



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

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

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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 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 Ouarter 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: <u>https://portal.cms.gov</u>. The CMS Portal Home Page is shown in Figure 2-1.

CMS.gov Enterprise Portal Home | About CMS | Newsroom | Archive | 😯 Help & FAQs | 😞 Email | 🛶 Print | Learn about your healthcare options Search CMS.pov Centers for Medicare & Medicaid Services Health Care Quality Improvement System Provider Resources CMS Portal > Welcome to CMS Portal CMS Secure Portal Physician Value To log into the CMS Portal a CMS user account is required. The physician value portiet allows physician group practices to select their PORS reporting mechanism, elect quality tering to calculate the group's value Based Payment Modifier, and were their Quality and Resource Use Reports. It also allows individual eligible professionals elect the ORS-calculated Administrative Calitons reporting mechanism 1 . select the CRS-carculated A avoid the PORS payment ac Help Desk Contact Informa 1-888-734-5433 pyhelpdesk@cms.hhs.doy Forgot User ID? Forgot Password? Please note registration is now open through October 18, 2013. New User Registration CMS Enterprise Portal Medicaid/CHIP Medicare Shared Savings Program CMS News Information for people with Medicare, Medicare open CMS Provides Health Coverage for 100 States Moving Forward to Implement Health Reform Million People... enrollment, and benefits, Easier electronic funds transfers mean more time with patients and cost savings Information for children up to the age of 19 in need of health Healthcare Professionals Selected as Innovation Advisors will Improve Care .through Medicare, Medicaid, and the Children's Health Insurance Program. care coverage. And with health insurance reforms and health care exchanges, we are 10.000 People with Medicare Can Get Most Care at Home with Demonstration improving health care and ensuring coverage for all Americans. Information to take health care Health Care .gov 32 Health Systems Ready to Improve into your own hands, explore insurance coverage options and learn how the Affordable Care, Saving up to \$1.1 Billion Learn more about how CMS is implementing the Affordable Care Act Care Act impacts you. View More News & Events Medicaid and CHIP Stay Connected with CMS Providing our State partners with a Single point of Access to vital systems and information. You St MACPro TMSIS ass Intelligence -8 Learn More nd m dh Top 5 Links Manuals Access Provider Resources Site Access HCQIS Site Medicare Coverage Database This website provides access to online applications to: The Health Care Quality Information Systems portal provides CMS Forms healthcare quality improvement news, resources and data reporting tools and applications used by healthcare providers and others. Transmittals Obtain and maintain Nation Provider Identifier (NPI) · Enroll and update your information in the Medicare Provider MLN Products Enrollment System. Register and Assist in the Medicare and Medicaid Electronic Health To begin, you must request access to specific programs within the portal Records (EHR) Incentive Programs Get Started Get Started CMS.gov Enterprise Portal Andraral government website managed by the Centers for Medicare & Medicar

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

CMS. GOV Enterprise Portal	Home About CMS Newsroom Archive 🕖 Help &	EAQa 😞 Email 🕁 Print
Centers for Medicare & Medicaid Services	Learn about your healthcare options	Search CMS.gov
Health Care Quality Improvement System Provider Resources		
CMS Portal > Registration		
1		
Terms and Conditions		
Consent To Monitoring		
By logging onto this website, you consent to be monitored. Unauthorized attempts to upload informal subject to prosecution under the Computer Fraud and Abuse Act of 1986 and Title 18 U.S.C. Sec.10 details.	ion and/or change information on this web site are strictly prohibited and : D1 and 1030. We encourage you to read the <u>HHS Rules of Behavior</u> for m	are lore
Protecting Your Privacy		
Protecting your Privacy is a top priority at CMS. We are committed to ensuring the security and cont <u>Statement</u> which describes how we use the information you provide.	identiality of the user registering to EIDM. Please read the <u>CMS Privacy A</u>	Act
Collection Of Personal Identifiable Information (PII)		
"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 system. We may also use your answers to the challenge questions and other PII to later identify you	only collect personal data to uniquely identify the user registering with the (in case you forget or misplace your User ID /Password.	
I have read the HHS Rules of Behavior (HHS RoB), version 2010-0002 0015, dated August 26 2010 a violations of the HHS RoB or information security policies and standards may lead to disciplinary act work on Federal contracts or projects; and/or revocation of access to Federal information, information imprisonment. I understand that exceptions to the HHS RoB must be authorized in advance in writing that violation of laws, such as the Privacy Act of 1974, copyright law, and 18 USC 2071, which the H may result in imprisonment.	nd understand and agree to comply with its provisions. I understand that on, up to and including termination of employment; removal or debarment systems, and/or facilities, and may also include criminal penalities and/or by the OPDU Chief Information Officer or his/her designee. I also unders HS RoB draw upon, can result in monetary fines and/or criminal charges t	from r tand hət
l agree to the terms and conditions		
Cancel	Heat	

