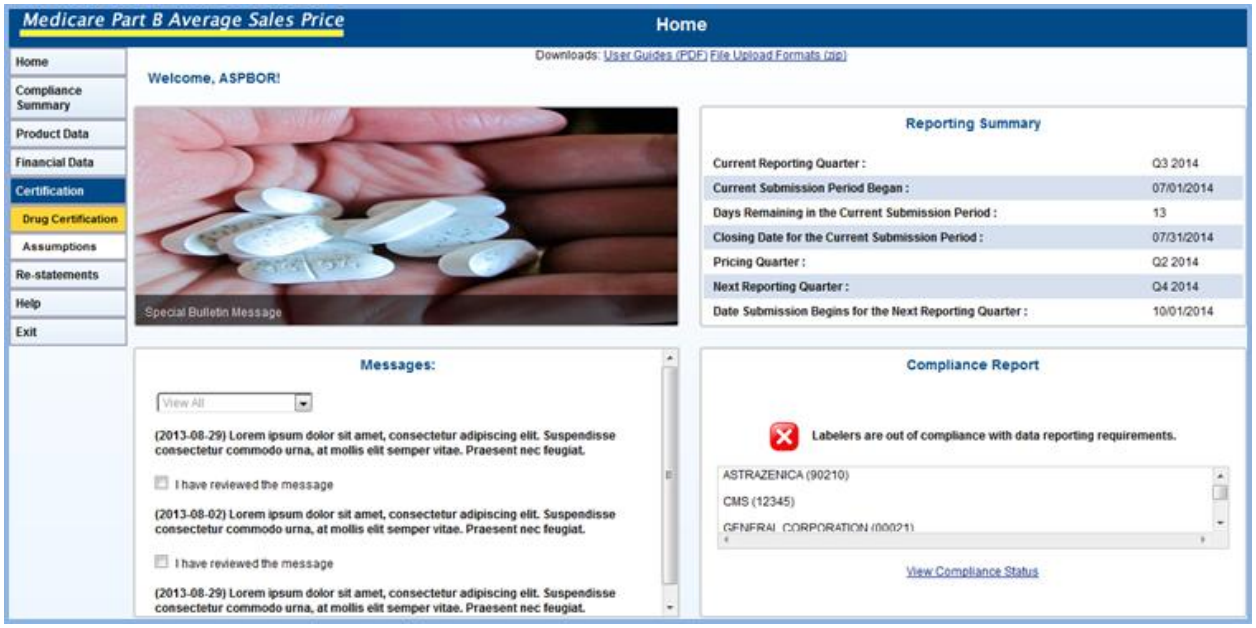
Data certification is a process where a drug manufacturer certifies the accuracy of the drug data. In this section, data are selected and marked for immediate certification or later certification. Selection may be one drug product item, a list of drug items or all drug items pending certification for 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.

5.1 Certify Drug Data Online

If you have the appropriate user access, the ASP Application provides drug manufacturers the ability to certify the accuracy of drug data that has been previously submitted. Perform the following steps to certify drug data online:

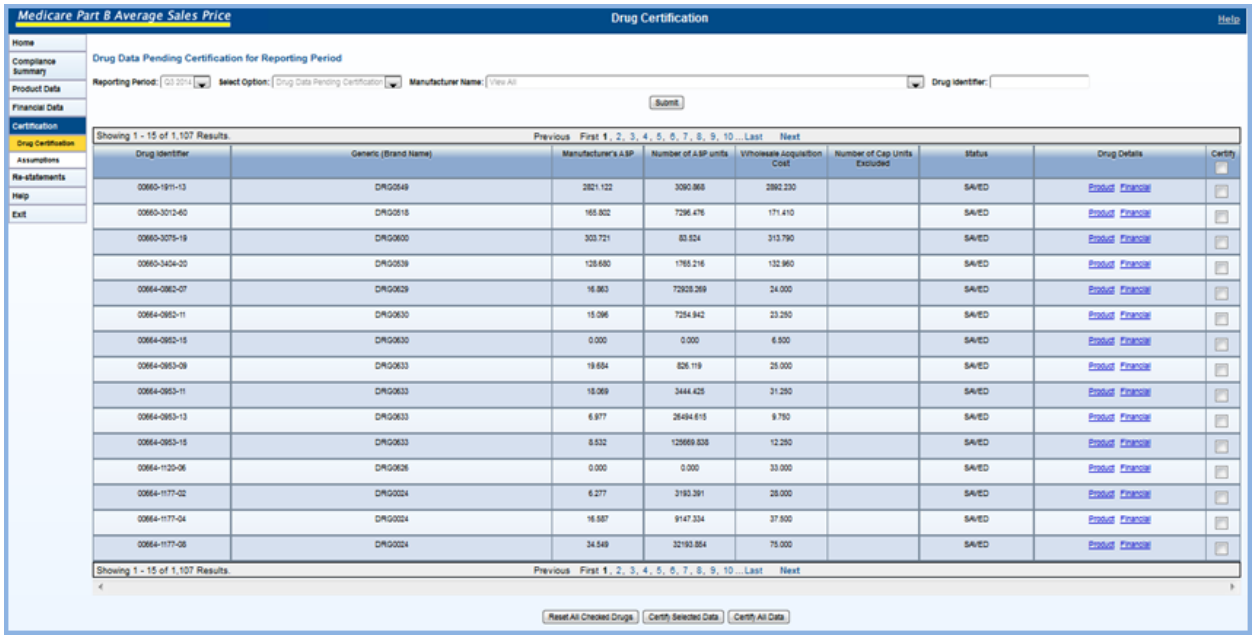
1. Begin certifying drug data by clicking the **Certification** button on the left side menu on the ASP Application Home Page and select **Drug Certification** from the drop-down list, as shown in Figure 5-1.

Figure 5-1: Drug Certification Selection



2. Click **Drug Certification**. The Drug Certification page opens, as shown in Figure 5-2.

Figure 5-2: Drug Certification Home Page



The following table describes the fields and the user actions on the Drug Certification Screen..

Table 5-1 Select Certification Status Page Information

Name	User Action	Comments
– Reporting Period	– Click the arrow on drop-down box and select the desired quarterly reporting period.	• Defaults to the current quarterly reporting period.
– Selection Option	– Click the arrow on the drop-down box and scroll through the list of values. Click the desired value.	• Results will be displayed depending on the selection of one of the following values: Drug Data Pending Certification; Drug Data Certified this Period; and View All Drugs in Period.
– Manufacturer Name	– Click the arrow on the drop-down box to display the list of manufacturer names	• Defaults to the View All value, which will display all of the manufacturers' names for the selected quarterly reporting period.
– Drug Identifier	– Enter all or part of the drug identifier in the Drug Identifier field.	• This field is optional.

3. Select the desired quarterly reporting period from the **Reporting Period** drop-down list.
4. Select **Drug Data Pending Certification** from the **Selection Option** drop-down list (**Drug Data Pending Certification** is the default value).

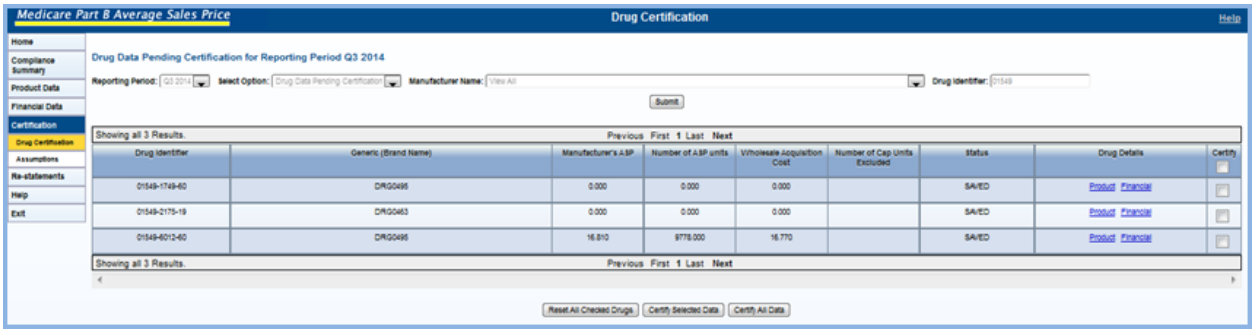
5. Select the desired drug identifier from the **Manufacturer Name** drop-down list. The **View All** value is the default value and will display all of the drugs for the selected quarterly reporting period in the results,

   OR

   Enter all of part of the drug identifier in the **Drug Identifier** field.

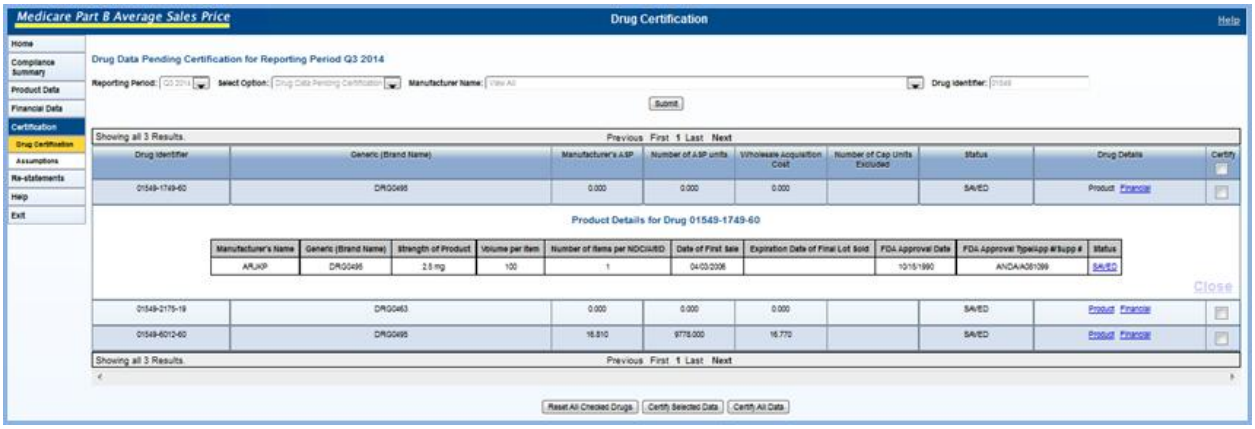
6. Click the **Submit** button. The Drug Certification page shown in Figure 5-3 is displayed. This page lists the drug data that are pending certification for the selected quarterly reporting period. Each drug that is listed displays the following data: Drug Identifier; Generic (Brand Name); Manufacturer's ASP; Number of ASP Units; Wholesale Acquisition Cost; Number of CAP Units Excluded; Status and Drug Details links.

Figure 5-3: Drug Certification Page – Pending



7. Click the **Product** link on any of the listed drugs to review the drug's product details. The drug product details are displayed in Figure 5-4.

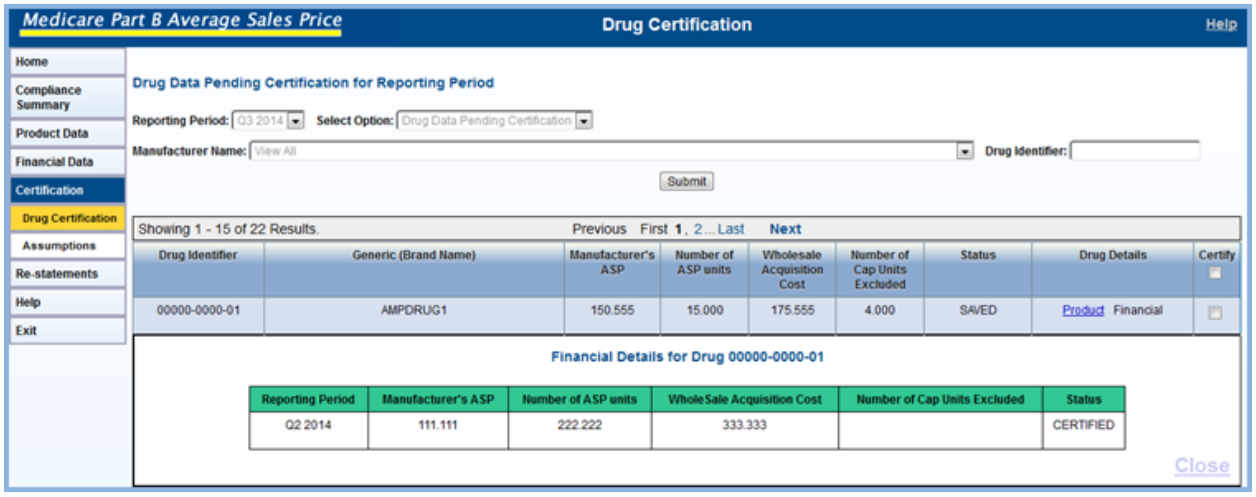
Figure 5-4: Product Details



8. The drug's product details that are displayed are the following: Manufacturer's Name; Generic (Brand Name); Strength of Product; Volume Per Item; Number of Items per NDC/AltID; Date of First Sale; Expiration Date of Final Lot Sold; FDA Approval Date; FDA Approval Type/App #/Supp #; and Status. Click the **Close** link to hide the drug product data details.

9. Click the **Financial** link on any of the listed drugs to review the drug's financial details. The drug financial details are displayed in Figure 5-5.

Figure 5-5: Financial Details



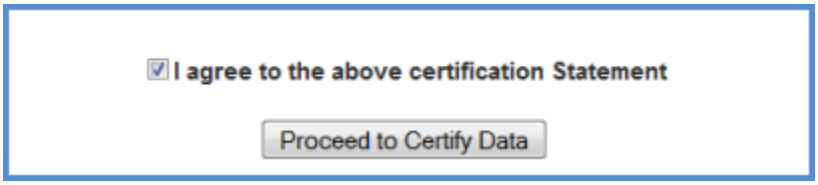
10. The drug's financial details that are displayed are the following: Reporting Period; Manufacturer's ASP; Number of ASP Units; Wholesale Acquisition Cost; Number of CAP Units Excluded; Status; and Drug Details links. Click the **Close** link to hide the drug financial data.
11. Select the drugs to be certified. This can be done by clicking the **Certify** check box of the individual drugs or by clicking the **Certify All Data** button at the bottom of the page. If a drug is checked inadvertently, click the **Reset All Checked Drugs** button to clear the drug check boxes.
12. Click the **Certify Selected Data** button or the **Certify All Data** button to begin the certification process. The Data Certification Statement opens in a pop-up window as shown in Figure 5-6.

Figure 5-6: Data Certification Statement

13. Review the certification statement that pertains to product certifications.

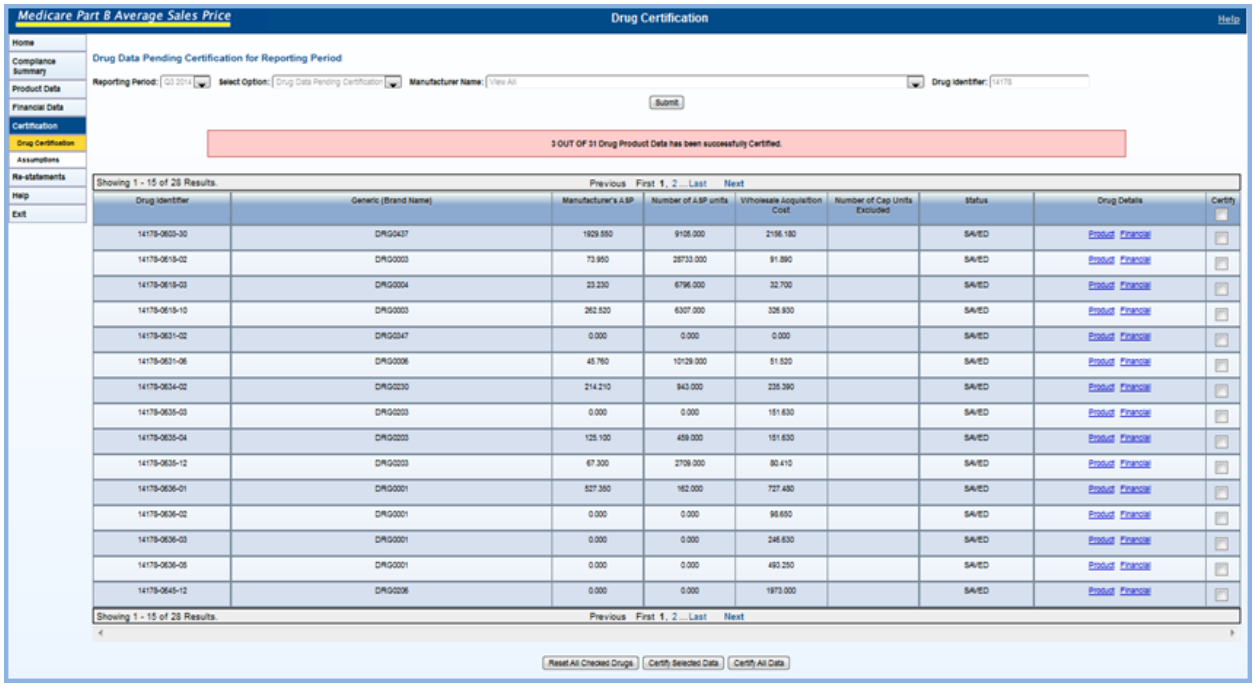
14. Check the box next to **I agree to the above certification statement** to continue the certification process.
15. Click the **Proceed to Certify Data** button located beneath the certification statement checkbox. The **Proceed to Certify Data** button is shown in Figure 5-7.

Figure 5-7: Proceed to Certify Data Button



16. The ASP Application certifies the drug(s) and displays the confirmation message displayed in Figure 5-8.

Figure 5-8: Certification Confirmation Message



5.2 View Drug Data

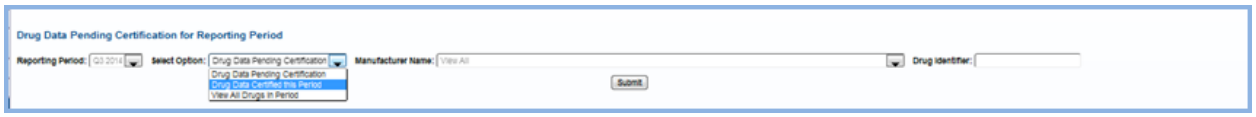
Drug Manufacturers have the ability to view all drug data that were certified during a selected reporting period. In addition, Drug Manufacturers also have the ability to view all drug data, with the statuses of Certified, Saved, or Pending, in a selected reporting period. These functions allow drug manufacturers to view the drug data certification history for each submission.

5.2.1 View Drug Data Certified in the Reporting Period

Perform the following steps to view drug data that were certified during a selected reporting period:

1. Click the **Certification** button on the left side menu on the ASP Application Home Page and select **Drug Certification** from the drop-down list. The Drug Certification page opens (See Figure 5-2).
2. Select the desired reporting period from the **Reporting Period** drop-down list.
3. Select the **Drug Data Certified this Period** option from the **Select Option** drop-down list, as shown in Figure 5-9.

