



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

Version: 2.0
Last Modified: July 21, 2014

Document Number: ASP-V1.0 UMX-2.00
Contract Number: HHSM-500-2009-00087G

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0921. The time required to complete this information collection is estimated to average (13 hours) per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. CMS 10110 approval XX/XX/XXXX

APPROVALS

Submitting Organization's Approving Authority:

	Ray Lee		410-992-3760
Signature	Printed Name	Date	Phone Number
<hr/>			
DCCA			
<hr/>			

CMS' Approving Authority:

	Dona Coffman		410-786-0260
Signature	Printed Name	Date	Phone Number
<hr/>			
Project Officer			
<hr/>			

CMS Business Owner:

	Sarah Harding		410-786-4001
Signature	Printed Name	Date	Phone Number
<hr/>			
Government Task Leader			
<hr/>			

Table of Contents

1	Introduction.....	1
1.1	What is the Medicaid Part B Average Sales Price (ASP) Application?.....	1
1.2	Purpose of the ASP Application.....	1
1.3	ASP User Roles.....	3
2	ASP Application Access.....	5
2.1	ASP Application Access Process.....	5
2.1.1	Obtaining a CMS Portal Username and Password.....	5
2.1.2	Requesting ASP Application Access.....	10
3	ASP Application Home Page.....	18
4	Data Submission.....	19
4.1	Online Product Data.....	19
4.2	Upload Product Data – File Transfer.....	22
4.3	Add Financial Data – Online Data Entry.....	27
4.4	Upload Financial Data – File Transfer.....	29
4.5	View Submitted Drug Data.....	34
5	Certifications.....	36
5.1	Certify Drug Data Online.....	36
5.2	View Drug Data.....	40
5.2.1	View Drug Data Certified in the Reporting Period.....	40
5.2.2	View All Drug Data in the Reporting Period.....	42
5.3	Certification Assumptions.....	43
6	Re-statements.....	45
6.1	Restate Drug Financial Data – Online.....	45
6.2	Restate Drug Product Data – Online.....	50
6.3	Add New Product – Re-statement Tab.....	56
6.4	Restate Financial Data – File Upload.....	57
6.5	Restate Drug Product Data – File Upload.....	62
7	Compliance.....	66
7.1	Compliance Summary Overview.....	66
7.2	Compliance Overview.....	67
7.2.1	Missing Drugs.....	68

7.2.2	Pending Certifications.....	68
7.2.3	Pending Restatement Certifications.....	70
7.2.4	Total Certified.....	71
7.2.5	Total Restatement Certified.....	72
7.2.6	Total New Drugs.....	72
7.3	Export Options.....	73

Table of Figures

Figure 2-1: CMS Portal Home Page	6
Figure 2-2: CMS Secure Portal Section.....	7
Figure 2-3: CMS Portal Terms and Conditions Page	7
Figure 2-4: CMS Portal Registration Page	8
Figure 2-5: CMS Portal User ID and Password Selection.....	9
Figure 2-6: CMS Portal Registration Complete.....	10
Figure 2-7: CMS Portal Home Page	11
Figure 2-8: CMS Secure Portal Section.....	12
Figure 2-9: CMS Portal Terms and Conditions Page	12
Figure 2-10: CMS Portal Log In Page	13
Figure 2-11: Request Application Access Button.....	13
Figure 2-12: View and Manage My Access Page.....	14
Figure 2-13: Request New Application Access Page	14
Figure 2-14: Request New Application Access Page – Select Role.....	15
Figure 2-15: Identity Verification Page	15
Figure 2-16: Terms and Conditions	16
Figure 2-17: Your Information Page.....	17
Figure 3-1: ASP Application Home Page.....	18
Figure 4-1: Add Product Data Selection.....	19
Figure 4-2: Add Product Data.....	20
Figure 4-3: Add Product Data – Alternate ID.....	20
Figure 4-4: Product Data Upload Selection	23
Figure 4-5: Product Data Upload.....	23
Figure 4-6: Attachment Upload -- .zip File	24
Figure 4-7: Acceptable File Format Templates	24
Figure 4-8: Sample Product Data Template.....	25
Figure 4-9: Upload Product Data – File to be Uploaded	25
Figure 4-10: Product Data Upload Result.....	26
Figure 4-11: Product Data Upload – Error	26
Figure 4-12: Add/Edit Financial Data Selection.....	27
Figure 4-13: Add or Edit Financial Data Home Page.....	28

Figure 4-14: Add or Edit Financial Data – Financial Data Saved 29

Figure 4-15: Financial Data Upload Selection..... 30

Figure 4-16: Financial Data Upload Page..... 30

Figure 4-17: Attachment Upload -- .zip File 31

Figure 4-18: Acceptable File Format Templates 31

Figure 4-19: Sample Financial Data Template 32

Figure 4-20: Financial Data Upload – File to be Uploaded..... 32

Figure 4-21: Financial Data Upload -- Result..... 33

Figure 4-22: Financial Data Upload – Error 33

Figure 4-23: View Submitted Drugs Selection..... 34

Figure 4-24: View Submitted Drugs..... 35

Figure 5-1: Drug Certification Selection 36

Figure 5-2: Drug Certification Home Page..... 37

Figure 5-3: Drug Certification Page – Pending 38

Figure 5-4: Product Details..... 38

Figure 5-5: Financial Details 39

Figure 5-6: Data Certification Statement..... 39

Figure 5-7: Proceed to Certify Data Button..... 40

Figure 5-8: Certification Confirmation Message..... 40

Figure 5-9: Drug Data Certified This Period Option 41

Figure 5-10: Drug Data Certified This Period Results 41

Figure 5-11: View All Drugs in Period Option 42

Figure 5-12: View All Drugs in Period Results..... 42

Figure 5-13: Certification Assumptions Selection..... 43

Figure 5-14: Certification Assumptions Page..... 43

Figure 5-15: Certification Assumptions Page -- Upload 44

Figure 5-16: Certification Assumptions Saved..... 44

Figure 5-17: Uploaded Certification Assumptions 44

Figure 6-1: Restate Online Selection Screen 45

Figure 6-2: Restate Online Screen – Main..... 46

Figure 6-3: Restate Online Selection Screen 46

Figure 6-4: Restate Online – Drugs Available for Re-Statement Selections..... 48

Figure 6-5: Restate Online -- Drugs Selected for Re-Statement..... 48

Figure 6-6: Restate Online -- Review Re-Statement List	48
Figure 6-7: Re-State Product Data – Financial Data Saved.....	50
Figure 6-8: Restate Online Selection Screen	51
Figure 6-9: Restate Online – Update Product Data Tab	51
Figure 6-10: Restate Online – Product Data.....	52
Figure 6-11: Restate Online -- Selections.....	53
Figure 6-12: Restate Online --Drug Products Selected for Re-Statement	53
Figure 6-13: Restate Online -- Re-Statement Product List.....	54
Figure 6-14: Update Product Data Re-Statement Page.....	54
Figure 6-15: Re-stated Product Data Saved.....	56
Figure 6-16: Restate Online – Add New Product	57
Figure 6-17: Restate Financial Data Upload Selection.....	58
Figure 6-18: Restate Financial Data Upload.....	58
Figure 6-19: Attachment Upload -- .zip File	59
Figure 6-20: Acceptable File Format Templates	59
Figure 6-21: Sample Financial Data Template	60
Figure 6-22: Restate Financial Data Upload – File to be Uploaded.....	60
Figure 6-23: Restate Financial Data Upload -- Result.....	61
Figure 6-24: Upload Restate Financial Data Result -- Error	61
Figure 6-25: Restate Product Data Upload Selection	62
Figure 6-26: Restate Product Data Upload	62
Figure 6-27: Attachment Upload -- .zip File	63
Figure 6-28: Acceptable File Format Templates	63
Figure 6-29: Sample Product Data Template.....	64
Figure 6-30: Restate Product Data Upload – File to be Uploaded	64
Figure 6-31: Restate Product Data Upload -- Result	65
Figure 6-32: Restate Product Data Upload Result -- Error.....	65
Figure 7-1: Compliance Summary Overview	66
Figure 7-2: Manufacturer’s Compliance Summary Report	67
Figure 7-3: Compliance Summary Overview—Missing Drugs	68
Figure 7-4: Compliance Summary Overview—Resolve	68
Figure 7-5: Compliance Summary Overview—Pending Certifications	69
Figure 7-6: Compliance Summary Overview—Resolve Pending Certifications	69

Figure 7-7: Compliance Summary Overview—Pending Restatement Certification	70
Figure 7-8: Compliance Summary Overview—Resolve Pending Restatement Certification	71
Figure 7-9: Compliance Summary Overview—Total Certified	71
Figure 7-10: Compliance Summary Overview—Total Restatement Certified.....	72
Figure 7-11: Compliance Summary Overview—Total New Drugs	73
Figure 7-12: Export Options	74
Figure 7-13: Export Options Dialog Box.....	74
Figure 7-14: CSV Export Option.....	75
Figure 7-15: PDF Export Option	75

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

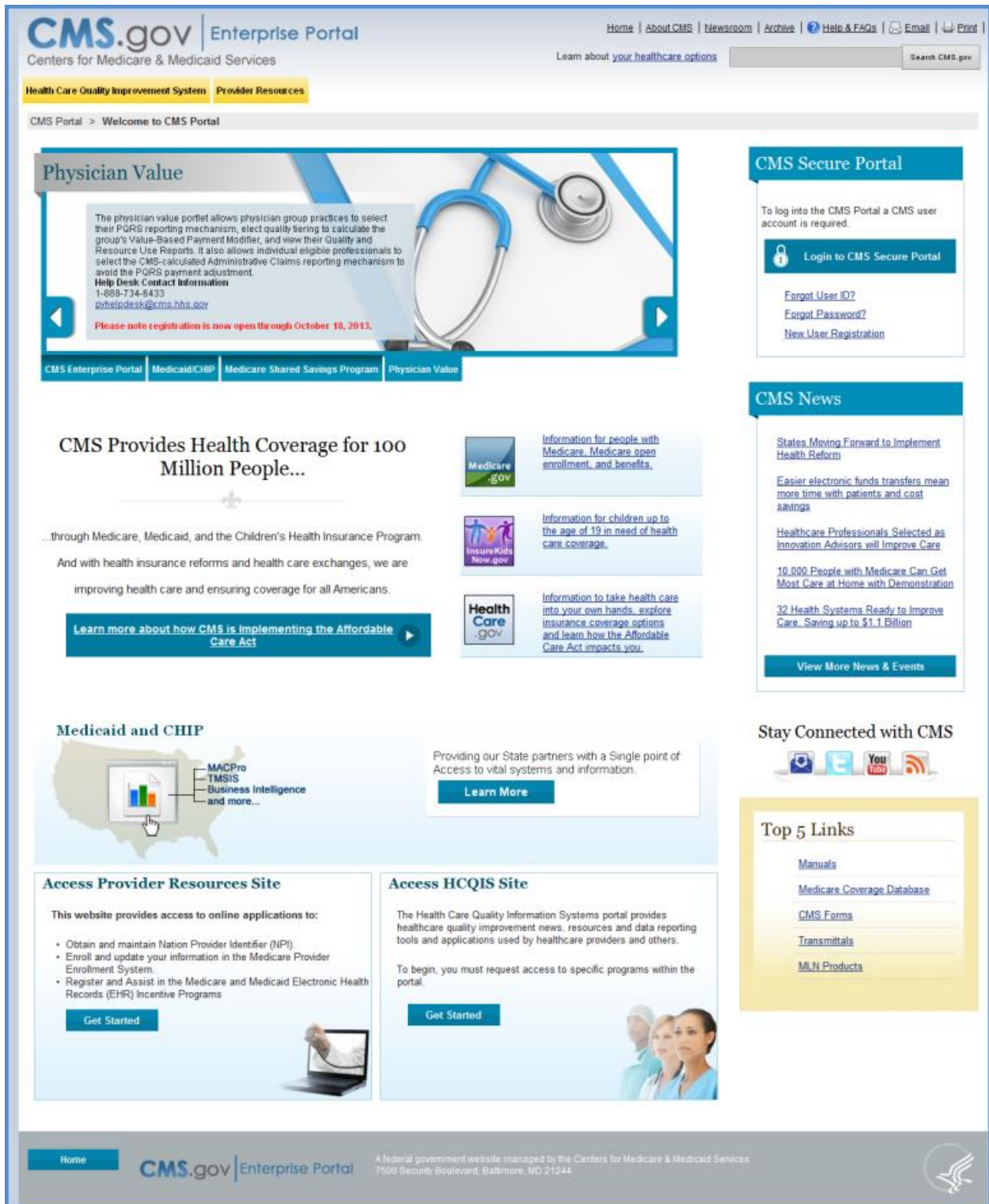
ASP users with an existing CMS Portal username and password can skip Section 2.1.1 and continue on to Section 2.1.2, Requesting ASP Application Access.

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



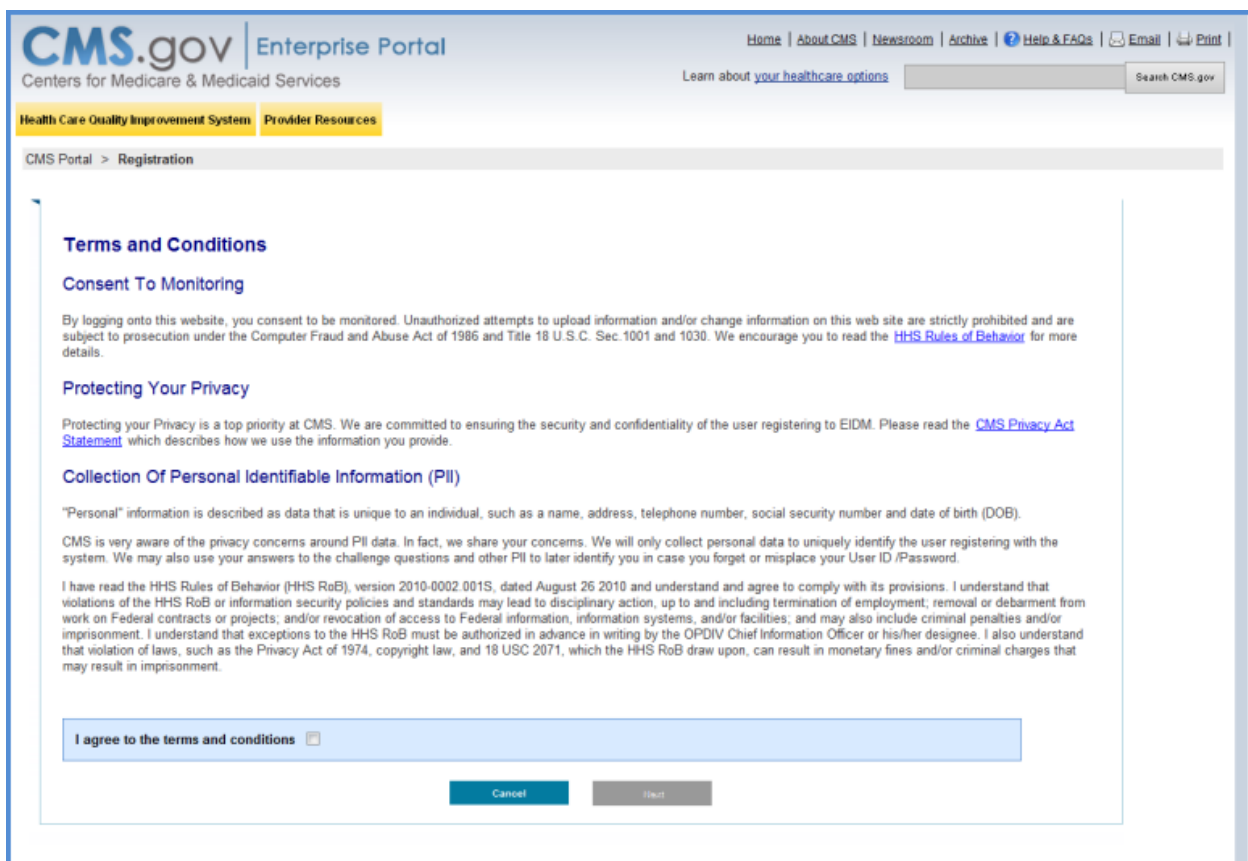
2. Click the **New User Registration** link in the CMS Secure Portal section located in the top-right section of the CMS Portal home page. The CMS Secure Portal section of the page is shown in Figure 2-2.

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.