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.

Learn about your healthcare options Search CMS get Middle Name:	rs for Medicare & Medicaid \$	iterprise Portal	Home About CMS Newsroom Arc	nive 🕐 Help & FAUS 🖂 Email 🤤 Pr
Middle Name:		Services	Learn about your healthcare options	Search CMS.gr
Middle Name:	are Quality Improvement System Pro	wider Resources		
Middle Name:	ortal > Registration			
Middle Name:				
Middle Name:	Your Information	mation		
Middle Name:	Tour mormation from the			
Middle Name:	Your Information			
	Enter your legal first name and last n	ame, as it may be required for identity v	erification. Middle Name	
	First Name:		HIGUE HEITE.	
	- Last Name:	Suffix		
	Enter your email address, as it will be	e used for account related communication	ns.	
	E-mail Address:			
	Re-enter your email address.			
	Contrm E-mail Address:			
	Enter your full 9 digit social security n	umber, as it may be required for identity	verification.	
	Social Security Number:			
	Enter your date of birth, as it may be r	equired for identity verification.		
	Enter your date of birth, as it may be n Date of Birth:	equired for identity verification.		
	Enter your date of birth, as it may be r Date of Birth: MM DD YYYY	equired for identity verification.		
	Enter your date of birth, as it may be r Date of Birth: MM DD YYYY Enter your current or most recent ho	equired for identity verification.	entity verification.	
	Enter your date of birth, as it may be r Date of Birth: MM DD YYYY Enter your current or most recent ho - Home Address Line 1:	equired for identity verification. me address, as it may be required for id	entity verification.	
	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent hor - Home Address Line 1:	equired for identity verification. me address, as it may be required for id	entity verification.	
	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent hou ~ Home Address Line 1: Home Address Line 2:	equired for identity verification. me address, as it may be required for id	entity verification.	
	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent hor - Home Address Line 1: Home Address Line 2:	equired for identity verification. me address, as it may be required for id	entity verification.	
ip Code Extension: Country: USA	Enter your date of birth, as it may be n Date of Birth: MM DD YYYYY Enter your current or most recent hor - Home Address Line 1: Home Address Line 2: - City:	equired for identity verification. me address, as it may be required for id	• Zip Code: Zip Code Extension: Country: USA	
	Inter your date of birth, as it may be n Date of Birth: MM DD YYYYY Enter your current or most recent how - Home Address Line 1:	equired for identity verification. me address, as it may be required for id	entity verification.	
	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent ho - Home Address Line 1: Home Address Line 2:	equired for identity verification. me address, as it may be required for id	entity verification.	
	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent ho - Home Address Line 1: Home Address Line 2:	equired for identity verification. me address, as it may be required for id	entity verification.	
ip Code Extension: Country: USA	Enter your date of birth, as it may be n Date of Birth: MM DD YYYY Enter your current or most recent ho - Home Address Line 1: Home Address Line 2: - City:	equired for identity verification. me address, as it may be required for id	• Zip Code: Zip Code Extension:	

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.

CMS.gov Enterprise Portal A federal government website managed by the 7500 Security Boulevard, Baltimore, MD 21244 6. Click **Next** when completed. The screen shown in Figure 2-5will be displayed.