Figure 5-9: Drug Data Certified This Period Option

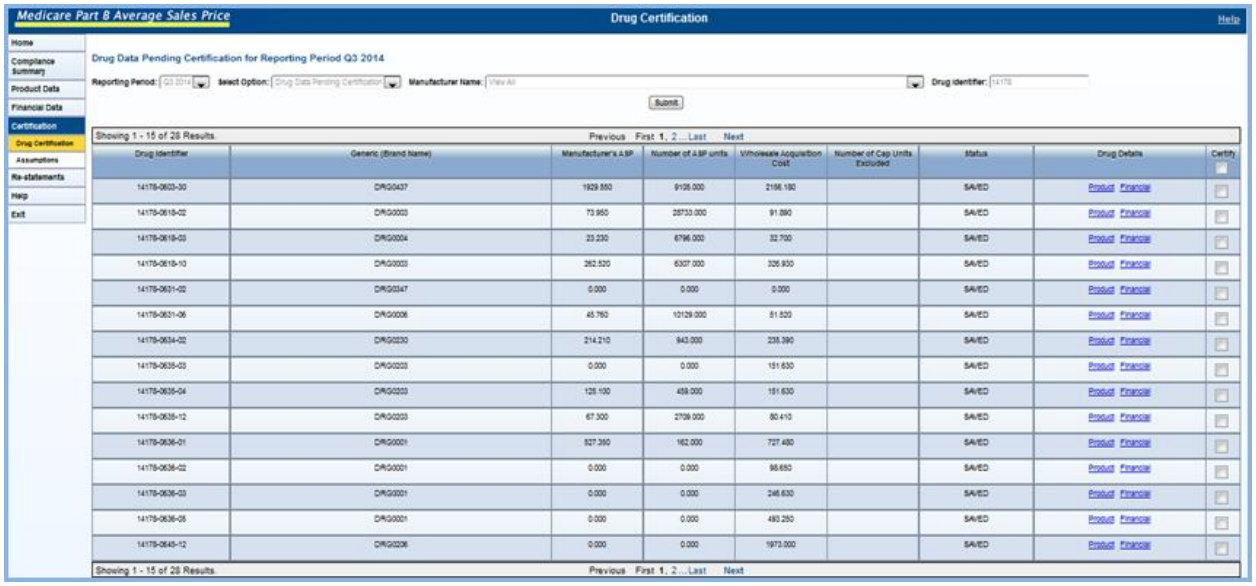


4. Select the desired manufacturer from the **Manufacturer Name** drop-down list. The **View All** value is the default value and will display all of the drugs for the selected quarterly reporting period in the results,

   OR

   Enter all of part of the drug identifier in the **Drug Identifier** field.
5. Click the **Submit** button. The search results will be displayed, as shown in Figure 5-10.

Figure 5-10: Drug Data Certified This Period Results



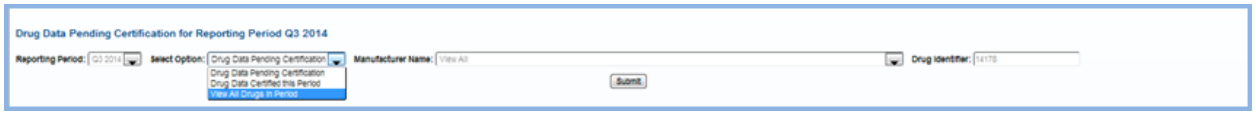
6. Each record of drug data that has been certified displays the following: Drug Identifier; Generic (Brand Name); Manufacturer's ASP; Number of ASP Units; Wholesale Acquisition Cost; Number of CAP Units Excluded; Status and Drug Details links. Click the **Product** or **Financial** links under **View Details** to review the product or financial data for a selected drug (See Figure 5-4 and Figure 5-5). Click the **Close** link to hide the drug product data and drug financial data.

5.2.2 View All Drug Data in the Reporting Period

Perform the following steps to view all drug data with statuses of Certified, Saved, or Pending during a selected reporting period:

1. Click the **Certification** button on the left side menu on the ASP Application Home Page and select **Drug Certification** from the drop-down list. The Drug Certification page opens (See Figure 5-2).
2. Select the desired reporting period from the **Reporting Period** drop-down list.
3. Select the **View All Drugs in Period** option from the **Select Option** drop-down list, as shown in Figure 5-11.

Figure 5-11: View All Drugs in Period Option



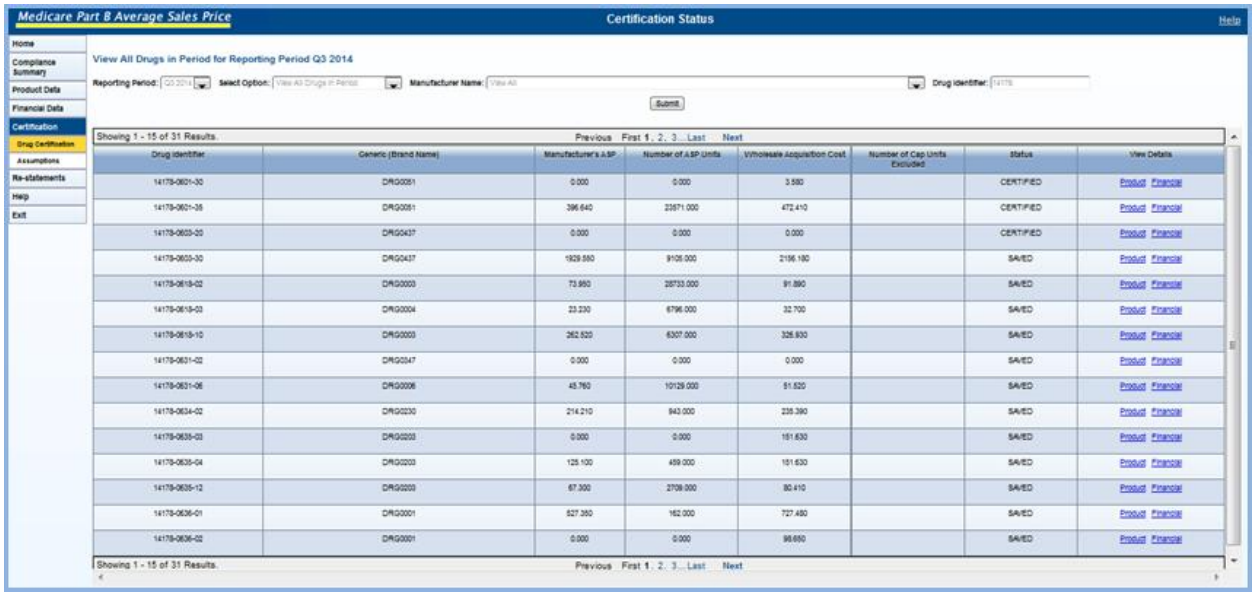
4. Select the desired manufacturer from the **Manufacturer Name** drop-down list. The **View All** value is the default value and will display all of the drugs for the selected quarterly reporting period in the results,

   OR

   Enter all of part of the drug identifier in the **Drug Identifier** field.

5. Click the **Submit** button or press **Enter**. The search results will be displayed, as shown in Figure 5-12.

Figure 5-12: View All Drugs in Period Results



6. Each record of the View All Drugs in Period Results displays the following: Drug Identifier; Generic (Brand name): Manufacturer's ASP; Number of ASP Units; Wholesale Acquisition Cost; Number of CAP Units Excluded; Status and View Details links. Click the **Product** or **Financial** links under **View Details** to review the product or financial data

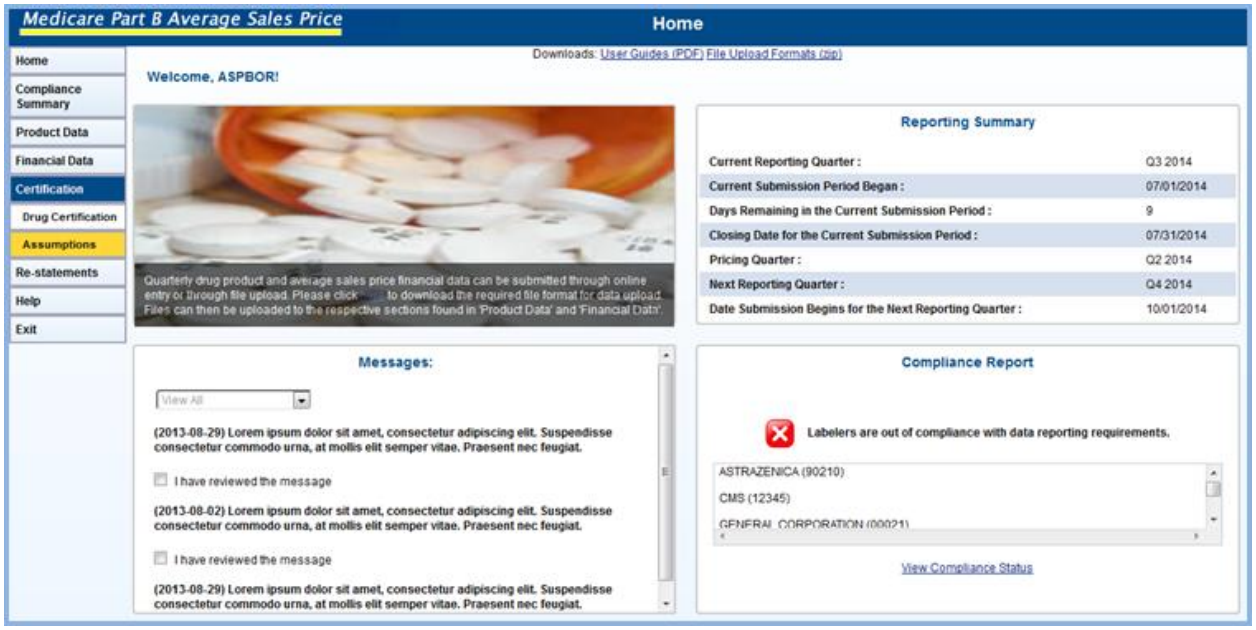
for a selected drug (See Figure 5-4 and Figure 5-5). Click the **Close** link to hide the drug product data and drug financial data.

5.3 Certification Assumptions

Drug Manufacturers can submit comments regarding their certifications to CMS. These comments may be submitted during both the current and prior reporting periods. Perform the following steps to submit certification assumptions to CMS:

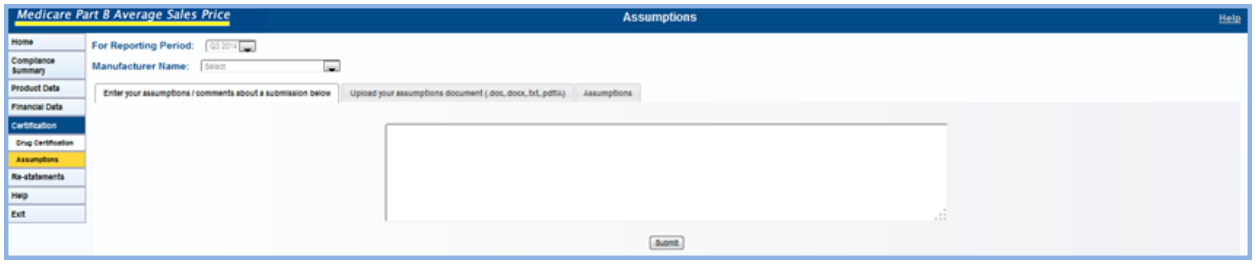
1. Begin certifying drug data by clicking the **Certification** button on the left side menu on the ASP Application Home Page and select **Assumptions** from the drop-down list. The Assumptions selection is shown in Figure 5-13.

Figure 5-13: Certification Assumptions Selection



2. The Certification Assumptions pages opens, as shown in Figure 5-14.

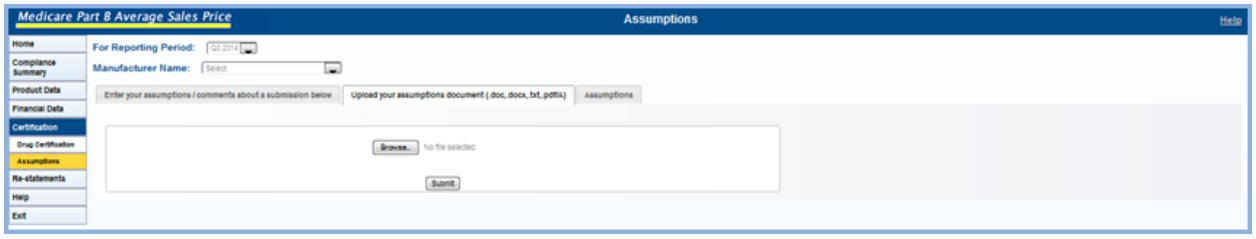
Figure 5-14: Certification Assumptions Page



3. Select the desired reporting period from the **Reporting Period** drop-down list.
4. Select the desired manufacturer name from the **Manufacturer Name** drop-down list.
5. The ASP Application allows assumptions to be submitted by entering them directly in the text box shown in Figure 5-14, or by uploading an attachment. Click the **Upload your assumptions document (.doc, .docx, .txt, .pdf/A)** tab to open the Certification Assumptions Page – Upload.

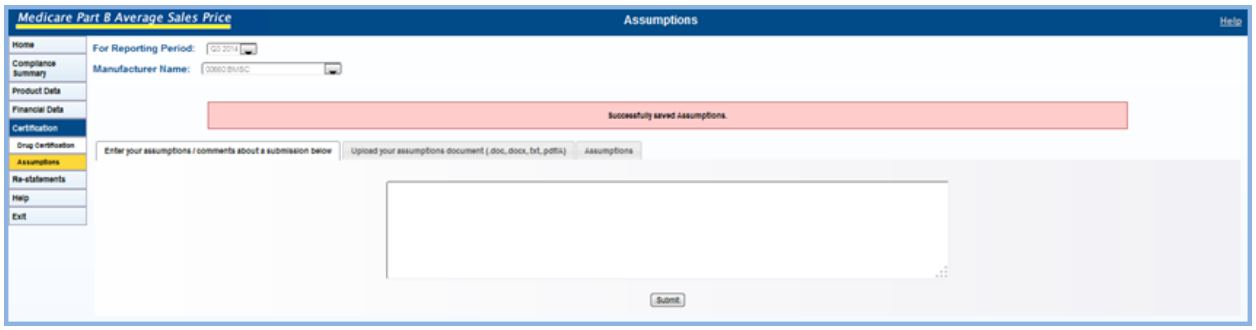
6. The Certification Assumptions Page – Upload is shown in Figure 5-15.

Figure 5-15: Certification Assumptions Page -- Upload



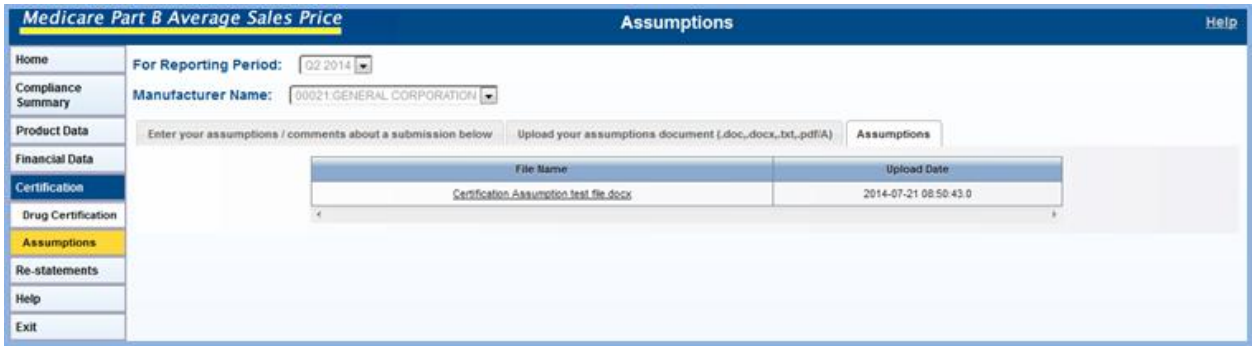
7. Enter the assumptions and comments about a submission in the text box and click the **Submit** button, or
8. Click the **Browse** button on the **Upload your assumptions document (.doc, .docx, .txt, or.pdf/A)** tab, select the document to upload, and click the **Submit** button. The document file must have one of the following extensions: .doc., .docx, or .txt, or .pdf/A.
9. The ASP Application will save the Certification Assumption and display a message as shown in Figure 5-16.

Figure 5-16: Certification Assumptions Saved



10. Certification Assumptions that have been uploaded can be viewed by clicking the **Assumptions** tab. The screen shown Figure 5-17 shows an example of a certification assumption that has been uploaded.

Figure 5-17: Uploaded Certification Assumptions



11. The Certification Assumptions can be viewed and opened by clicking the file link in the **File Name** column.

6 Re-statements

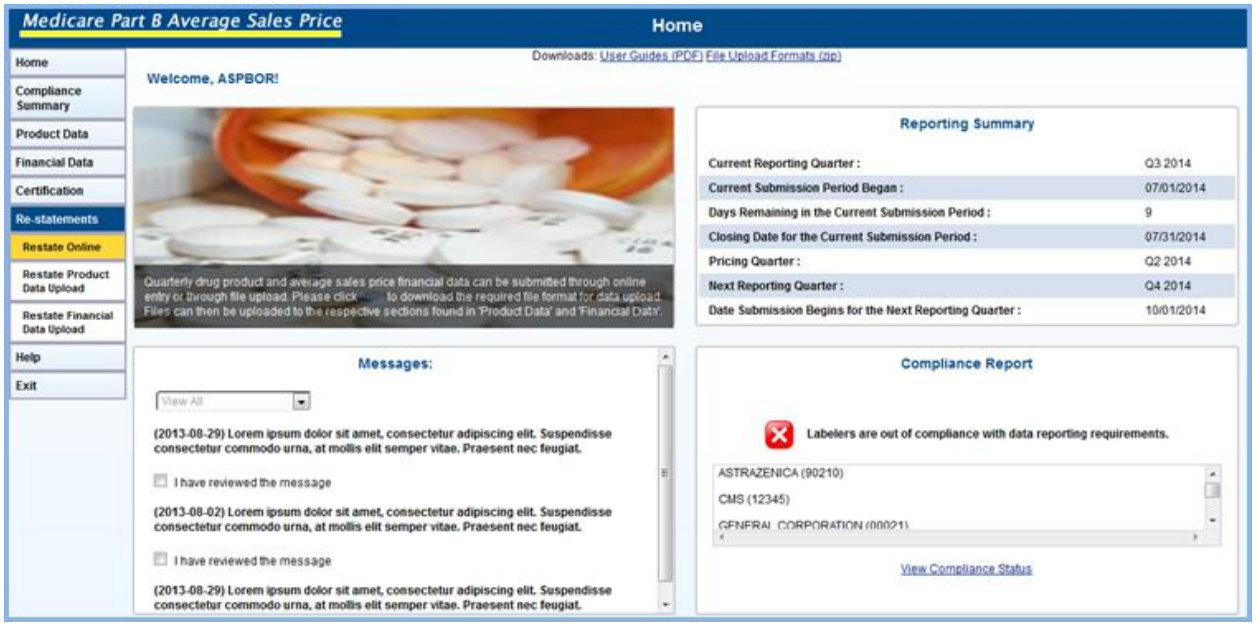
Drug Manufacturers have the ability to resubmit drug data from prior quarters using the ASP application. Drug data that can be restated includes both drug product data and drug financial data. The drug data must have been certified in order for it to be restated. Restated data can be submitted for any reporting period, including the current reporting period; however, the data must have been certified. The ASP Application will then validate the drug product data or drug financial data. The following subsections describe the steps to follow to restate both drug product data and drug financial data.