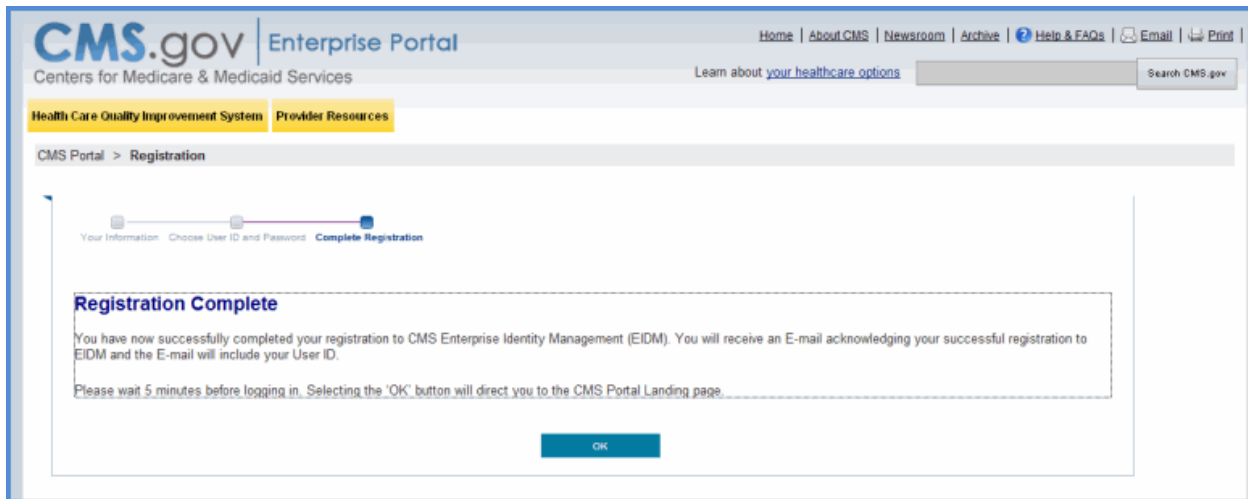
6. Click **Next** when completed. The screen shown in Figure 2-5 will be displayed.

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:
- Be changed at least every sixty (60) days;
 - Be a minimum of eight (8) and a maximum of twenty (20) characters;
 - Be changed only once a day;
 - Contain at least one (1) letter and one (1) number;
 - Contain at least one (1) uppercase and one (1) lowercase letter;
 - Not contain your User ID; and
 - 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.

- 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



- 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:

- 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



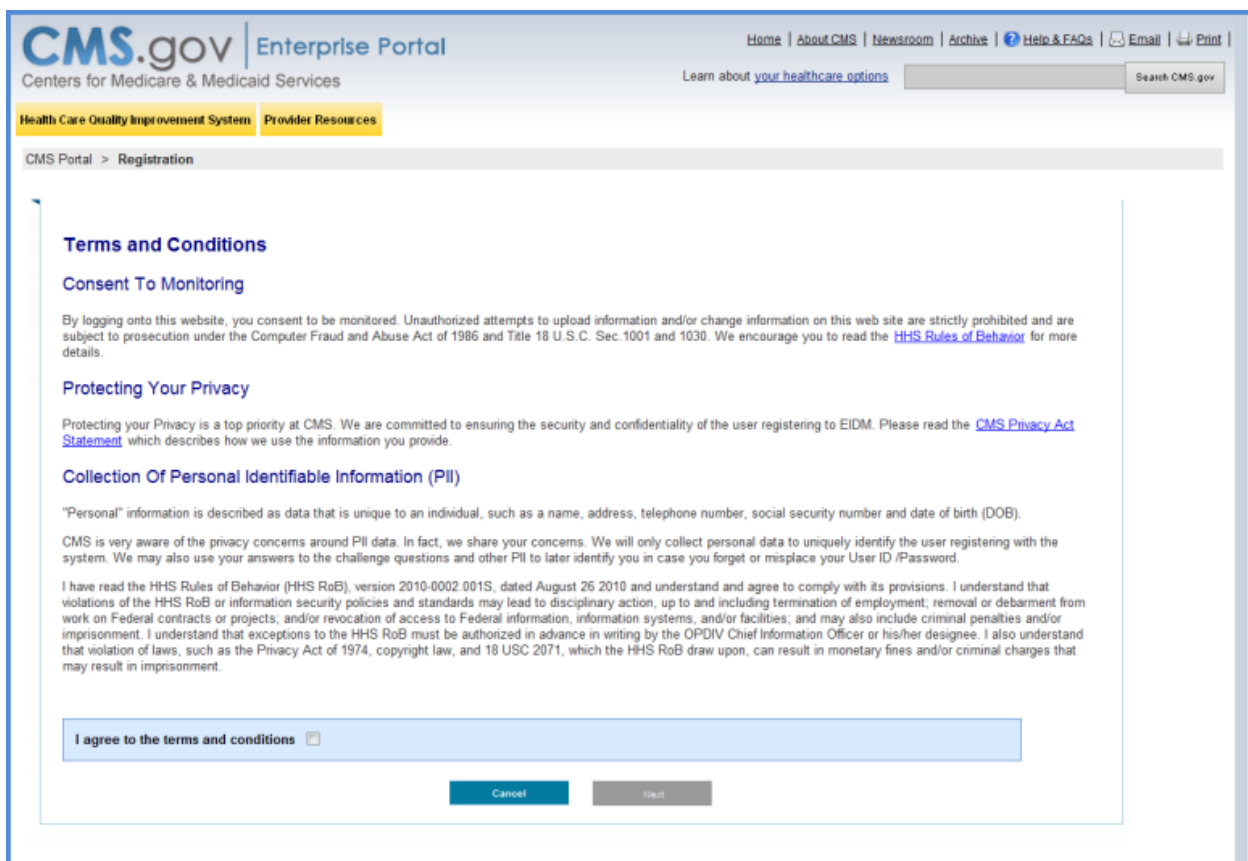
2. Click the **Login to CMS Secure Portal** button in the CMS Secure Portal section located in the top-right section of the CMS Portal home page. The CMS Secure Portal section of the page is shown in Figure 2-2.

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.

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

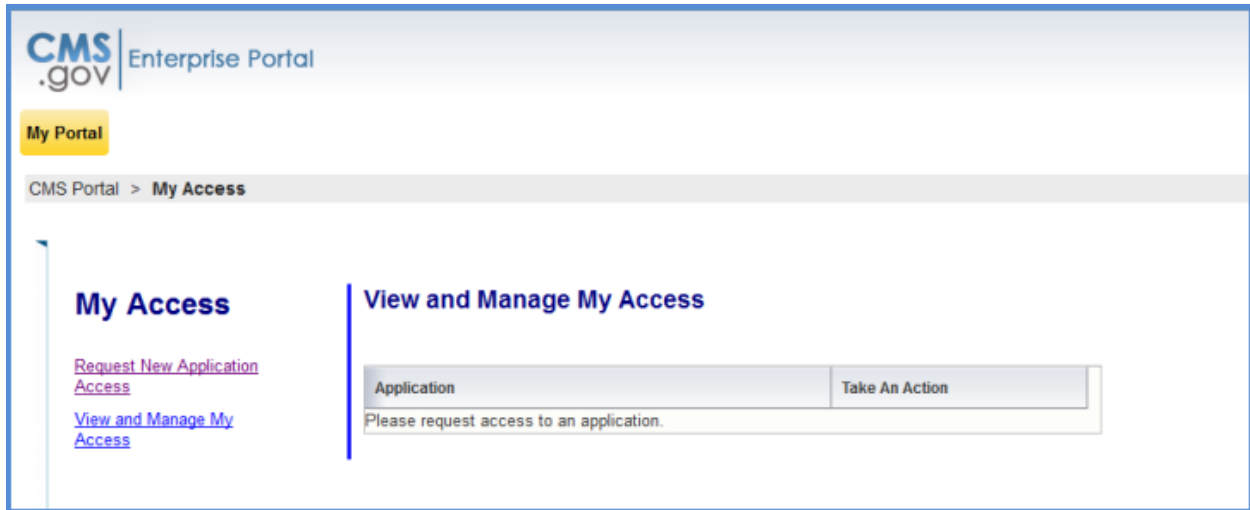
Figure 2-10: CMS Portal Log In Page

- 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

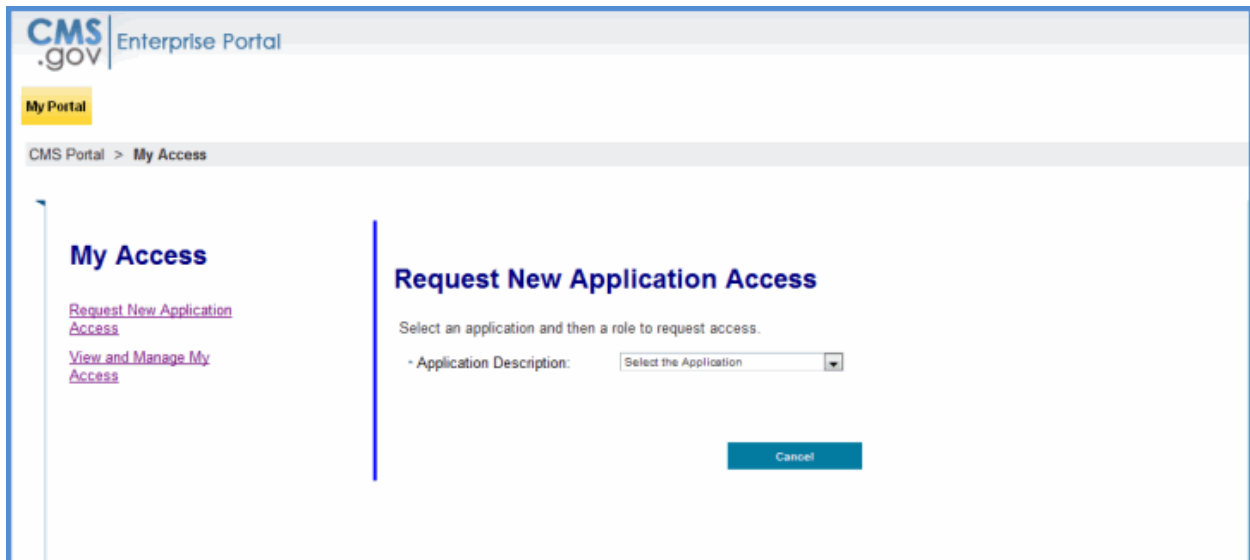
- The View and Manage My Access page opens after clicking the Request Access Now button, as shown in Figure 2-12.

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

The screenshot shows the 'Request New Application Access' page. The header includes the CMS .gov logo and 'Enterprise Portal'. Below the header is a 'My Portal' button and a breadcrumb trail 'CMS Portal > My Access'. The main content area is split into two columns. The left column, titled 'My Access', contains links for 'Request New Application Access' and 'View and Manage My Access'. The right column, titled 'Request New Application Access', contains the instruction 'Select an application and then a role to request access.' followed by two dropdown menus: 'Application Description' (with 'ESD - ESD Application' selected) and 'Role' (with 'Select the Role' selected). A 'Cancel' button is located at the bottom right of the form area.

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

The screenshot shows the 'Identity Verification' page. The header and breadcrumb trail are the same as in Figure 2-14. The left sidebar remains the same. The main content area is titled 'Identity Verification' and contains the following text: 'You have selected a role that requires a higher level of security. You will need to complete Identity Verification successfully, before requesting access to the selected role. Below are a few items to keep in mind.' This is followed by a bulleted list of requirements:

- Ensure that you have entered your legal name, current home address, primary phone number and email address correctly. We will only collect personal information to verify your identity with Experian, an external identity verification provider.
- Identity Verification involves Experian using information from your credit report to help confirm your identity. As a result, you may see an entry called a "soft inquiry" on your Experian credit report. Soft inquiries do not affect your credit score and you do not incur any charges related to them.
- Confirm that you have your personal and financial information available, as the Experian application will pose questions to you, based on data in their files. You may want to obtain a copy of your credit report, before proceeding with the role request by selecting this link and following the directions provided - <http://www.experian.com>. For additional information, please see the Experian Consumer Assistance link - <http://www.experian.com/help>

Below the list, there is a note: 'If you elect to proceed now, you will be prompted with a Terms and Conditions statement that explains how your Personal Identifiable Information (PII) is used to confirm your identity. Do you want to continue?'. At the bottom right, there are two buttons: 'Cancel' and 'Next'.

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

My Portal

CMS Portal > My Access

My Access

[Request New Application Access](#)

[View and Manage My Access](#)

Terms and Conditions

Protecting Your Privacy

Protecting your Privacy is a top priority at CMS. We are committed to ensuring the security and confidentiality of the user registering to EIDM. Please read the [CMS Privacy Act Statement](#), which describes how we use the information you provide.

Personal information is described as data that is unique to an individual, such as a name, address, telephone number, social security number, and date of birth (DOB). CMS is very aware of the privacy concerns around PII data. In fact, we share your concerns. We will only collect personal information to verify your identity. Your information will be disclosed to Experian, an external authentication service provider, to help us verify your identity. If collected, we will validate your Social Security number with Experian only for the purposes of verifying your identity. Experian verifies the information you give us against their records. We may also use your answers to the challenge questions and other PII to later identify you in case you forget or misplace your User ID /Password.

HHS Rules Of Behavior

We encourage you to read the [HHS Rules of Behavior](#), which provides the appropriate use of all HHS information technology resources for Department users, including Federal employees, contractors, and other system users.

I have read the HHS Rules of Behavior (HHS RoB), version 2010-0002.001S, dated August 26 2010 and understand and agree to comply with its provisions. I understand that violations of the HHS RoB or information security policies and standards may lead to disciplinary action, up to and including termination of employment; removal or debarment from work on Federal contracts or projects; and/or revocation of access to Federal information, information systems, and/or facilities; and may also include criminal penalties and/or imprisonment. I understand that exceptions to the HHS RoB must be authorized in advance in writing by the OPDIV Chief Information Officer or his/her designee. I also understand that violation of laws, such as the Privacy Act of 1974, copyright law, and 18 USC 2071, which the HHS RoB draw upon, can result in monetary fines and/or criminal charges that may result in imprisonment.

Identity Verification

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

I agree to the terms and conditions

Cancel **Next**

13. Read through the Terms and Conditions on the page. The page states that you consent to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it 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

The screenshot displays the 'Your Information' page within the CMS Enterprise Portal. The page header includes the CMS.gov logo and 'Enterprise Portal'. A 'My Portal' button is visible. The breadcrumb trail shows 'CMS Portal > My Access'. The main content area is titled 'Your Information' and includes a progress indicator with 'Your Information' and 'Verify Your Identity' steps. The form contains the following fields and instructions:

- First Name:** Joseph
- Middle Name:** (empty field)
- Last Name:** Doe
- Suffix:** (dropdown menu)
- E-mail Address:** jdoe@yahoo.com
- Confirm E-mail Address:** jdoe@yahoo.com
- Social Security Number:** (masked field with dots)

Instructions for each field are provided, such as 'Enter your legal first name and last name, as it may be required for identity verification.' and 'Enter your email address, as it will be used for account related communications.'

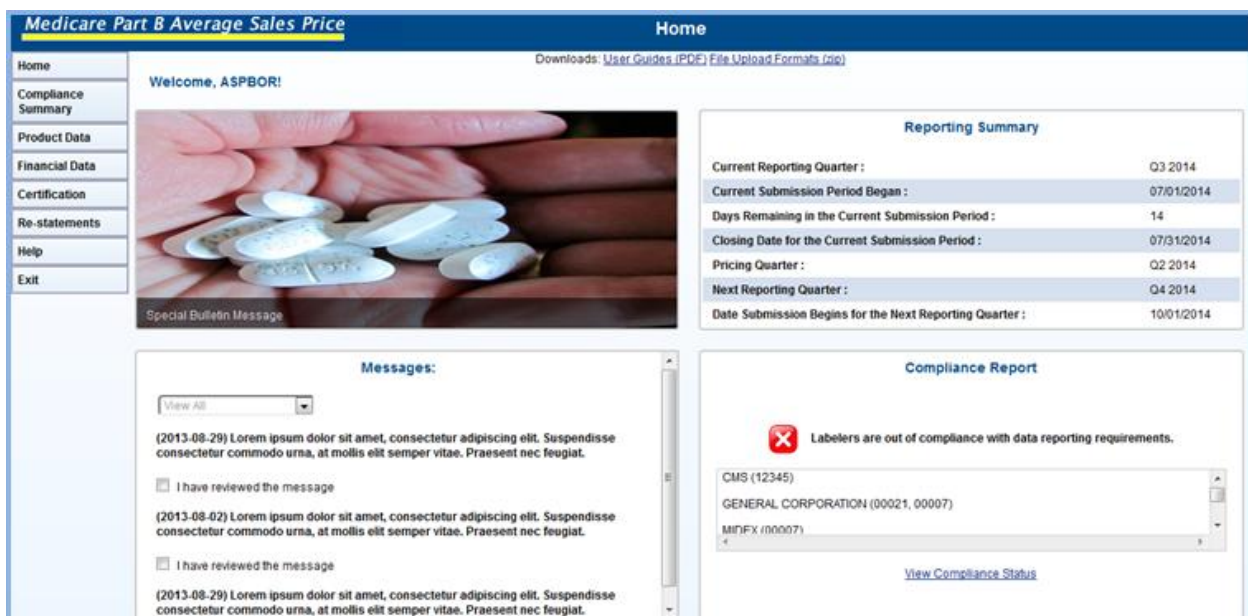
14. Much of the information on this page will be pre-populated in the corresponding fields. Enter any missing information in the fields and click the **Next** button. A page will open that will ask you a series of questions to verify your identity. These questions are generated from the information in 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

- 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).	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> • Link displayed when the “Add by NDC” tab is selected.
– Add by Existing NDC1	– Click the link to enter an existing NDC1.	<ul style="list-style-type: none"> • Link is displayed when Add new NDC1 link is selected.
– NDC2	– Enter the NDC2 in the field.	<ul style="list-style-type: none"> • NDC2 is a required field if Alternate ID is missing. • NDC2 is a 4-digit numeric entry.
– NDC3	– Enter the NDC3 in the field.	<ul style="list-style-type: none"> • NDC3 is a required field if Alternate ID is missing. • NDC3 is a 2-digit numeric entry.
– Alternate ID	– Enter the Alternate Product ID	<ul style="list-style-type: none"> • Alt ID is required if NDC is missing.
– Manufacturer Name	– Enter the name of the drug’s manufacturer.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • The Generic Name is required.
– Date of First Sale	– Enter the date when the drug was first available for sale.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> The Number of Items per NDC is required.
– FDA Application Number	– Enter the FDA Application Number in the field.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.