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

CMS.gov Enterprise Portal Centers for Medicare & Medicaid Services	Home About CMS Newsroom Archive 🕜 Help & FAQs 😔 Email 🛶 Print Learn about <u>your healthcare options</u> Search CMS.gev			
Health Care Quality Improvement System Provider Resources				
CMS Portal > Registration				
Choose User ID and Password Create User Choose User ID and Password				
Choose User ID And Password				
- User ID				
- Password				
Confirm Password				
Select your Challenge Questions and Answers: Your challenge questions and answers will be required for password and account management functions.				
- Question:1	- Answer:1			
- Question:2	- Answer:2			
- Question:3	* Answer.3			
	Cancel Next			

- 7. Enter your desired User ID in the **User ID** field. The User ID must be a minimum of 6 and a maximum of 74 alphanumeric characters. Allowed special characters are dashes (-), underscores (_), apostrophes ('), @ and periods (.).
- 8. Enter your desired password in the **Password** field. The CMS Portal password must conform to the following CMS ARS Password Policy:
 - a. Be changed at least every sixty (60) days;
 - b. Be a minimum of eight (8) and a maximum of twenty (20) characters;
 - c. Be changed only once a day;
 - d. Contain at least one (1) letter and one (1) number;
 - e. Contain at least one (1) uppercase and one (1) lowercase letter;
 - f. Not contain your User ID; and
 - g. Be different from your previous six (6) passwords.
- 9. Re-enter your desired password in the Confirm Password field.
- 10. Select a Challenge Question from each of the three (3) drop-down lists for which the answer is known.
- 11. Enter the answers to the Challenge Questions in the corresponding **Answer** fields. The special characters that are allowed are apostrophes ('), hyphens (-), and spaces followed by alphanumeric characters.

-

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

Figure 2-6: CMS Portal Registration Complete		ortal Registration Complete
	Enterorise Portal	Home About CMS Newsroom Archive 🚱 He

LAND. OOV Enterprise Portal	
Centers for Medicare & Medicaid Services	Learn about your healthcare options Search CMS.pd
ealth Care Quality Improvement System Provider Resources	
CMS Portal > Registration	
Your Information Choose User ID and Password Complete Registration	
You have now successfully completed your registration to CMS Enterprise Identity Management EIDM and the E-mail will include your User ID.	(EIDM). You will receive an E-mail acknowledging your successful registration to
Please wait 5 minutes before logging in. Selecting the 'OK' button will direct you to the CMS Po	rtal Landing page.
СК	

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

2.1.2 Requesting ASP Application Access

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

1. Enter the address for the CMS portal (<u>https://portal.cms.gov</u>) 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