6.1 Restate Drug Financial Data – Online

The ASP Application provides drug manufacturers the ability to restate drug financial data that has been previously submitted and certified. Perform the following to re-state drug financial data:

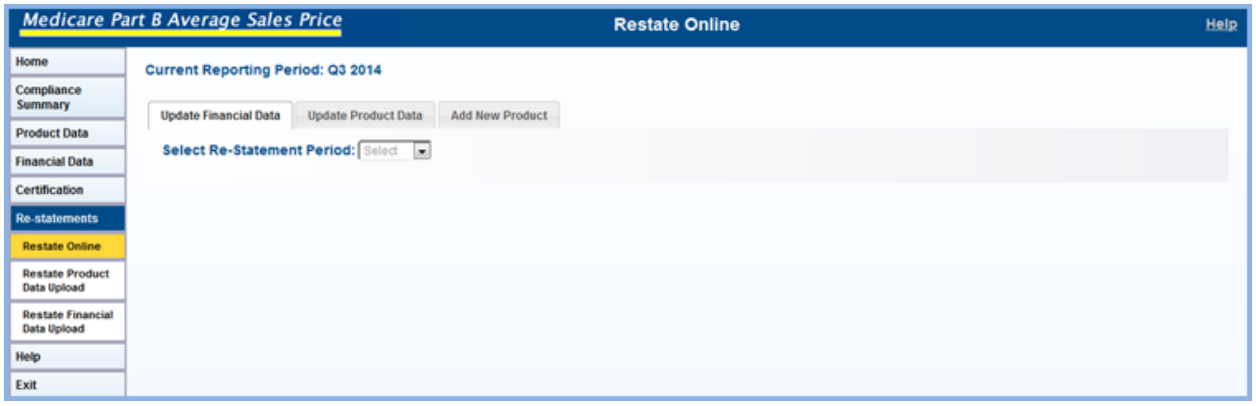
1. Begin re-stating drug data by clicking the **Re-statements** button on the left side menu on the ASP Application Home Page. Select **Restate Online** from the drop-down list. The Restate Online Selection on the ASP Application home page is shown in Figure 6-1.

Figure 6-1: Restate Online Selection Screen



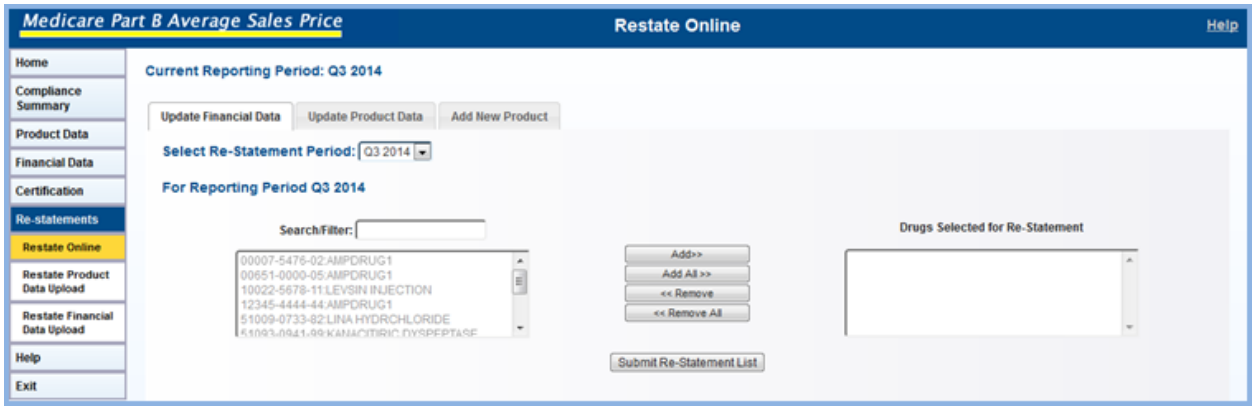
2. Click **Restate Online**. The Restate Online page opens, as shown in Figure 6-2. The Restate Online screen defaults to the Update Financial Data tab.

Figure 6-2: Restate Online Screen – Main



3. Select the desired reporting period from the **Select Re-Statement Period** drop-down list. The **Drugs Available for Re-Statement** field will be populated with all of the drugs that are available for restatement in the reporting period that was selected (in the box on the left). The Restate Online Selection screen opens as shown in Figure 6-3.

Figure 6-3: Restate Online Selection Screen



The following table describes the fields and the user actions on the Restate Online Selection Screen on the Update Finance tab.

Table 6-1 Restate Online Page Information – Update Financial Data Tab

Name	User Action	Comments
– Select Re-Statement Period	– Click the arrow on drop-down box and select the desired quarterly reporting period.	• The available Drug Identifiers will be listed after the Re-Statement Period is selected.
– Drugs Available for Re-Statement	– Click the arrow on the drop-down box and scroll through the list of values. Click the desired value.	• This box is on the left side of the screen. • Multiple Drug Identifiers can be selected.

Name	User Action	Comments
– Search/ Filter	– Enter a few letters of the drug's generic name or the numbers of the Drug Identifier to filter the selections in the field.	• This field is optional.
– Drugs Selected for Re-Statement	– Click the arrow on the drop-down box to display the list of drug identifiers.	• The box will be populated with drugs available for re-statement after a re-statement period is selected.
– Add>>	– Click **Add>>** to move the selected drugs available for re-statement (in the box on the left) to the Drugs Selected for Re-Statement field.	• Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for restatement.
– Add All>>	– Click **Add All>>** to move all available for re-statement (in the box on the left) to the Drugs Selected for Re-Statement field.	• Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for restatement.
– <<Remove	– Click **<<Remove** to remove the selected drugs from the Drugs Selected for Re-Statement field.	• N/A
– << Remove All	– Click **<<Remove All** to remove all drugs from the the Drugs Selected for Re-Statement field.	• N/A
– Submit Re-Statement List	– Click the **Submit Re-Statement List** button to submit the selected drugs for re-statement.	• N/A

4. Enter a few letters of the name of the drug or the first few numbers of the drug identifier to filter the search results. ***Note:*** This step is optional. The drugs available for re-statement will be displayed as shown in Figure 6-4.

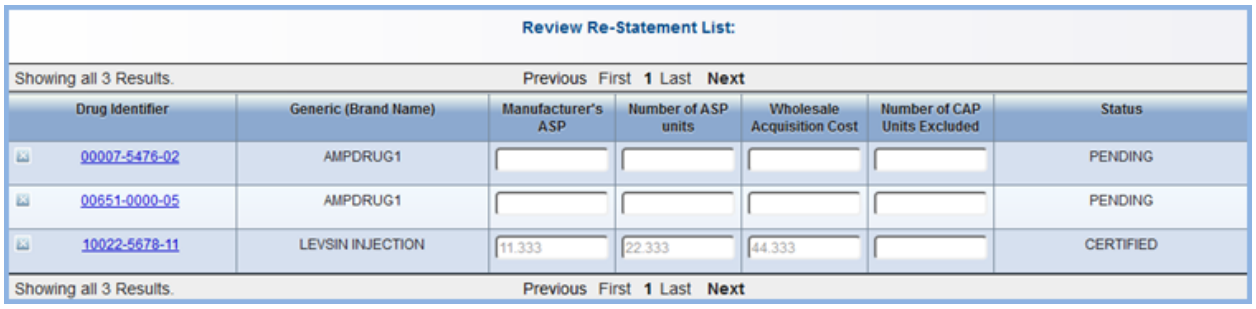
Figure 6-4: Restate Online – Drugs Available for Re-Statement Selections

5. Click the drug(s) you want to re-state and click **Add**>> or click **Add All**>> to select all available drugs for re-statement. The selections have been moved and are to be populated in the Drugs Selected for Re-Statement field as shown in Figure 6-5.

Figure 6-5: Restate Online -- Drugs Selected for Re-Statement

6. Click the **Submit Re-Statement List** button. The Review Re-Statement List opens as shown in Figure 6-6.

Figure 6-6: Restate Online -- Review Re-Statement List



Review Re-Statement List:

Showing all 3 Results. Previous First 1 Last Next

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of CAP Units Excluded	Status
00007-5476-02	AMPDRUG1					PENDING
00651-0000-05	AMPDRUG1					PENDING
10022-5678-11	LEVSIN INJECTION	11.333	22.333	44.333		CERTIFIED

Showing all 3 Results. Previous First 1 Last Next

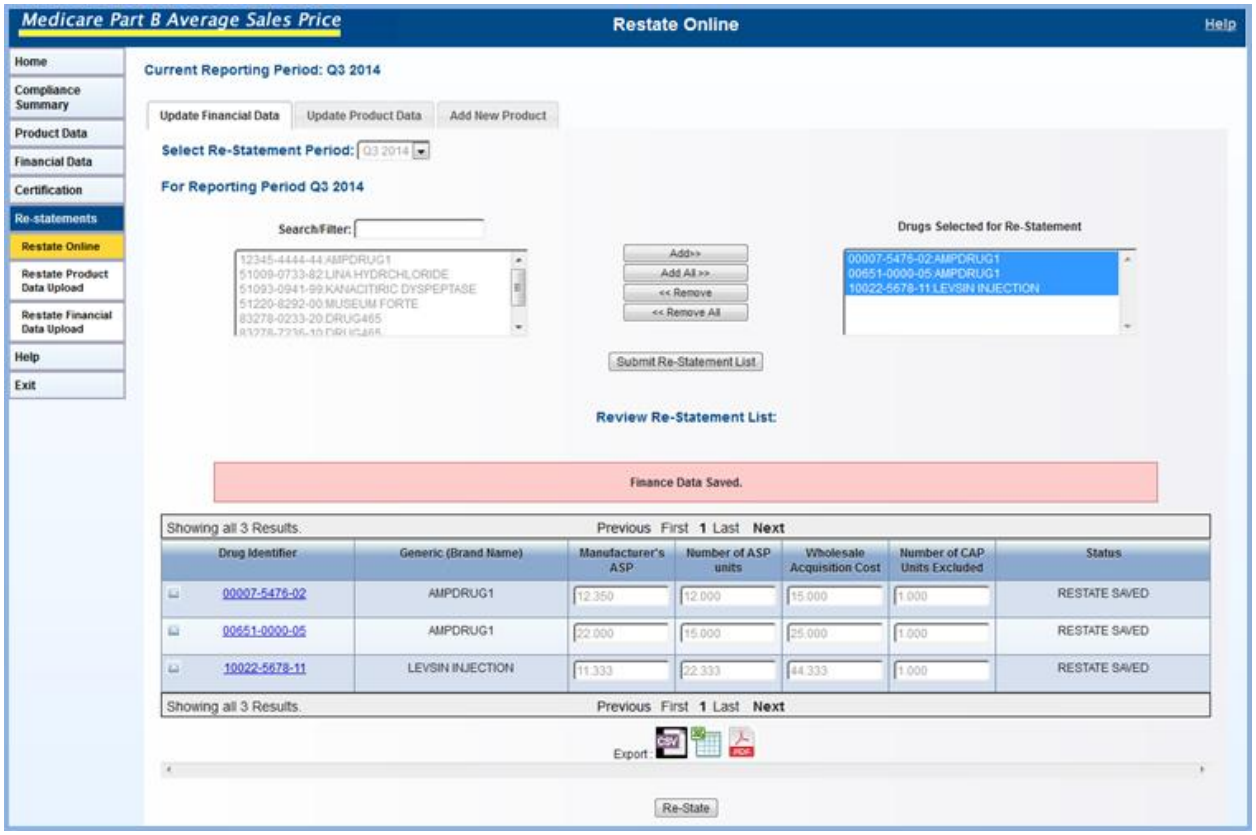
The drug's financial details that can be modified are the following: ASP; ASP Units; WAC; and CAP Units. The following table describes the fields and the user actions on the Add or Edit Financial Data screen.

Table 6-2 Add or Edit Financial Data on the Re-Statement List Page

Name	User Action	Comments
– Manufacturer's ASP	– Enter or update the Manufacturer's ASP in the field.	• The Manufacturer's ASP is a required field. • The Manufacturer's ASP must be in a numeric format. • The Manufacturer's ASP must have three decimal places. • The Manufacturer's ASP can be a positive number, a negative number, or be equal to 0.
– Number of ASP Units	– Enter the number of ASP Units in the field.	• The Number of ASP Units is a required field. • The Number of ASP Units must be in a numeric format. • The Number of ASP Units must have three decimal places. • The number of Number of ASP Units must be greater than zero (0).
– Wholesale Acquisition Cost	– Enter the Wholesale Acquisition Cost (WAC) in the field.	• The WAC is a required field. • The WAC must be in a numeric format. • The WAC must have three decimal places. • The WAC cannot be equal to zero (0).
– Number of CAP Units Excluded	– Enter the number of CAP unites excluded	• The Number of CAP Units Excluded is an optional field. • The Number of CAP Units Excluded must be in a numeric format. • The Number of CAP Units Excluded must have three decimal places. • The Number of CAP Units Excluded must be greater than zero (0).

7. Enter the necessary re-statement amounts for the Manufacturer's Number of ASP Units; Wholesale Acquisition Cost; and the Number of CAP Units Excluded values in the respective fields.
8. Click the **Re-State** button located at the bottom of the screen. The re-stated financial data will be saved and the screen shown in Figure 6-7 will be displayed.

Figure 6-7: Re-State Product Data – Financial Data Saved



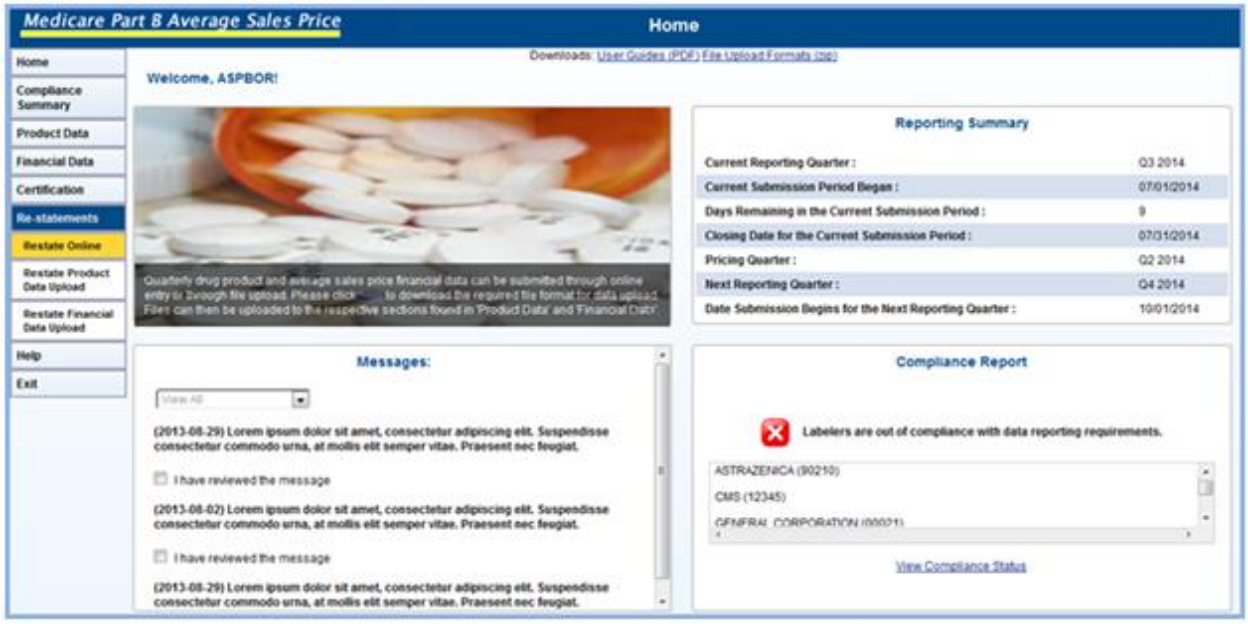
9. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

6.2 Restate Drug Product Data – Online

The ASP Application provides drug manufacturers the ability to restate drug product data that has been previously submitted and certified. Perform the following to re-state drug product data:

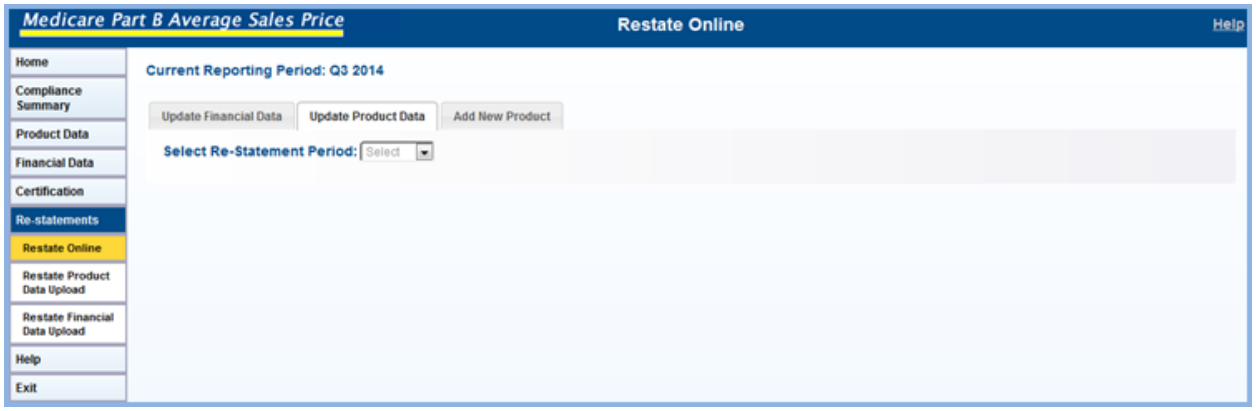
1. Begin re-stating drug data by clicking the **Re-statements** button on the left side menu on the ASP Application Home Page. Select **Restate Online** from the drop-down list. The Restate Online Selection on the ASP Application home page is shown in Figure 6-8.