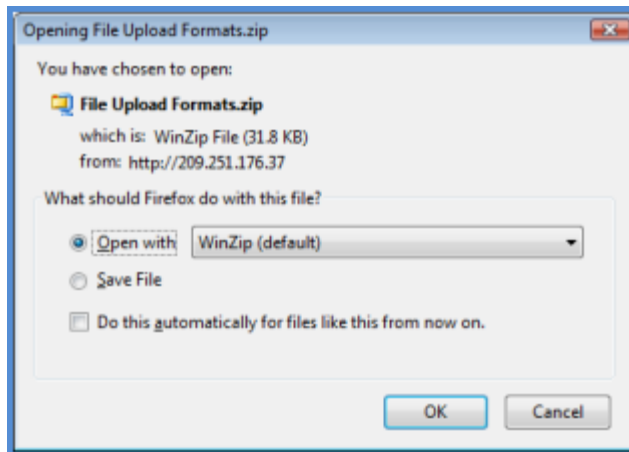
Figure 4-4: Product Data Upload Selection

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

Name	Type	Modified	Size	Ratio	Packed	Path
financeTemplate.xls	Microsoft Of...	7/26/2013 9:51 AM	30,208	78%	6,538	
financeTemplate.xlsx	Microsoft Of...	7/26/2013 9:50 AM	11,418	27%	8,314	
financeTemplate.csv	Microsoft Of...	7/1/2013 4:22 PM	184	26%	137	
productTemplate.csv	Microsoft Of...	6/26/2013 4:14 PM	528	57%	226	
productTemplate.xlsx	Microsoft Of...	7/26/2013 10:01 AM	13,408	24%	10,170	
productTemplate.xls	Microsoft Of...	7/26/2013 10:01 AM	27,648	78%	6,212	

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.

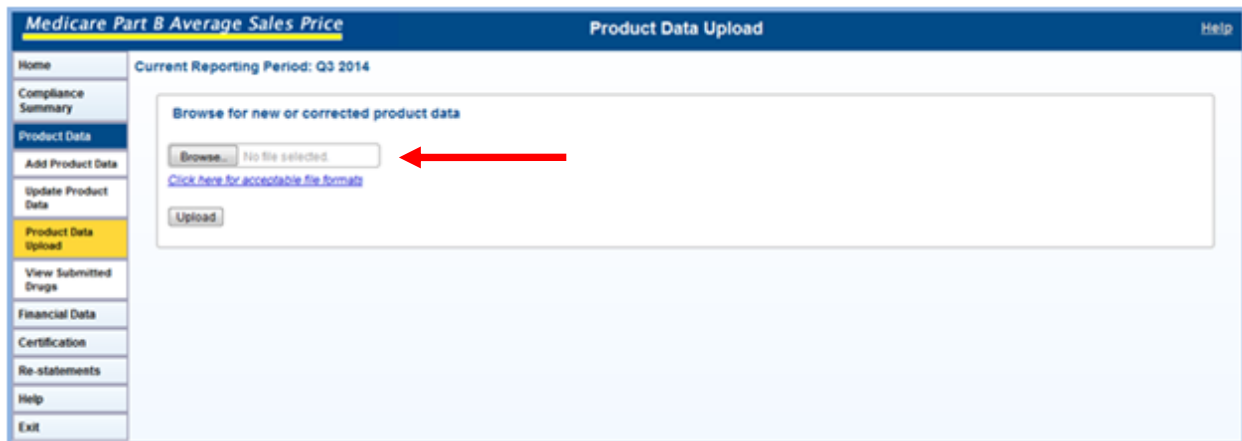
Figure 4-8: Sample Product Data Template

	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

The screenshot shows the 'Product Data Upload' interface. At the top, it says 'Medicare Part B Average Sales Price' and 'Product Data Upload'. The current reporting period is 'Q3 2014'. There is a 'Browse for new or corrected product data' section with a 'Browse...' button (no file selected) and an 'Upload' button. Below this is a 'Report of Transmitted Drugs via File Upload' section with an upload date of '2014-07-16 14:29:10.0'. A red banner indicates '1 Out Of 1 Product Data has been Successfully Saved.' Below this is a table with the following data:

Drug Identifier	Manufacturer Name	Generic (Brand Name)	Strength of Product	Volume per Item	Number of Items per NDC/ATID	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval Type/App #/Supp #	FDA Approval Date	Status
Insulin	AstraZeneca	insulin(Gluocyn)	2s	1v	10	07/31/2013	05/30/2016	ANDA / A123789 / B666777	01/01/2013	Uploaded-Success

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

The screenshot shows the 'Product Data Upload' interface. The current reporting period is 'Q3 2014'. The upload date is '2014-07-17 09:21:50.0'. A red banner indicates 'No Valid Data Present to be saved. Total 1 drugs uploaded.' Below this is a table with the following data:

Drug Identifier	Manufacturer Name	Generic (Brand Name)	Strength of Product	Volume per Item	Number of Items per NDC/ATID	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval Type/App #/Supp #	FDA Approval Date	Status
Insulin	AstraZeneca	INSULIN(Gluocyn)	2s	1v	10	07/31/2013	05/30/2016	/ A123789 / B666777	01/01/2013	FDA Approval Type Required.

A red arrow points to the 'Status' column of the table.

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

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	View Details
00000-0000-01	AMPDRUG1					PENDING	Product Financial
00000-9797-97	AMPDRUG1					PENDING	Product Financial
00001-0000-03	AMPDRUG1					PENDING	Product Financial
00007-0000-02	AMPDRUG1					PENDING	Product Financial
00007-5476-02	AMPDRUG1					PENDING	Product Financial
00021-0000-06	AMPDRUG1	2.000	2.000	16.000		SAVED	Product Financial
00033-0000-04	AMPDRUG1					PENDING	Product Financial
00651-0000-05	AMPDRUG1					PENDING	Product Financial
00652-0000-07	AMPDRUG1	1235.369	4569.365	8656.334		SAVED	Product Financial
10022-5678-11	LEVSIN INJECTION	11.333	22.333	44.333		CERTIFIED	Product Financial
12345-4444-44	AMPDRUG1	2456.898	2222.222	3333.333		RE-STATEd CERTIFIED	Product Financial
51009-0733-82	LINA HYDRCHLORIDE	22.333	374.373	566.333		CERTIFIED	Product Financial
51093-0941-99	KANACITIRIC DYSPEPTASE	1211.333	2374.373	9555.333		RE-STATEd CERTIFIED	Product Financial
51220-8292-00	MUSEUM FORTE	361.333	274.373	1236.396		RE-STATEd CERTIFIED	Product Financial
83278-0233-20	DRUG465	0.000	0.000	84.250	2.000	SAVED	Product Financial
83278-7236-10	DRUG465	22.995	1001.664	32.790	2.000	SAVED	Product Financial
83336-0775-01	DRUG464	14.399	26700.963	35.000	2.000	SAVED	Product Financial
8533607009	DRUG466	8.057	14794.647	23.260	2.000	SAVED	Product Financial

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

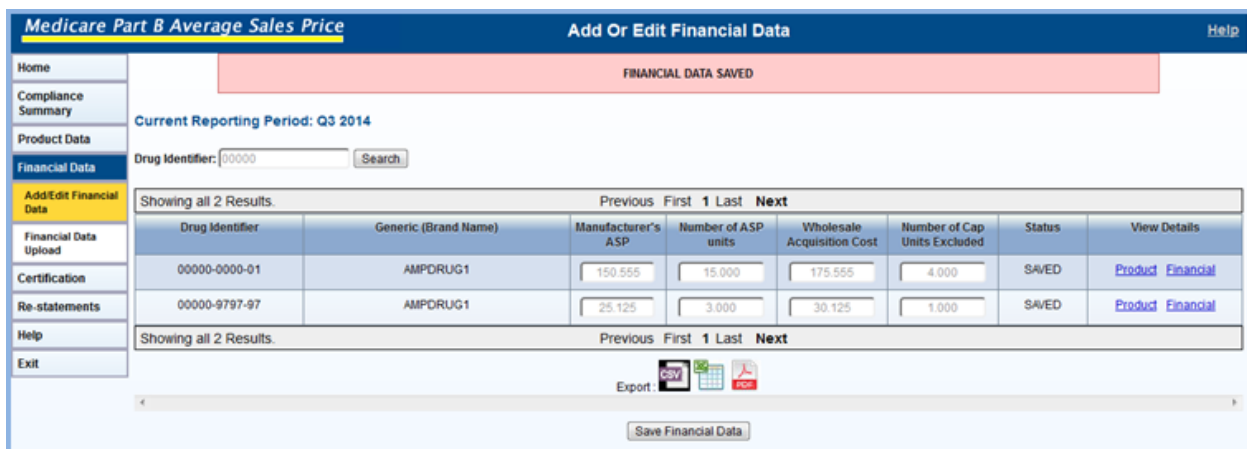
Table 4-2 Add or Edit Financial Data Home Page Information

Name	User Action	Comments
- Manufacturer's ASP	- Enter or update the Manufacturer's Average Sale Price (ASP) in the field.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> The Number of CAP Units Excluded is a required field. The Number of CAP Units Excluded must have three decimal places (i.e., XXXXXXXXXXXX.XXX). The Number of CAP Units Excluded can be a positive number, a negative number, or equal to zero (0).

- 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.
- Enter the **Manufacturer’s ASP, Number of ASP Units, Wholesale Acquisition Cost, and Number of CAP Units Excluded** in the respective fields.
- 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

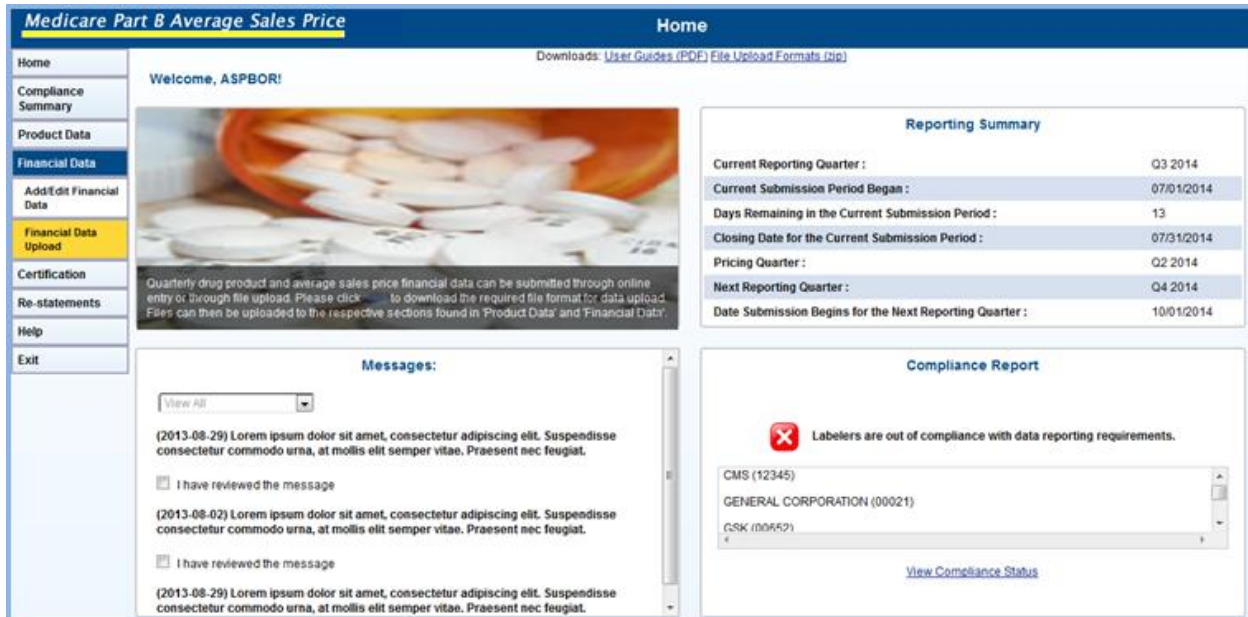


4.4 Upload Financial Data – File Transfer

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:

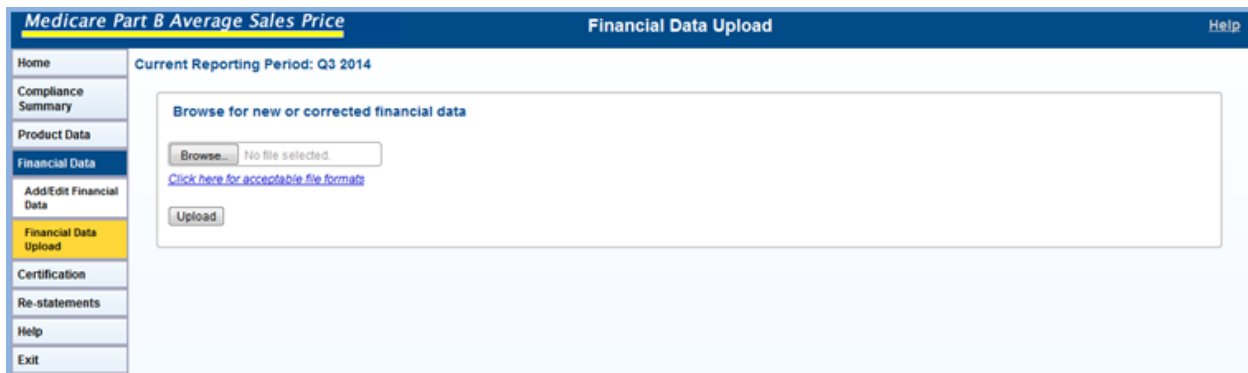
1. Click the **Financial Data** button on the left side menu on the ASP Application Home Page and select **Financial Data Upload** from the drop-down list. The Financial Data Upload selection on the ASP Application home page is shown in Figure 4-15.

Figure 4-15: Financial Data Upload Selection



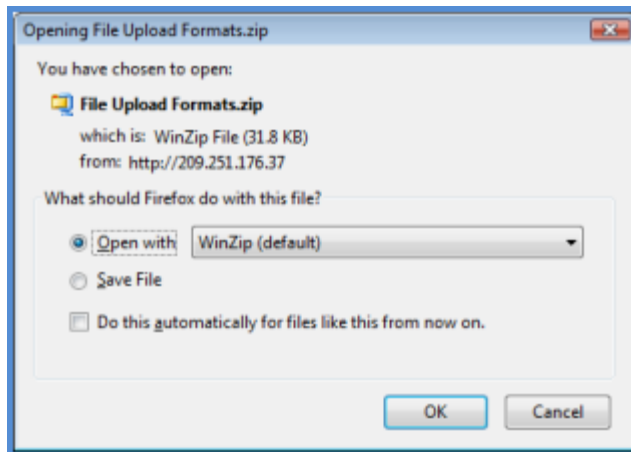
2. Click **Financial Data Upload**. The Financial Data Upload page opens, as shown in Figure 4-16.