<form><form><form></form></form></form>						
term about your healthcare options the resource op	MS.QOV Enterprise Portal	Home About CMS Newsroom Archive 😢 Hel	p&FAQs 🛃 Email 🖨 Prir			
Marken Canada Marken Canada Ca	nters for Medicare & Medicaid Services	Learn about your healthcare options	Search CMS.gov			
Mark Mark Mark Mark Mark Mark Mark Mark	th Care Quality Improvement System Provider Resources					
<section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header>	S Portal > Registration					
<section-header><section-header><section-header><section-header><section-header><text><text><text><text></text></text></text></text></section-header></section-header></section-header></section-header></section-header>						
	Terms and Conditions					
By loging onto this website, you consent to be monitored. Unauthonized attempts to upload information and/or change information on this web site are strictly prohibited and are details. Detacting Your Privacy The privacy is a top priority at CMS. We are committed to ensuing 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. Detacting Your Privacy The privacy is a top priority at CMS. We are committed to ensuing 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. Detaction Of Dersonal Identifiable Information (PII) 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). The resonal' 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). The resonal' 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). The resonal' 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). The resonal' information is described as data that is unique to an individual, such as a possion such distribution and the distribution and the PII is later individual dividual and the such as your cance your later to PI assword. Integret advantants to the challenge questions and other PII is later individual dividual	Consent To Monitoring					
Protecting Your Privacy is a top priority at CMS. We are committed to ensuing the security and confidentiality of the user registering to EIDM. Please read the <u>CMS Privacy Act</u> Statement which describes how we use the information you provide. Collection Of Personal Identifiable Information (PII) ^{There} were and the privacy concerns around PII data. In fact, we share your concerns. We will only collect personal data to uniquely identify the user registering with the system. We may also use your answers to the challenge questions and other PII to later identify you in case you forget or mixplace your User ID /Password. 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 forderal contracts or projects; 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 standards may lead to disciplinary action, up to and including termination of employment; removal or debarment from 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 may result in imprisonment. I largee to the terms and conditions	By logging onto this website, you consent to be monitored. Unauthorized attempts to upload in subject to prosecution under the Computer Fraud and Abuse Act of 1986 and Title 18 U.S.C. 5 details.	nformation and/or change information on this web site are strictly prohibited and Sec.1001 and 1030. We encourage you to read the <u>HHS Rules of Behavior</u> fo	nd are r more			
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. Collection Of Personal Identifiable Information (PII) Presonal" 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 data to uniquely identify the user registering with the system. 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 <i>Plassword</i> . I have read the HHS Rules of Behavior (HHS RaB), version 2010-0002.001S, dated August 26 2010 and understand and agree to comply with its provisions. I understand that work on federal contracts or projects, and for encoacting or federal information of access to Federal information, accurity 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 for encoacting or federal information of access to Federal information. Information systems, and/or facilities; and may also include criminal penalties and/or criminal charges that may result in 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 may result in imprisonment. I agree to the terms and conditions Cms Cancel Description Descr	Protecting Your Privacy					
Collection Of Personal Identifiable Information (PII) "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 data to uniquely identify the user registering with the system. We wary 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. Ihave 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 form york on federal contractors or pricescits or projects: and/or revocation of access to Federal information, information, information, information, officilities; and may also include criminal penalties and/or revision of access to Federal information, officilities; and standards may lead to disciplinary action, up to and including termination of employment; removal or debarment from york on federal contractors or pricesci, and/or revocation of access to Federal information, information, information, information, officilities; and may also include criminal penalties and/or criminal charges that wiolation 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. I agree to the terms and conditions	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 data to uniquely identify the user registering with the system. 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. 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 work on federal contracts or projects, and/or revocation of access to Federal information, systems, and/or facilities; and/or revocation of access to Federal information, systems, and/or facilities 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. I agree to the terms and conditions	Collection Of Personal Identifiable Information (PII)					
CMS is very aware of the privacy concerns around PII data. In fact, we share your concerns. We will only collect personal data to uniquely identify the user registering with the system. 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. 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 woldations of the HHS RoB in 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 work on Federal contracts or projects; and/or revocation of access to Federal information, information graves upon, can result in monetary fines and/or criminal charges that may result in imprisonment.	"Personal" information is described as data that is unique to an individual, such as a name, ad	dress, telephone number, social security number and date of birth (DOB).				
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 exceptions of a scess to Even 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.	CMS is very aware of the privacy concerns around PII data. In fact, we share your concerns. V system. We may also use your answers to the challenge questions and other PII to later ident	Ve will only collect personal data to uniquely identify the user registering with ify you in case you forget or misplace your User ID /Password.	the			
I agree to the terms and conditions Cancel	I have read the HHS Rules of Behavior (HHS RoB), version 2010-0002.001S, dated August 26 i violations of the HHS RoB or information security policies and standards may lead to disciplina work on Federal contracts or projects; and/or revocation of access to Federal information, infor imprisonment. I understand that exceptions to the HHS RoB must be authorized in advance in that violation of laws, such as the Privacy Act of 1974, copyright law, and 18 USC 2071, which may result in imprisonment.	2010 and understand and agree to comply with its provisions. I understand thi ary action, up to and including terminiation of employment; removal or debarm mation systems, and/or facilities; and may also include criminal penalties an writing by the OPDIV Chief Information Officer or his/her designee. I also und the HHS RoB draw upon, can result in monetary fines and/or criminal charge	nt ent from d/or erstand is that			
I agree to the terms and conditions Cancel						
Cancel Heat	I agree to the terms and conditions					
	Cancel	lited				

4. Read through the Terms and Conditions on the page. The page states that you content to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it will only be used to uniquely identify the new user who is registering with the system. The page provides

links to the *HHS Rules of Behavior* and the *CMS Privacy Act Statement*. If you agree to the terms and conditions, click the corresponding check box and click the **Next** button. Users must agree to the terms and conditions to continue the log-in process.