Figure 6-8: Restate Online Selection Screen



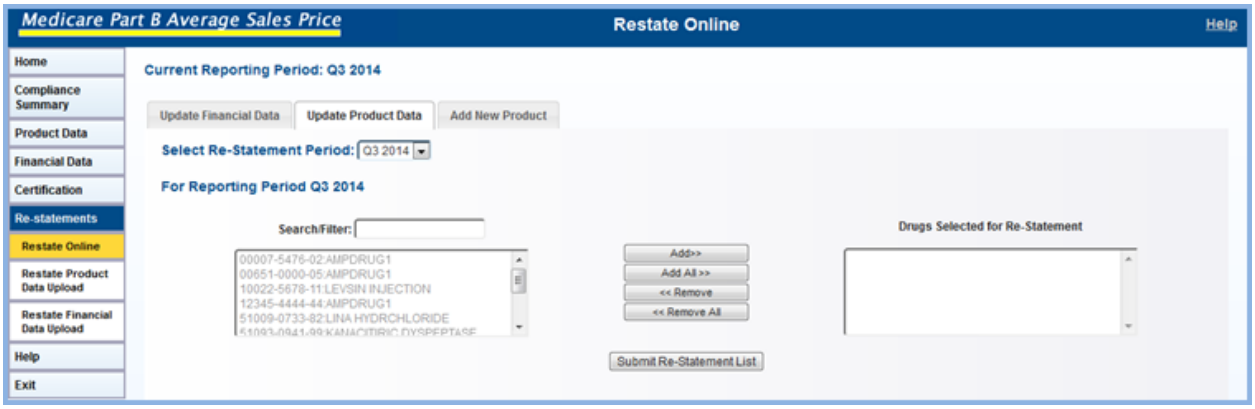
2. Click **Restate Online**. The Restate Online page opens, as shown in Figure 6-2. The Restate Online screen defaults to the Update Finance tab. Click the Update Product tab and select the Re-Statement Period from the **Select Re-Statement Period** drop-down list as shown in Figure 6-9.

Figure 6-9: Restate Online – Update Product Data Tab



3. The Restate Online -- Product Data screen opens, as shown in Figure 6-10.

Figure 6-10: Restate Online – Product Data



The following table describes the fields and the user actions on the Restate Online Product Data screen on the Update Product Data tab.

Table 6-3 Restate Online -- Product Data Page Information

Name	User Action	Comments
– Select Re-Statement Period	– Click the arrow on drop-down box and select the desired quarterly reporting period.	• The available Drug Identifiers will be listed after the Re-Statement Period is selected.
– Drugs Available for Re-Statement	– Click the arrow on the drop-down box and scroll through the list of values. Click the desired value.	• This box is on the left side of the screen. • Multiple Drug Identifiers can be selected.
– Search/ Filter	– Enter a few letters of the drug's generic name or the numbers of the Drug Identifier to filter the selections in the field.	• This field is optional.
– Drugs Selected for Re-Statement	– Click the arrow on the drop-down box to display the list of drug identifiers.	• The box will be populated with drugs available for re-statement after a re-statement period is selected.
– Add>>	– Click **Add>>** to move the selected drugs available for re-statement (in the box on the left) to the Drugs Selected for Re-Statement field.	• Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for restatement.
– Add All>>	– Click **Add All>>** to move all available for re-statement (in the box on the left) to the Drugs Selected for Re-Statement field.	• Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for restatement.

Name	User Action	Comments
– <<Remove	– Click **<<Remove** to remove the selected drugs from the Drugs Selected for Re-Statement field.	• N/A
– << Remove All	– Click **<<Remove All** to remove all drugs from the the Drugs Selected for Re-Statement field.	• N/A
– Submit Re-Statement List	– Click the **Submit Re-Statement List** button to submit the selected drugs for re-statement.	• N/A

4. Enter a few letters of the name of the drug or the first few numbers of the drug identifier to filter the search results. ***Note:*** This step is optional. The drugs available for re-statement will be displayed as shown in Figure 6-11.

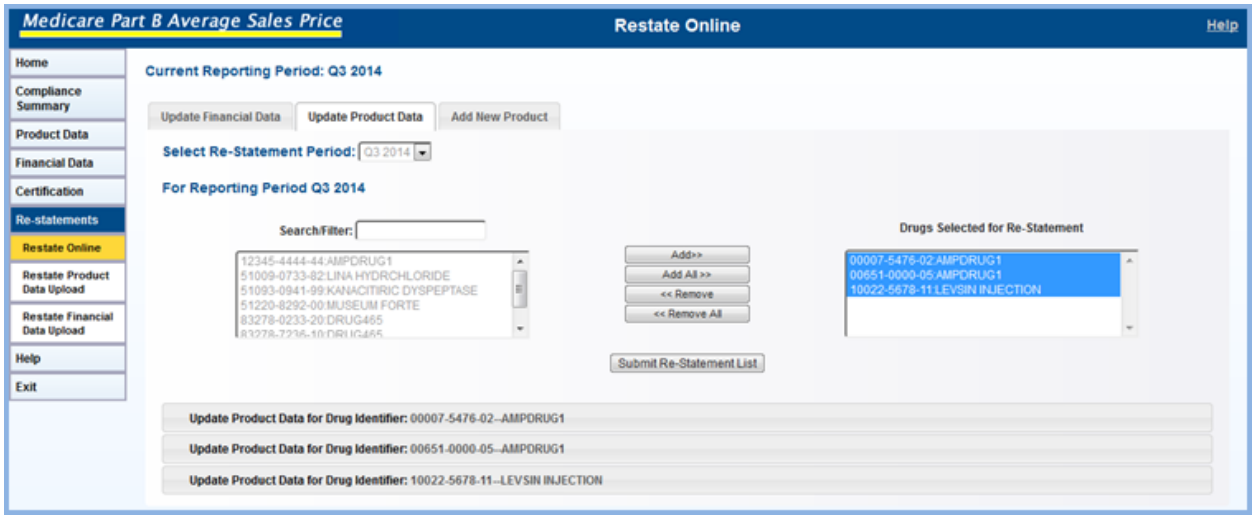
Figure 6-11: Restate Online -- Selections

5. Click the drug(s) you want to re-state and click **Add>>** or click **Add All>>** to select all available drugs for re-statement. The selections have been moved and are be populated in the Drugs Selected for Re-Statement field as shown in Figure 6-12.

Figure 6-12: Restate Online --Drug Products Selected for Re-Statement

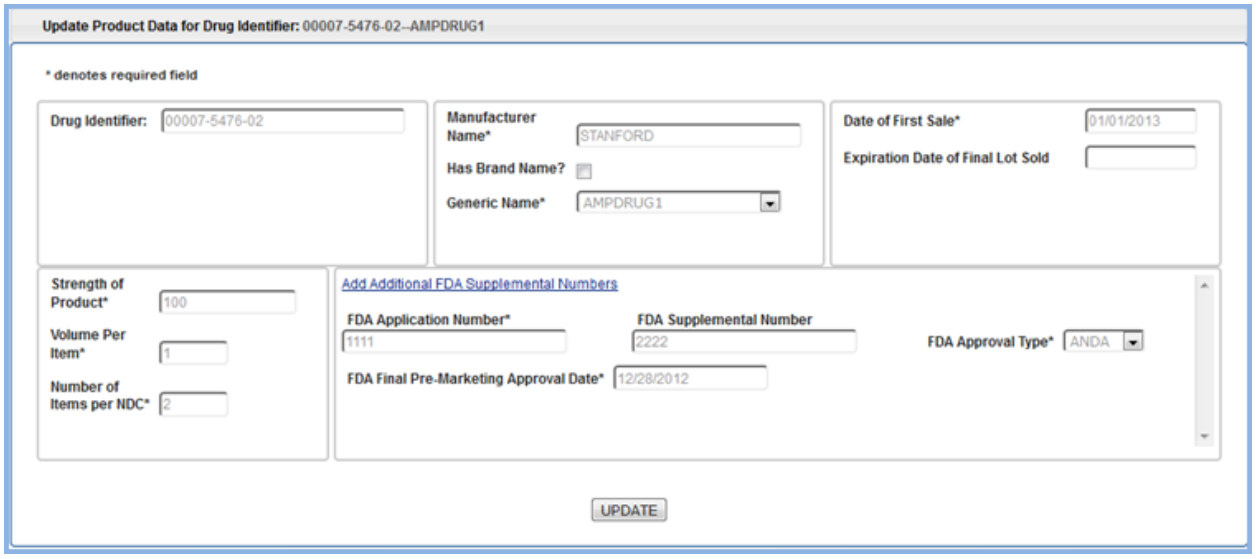
7. Click the **Submit Re-Statement List** button. The Restate Online -- Re-Statement Product List opens as shown in Figure 6-13.

Figure 6-13: Restate Online -- Re-Statement Product List



8. Click on any of the drugs' links to begin the re-statement process. A sample Update Product Data Re-Statement page is shown in Figure 6-14.

Figure 6-14: Update Product Data Re-Statement Page



The following table describes the fields and the user actions on the Update Product Data Re-Statement page.

Table 6-4 Update Product Data Re-Statement Page Information

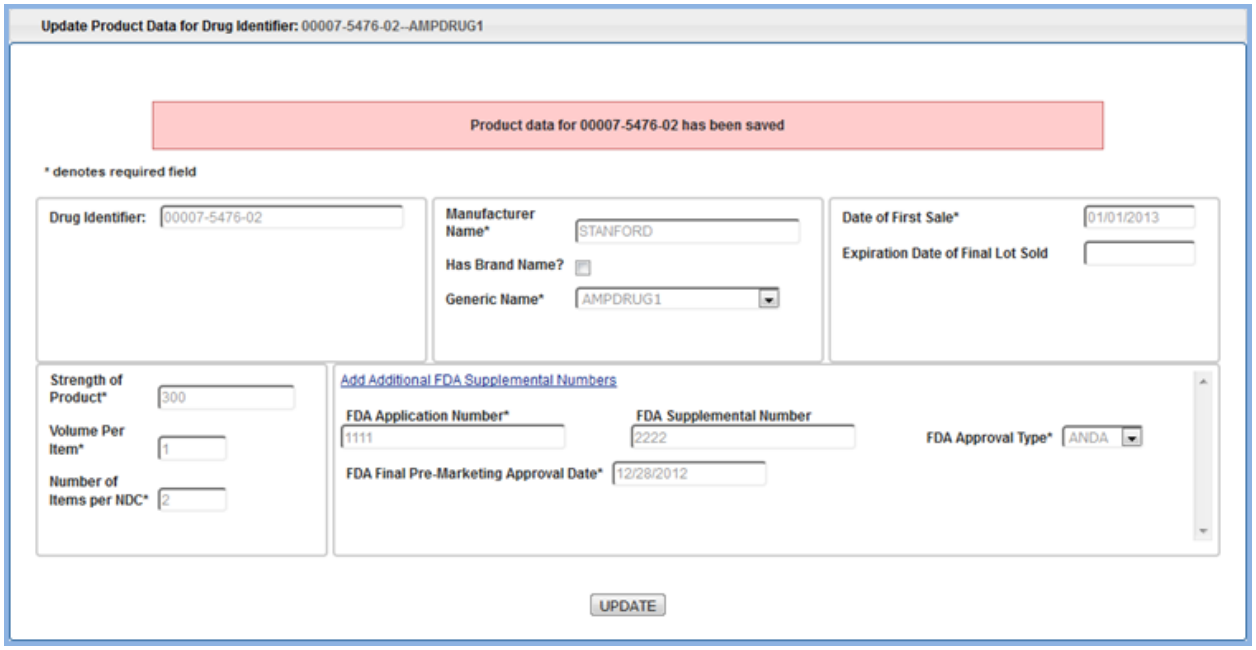
Name	User Action	Comments
– Drug Identifier	– Enter the Drug Identifier in the field.	• Select Drug Identifier is for display only.

Name	User Action	Comments
– Manufacturer Name	– Enter the name of the drug's manufacturer.	• If a new manufacturer is entered into the ASP Application, the manufacturer's name will be marked 'Pending.'
– Brand Name	– Enter the brand name of the drug in the field.	• The Brand Name field is only displayed when the Has Brand Name? box is checked. • Brand Name is required if the Has Brand Name? box is checked. • The Brand Name is limited to 250 characters.
– Generic Name	– Select the Generic Name from the drop-down list.	• The Generic Name is required.
– Date of First Sale	– Enter the date when the drug was first available for sale.	• The Date of First Sale is required. • The date format is MM/DD/YYYY.
– Expiration Date of Final Lot Sold	– Enter the expiration date of the final lot that was sold. Scroll through the pop-up calendar for the desired date, or enter the date directly into the field.	• The date format is MM/DD/YYYY.
– Strength of Product	– Enter the Strength of product in the field.	• The Strength of Product is required. • The Strength of Product has a limit of 250 characters. • The Strength of Product includes both the amount and units (i.e., 6 ml).
– Volume per Item	– Enter the Volume per Item in the field.	• The Volume per Item is required. • The Volume per Item has a limit of 250 characters. • The Strength of Product includes both the amount and units (i.e., 6 ml).
– Number of Items per NDC	– Enter the Number of Items per NDC in the field.	• The entry must be in a numeric format.
– FDA Application Number	– Enter the FDA Application Number in the field.	• The FDA Application Number is required. • The FDA Application Number format must be alphanumeric.
– FDA Final Pre-marketing Approval Date	– Enter the FDA Final Pre-marketing approval date. Scroll through the pop-up calendar for the desired date, or enter the date directly into the field.	• The FDA Final Pre-marketing Approval Date is required. • The date format is MM/DD/YYYY. • The FDA Final Pre-marketing Approval Date cannot be after the upload date.
– FDA Supplemental Number	– Enter the FDA Supplemental Number in the field.	• The FDA Supplemental Number format must be alphanumeric. • This field is optional

Name	User Action	Comments
– FDA Approval Type	– Select the FDA Approval Type from the drop-down list.	• The FDA Approval Type is required.

9. Enter the necessary re-statement amounts for the desired fields.
10. Click the **Update** button located at the bottom of the screen. The re-stated product data will be saved and the screen shown in Figure 6-15 will be displayed.

Figure 6-15: Re-stated Product Data Saved



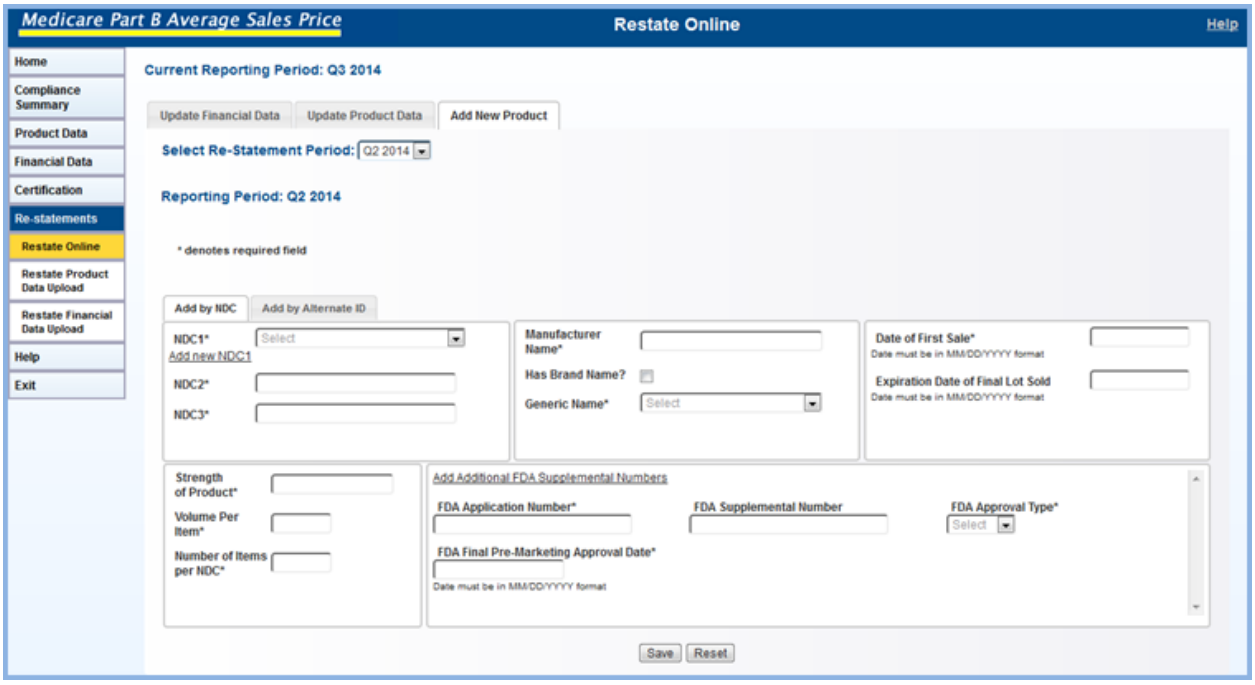
11. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

6.3 Add New Product – Re-statement Tab

The Re-Statement Online functions allow drug manufacturers to add new drug product data for previous reporting periods. Perform the following steps to add new product data using the Re-Statement feature:

1. Click the **Re-statements** button on the left side menu on the ASP Application Home Page. Select **Restate Online** from the drop-down list, and click the **Add New Product** tab.
2. Select a previous re-statement period from the **Select Re-Statement Period** drop-down list. The screen shown in Figure 6-16 will be displayed.

Figure 6-16: Restate Online – Add New Product



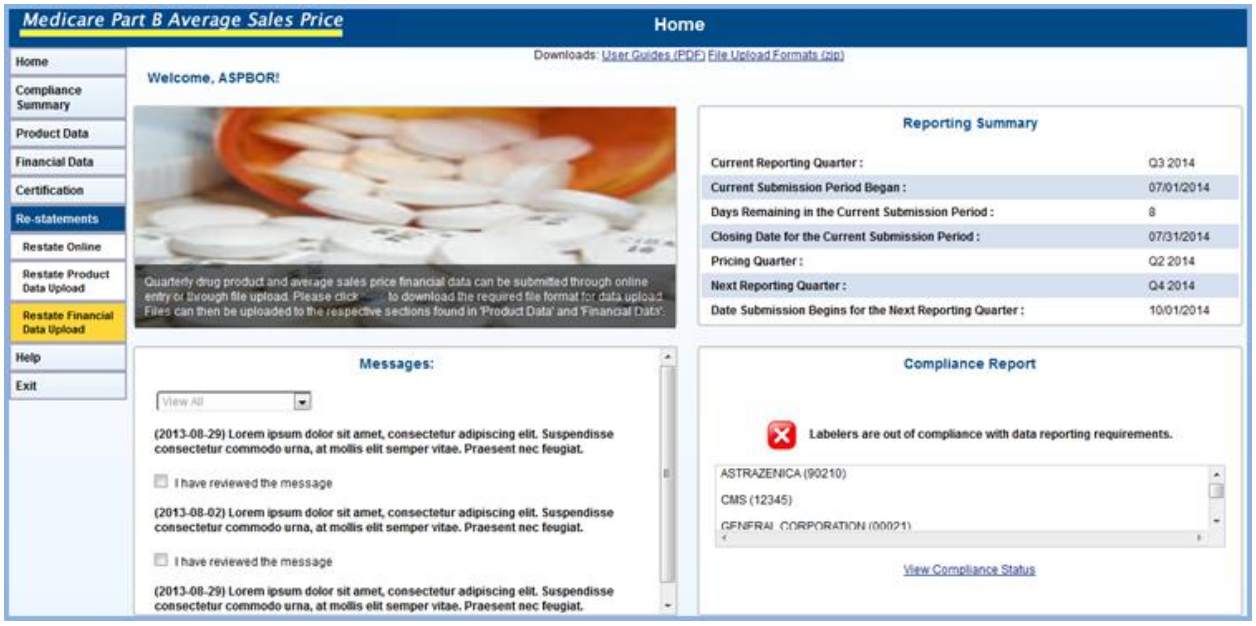
4. Refer to Section 4, Data Submission, for the steps needed to add new Product Data, and click **Save** when complete.