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

Name	Type	Modified	Size	Ratio	Packed	Path
financeTemplate.xls	Microsoft Of...	7/26/2013 9:51 AM	30,208	78%	6,538	
financeTemplate.xlsx	Microsoft Of...	7/26/2013 9:50 AM	11,418	27%	8,314	
financeTemplate.csv	Microsoft Of...	7/1/2013 4:22 PM	184	26%	137	
productTemplate.csv	Microsoft Of...	6/26/2013 4:14 PM	528	57%	226	
productTemplate.xlsx	Microsoft Of...	7/26/2013 10:01 AM	13,408	24%	10,170	
productTemplate.xls	Microsoft Of...	7/26/2013 10:01 AM	27,648	78%	6,212	

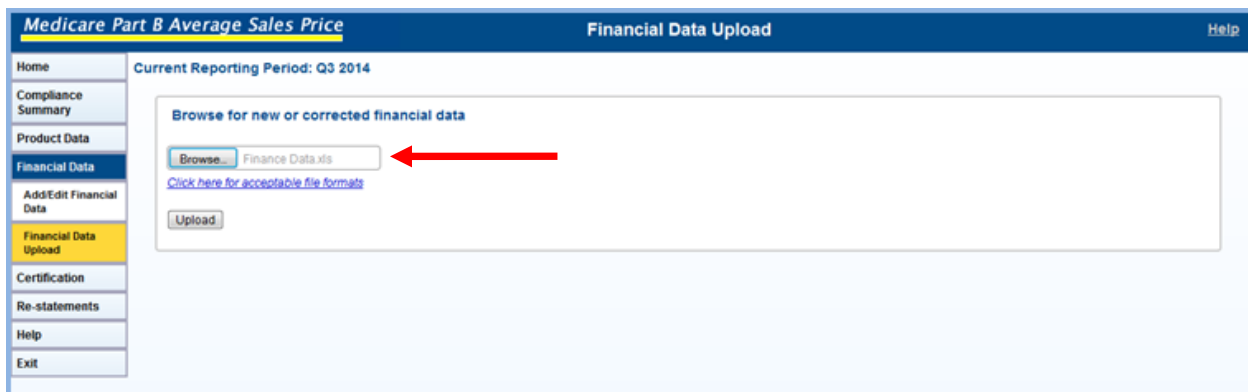
6. Click any one of Finance Template files to open a finance data template. There are three finance upload template options: financeTemplate.csv, financeTemplate.xlsx and financeTemplate.xls. A sample template is shown in Figure 4-19.

Figure 4-19: Sample Financial Data Template

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

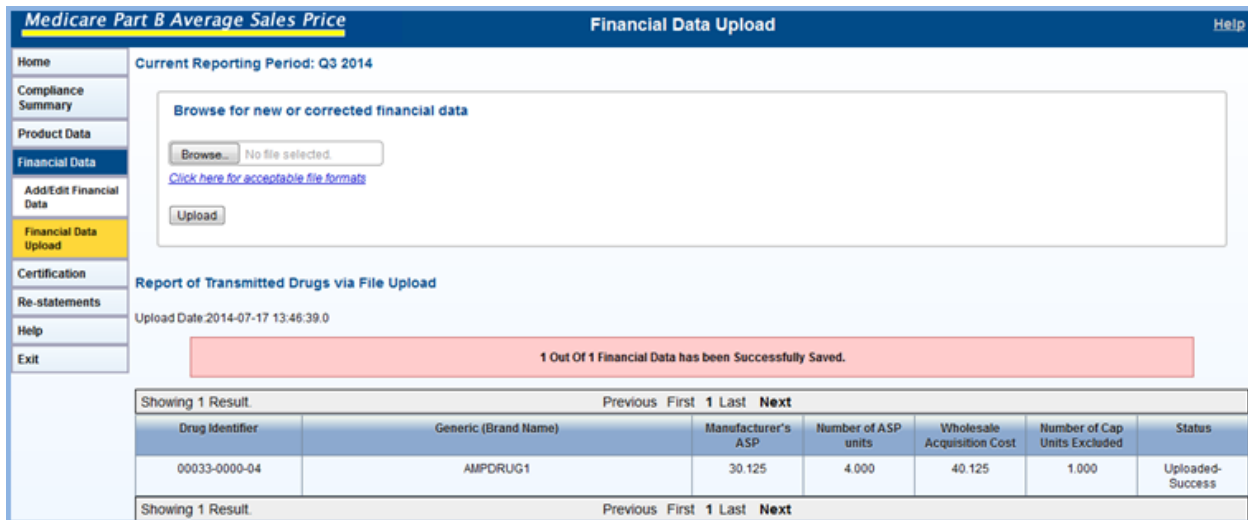
7. Enter the drug financial information on the template. The entries on the template consist of the same fields that are described in Section 2.3, Add Financial Data – Online Entry. Refer to Table 2-2 for a description of the fields and which fields are required. Save the file using a different name 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



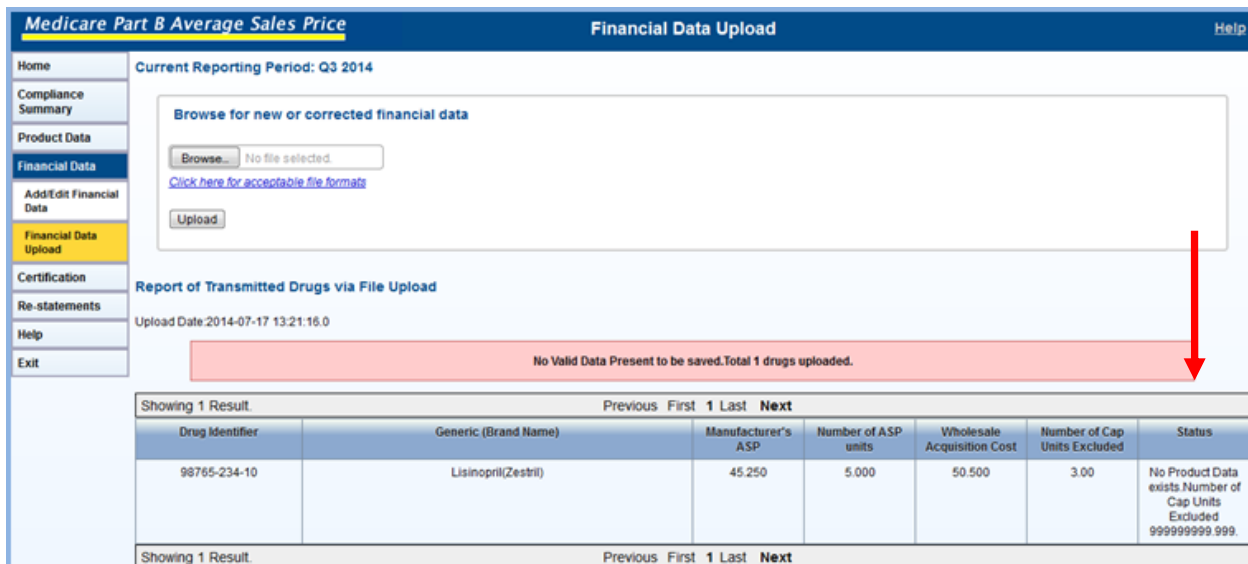
10. Click **Upload**. The Upload Financial Data Result screen will open, as shown in Figure 4-21.

Figure 4-21: Financial Data Upload -- Result



- 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



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

The screenshot displays the ASP Application Home Page. The top navigation bar includes 'Medicare Part B Average Sales Price' and 'Home'. A left sidebar menu lists various options, with 'View Submitted Drugs' highlighted in yellow under the 'Product Data' section. The main content area features a 'Welcome, ASPBOR!' message, a 'Reporting Summary' table, a 'Messages' section with a 'View All' dropdown, and a 'Compliance Report' section showing a red error icon and the message 'Labelers are out of compliance with data reporting requirements.' Below this, a list of drug entries is visible, including 'ASTRAZENICA (90210)', 'CMS (12345)', and 'GENERAL CORPORATION (00021)'. A 'View Compliance Status' link is located at the bottom of the compliance report section.

Field	Value
Current Reporting Quarter :	Q3 2014
Current Submission Period Began :	07/01/2014
Days Remaining in the Current Submission Period :	13
Closing Date for the Current Submission Period :	07/31/2014
Pricing Quarter :	Q2 2014
Next Reporting Quarter :	Q4 2014
Date Submission Begins for the Next Reporting Quarter :	10/01/2014

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

Figure 4-24: View Submitted Drugs

Medicare Part B Average Sales Price		View Submitted Drugs						Help
Home	Current Reporting Period: Q3 2014							
Compliance Summary	Drug Identifier: <input type="text"/> <input type="button" value="Search"/>							
Product Data	Showing 1 - 20 of 28 Results. Previous First 1, 2... Last Next							
Add Product Data	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	
Update Product Data	00000-0000-01	AMPDRUG1	150.555	15.000	175.555	4.000	SAVED	
Product Data Upload	00000-2334-98	AMPDRUG1					PENDING	
View Submitted Drugs	00000-9797-97	AMPDRUG1	25.125	3.000	30.125	1.000	SAVED	
Financial Data	00007-0000-02	AMPDRUG1					PENDING	
Certification	00021-0000-06	AMPDRUG1	2.000	2.000	16.000		SAVED	
Re-statements	00033-0000-04	AMPDRUG1	30.125	4.000	40.125	1.000	SAVED	
Help	00652-0000-07	AMPDRUG1	1235.369	4569.365	8856.334		SAVED	
Exit	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	

- 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

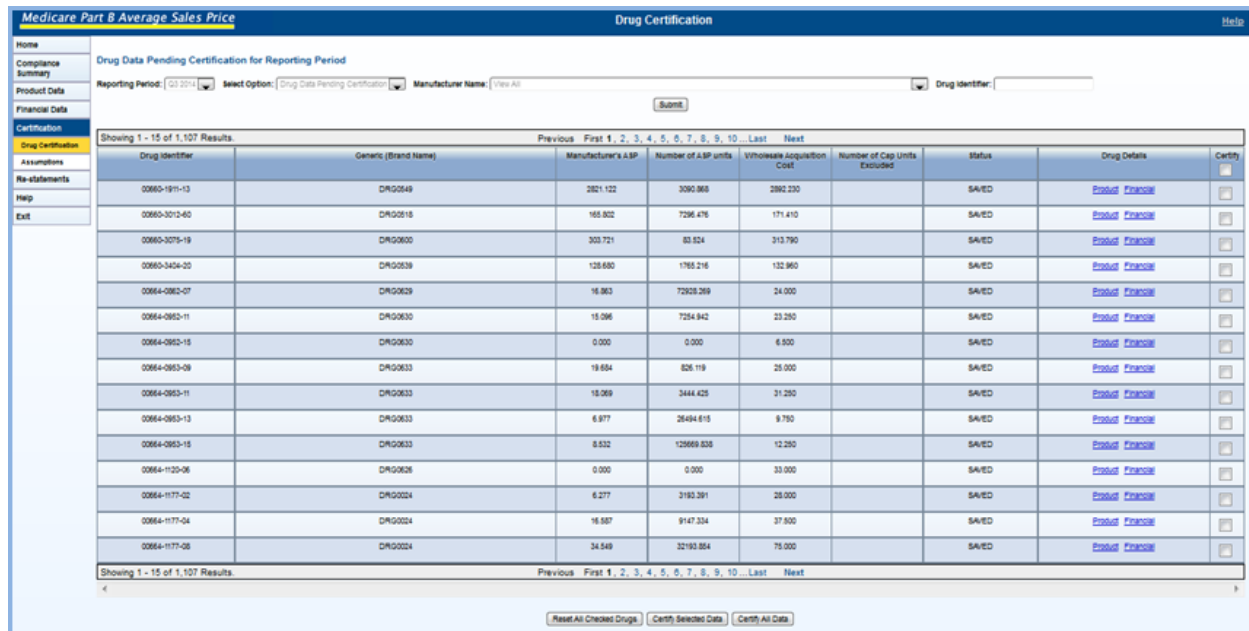
The screenshot displays the ASP application interface. The top navigation bar includes 'Medicare Part B Average Sales Price' and 'Home'. A left-hand menu lists various options, with 'Drug Certification' highlighted. The main content area is divided into several sections:

- Reporting Summary:** A table providing key dates and periods.

Current Reporting Quarter :	Q3 2014
Current Submission Period Began :	07/01/2014
Days Remaining in the Current Submission Period :	13
Closing Date for the Current Submission Period :	07/31/2014
Pricing Quarter :	Q2 2014
Next Reporting Quarter :	Q4 2014
Date Submission Begins for the Next Reporting Quarter :	10/01/2014
- Compliance Report:** A section with a red error icon and the message: "Labelers are out of compliance with data reporting requirements." Below this, a list of labelers is shown:
 - ASTRAZENCA (90210)
 - CMS (12345)
 - GENFRAI CORPORATION (000211)
 A link for "View Compliance Status" is provided at the bottom.
- Messages:** A section with a "View All" dropdown and three placeholder messages, each with a "I have reviewed the message" checkbox.

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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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).

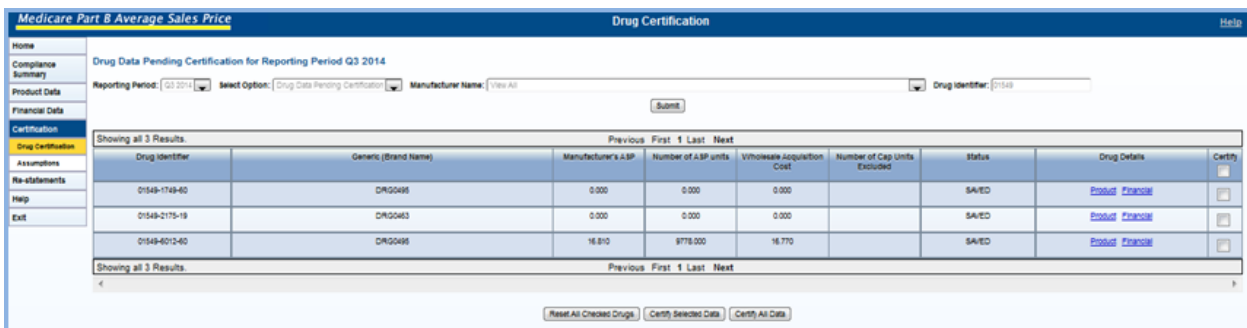
5. Select the desired drug identifier from the **Manufacturer Name** drop-down list. The **View All** value is the default value and will display all of the drugs for the selected quarterly reporting period in the results,

OR

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

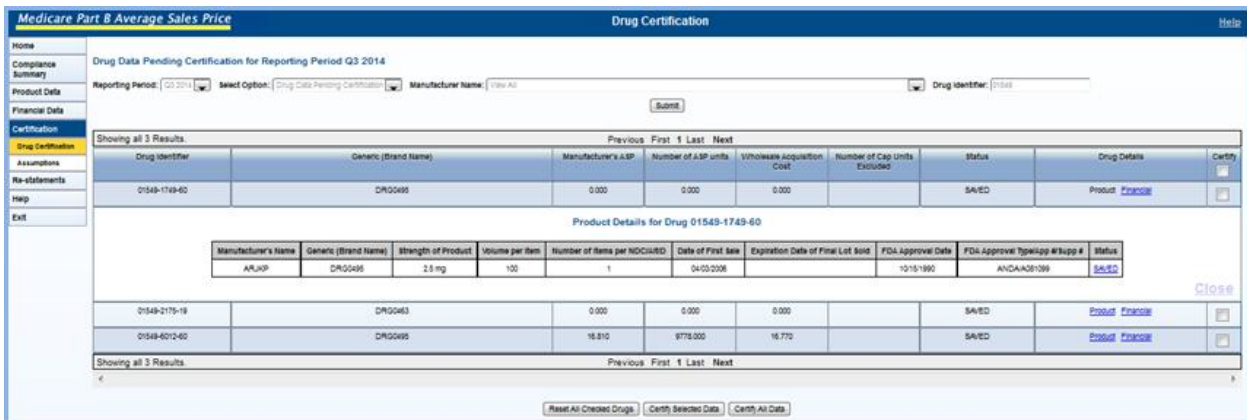
6. Click the **Submit** button. The Drug Certification page shown in Figure 5-3 is displayed. This page lists the drug data that are pending certification for the selected quarterly reporting period. Each drug that is listed displays the following data: Drug Identifier; Generic (Brand Name); Manufacturer’s 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

The screenshot shows the 'Medicare Part B Average Sales Price Drug Certification' interface. It includes a navigation menu on the left with options like Home, Compliance Summary, Product Data, Financial Data, Certification, Drug Certification, Assumptions, Re-statements, Help, and Exit. The main area displays 'Drug Data Pending Certification for Reporting Period' with fields for Reporting Period (Q3 2014) and Select Option (Drug Data Pending Certification). Below this is a table listing drug data with columns for Drug Identifier, Generic (Brand Name), Manufacturer's ASP, Number of ASP units, Wholesale Acquisition Cost, Number of Cap Units Excluded, Status, Drug Details, and Certify. The table shows one entry for drug 00000-0000-01 (AMPDRUG1) with a status of 'SAVED'. Below the table, there is a section titled 'Financial Details for Drug 00000-0000-01' containing a smaller table with columns for Reporting Period, Manufacturer's ASP, Number of ASP units, Wholesale Acquisition Cost, Number of Cap Units Excluded, and Status. The data row shows Q2 2014, 111.111, 222.222, 333.333, and a status of 'CERTIFIED'. A 'Close' link is visible at the bottom right of the interface.