6.4 Restate Financial Data – File Upload

The ASP database provides drug manufacturers the ability re-state Medicaid Part B financial data to CMS. The ASP Application provides drug manufacturers the ability to restate drug product data and drug financial data that has been previously submitted and certified. Also, the ASP Application allows entry of prior quarters' financial data through the use of the re-statement function. This covers data that did not exist before the particular quarter. Perform the following steps to re-state drug financial data using the file transfer process:

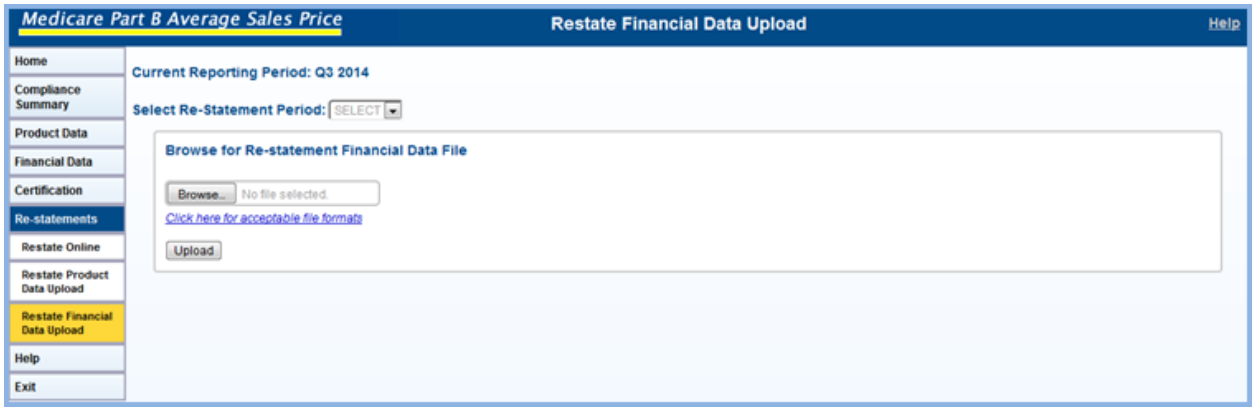
1. Click the **Re-Statements** button on the left side menu on the ASP Application Home Page and select **Restate Financial Data Upload** from the drop-down list. The Restate Financial Data Upload selection on the ASP Application home page is shown in Figure 6-17.

Figure 6-17: Restate Financial Data Upload Selection



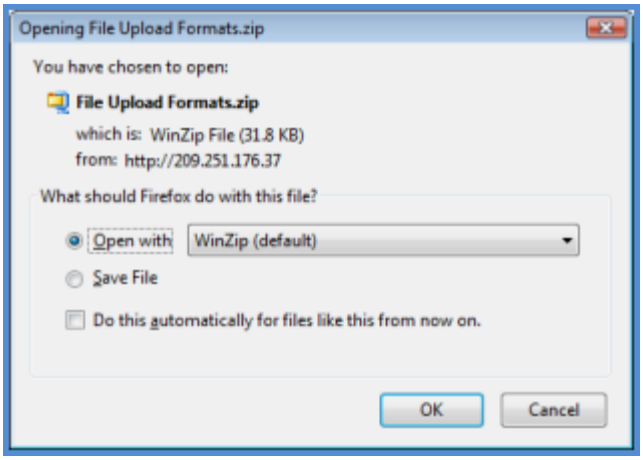
2. Click **Restate Financial Data Upload**. The Restate Upload Financial Data Upload screen opens, as shown in Figure 6-18.

Figure 6-18: Restate Financial Data Upload



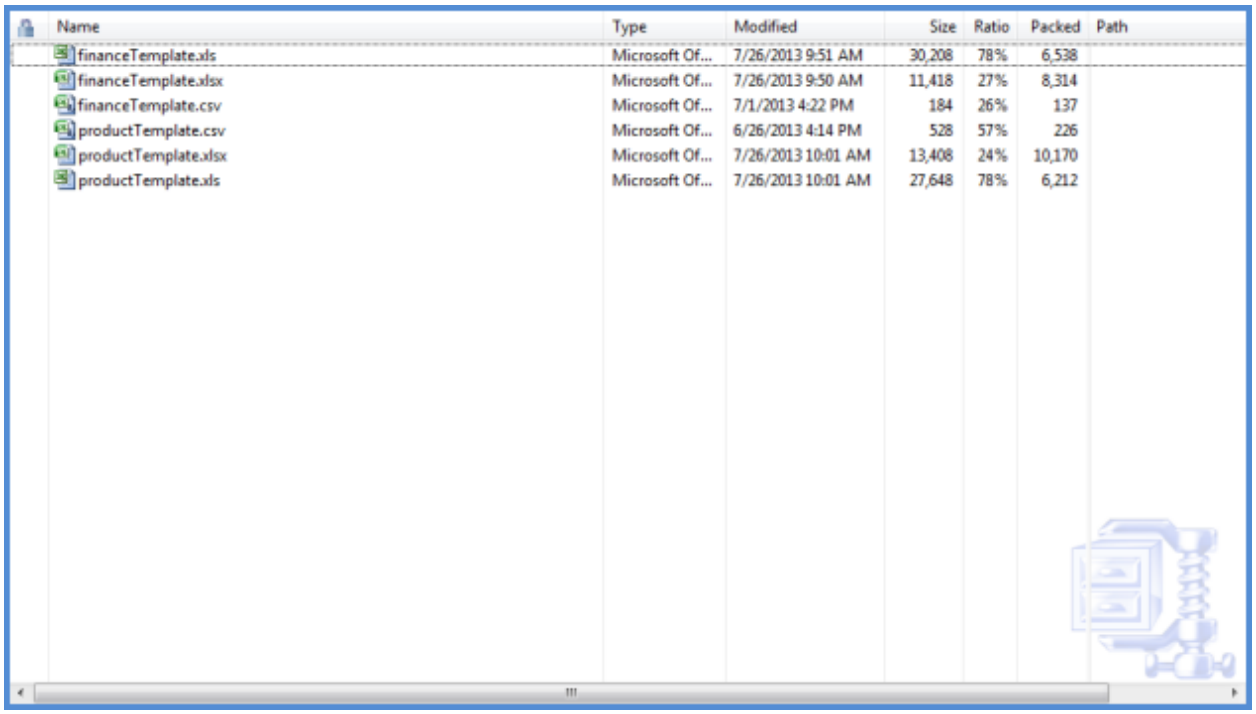
3. Select the desired re-statement period from the **Select Re-Statement Period** drop-down list.
4. If the re-stated drug financial data has been entered and saved to a file of an acceptable file format (.xls, .xlsx, or .csv), click **Browse** to locate the file path and the name of the file to be uploaded.
5. If the re-stated drug financial data has not been entered and saved to a file of an acceptable file format click the **Click here of acceptable file formats** link. A pop-up window opens asking for authorization to upload a .zip file containing the file formats, as shown in Figure 6-19.

Figure 6-19: Attachment Upload -- .zip File



6. Click **OK** to upload the .zip file. The .zip file opens displaying the acceptable file form templates, as shown in Figure 6-20.

Figure 6-20: Acceptable File Format Templates



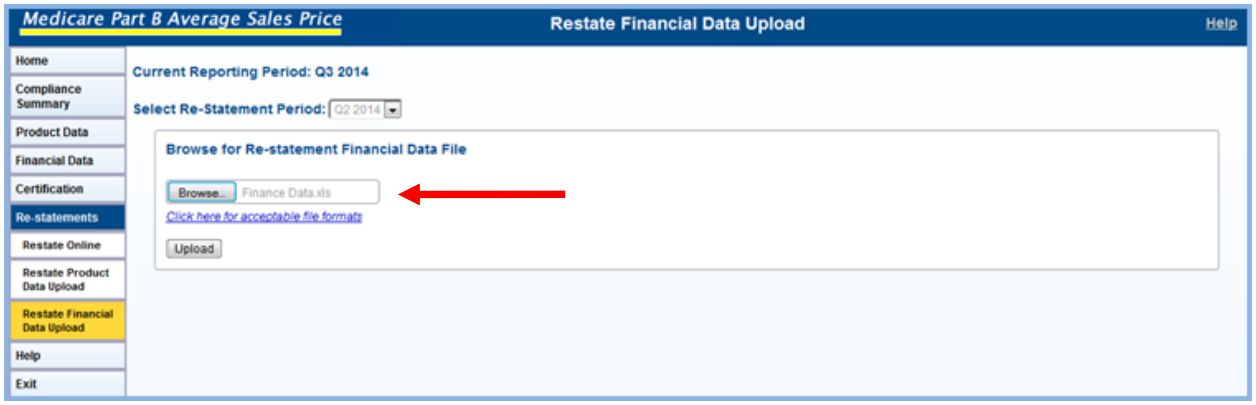
7. Click any one of Finance Template files to open a product data template. A sample template is shown in Figure 6-21.

Figure 6-21: Sample Financial Data Template

	A	B	C	D	E	F	G	H	I	J	K
1	Manufacturer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Manufacturer's Average Sales Price	Number of ASP Units	Wholesale Acquisition Cost	Number of CAP Units Excluded
2											
3											
4											
5											
6											
7											

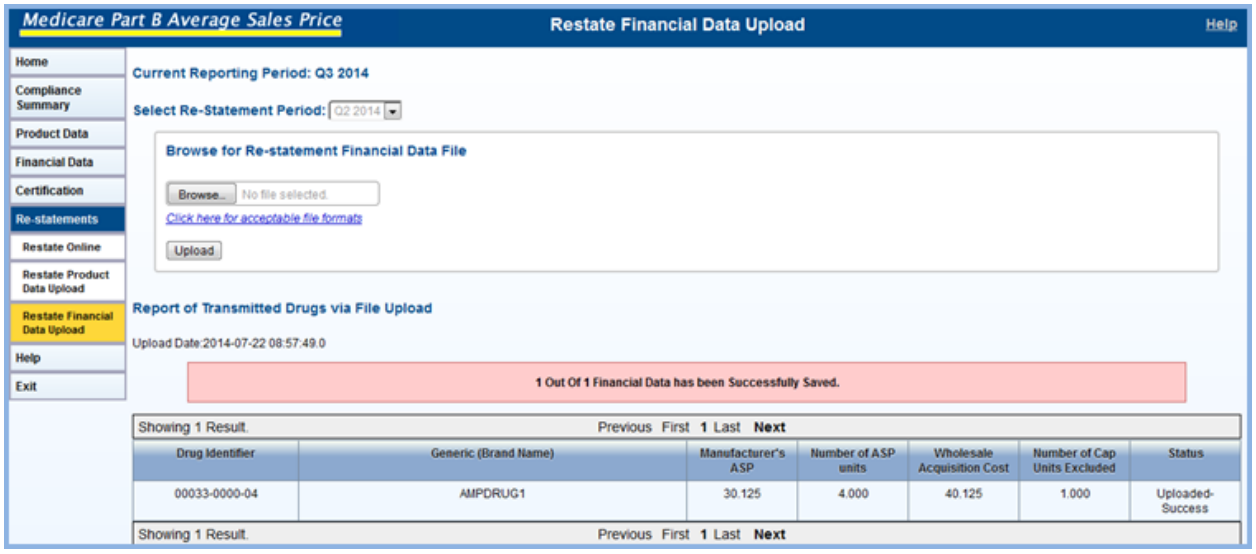
8. Enter the re-stated drug financial information on the template. The entries on the template consist of the same fields that are described in Section 6.1, Re-State Drug Financial Data – Online Entry. Refer to Table 6-2 for a description of the fields and which fields are required. Save the file using a different name and to an easily accessible location on your computer. Close the file and return to the Restate Upload Financial Data page.
9. Click **Browse** to locate the file path and name of the file to be uploaded. A file upload window will open.
10. Locate the file, click on the file, and click **Open**. The File Upload window will close, and the file to be uploaded will be displayed on the Restate Financial Data Upload page, as shown in Figure 6-22.

Figure 6-22: Restate Financial Data Upload – File to be Uploaded



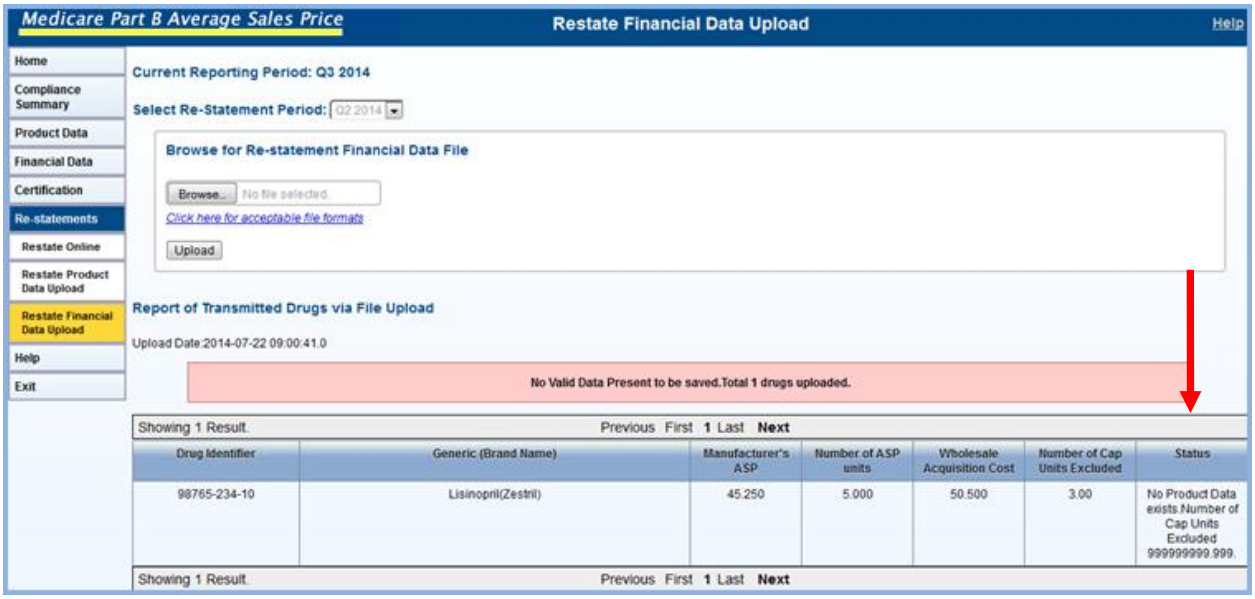
11. Click **Upload**. The Restate Financial Data upload -- Result screen will open, as shown in Figure 6-23.

Figure 6-23: Restate Financial Data Upload -- Result



12. The Restate Financial Data Upload -- Result screen displays a report of the restated drug financial data that was just uploaded using the file transfer process. Review the data on the screen. Data with no errors is saved, and the upload status will display a message stating that the data has been successfully saved. Data that contains errors will display the errors in the Status column. A sample upload with erroneous data is shown in Figure 6-24.

Figure 6-24: Upload Restate Financial Data Result -- Error



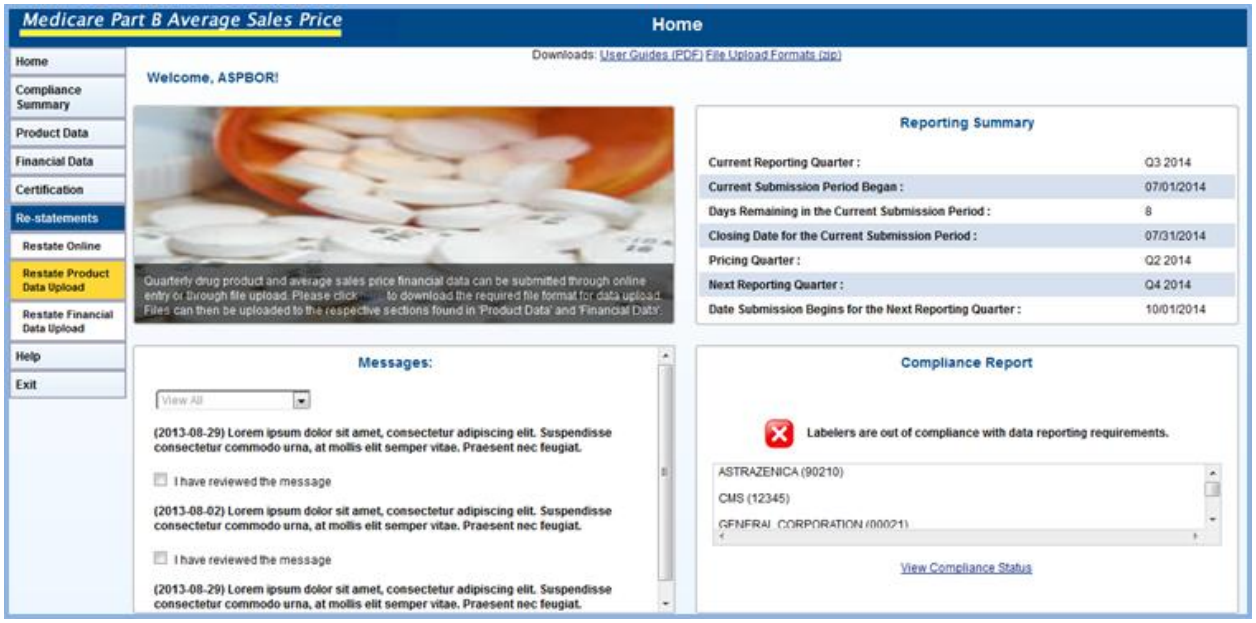
13. Reopen the file that was uploaded and make the necessary corrections. Save the file, and repeat Step 8 through Step 10.
14. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

6.5 Restate Drug Product Data – File Upload

The ASP database provides drug manufacturers the ability re-state Medicaid Part B drug data to CMS. Perform the following steps to re-state drug product data using the file transfer process:

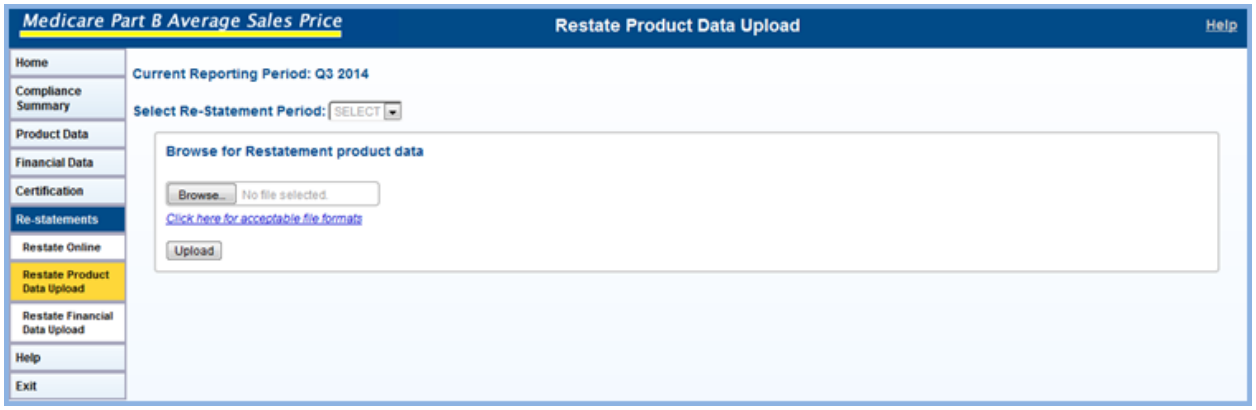
1. Click the **Re-Statements** button on the left side menu on the ASP Application Home Page and select **Restate Product Data Upload** from the drop-down list. The Restate Product Data Upload Selection on the ASP Application home page is shown in Figure 6-25.

Figure 6-25: Restate Product Data Upload Selection



2. Click **Restate Product Data Upload**. The Upload Product Data page opens, as shown in Figure 6-26.

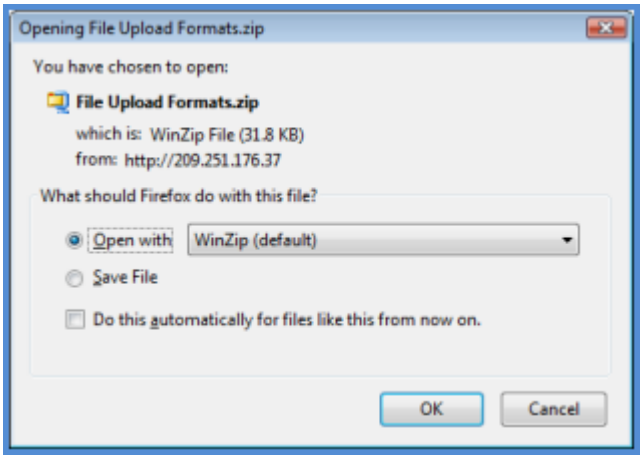
Figure 6-26: Restate Product Data Upload



3. If the drug product data has been entered and saved to a file of an acceptable file format (.xls, .xlsx, or .csv), click **Browse** to locate the file path and the name of the file to be uploaded.

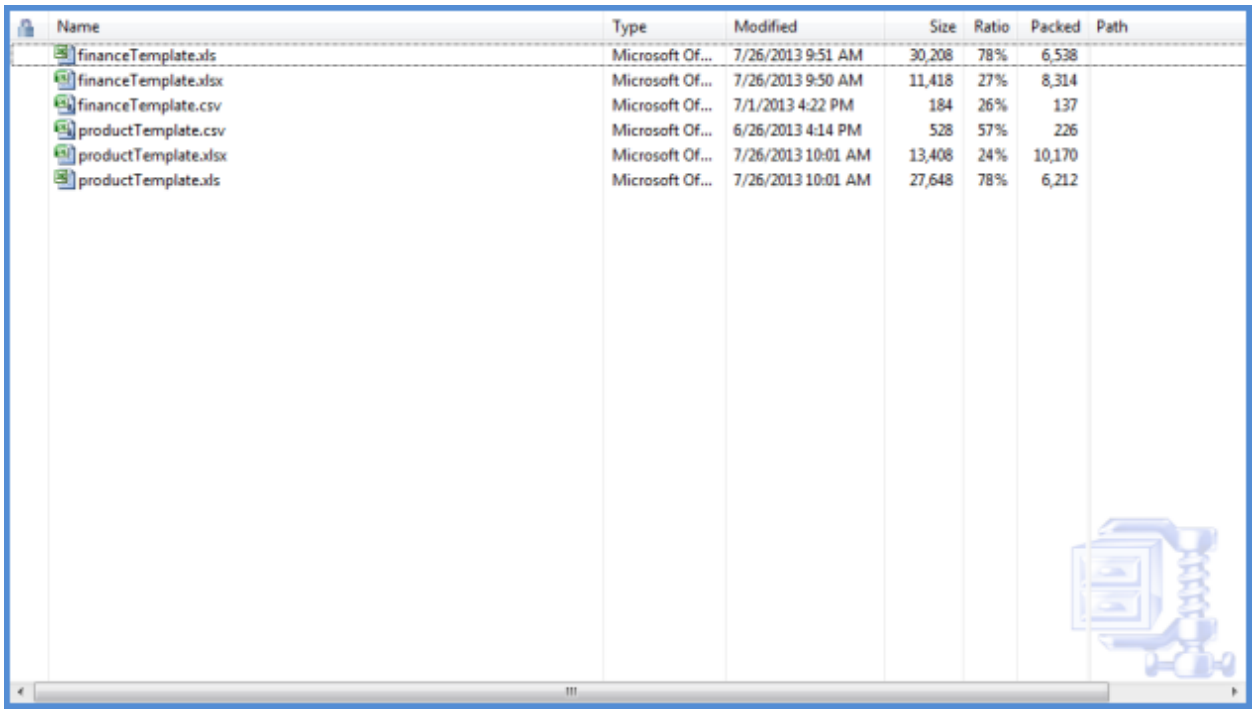
4. If the drug data has not been entered and saved to a file of an acceptable file format click the **Click here of acceptable file formats** link. A pop-up window opens asking for authorization to upload a .zip file containing the file formats, as shown in Figure 6-27.

Figure 6-27: Attachment Upload -- .zip File



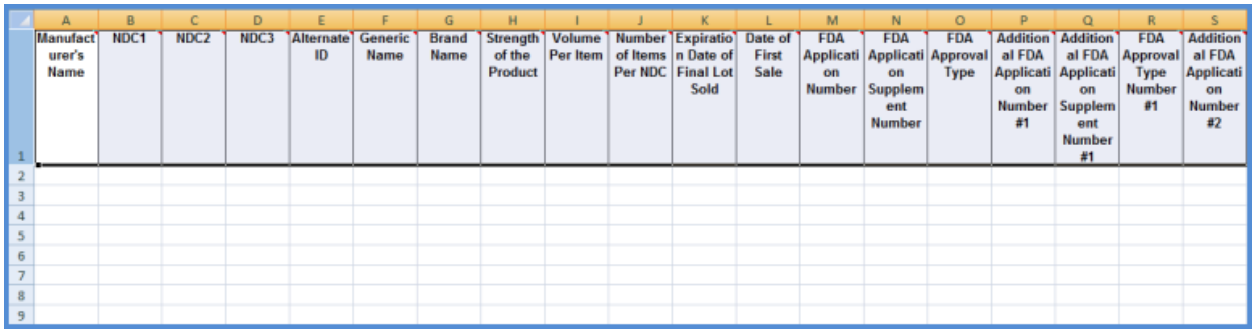
5. Click **OK** to upload the .zip file. The .zip file opens displaying the acceptable file form templates, as shown in Figure 6-28.

Figure 6-28: Acceptable File Format Templates



6. Click any one of Product Template files to open a product data template. A sample template is shown in Figure 6-29.

Figure 6-29: Sample Product Data Template

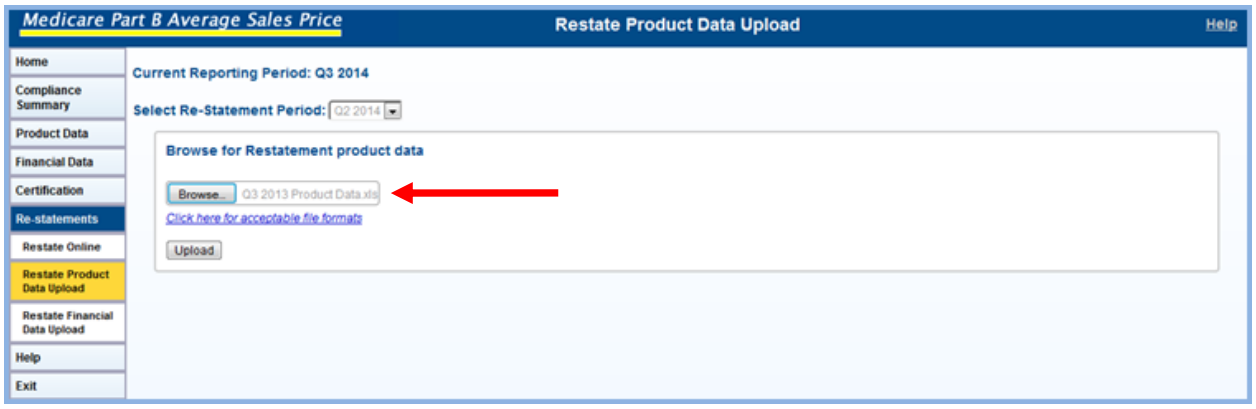


	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	Manufacturer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Strength of the Product	Volume Per Item	Number of Items Per NDC	Expiration Date of Final Lot Sold	Date of First Sale	FDA Application Number	FDA Application Supplement Number	FDA Approval Type	Additional FDA Application Number #1	Additional FDA Application Supplement Number #1	FDA Approval Type Number #1	Additional FDA Application Number #2
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			

* Please note that not all rows of the template are displayed in Figure 6-29.

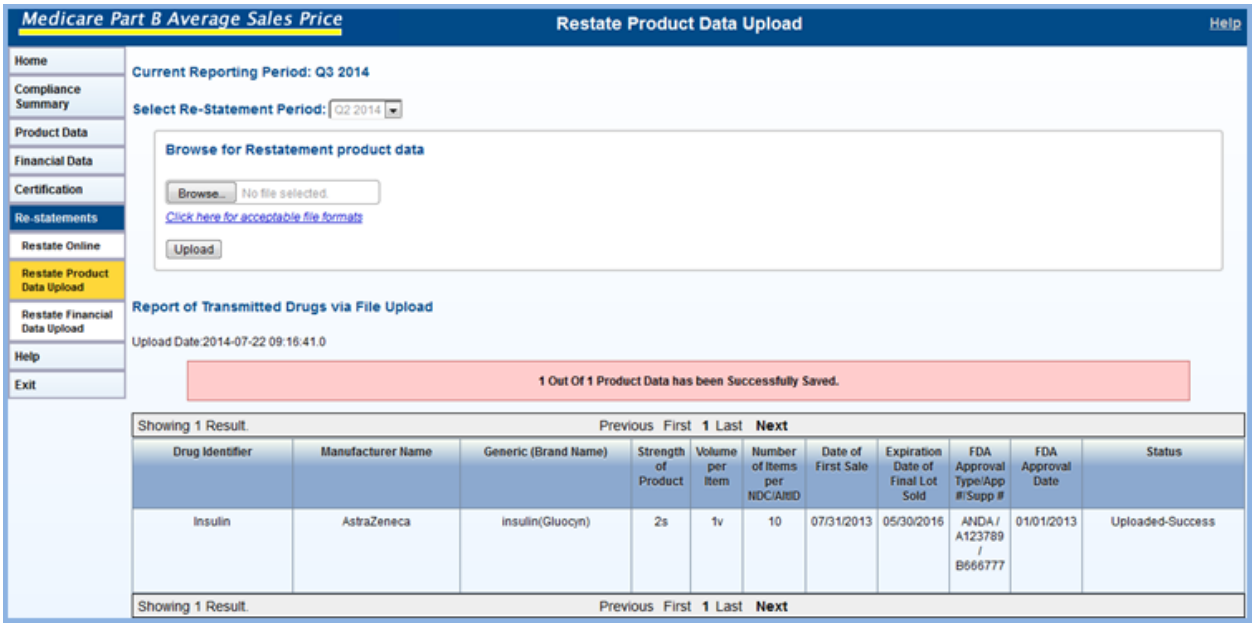
7. Enter the drug product information on the template. The entries on the template consist of the same fields that are described in Section 2.2, Upload Product Data – Online Data Entry. Refer to Table 2-1 for a description of the fields and which fields are required. Save the file using a different name and to an easily accessible location on your computer. Close the file and return to the Upload Product Data page.
8. Click **Browse** to locate the file path and name of the file to be uploaded. A file upload window will open.
9. Locate the file, click on the file, and click **Open**. The File Upload window will close, and the file to be uploaded will be displayed on the Upload Product Data page, as shown in Figure 6-30.

Figure 6-30: Restate Product Data Upload – File to be Uploaded



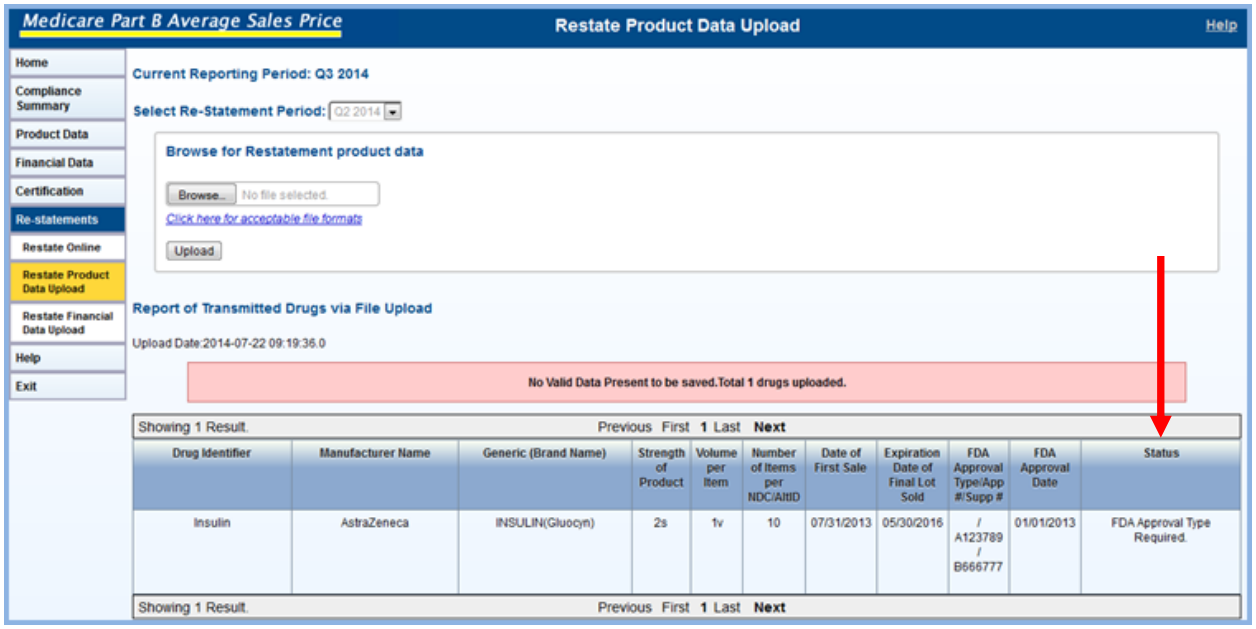
10. Click **Upload**. The Upload Product Data Result screen will open, as shown in Figure 6-31.

Figure 6-31: Restate Product Data Upload -- Result



11. The Upload Product Data Result screen display a report of the drug product data that was just uploaded using the file transfer process. Review the data on the screen. Data with no errors is saved, and the upload status will display a message stating that the data has been successfully saved. Data that contains errors will display the errors in the Status column. A sample upload with erroneous data is shown in Figure 6-32.

Figure 6-32: Restate Product Data Upload Result -- Error



12. Reopen the file that was uploaded and make the necessary corrections. Save the file, and repeat Step 8 through Step 10.

13. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

7 Compliance

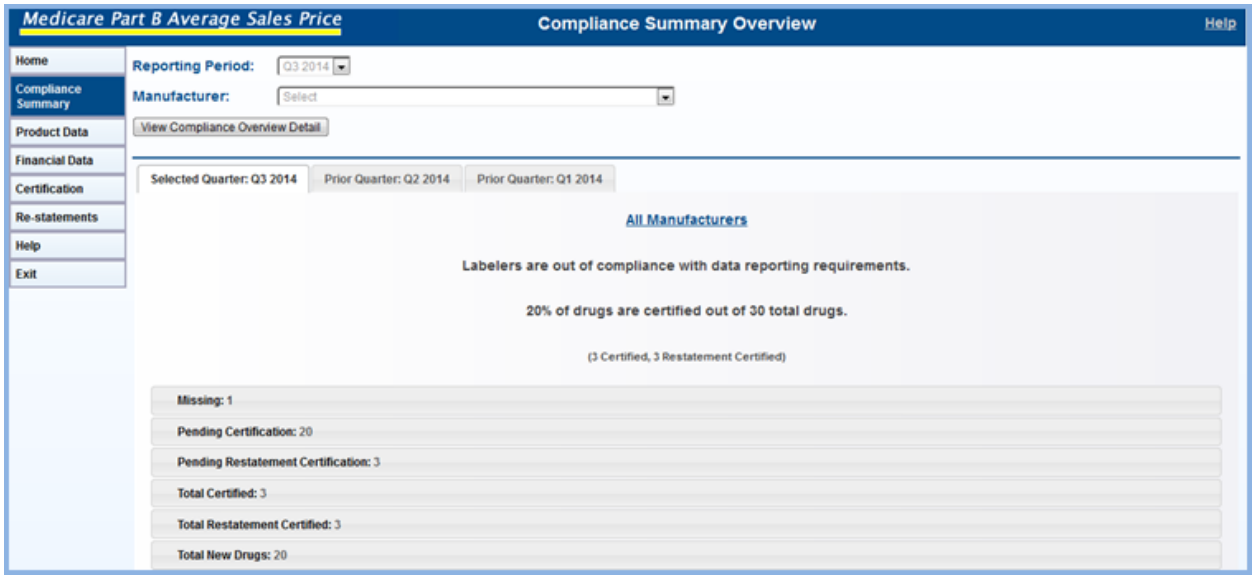
The Compliance features allow Drug Manufacturers to view whether a drug is in compliance with the drug submission reporting requirements. Drug Manufacturers can view compliance statuses in one of two ways: CMS may send the Drug Manufacturer a compliance report notification on their home page informing them that some data is out of compliance. Or Drug Manufacturers can access a compliance summary for all drugs using the Compliance Summary menu button on the ASP Application Home Page. The following subsections describe the steps to view compliance reports using each method.

7.1 Compliance Summary Overview

In this scenario, CMS must have previously sent a bulletin to the Drug Manufacturer notifying them of the compliance status. Perform the following steps to view compliance data using this method:

1. Click the **Compliance Summary** selection on the ASP Application home page. The Compliance Summary Overview page opens as shown in Figure 7-1.

Figure 7-1: Compliance Summary Overview



The following table describes the fields and the user actions on the Compliance Summary Overview screen.