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.

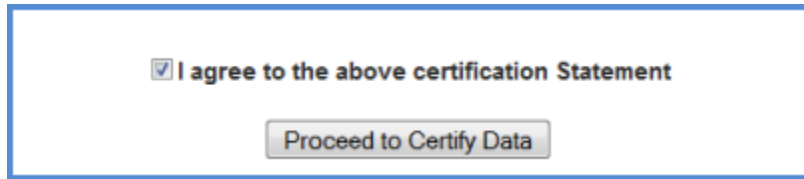
Figure 5-6: Data Certification Statement

The screenshot shows a pop-up window titled 'Data Certification Statement:'. The text inside reads: 'I certify that the reported Average Sales Prices were calculated accurately and that all information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.' Below the text is a checkbox labeled 'I agree to the above certification Statement' which is currently unchecked. At the bottom of the window is a button labeled 'Proceed to Certify Data'.

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

The screenshot displays the "Medicare Part B Average Sales Price Drug Certification" interface. At the top, there is a navigation menu with options like Home, Compliance Summary, Product Data, Financial Data, Certification, Assumptions, Re-statements, HWP, and Exit. The main area shows "Drug Data Pending Certification for Reporting Period" with filters for Reporting Period (Q3 2014), Select Option (Drug Data Pending Certification), Manufacturer Name (View All), and Drug Identifier (14175). A "Submit" button is present. A red confirmation message states "3 OUT OF 31 Drug Product Data has been successfully Certified." Below this is a table with 28 results, showing columns for Drug Identifier, Generic (Brand Name), Manufacturer's ASP, Number of ASP units, Wholesale Acquisition Cost, Number of Cap Units Excluded, Status, Drug Details, and a Certify checkbox.

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify
14175-0603-30	DRG0437	1928.850	9126.000	2106.180		SAVED	Product Profile	<input type="checkbox"/>
14175-0610-02	DRG0203	73.950	28733.000	91.890		SAVED	Product Profile	<input type="checkbox"/>
14175-0610-03	DRG0204	23.230	6798.000	32.700		SAVED	Product Profile	<input type="checkbox"/>
14175-0610-10	DRG0203	262.820	6307.000	326.830		SAVED	Product Profile	<input type="checkbox"/>
14175-0631-02	DRG0247	0.000	0.000	0.000		SAVED	Product Profile	<input type="checkbox"/>
14175-0631-06	DRG0206	48.760	10129.000	91.830		SAVED	Product Profile	<input type="checkbox"/>
14175-0634-02	DRG0230	214.210	943.000	235.390		SAVED	Product Profile	<input type="checkbox"/>
14175-0635-03	DRG0203	0.000	0.000	161.630		SAVED	Product Profile	<input type="checkbox"/>
14175-0635-04	DRG0203	125.130	458.000	161.630		SAVED	Product Profile	<input type="checkbox"/>
14175-0635-12	DRG0203	67.300	2738.000	80.410		SAVED	Product Profile	<input type="checkbox"/>
14175-0636-01	DRG0201	627.350	162.000	727.480		SAVED	Product Profile	<input type="checkbox"/>
14175-0636-02	DRG0201	0.000	0.000	96.680		SAVED	Product Profile	<input type="checkbox"/>
14175-0636-03	DRG0201	0.000	0.000	246.630		SAVED	Product Profile	<input type="checkbox"/>
14175-0636-06	DRG0201	0.000	0.000	493.250		SAVED	Product Profile	<input type="checkbox"/>
14175-0645-12	DRG0206	0.000	0.000	1973.000		SAVED	Product Profile	<input type="checkbox"/>

5.2 View Drug Data

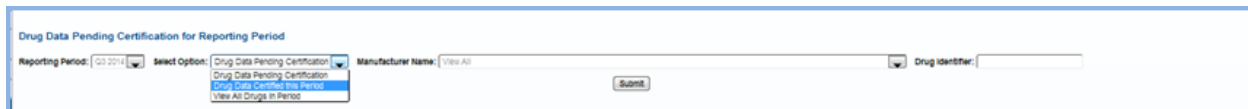
Drug Manufacturers have the ability to view all drug data that were certified during a selected reporting period. In addition, Drug Manufacturers also have the ability to view all drug data, with the statuses of Certified, Saved, or Pending, in a selected reporting period. These functions allow drug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

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify
14175-0603-30	DRG0437	1929.850	9128.000	2196.190		SAVED	Product Financial	<input type="checkbox"/>
14175-0619-02	DRG0003	73.960	20733.000	91.860		SAVED	Product Financial	<input type="checkbox"/>
14175-0619-03	DRG0004	33.230	4796.000	32.700		SAVED	Product Financial	<input type="checkbox"/>
14175-0619-10	DRG0003	362.520	6307.000	326.930		SAVED	Product Financial	<input type="checkbox"/>
14175-0631-02	DRG0347	0.000	0.000	0.000		SAVED	Product Financial	<input type="checkbox"/>
14175-0631-06	DRG0006	46.760	10129.000	51.520		SAVED	Product Financial	<input type="checkbox"/>
14175-0634-02	DRG0230	214.210	943.000	238.390		SAVED	Product Financial	<input type="checkbox"/>
14175-0635-03	DRG0203	0.000	0.000	191.630		SAVED	Product Financial	<input type="checkbox"/>
14175-0635-04	DRG0203	126.100	458.000	191.630		SAVED	Product Financial	<input type="checkbox"/>
14175-0635-12	DRG0203	67.300	2769.000	80.410		SAVED	Product Financial	<input type="checkbox"/>
14175-0636-01	DRG0001	527.360	162.000	727.480		SAVED	Product Financial	<input type="checkbox"/>
14175-0636-02	DRG0001	0.000	0.000	96.650		SAVED	Product Financial	<input type="checkbox"/>
14175-0636-03	DRG0001	0.000	0.000	246.630		SAVED	Product Financial	<input type="checkbox"/>
14175-0636-05	DRG0001	0.000	0.000	483.250		SAVED	Product Financial	<input type="checkbox"/>
14175-0640-12	DRG0206	0.000	0.000	1973.000		SAVED	Product Financial	<input type="checkbox"/>

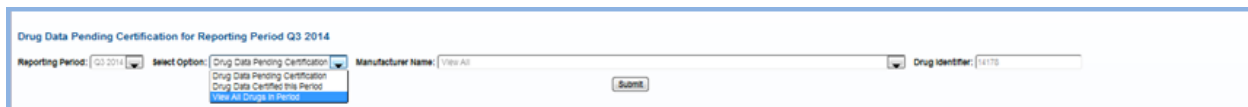
6. Each record of drug data that has been certified displays the following: Drug Identifier; Generic (Brand Name); Manufacturer's ASP; Number of ASP Units; Wholesale Acquisition Cost; Number of CAP Units Excluded; Status and Drug Details links. Click the **Product** or **Financial** links under **View 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 or 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

The screenshot shows the 'Medicare Part B Average Sales Price' page with the 'Certification Status' tab selected. The table 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	View Details
14175-0021-00	DRG0091	0.000	0.000	3.580		CERTIFIED	Product Financial
14175-0021-08	DRG0091	396.640	23071.000	472.410		CERTIFIED	Product Financial
14175-0025-00	DRG0437	0.000	0.000	0.000		CERTIFIED	Product Financial
14175-0025-00	DRG0437	1929.580	9106.000	2196.190		SAVED	Product Financial
14175-0819-02	DRG0003	72.800	28733.000	91.980		SAVED	Product Financial
14175-0819-03	DRG0004	23.230	6796.000	32.700		SAVED	Product Financial
14175-0819-10	DRG0003	262.020	6307.000	326.930		SAVED	Product Financial
14175-0821-02	DRG0247	0.000	0.000	0.000		SAVED	Product Financial
14175-0821-06	DRG0006	45.760	10129.000	51.520		SAVED	Product Financial
14175-0824-02	DRG0230	214.210	942.000	236.390		SAVED	Product Financial
14175-0830-03	DRG0203	0.000	0.000	181.630		SAVED	Product Financial
14175-0830-04	DRG0203	125.100	409.000	101.630		SAVED	Product Financial
14175-0830-12	DRG0203	67.300	2709.000	30.410		SAVED	Product Financial
14175-0836-01	DRG0001	627.350	162.000	727.480		SAVED	Product Financial
14175-0836-02	DRG0001	0.000	0.000	98.690		SAVED	Product Financial

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

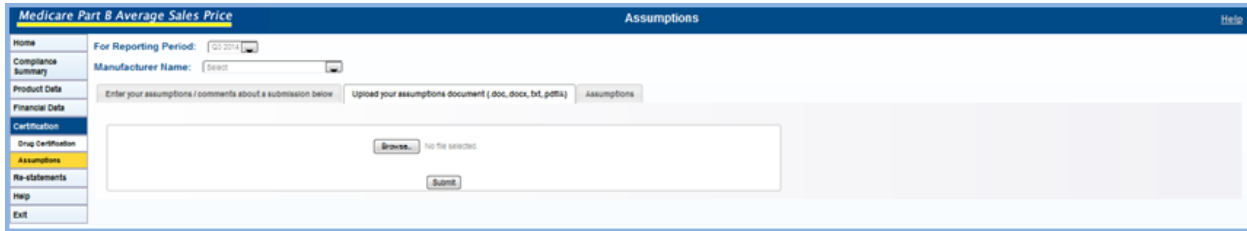
2. The Certification Assumptions page opens, as shown in Figure 5-14.

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.

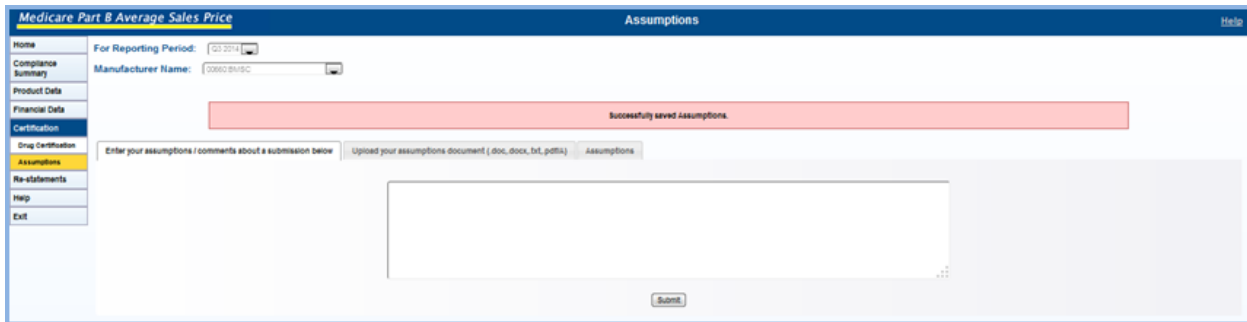
- The Certification Assumptions Page – Upload is shown in Figure 5-15.

Figure 5-15: Certification Assumptions Page -- Upload



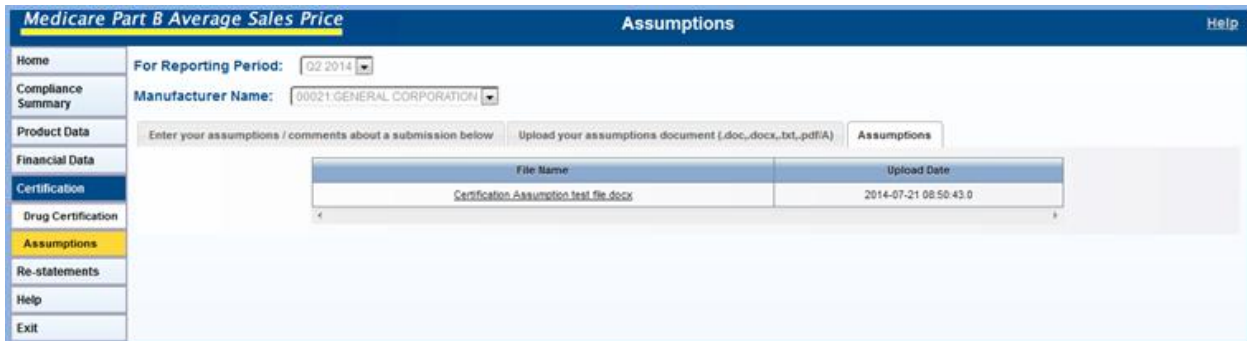
- Enter the assumptions and comments about a submission in the text box and click the **Submit** button, or
- Click the **Browse** button on the **Upload your assumptions document (.doc, .docx, .txt, or.pdf/A)** tab, select the document to upload, and click the **Submit** button. The document file must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

Figure 5-16: Certification Assumptions Saved



- 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



- 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

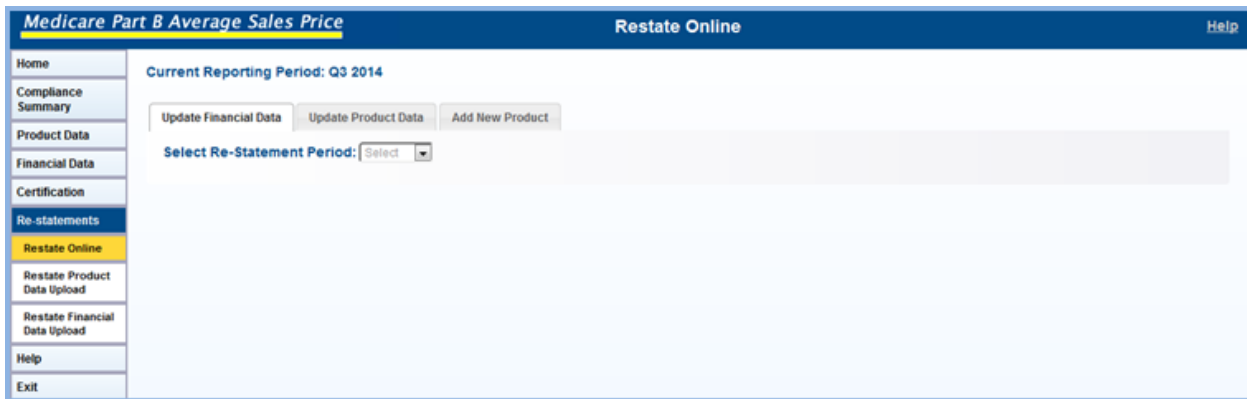
The ASP Application provides drug manufacturers the ability to restate drug financial data that has been previously submitted and certified. Perform the following to re-state drug financial data:

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

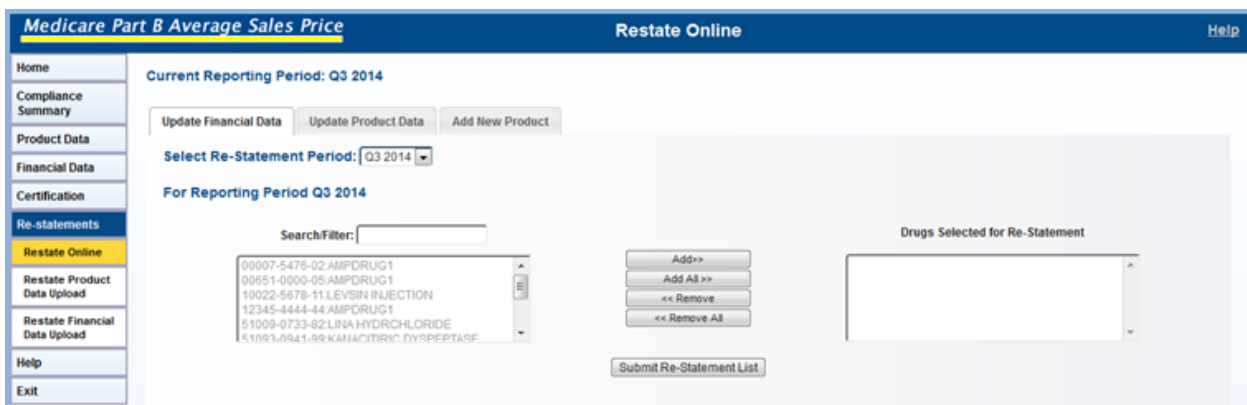
2. Click **Restate Online**. The Restate Online page opens, as shown in Figure 6-2. The Restate Online screen defaults to the Update Financial Data tab.

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.

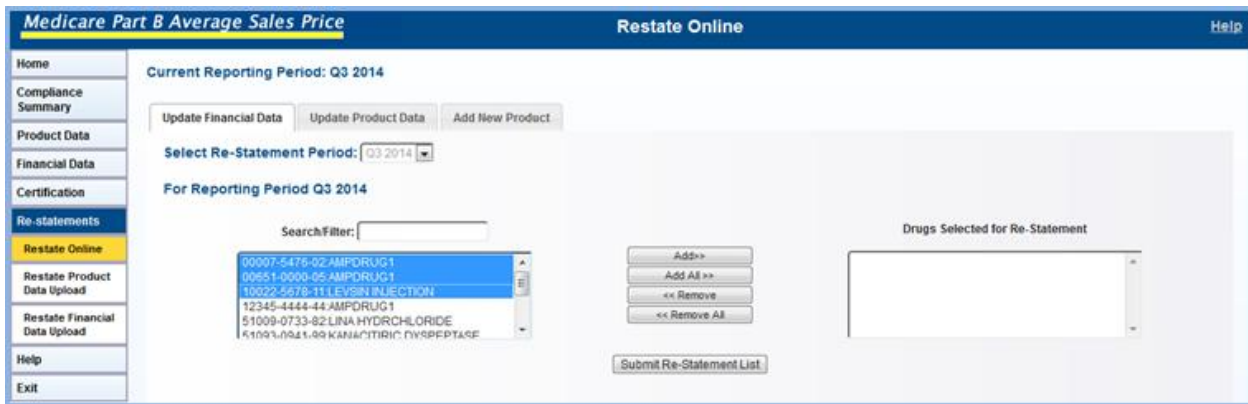
Table 6-1 Restate Online Page Information – Update Financial Data Tab

Name	User Action	Comments
– Select Re-Statement Period	– Click the arrow on drop-down box and select the desired quarterly reporting period.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> • This field is optional.
– Drugs Selected for Re- Statement	– Click the arrow on the drop-down box to display the list of drug identifiers.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • N/A
– << Remove All	– Click <<Remove All to remove all drugs from the the Drugs Selected for Re-Statement field.	<ul style="list-style-type: none"> • N/A
– Submit Re- Statement List	– Click the Submit Re-Statement List button to submit the selected drugs for re-statement.	<ul style="list-style-type: none"> • 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



- 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



- 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	LEVSN INJECTION	11.333	22.333	44.333		CERTIFIED
Showing all 3 Results.						
Previous First 1 Last Next						

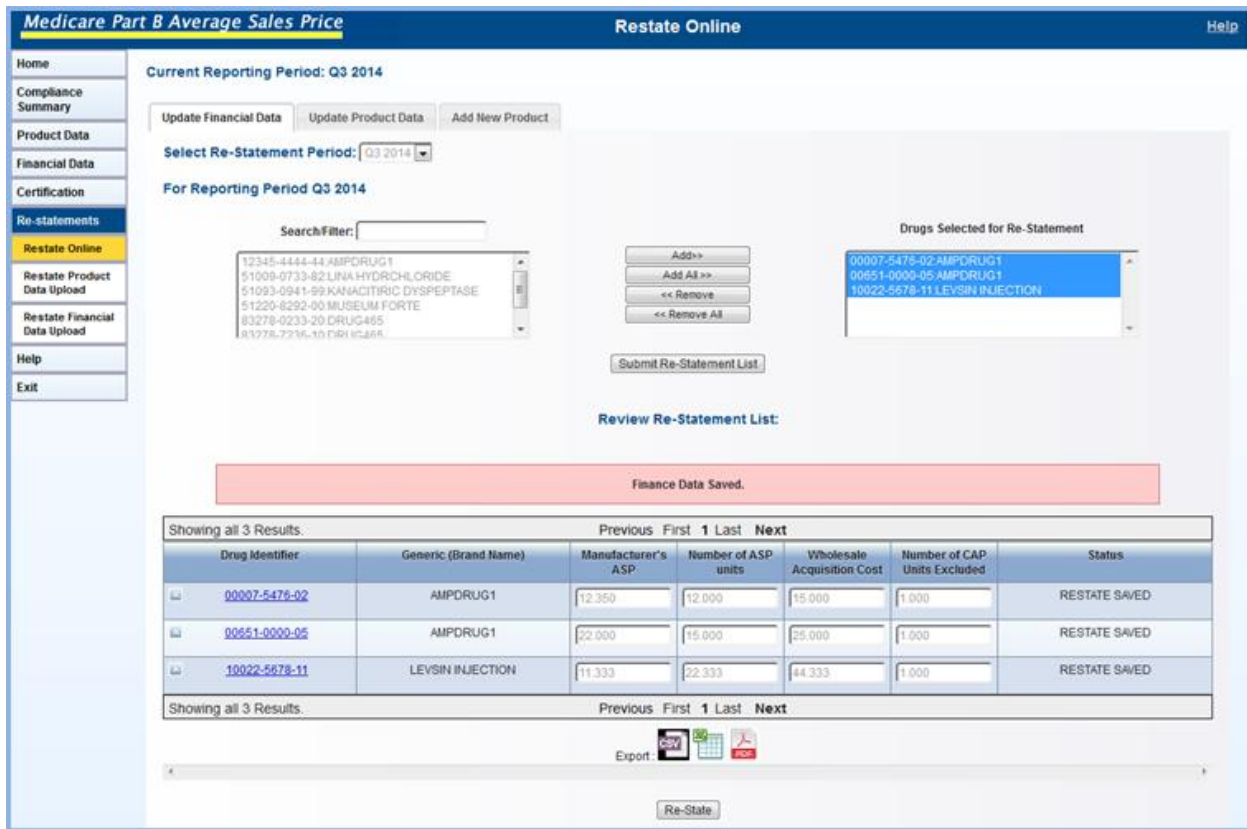
The drug's financial details that can be modified are the following: ASP; ASP Units; WAC; and CAP Units. The following table describes the fields and the user actions on the Add or Edit Financial Data screen.

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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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



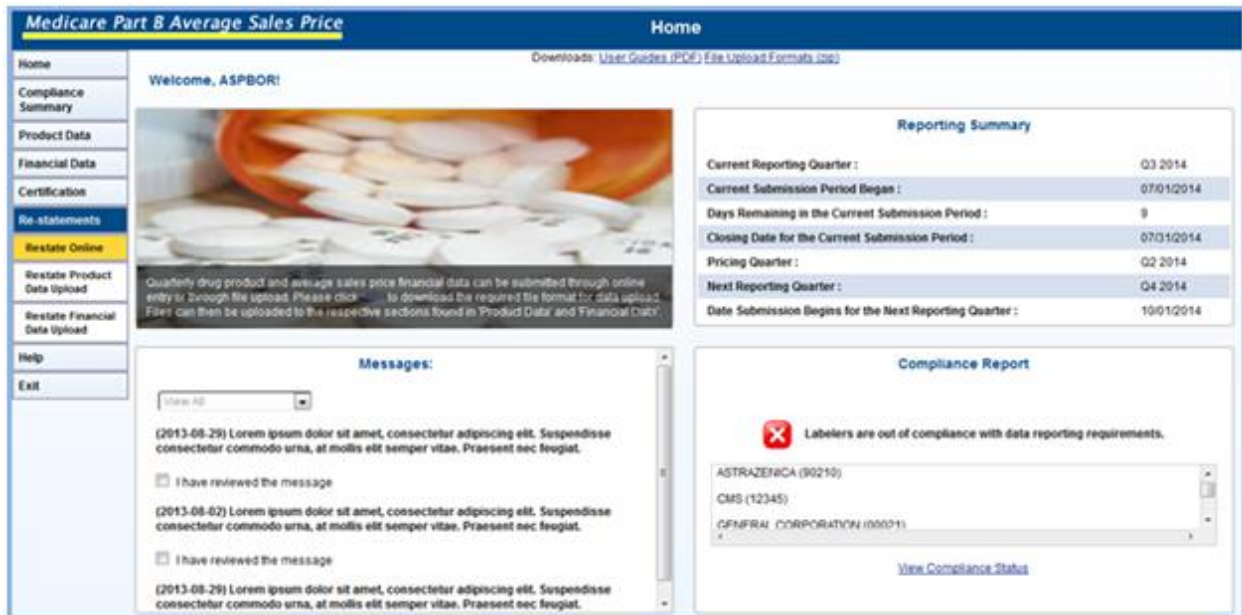
9. Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

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:

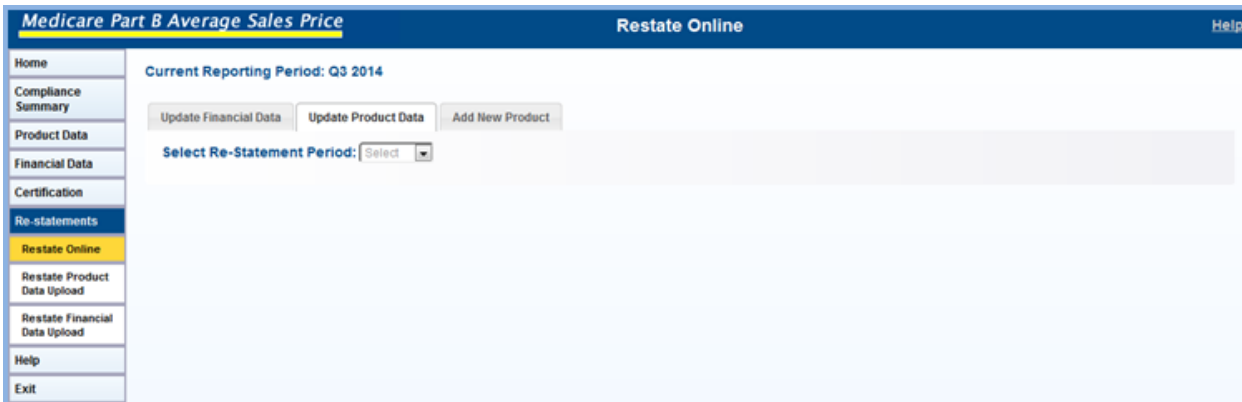
1. Begin re-stating drug data by clicking the **Re-statements** button on the left side menu on the ASP Application Home Page. Select **Restate Online** from the drop-down list. The Restate Online Selection on the ASP Application home page is shown in Figure 6-8.

Figure 6-8: Restate Online Selection Screen



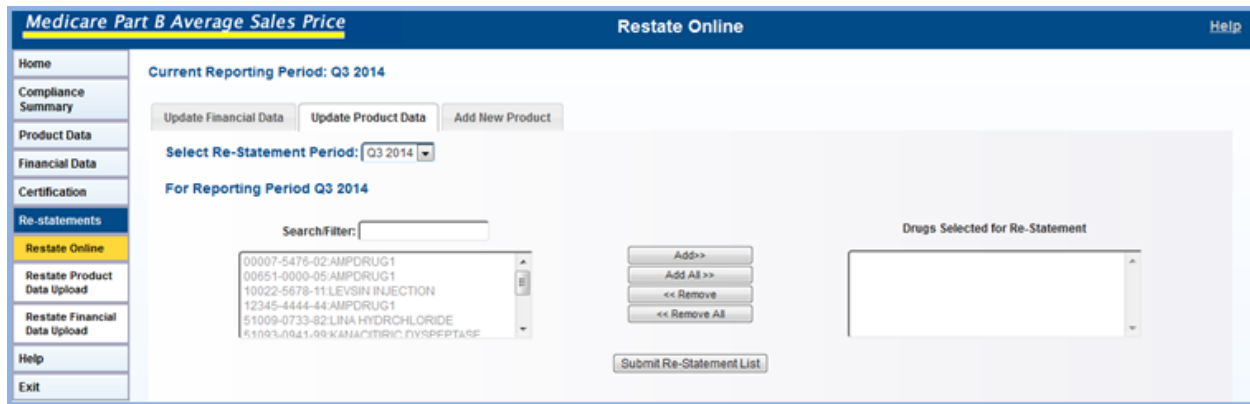
2. Click **Restate Online**. The Restate Online page opens, as shown in Figure 6-2. The Restate Online screen defaults to the Update Finance tab. Click the Update Product tab and select the Re-Statement Period from the **Select Re-Statement Period** drop-down list as shown in Figure 6-9.

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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> This field is optional.
– Drugs Selected for Re-Statement	– Click the arrow on the drop-down box to display the list of drug identifiers.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for re-statement.
– 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.	<ul style="list-style-type: none"> Once the drug identifiers are in the Drugs Selected for Re-Statement box, they can be submitted for re-statement.

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



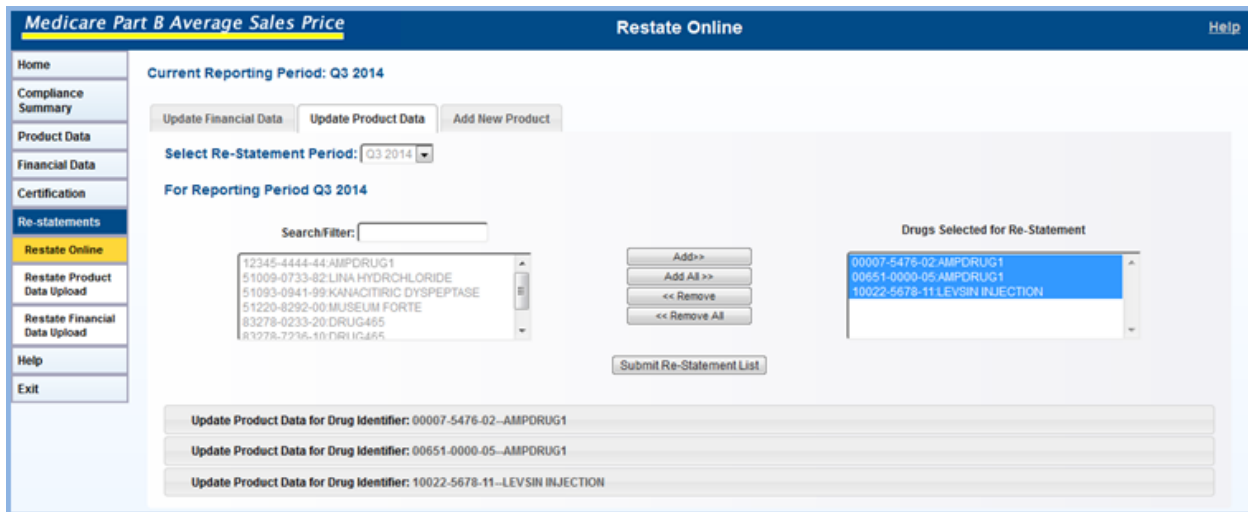
5. Click the drug(s) you want to re-state and click **Add>>** or click **Add All>>** to select all available drugs for re-statement. The selections have been moved and are be populated in the Drugs Selected for Re-Statement field as shown in Figure 6-12.

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



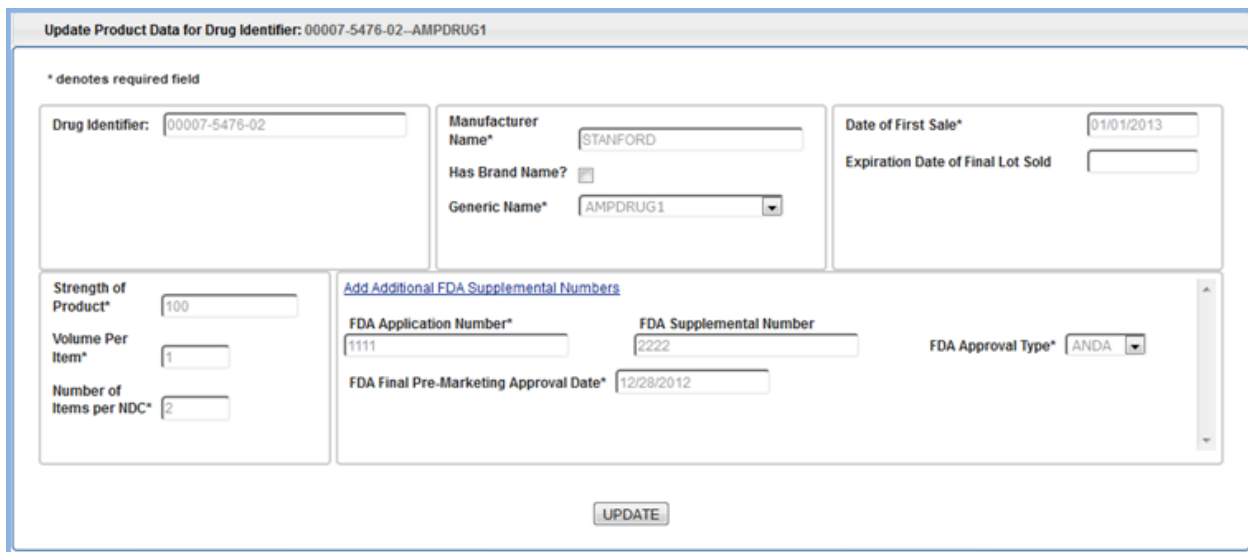
- Click the **Submit Re-Statement List** button. The Restate Online -- Re-Statement Product List opens as shown in Figure 6-13.