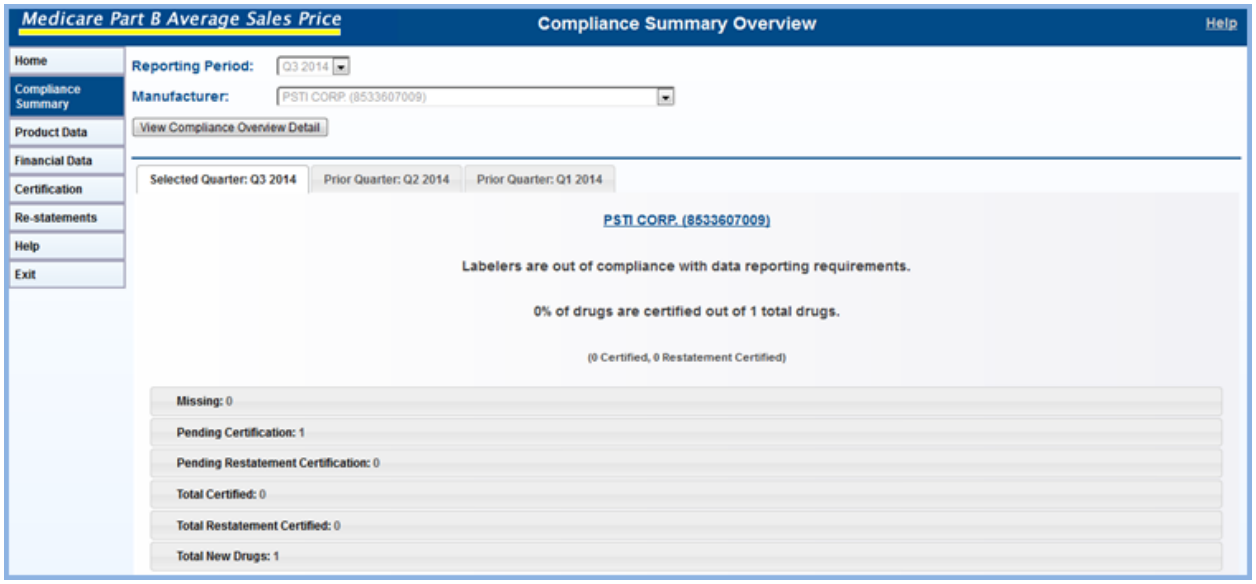
Table 7-1 Select Certification Status Page Information

Name	User Action	Comments
– Reporting Period	– Click the arrow on drop-down box and select the desired quarterly reporting period.	• Defaults to the current quarterly reporting period.

Name	User Action	Comments
– Manufacturer (NDC1 Code)	– Click the arrow on the drop-down box and scroll through the list of Manufacturers. Click the desired Manufacturer (and NCD1 Code).	• Results will be displayed depending on the selection of the Manufacturer.

2. The Compliance Summary Overview screen lists the compliance summary for all manufacturers as a default. Select the desired reporting period from the **Reporting Period** drop-down list and the desired manufacturer from the **Manufacturer** drop-down list to view a compliance summary for a specific manufacturer. Click the **View Compliance Overview Detail** button to display the summary report. A sample manufacturer compliance summary report is shown in Figure 7-2.

Figure 7-2: Manufacturer's Compliance Summary Report



3. The Compliance Summary Overview screen will display statements whether the Drug Manufacturer is within compliance for all drug data within the reporting period. Drugs that are listed in the columns as Missing; containing Saved Finance Data and Pending Certification; or containing Restated Saved Finance Data and Pending Certification are the drugs that are not compliant with the data reporting requirements. The additional columns on the Compliance Overview page and their contents are reviewed in further detail in the subsequent sections.

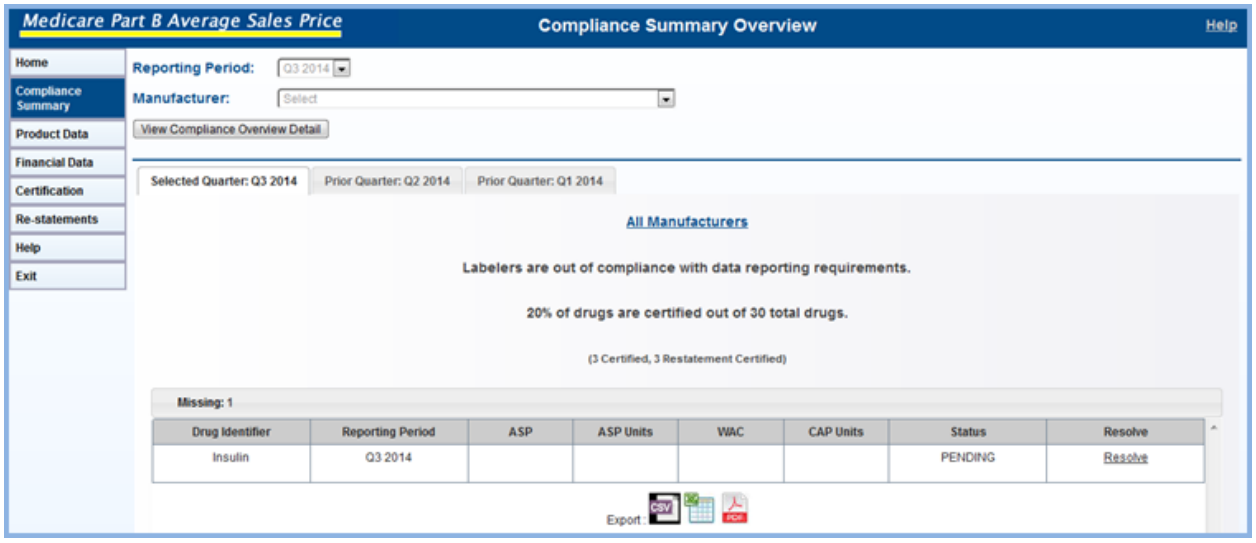
7.2 Compliance Overview

The Compliance Overview page displays all aspects of the reporting compliance for the selected reporting period. The Compliance Overview page displays a notice to drug manufacturers whether they are compliant with the data reporting requirements and the percentage of drugs that have been certified out of the total number of drugs that have been submitted. Each tab on the Compliance Overview page is further detailed in the following sub-sections.

7.2.1 Missing Drugs

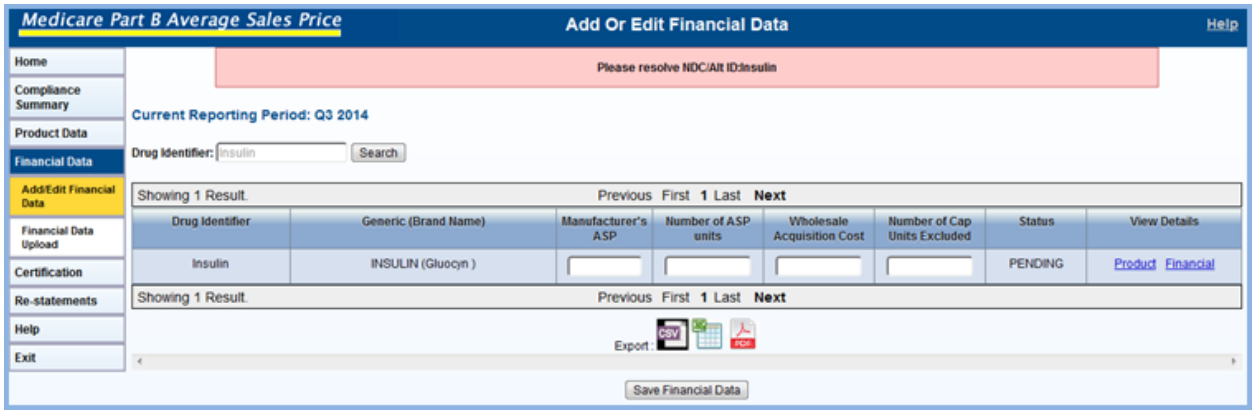
Drug Manufacturers can view and update drugs that are not compliant because the information about the drug is incomplete or insufficient by clicking on the Missing Drugs tab. The screen shown in Figure 7-3 will be displayed.

Figure 7-3: Compliance Summary Overview—Missing Drugs



Drug Manufacturers have the ability to correct the deficiencies in the drug data by clicking the **Resolve** link in the drug data's summary or information. Click the **Resolve** link, and the screen shown in Figure 7-4 opens displaying a warning banner that describes what needs to be resolved in order for the drug data to be in compliance.

Figure 7-4: Compliance Summary Overview—Resolve

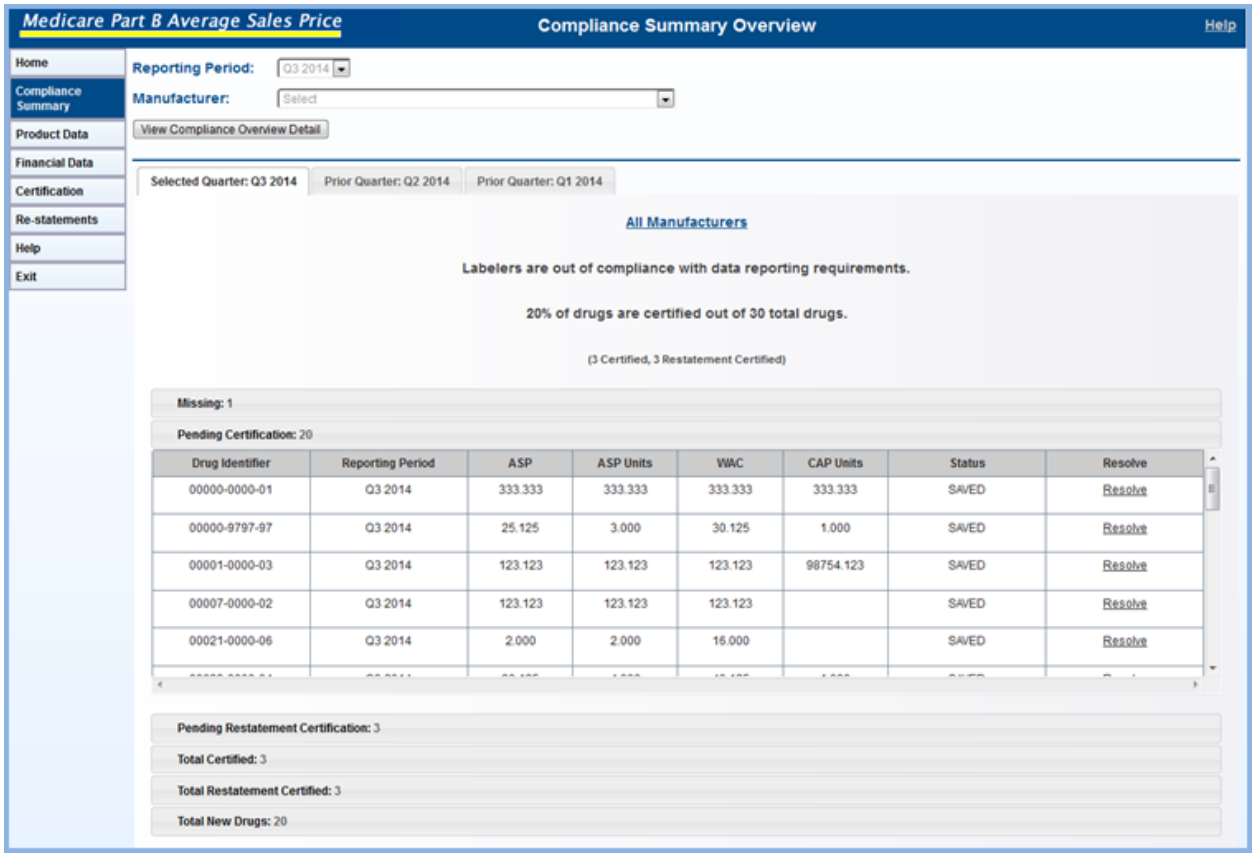


Refer to Section 4, Data Submission, for the steps needed to add and/or edit financial or drug data in order to resolve the deficiencies.

7.2.2 Pending Certifications

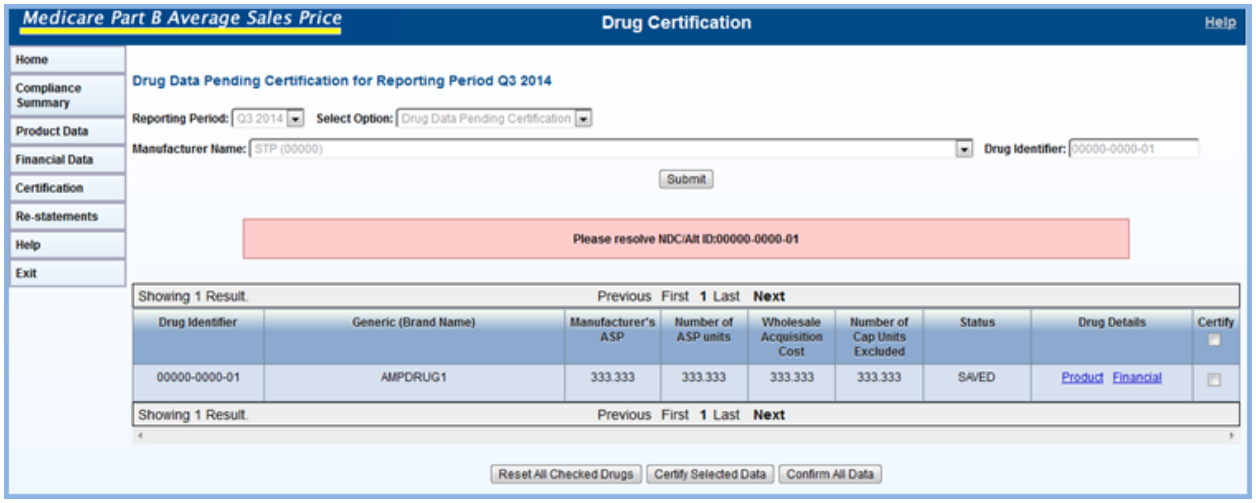
Drug Manufacturers can view and update drugs that have saved financial data but whose certifications are pending. Click the Pending Certification tab to view the drugs that require certification resolution. The screen shown in Figure 7-5 is displayed.

Figure 7-5: Compliance Summary Overview—Pending Certifications



Click the **Resolve** link on any drug listed to begin the resolution process. The screen shown in Figure 7-6 is displayed.

Figure 7-6: Compliance Summary Overview—Resolve Pending Certifications

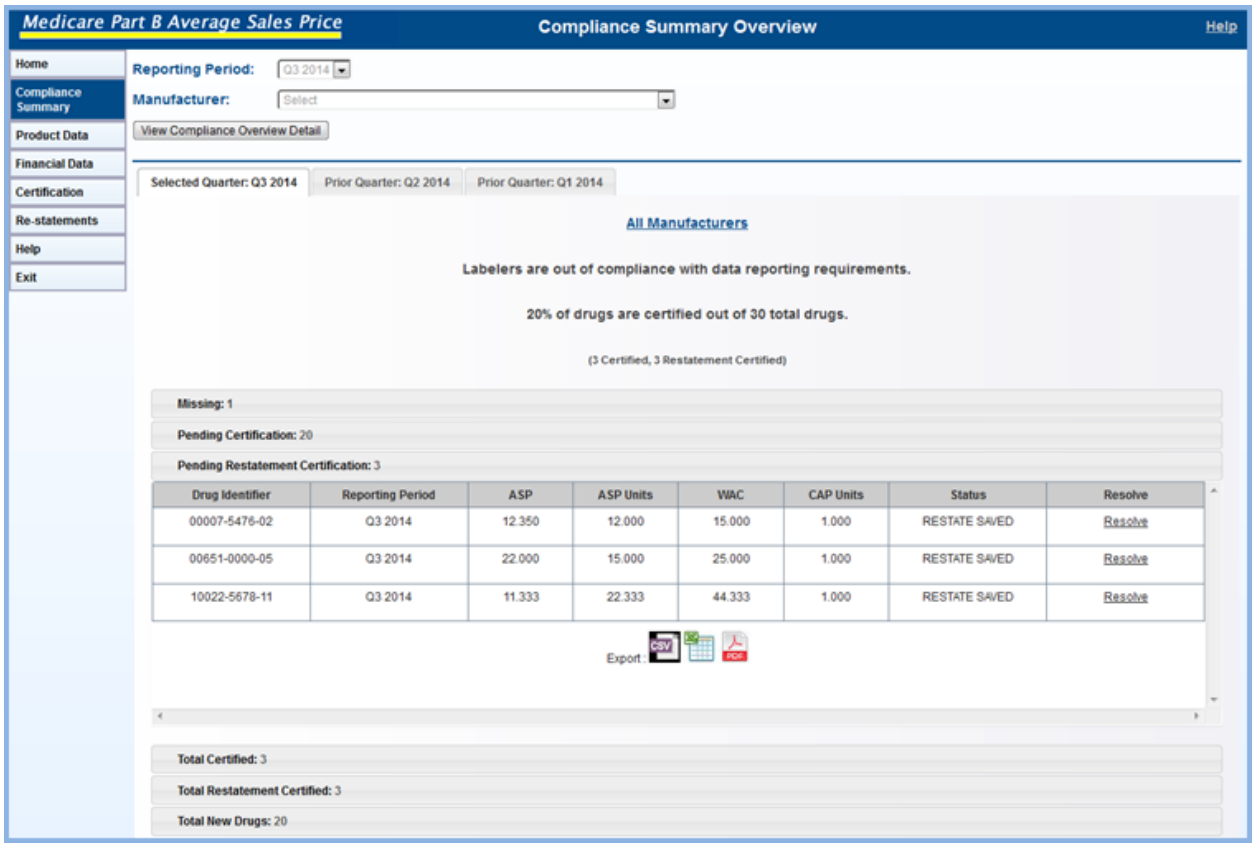


Refer to Section 5, Certifications, for the steps needed to certify drug data.

7.2.3 Pending Restatement Certifications

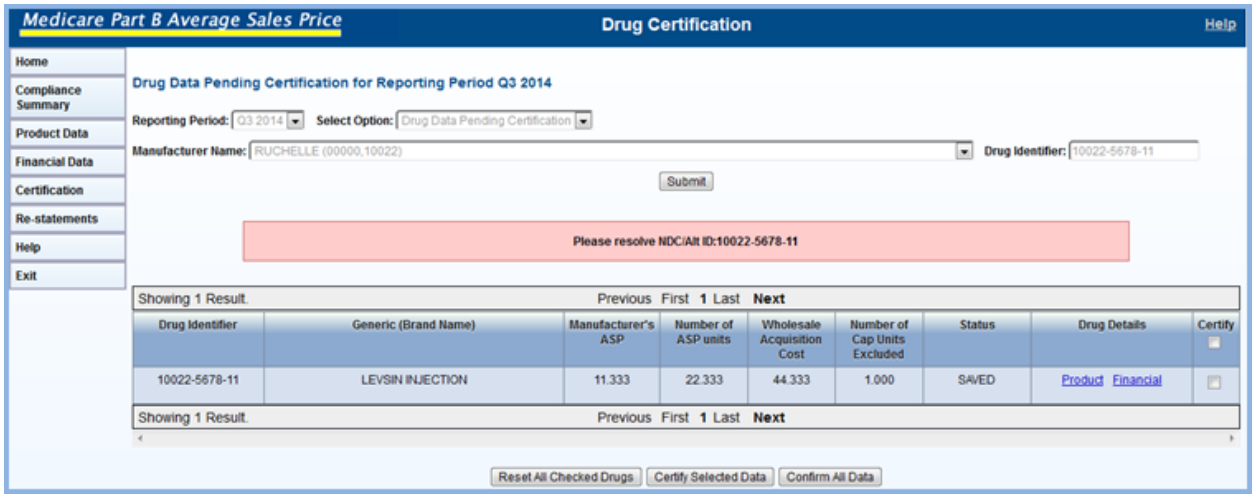
Drug Manufacturers can view and update drugs that have saved financial data that need to be restated but whose certifications are pending. Click the **Pending Restatement Certification** tab to view the drugs that require certification resolution. The screen shown in Figure 7-7 is displayed.