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



- 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • The Generic Name is required.
– Date of First Sale	– Enter the date when the drug was first available for sale.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • The date format is MM/DD/YYYY.
– Strength of Product	– Enter the Strength of product in the field.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • The entry must be in a numeric format.
– FDA Application Number	– Enter the FDA Application Number in the field.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> The FDA Approval Type is required.

- Enter the necessary re-statement amounts for the desired fields.
- 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

- 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:

- 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.
- 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

The screenshot shows the 'Restate Online' interface for adding a new product. The page title is 'Medicare Part B Average Sales Price' and the sub-header is 'Restate Online'. A navigation menu on the left includes options like Home, Compliance Summary, Product Data, Financial Data, Certification, Re-statements, Restate Online (highlighted), Restate Product Data Upload, Restate Financial Data Upload, Help, and Exit. The main content area shows the 'Current Reporting Period: Q3 2014' and 'Add New Product' button. Below this, there are tabs for 'Update Financial Data', 'Update Product Data', and 'Add New Product'. A 'Select Re-Statement Period' dropdown is set to 'Q2 2014', and the 'Reporting Period' is 'Q2 2014'. A note states '* denotes required field'. The form is divided into sections: 'Add by NDC' (with 'Add by Alternate ID' as an option) and 'Add Additional FDA Supplemental Numbers'. The 'Add by NDC' section includes fields for NDC1*, NDC2*, and NDC3*, with a dropdown for 'Add new NDC1'. The 'Add Additional FDA Supplemental Numbers' section includes fields for 'FDA Application Number*', 'FDA Supplemental Number', 'FDA Approval Type*' (with a dropdown), and 'FDA Final Pre-Marketing Approval Date*' (with a date format note). Other fields include 'Manufacturer Name*', 'Date of First Sale*' (with a date format note), 'Has Brand Name?' (checkbox), 'Generic Name*' (dropdown), and 'Expiration Date of Final Lot Sold' (with a date format note). 'Strength of Product*', 'Volume Per Item*', and 'Number of Items per NDC*' are also present. 'Save' and 'Reset' buttons are at the bottom.

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.

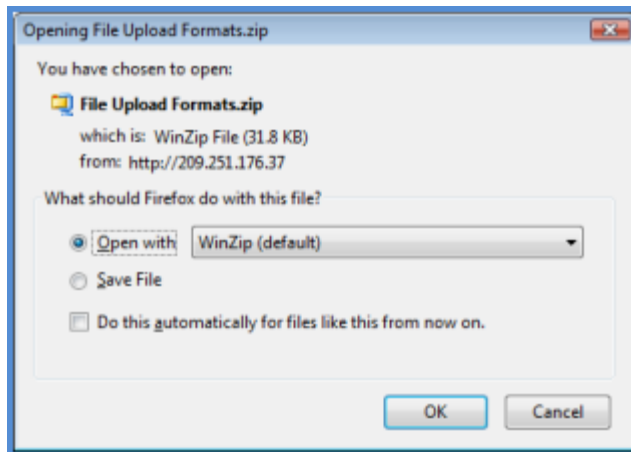
Figure 6-17: Restate Financial Data Upload Selection

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

Name	Type	Modified	Size	Ratio	Packed	Path
financeTemplate.xls	Microsoft Of...	7/26/2013 9:51 AM	30,208	78%	6,538	
financeTemplate.xlsx	Microsoft Of...	7/26/2013 9:50 AM	11,418	27%	8,314	
financeTemplate.csv	Microsoft Of...	7/1/2013 4:22 PM	184	26%	137	
productTemplate.csv	Microsoft Of...	6/26/2013 4:14 PM	528	57%	226	
productTemplate.xlsx	Microsoft Of...	7/26/2013 10:01 AM	13,408	24%	10,170	
productTemplate.xls	Microsoft Of...	7/26/2013 10:01 AM	27,648	78%	6,212	

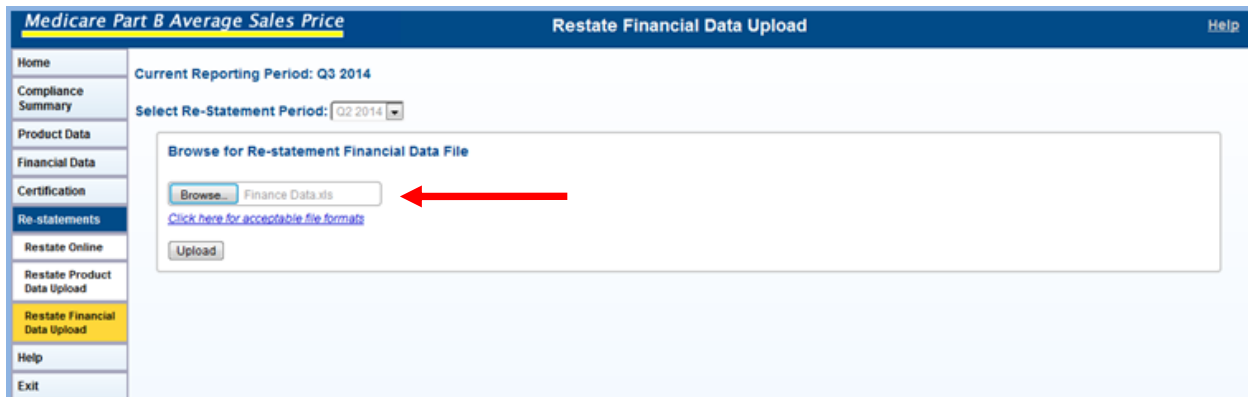
7. Click any one of Finance Template files to open a product data template. A sample template is shown in Figure 6-21.

Figure 6-21: Sample Financial Data Template

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

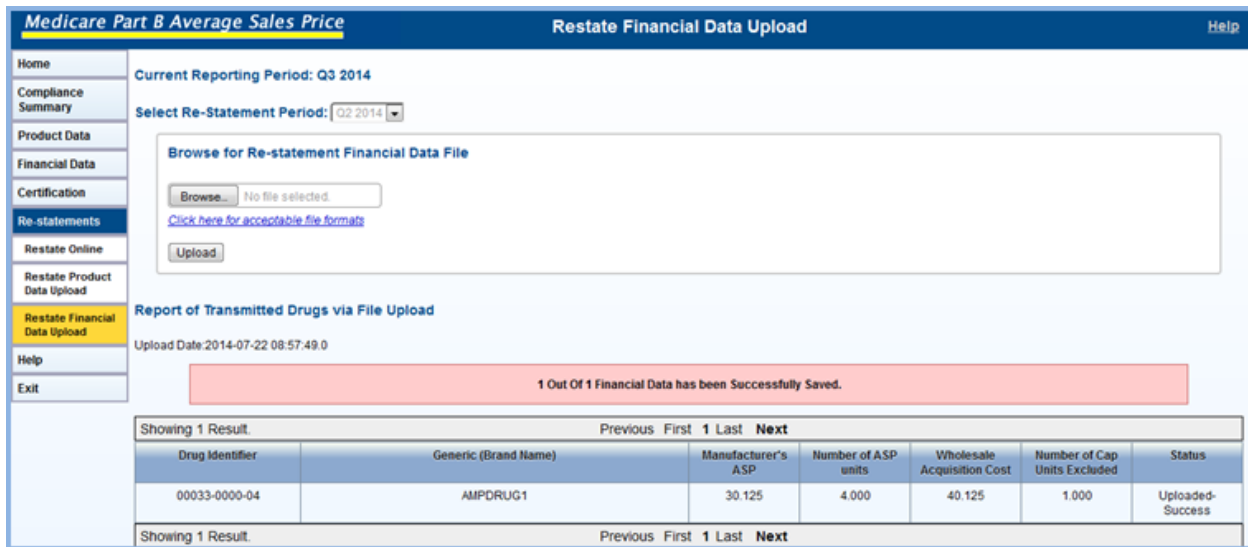
- Enter the re-stated drug financial information on the template. The entries on the template consist of the same fields that are described in Section 6.1, Re-State Drug Financial Data – Online Entry. Refer to Table 6-2 for a description of the fields and which fields are required. Save the file using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



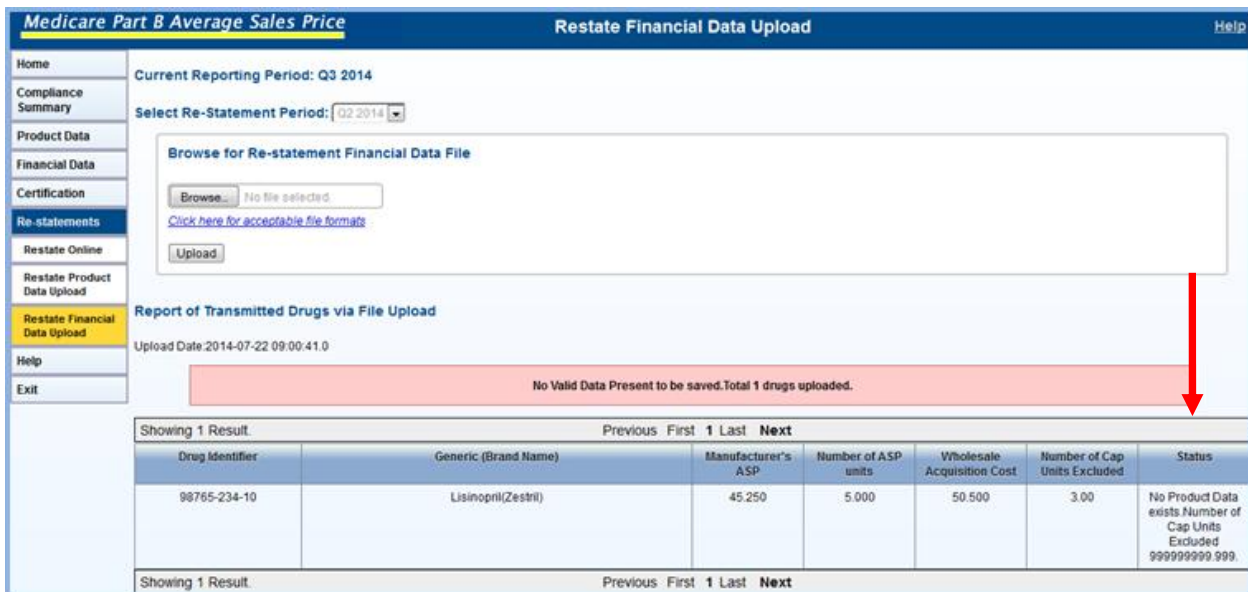
- Click **Upload**. The Restate Financial Data upload -- Result screen will open, as shown in Figure 6-23.

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

The screenshot shows the 'Medicare Part B Average Sales Price' Home page. The left navigation menu includes 'Home', 'Compliance Summary', 'Product Data', 'Financial Data', 'Certification', 'Re-statements', 'Restate Online', 'Restate Product Data Upload' (highlighted), 'Restate Financial Data Upload', 'Help', and 'Exit'. The main content area features a 'Welcome, ASPBOR!' message, a 'Downloads' link for 'User Guides (PDF) File Upload Formats (zip)', and a 'Reporting Summary' table:

Reporting Summary	
Current Reporting Quarter :	Q3 2014
Current Submission Period Began :	07/01/2014
Days Remaining in the Current Submission Period :	8
Closing Date for the Current Submission Period :	07/31/2014
Pricing Quarter :	Q2 2014
Next Reporting Quarter :	Q4 2014
Date Submission Begins for the Next Reporting Quarter :	10/01/2014

Below the reporting summary is a 'Compliance Report' section with a red 'X' icon and the message: 'Labelers are out of compliance with data reporting requirements.' It lists 'ASTRAZENICA (90210)', 'CMS (12345)', and 'GENFRAJ CORPORATION (00021)'. A 'View Compliance Status' link is provided. A 'Messages' section contains several placeholder messages with dates like '(2013-08-29)' and '(2013-08-02)'. A 'Restate Product Data Upload' section contains a text box with instructions: 'Quarterly drug product and average sales price financial data can be submitted through online entry or through file upload. Please click [link] to download the required file format for data upload. Files can then be uploaded to the respective sections found in 'Product Data' and 'Financial Data:'.

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

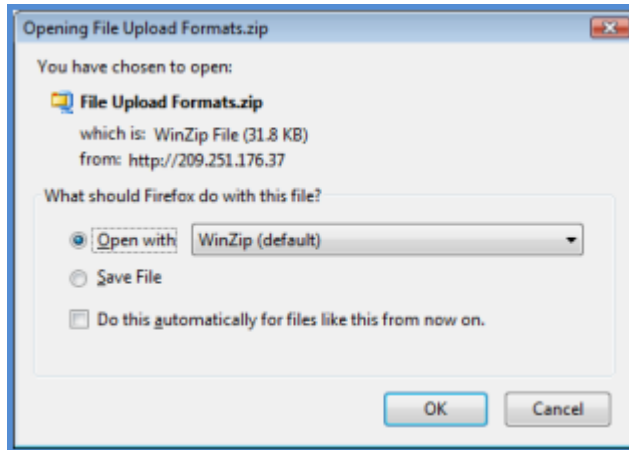
Figure 6-26: Restate Product Data Upload

The screenshot shows the 'Medicare Part B Average Sales Price' Restate Product Data Upload page. The left navigation menu is the same as in Figure 6-25, with 'Restate Product Data Upload' highlighted. The main content area displays 'Current Reporting Period: Q3 2014' and a 'Select Re-Statement Period:' dropdown menu. Below this is a 'Browse for Restatement product data' section with a 'Browse...' button, a text box showing 'No file selected', and a link to 'Click here for acceptable file formats'. An 'Upload' button is located at the bottom of the section.

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.

- 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



- 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

Name	Type	Modified	Size	Ratio	Packed	Path
financeTemplate.xls	Microsoft Of...	7/26/2013 9:51 AM	30,208	78%	6,538	
financeTemplate.xlsx	Microsoft Of...	7/26/2013 9:50 AM	11,418	27%	8,314	
financeTemplate.csv	Microsoft Of...	7/1/2013 4:22 PM	184	26%	137	
productTemplate.csv	Microsoft Of...	6/26/2013 4:14 PM	528	57%	226	
productTemplate.xlsx	Microsoft Of...	7/26/2013 10:01 AM	13,408	24%	10,170	
productTemplate.xls	Microsoft Of...	7/26/2013 10:01 AM	27,648	78%	6,212	

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

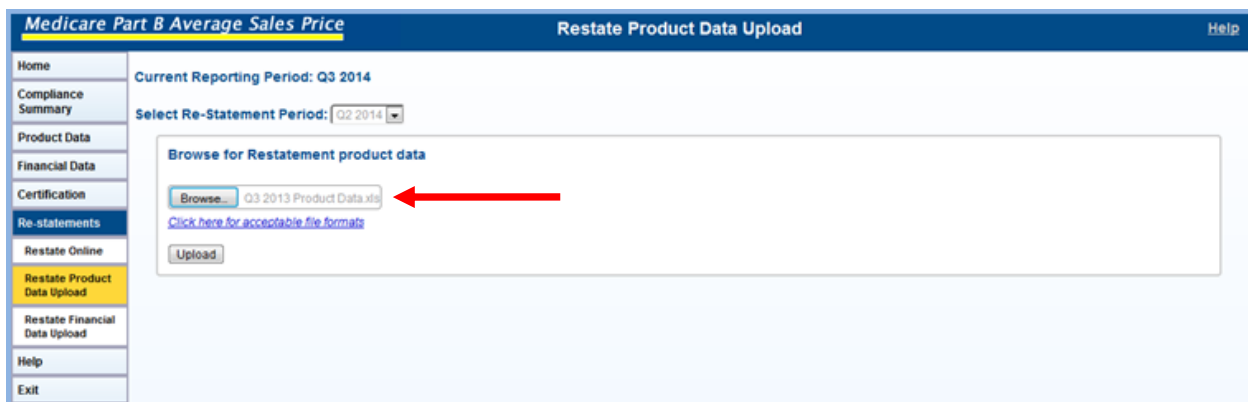
Figure 6-29: Sample Product Data Template

	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

The screenshot shows the 'Restate Product Data Upload' interface. At the top, it says 'Medicare Part B Average Sales Price' and 'Restate Product Data Upload'. The current reporting period is Q3 2014, and the re-statement period is Q2 2014. A message states '1 Out Of 1 Product Data has been Successfully Saved.' Below this is a table with the following data:

Drug Identifier	Manufacturer Name	Generic (Brand Name)	Strength of Product	Volume per Item	Number of Items per NDC/AMID	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval Type/App #/Supp #	FDA Approval Date	Status
Insulin	AstraZeneca	insulin(Glucoqyn)	2s	1v	10	07/31/2013	05/30/2016	ANDA / A123789 / B666777	01/01/2013	Uploaded-Success

- 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

The screenshot shows the 'Restate Product Data Upload' interface with an error message: 'No Valid Data Present to be saved.Total 1 drugs uploaded.' Below this is a table with the following data:

Drug Identifier	Manufacturer Name	Generic (Brand Name)	Strength of Product	Volume per Item	Number of Items per NDC/AMID	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval Type/App #/Supp #	FDA Approval Date	Status
Insulin	AstraZeneca	INSULIN(Glucoqyn)	2s	1v	10	07/31/2013	05/30/2016	/ A123789 / B666777	01/01/2013	FDA Approval Type Required.

A red arrow points to the 'Status' column of the table.

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

7 Compliance

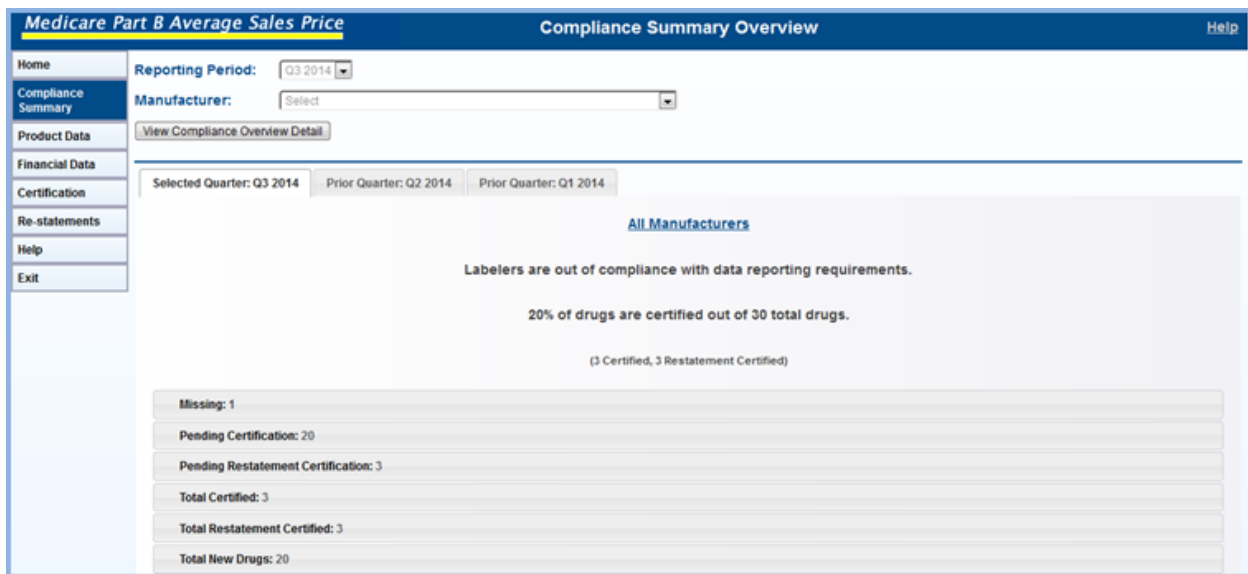
The Compliance features allow Drug Manufacturers to view whether a drug is in compliance with the drug submission reporting requirements. Drug Manufacturers can view compliance statuses in one of two ways: CMS may send the Drug Manufacturer a compliance report notification on their home page informing 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.	<ul style="list-style-type: none"> • 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).	<ul style="list-style-type: none"> Results will be displayed depending on the selection of the Manufacturer.

- 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



- 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.

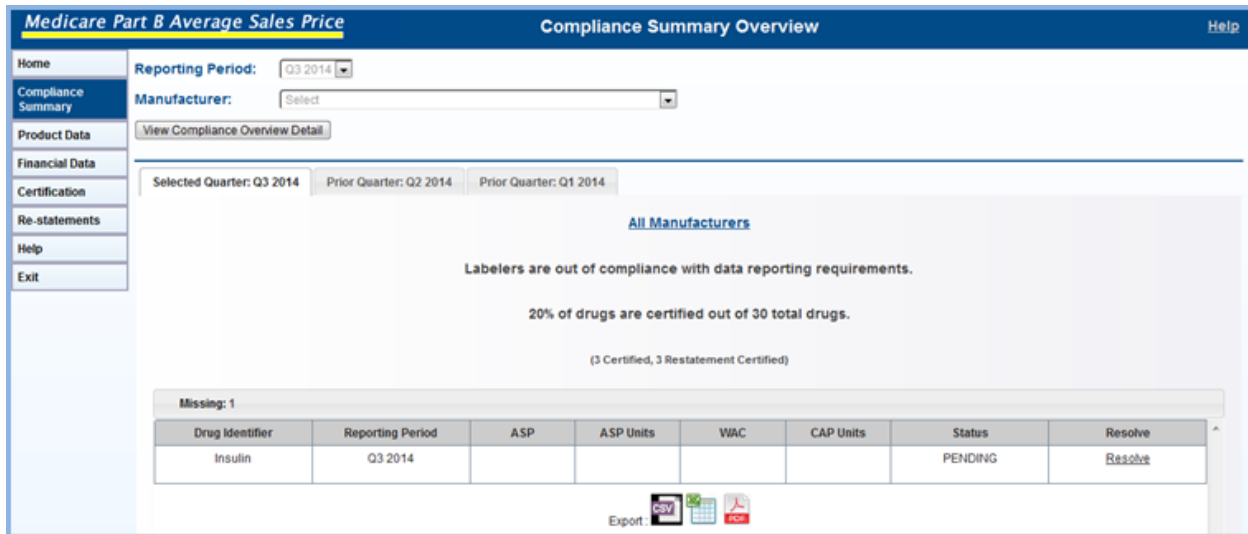
7.2 Compliance Overview

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

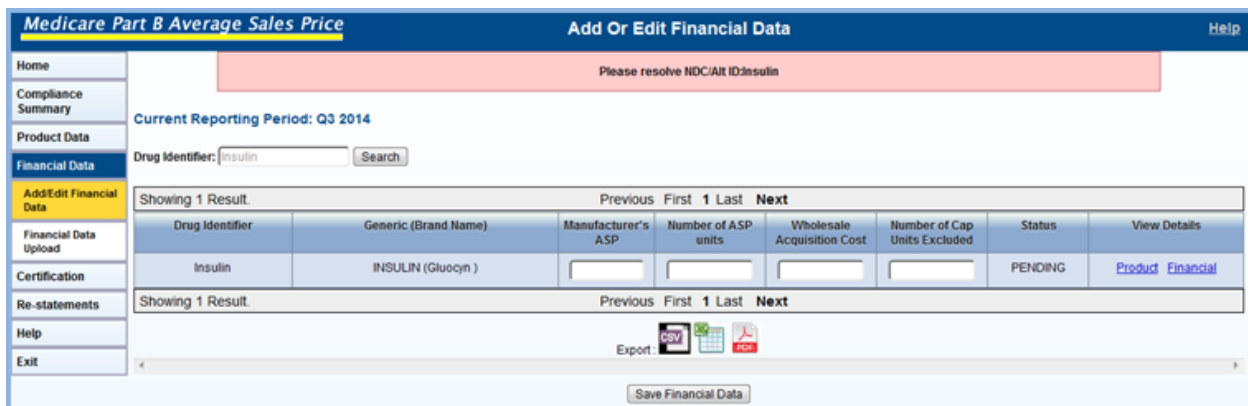
Drug Manufacturers can view and update drugs that are not compliant because the information about the drug is incomplete or insufficient by clicking on the Missing Drugs tab. The screen shown in Figure 7-3 will be displayed.

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

The screenshot shows the 'Compliance Summary Overview' page for Medicare Part B Average Sales Price. The reporting period is set to Q3 2014. A message states: 'Labelers are out of compliance with data reporting requirements. 20% of drugs are certified out of 30 total drugs. (3 Certified, 3 Restatement Certified)'. Below this, there are counts for 'Missing: 1', 'Pending Certification: 20', 'Pending Restatement Certification: 3', 'Total Certified: 3', 'Total Restatement Certified: 3', and 'Total New Drugs: 20'. A table lists the pending certifications with columns for Drug Identifier, Reporting Period, ASP, ASP Units, WAC, CAP Units, Status, and a Resolve link.

Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status	Resolve
00000-0000-01	Q3 2014	333.333	333.333	333.333	333.333	SAVED	Resolve
00000-9797-97	Q3 2014	25.125	3.000	30.125	1.000	SAVED	Resolve
00001-0000-03	Q3 2014	123.123	123.123	123.123	98754.123	SAVED	Resolve
00007-0000-02	Q3 2014	123.123	123.123	123.123		SAVED	Resolve
00021-0000-06	Q3 2014	2.000	2.000	16.000		SAVED	Resolve

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

The screenshot shows the 'Drug Certification' page. It displays 'Drug Data Pending Certification for Reporting Period Q3 2014'. The reporting period is Q3 2014 and the select option is 'Drug Data Pending Certification'. The manufacturer name is 'STP (00000)' and the drug identifier is '00000-0000-01'. A red message box says 'Please resolve NDC/AT ID:00000-0000-01'. Below is a table with one result for drug 00000-0000-01 (AMPDRUG1) with status 'SAVED'. At the bottom are buttons for 'Reset All Checked Drugs', 'Certify Selected Data', and 'Confirm All Data'.

Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify
00000-0000-01	AMPDRUG1	333.333	333.333	333.333	333.333	SAVED	Product Financial	<input type="checkbox"/>

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

Medicare Part B Average Sales Price Compliance Summary Overview

Home Reporting Period: Q3 2014
 Compliance Summary Manufacturer: Select
 Product Data View Compliance Overview Detail
 Financial Data
 Certification
 Re-statements
 Help
 Exit

Selected Quarter: Q3 2014 Prior Quarter: Q2 2014 Prior Quarter: Q1 2014

[All Manufacturers](#)

Labelers are out of compliance with data reporting requirements.

20% of drugs are certified out of 30 total drugs.

(3 Certified, 3 Restatement Certified)

Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status	Resolve
00007-5476-02	Q3 2014	12.350	12.000	15.000	1.000	RESTATE SAVED	Resolve
00651-0000-05	Q3 2014	22.000	15.000	25.000	1.000	RESTATE SAVED	Resolve
10022-5678-11	Q3 2014	11.333	22.333	44.333	1.000	RESTATE SAVED	Resolve

Export

Total Certified: 3
 Total Restatement Certified: 3
 Total New Drugs: 20

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

The screenshot shows the 'Compliance Summary Overview' interface for Medicare Part B Average Sales Price. The reporting period is set to Q3 2014. The main content area displays a summary of compliance status: 'Labels are out of compliance with data reporting requirements. 20% of drugs are certified out of 30 total drugs. (3 Certified, 3 Restatement Certified)'. Below this, a table lists the re-stated certified drugs:

Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status
12345-4444-44	Q3 2014	2456.898	2222.222	3333.333		RE-STATEd CERTIFIED
51093-0941-99	Q3 2014	1211.333	2374.373	9555.333		RE-STATEd CERTIFIED
51220-8292-00	Q3 2014	361.333	274.373	1236.396		RE-STATEd CERTIFIED

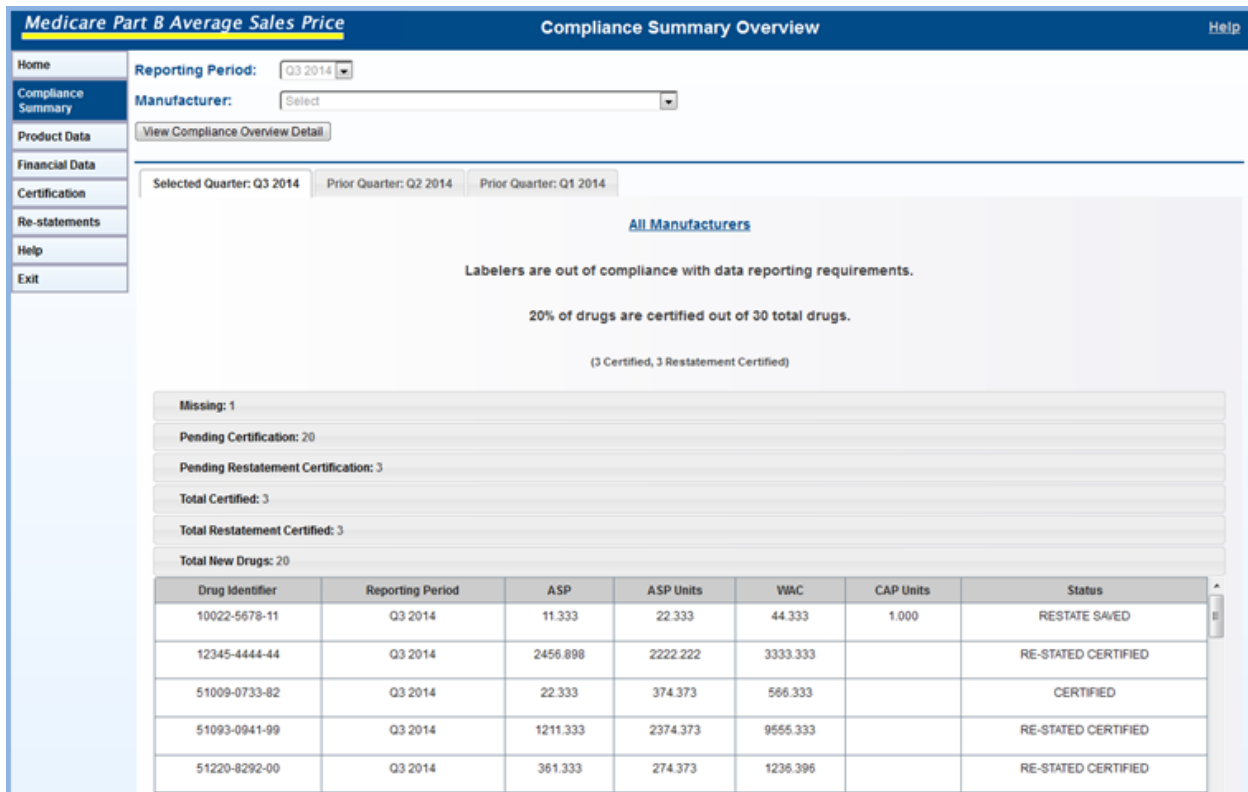
Additional summary statistics shown in the interface include: Missing: 1, Pending Certification: 20, Pending Restatement Certification: 3, Total Certified: 3, and Total Restatement Certified: 3. An 'Export' button with icons for CSV, Excel, and PDF is also visible.

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

Medicare Part B Average Sales Price Compliance Summary Overview

Reporting Period: Q3 2014
 Manufacturer: Select

Selected Quarter: Q3 2014 | Prior Quarter: Q2 2014 | Prior Quarter: Q1 2014

All Manufacturers

Labelers are out of compliance with data reporting requirements.

20% of drugs are certified out of 30 total drugs.

(3 Certified, 3 Restatement Certified)

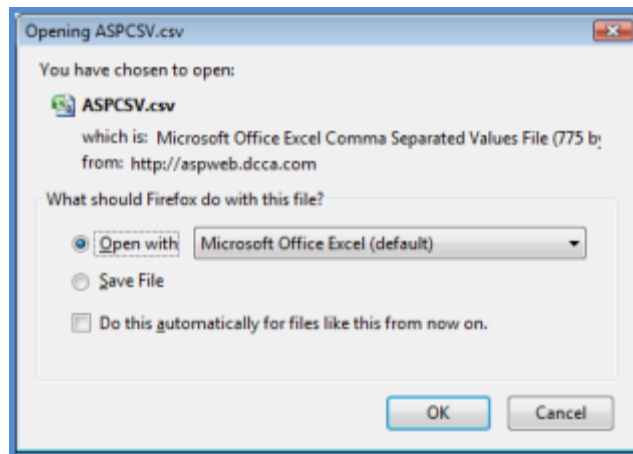
Missing: 1
 Pending Certification: 20
 Pending Restatement Certification: 3
 Total Certified: 3
 Total Restatement Certified: 3

Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status
12345-4444-44	Q3 2014	2456.898	2222.222	3333.333		RE-STATEd CERTIFIED
51093-0941-99	Q3 2014	1211.333	2374.373	9555.333		RE-STATEd CERTIFIED
51220-8292-00	Q3 2014	361.333	274.373	1236.396		RE-STATEd CERTIFIED

Export (CSV, Excel, PDF icons)

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