Figure 7-7: Compliance Summary Overview—Pending Restatement Certification



Click the **Resolve** link on any drug listed to begin the resolution process. The screen shown in Figure 7-8 is displayed.

Figure 7-8: Compliance Summary Overview—Resolve Pending Restatement Certification

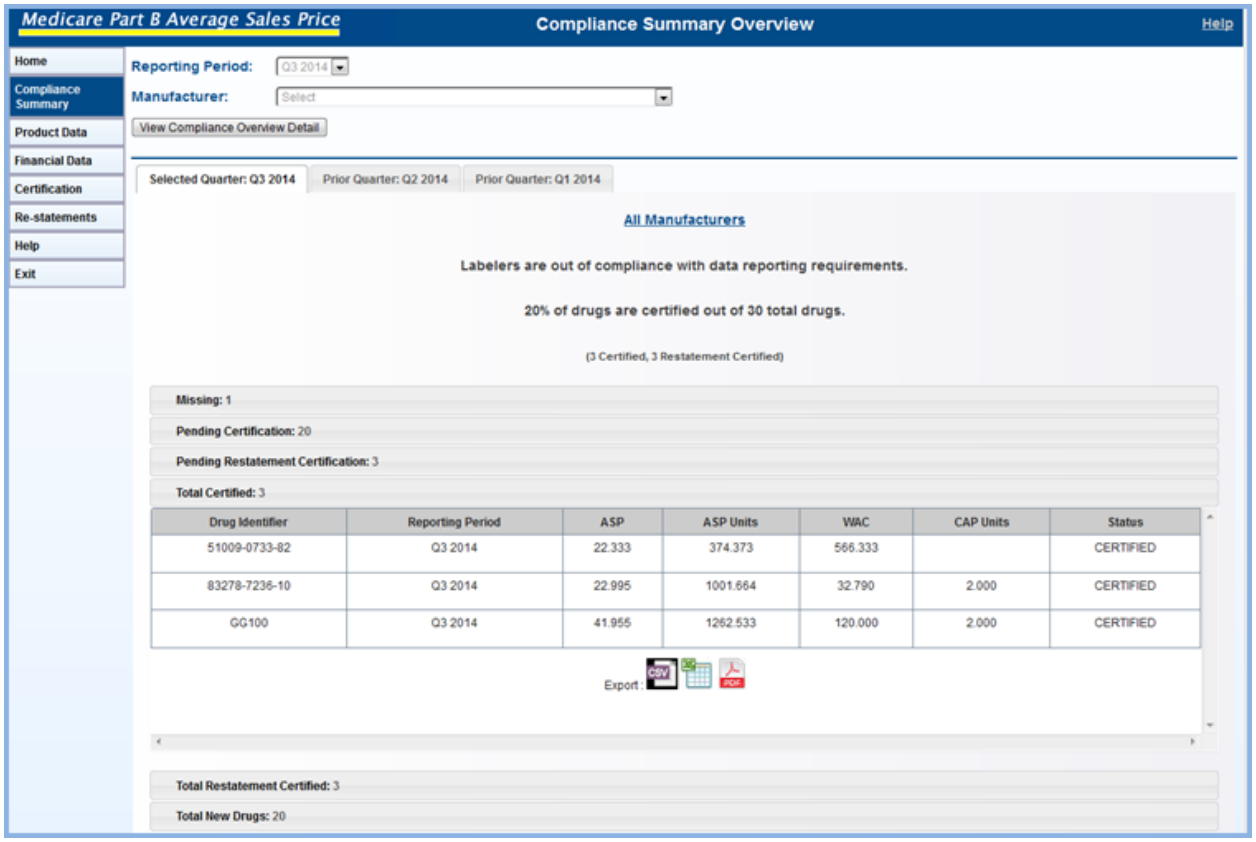


Refer to Section 5, Certifications, for the steps needed to certify drug data.

7.2.4 Total Certified

Drug Manufacturers can view and update drugs that have been certified during the selected reporting period. Drug manufacturers are only permitted to view this information; changes cannot be made on this tab. Click the **Total Certified** tab to view the drugs that have been certified during the selected reporting period. The screen shown in Figure 7-9 is displayed.

Figure 7-9: Compliance Summary Overview—Total Certified

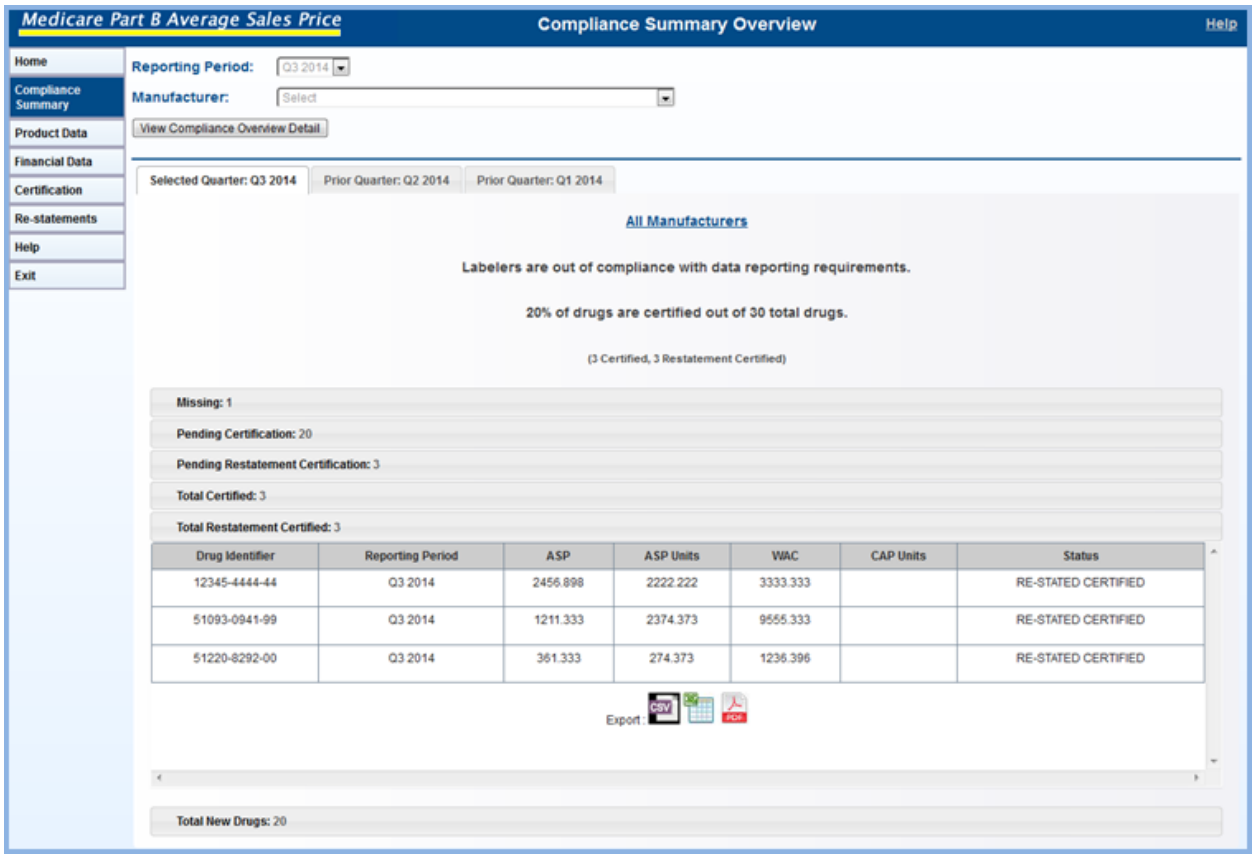


Click the **Total Certified** tab to hide the new certified drug information.

7.2.5 Total Restatement Certified

The Total Restatement Certified tab allows drug manufacturers to view the product and financial information for drugs that have been restated and certified. Drug manufacturers are only permitted to view this information; changes cannot be made on this tab. Click the **Total Restatement Certified** tab to view the restated drugs that have been certified. The screen shown in Figure 7-10 is displayed.

Figure 7-10: Compliance Summary Overview—Total Restatement Certified

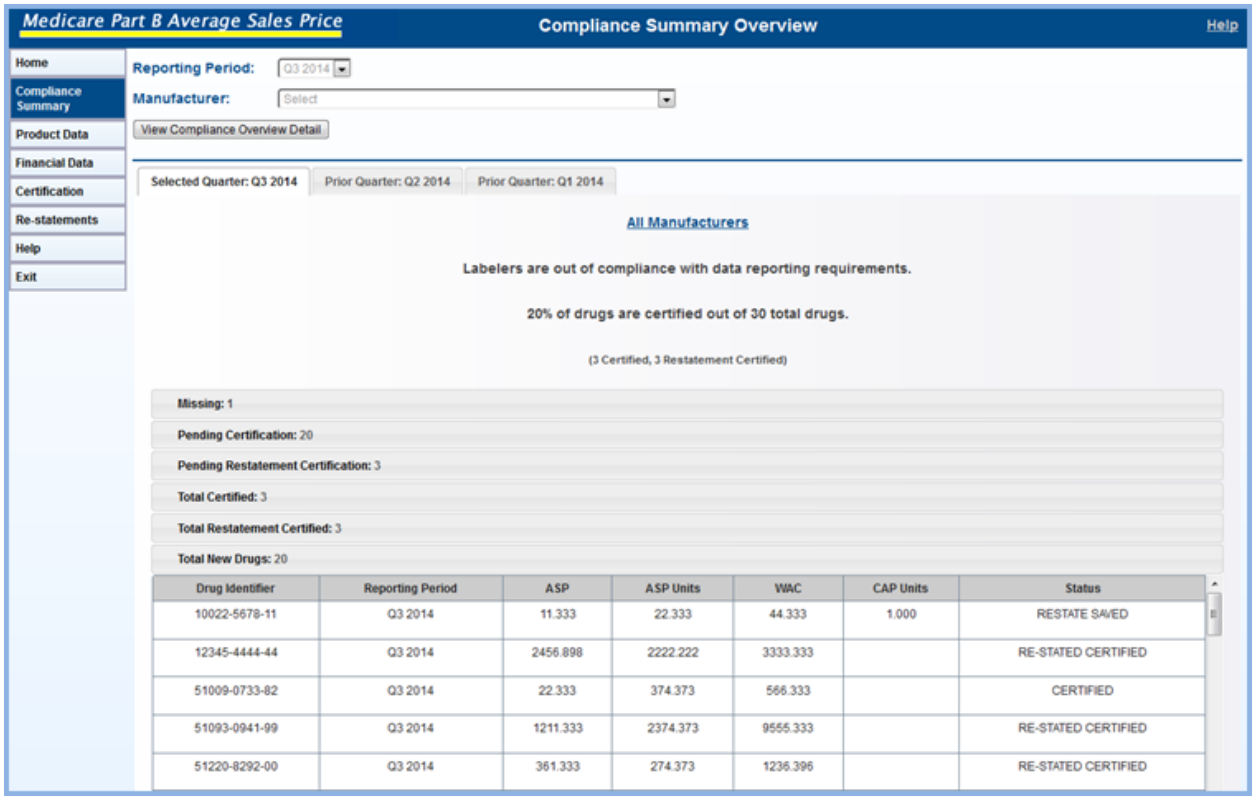


Click the **Total Restatement Certified** tab to hide the new certified drug information.

7.2.6 Total New Drugs

The Total New Drugs tab allows drug manufacturers to view the product and financial information for new drugs that have been certified or saved. Drug manufacturers are only permitted to view this information; changes cannot be made on this tab. Click the **Total New Drugs** tab to view the new drugs that have been certified or saved. The screen shown in Figure 7-11 is displayed.

Figure 7-11: Compliance Summary Overview—Total New Drugs

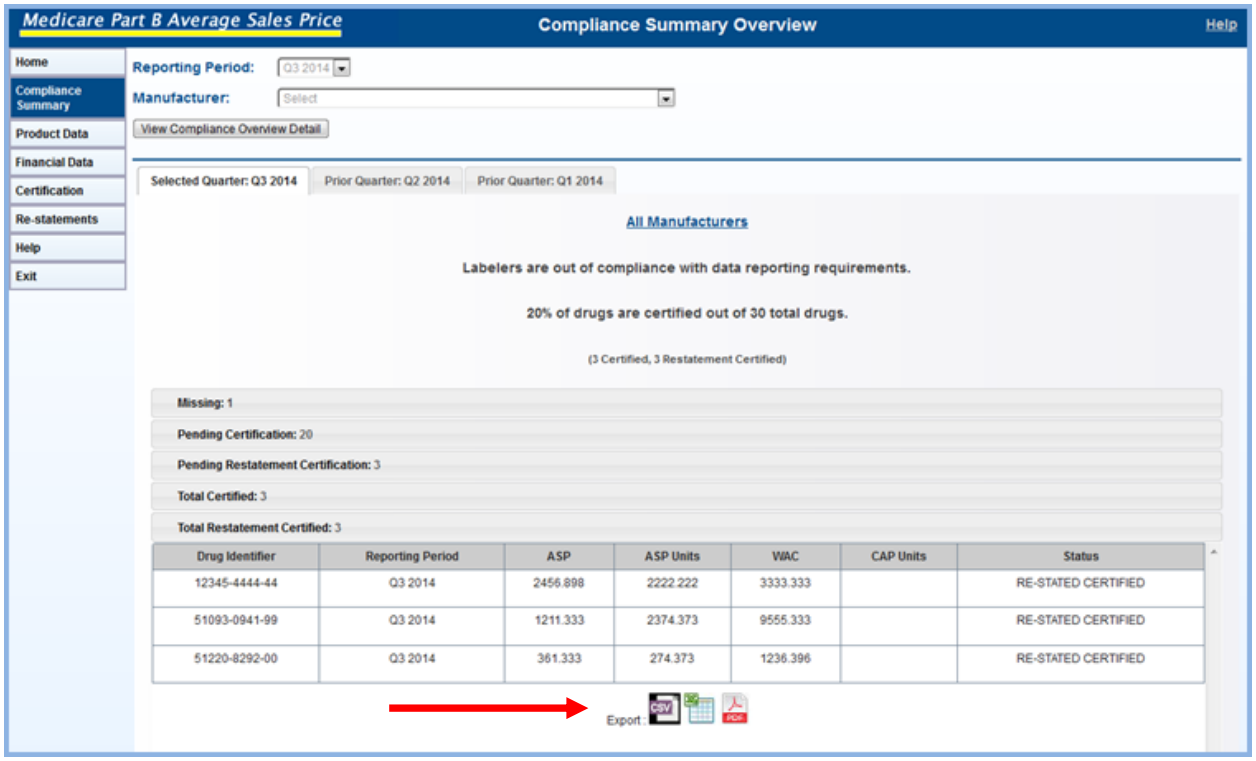


Click the **Total New Drugs** tab to hide the new certified drug information.

7.3 Export Options

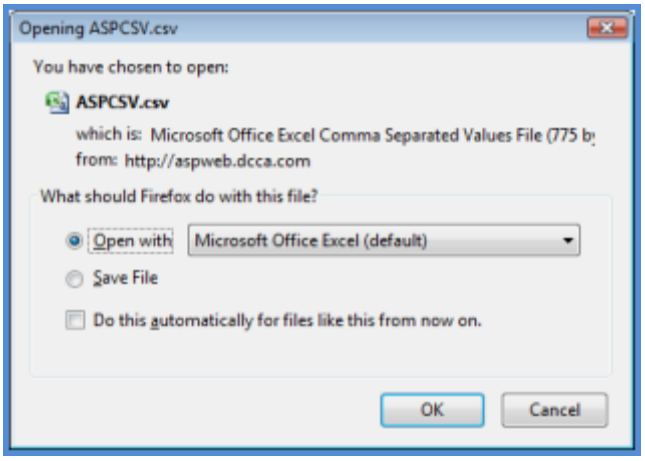
Drug Manufacturers have the ability to export any of the Compliance data into three different file formats: CSV, EXCEL, or PDF formats. The export options are listed at the bottom of a tab that has been opened to display the selected compliance data. An example of the export options are highlighted in Figure 7-12.

Figure 7-12: Export Options



Click the desired export option to view the results. A dialog box will open similar to what is shown in Figure 7-13

Figure 7-13: Export Options Dialog Box



Drug Manufacturers have the option to immediately open the file or save it to a selected location. A sample file export in the CSV format is shown in Figure 7-14.

Figure 7-14: CSV Export Option

	A	B	C	D	E	F	G	H
1	Drug Iden	Reporting	ASP	ASP Units	WAC	CAP Units	Status	
2	83286-654	Q4 2013	5444.909	784	88889	123456.8	CERTIFIED	
3	12345-343	Q4 2013	100	100	100		CERTIFIED	
4	11345-505	Q4 2013	100	100	100		CERTIFIED	
5	12345-092	Q4 2013	25	25	30		CERTIFIED	
6	12345-999	Q4 2013	4444.909	784	7888.999		CERTIFIED	
7	21117-999	Q4 2013	54444.91	784	88889		CERTIFIED	
8	11345-606	Q4 2013	100	100	100		CERTIFIED	
9	12345-777	Q4 2013	22.222	22.222	22.222		CERTIFIED	
10	12345-777	Q4 2013	94444.91	784	0	123456.8	CERTIFIED	
11	12345-122	Q4 2013	100	100	100		CERTIFIED	
12	12345-444	Q4 2013	100	100	100		CERTIFIED	
13	12589-222	Q4 2013	357.123	555.663	785.333		CERTIFIED	
14								

The Excel export option is similar in format to the CSV Export option. A sample file export in the PDF format is shown Figure 7-15

Figure 7-15: PDF Export Option

Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status
83286-6543-22	Q4 2013	5444.909	784.000	88888.999	123456.777	CERTIFIED
12345-3434-34	Q4 2013	100.000	100.000	100.000		CERTIFIED
11345-5050-50	Q4 2013	100.000	100.000	100.000		CERTIFIED
12345-0925-99	Q4 2013	25.000	25.000	30.000		CERTIFIED
12345-9999-99	Q4 2013	4444.909	784.000	7888.999		CERTIFIED
21117-9999-88	Q4 2013	54444.909	784.000	88888.999		CERTIFIED
11345-6060-60	Q4 2013	100.000	100.000	100.000		CERTIFIED
12345-7777-12	Q4 2013	22.222	22.222	22.222		CERTIFIED
12345-7777-13	Q4 2013	94444.909	784.000	0.000	123456.777	CERTIFIED
12345-1222-12	Q4 2013	100.000	100.000	100.000		CERTIFIED
12345-4444-44	Q4 2013	100.000	100.000	100.000		CERTIFIED
12589-2222-22	Q4 2013	357.123	555.663	785.333		CERTIFIED