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

CMS.gov Enterprise Portal Centers for Medicare & Medicaid Services	📮 Print
Welcome to CMS Enterprise Portal	
User ID Password	
Log In Cancel Forqot Password? Forqot User ID? Need an account? Click the link - <u>New user registration</u>	
Home CMS.gov Enterprise Portol Afederal government website managed by the Centers for Medicare & Medicaid Services 7500 Security Boulevard, Baltimore, MD 21244	

Figure 2-10: CMS Portal Log In Page

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

Figure 2-11: Request Application Access Button



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



CMS .gov Enterprise Portal					
My Portal					
CMS Portal > My Access					
My Access	View and Manage My Access				
Access	Application	Take An Action			
View and Manage My Access	Please request access to an application.				

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 N	New Application	Access Page
------------------------	-----------------	-------------

0	BOV Enterprise Portal					
My	My Portal					
Ch	IS Portal > My Access					
	My Access Request New Application Access	Request New Application Access Select an application and then a role to request access.				
	<u>View and Manage My</u> <u>Access</u>	Application Description: Select the Application Cancel				

- 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.

CMS .gov Enterprise Portal							
My Portal	My Portal						
CMS Portal > My Access							
1							
My Access Request New Application Access View and Manage My Access	Request New Application Access Select an application and then a role to request access. * Application Description: ESD - ESD Application						
	🤋 * Role:	Select the Role	set				

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

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

Ciaura	2 4 5.	I do natita	Varification	Dege
rigure	Z-15.	luentity	vernication	гауе

CMS .gov Enterprise Po	.gov Enterprise Portal				
My Portal					
CMS Portal > My Access					
1	1				
My Access	Identity Verification				
Request New Application Access View and Manage My Access	More 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. encline 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 provide. 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 the directions provided - http://www.experian.com. For additional information, please see the Experian Consumer Assistance link - http://www.experian.com/help More lect 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?				

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.

My Portal	
CMS Portal > My Access	
1	
My Access	Terms and Conditions
Request New Application Access	Protecting Your Privacy
View and Manage My Access	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 <u>CMS Privacy Act Statement</u> , 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 Pll 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 Pll 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
	Cancer

Figure 2-16: Terms and Conditions

13. Read through the Terms and Conditions on the page. The page states that you content to monitoring while accessing and using this website. The page also details the reasons for collecting Personal Identifiable Information (PII), which are that it will only be used to uniquely identify the new user who is registering with the system. The page provides links to the *HHS Rules of Behavior* and the *CMS Privacy Act Statement*. If you agree to the terms and conditions, click the corresponding check box and click the **Next** button. The Your Information page opens, as shown in Figure 2-17.

CMS .gov Enterprise Port	rtal	
My Portal		
CMS Portal > My Access		
1		
My Access	Your Information Verify Your Identity	
Request New Application Access	Your Information	
View and Manage My	Enter your legal first name and last name, as it may be required for identity verification. Middle Name:	
Access	* First Name: Joseph	
	+ Last Name: Suffix:	
	Doe	
	Enter your email address, as it will be used for account related communications.	

Figure 2-17: Your Information Page

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

3 ASP Application Home Page

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

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

Medicare Pa	rt B Average Sales Price H	ome				
Home	Downloads: User Guides	(PDE) File Upload Formats (zip)				
Compliance Summary	Welcome, ASPBUR:					
Product Data		Reporting Summary				
Financial Data		Current Reporting Quarter :	Q3 2014			
Certification		Current Submission Period Began :	07/01/2014			
Re-statements		Days Remaining in the Current Submission Period :	14			
Help	18	Closing Date for the Current Submission Period :	07/31/2014			
Evit	(100 miles)	Pricing Quarter :	Q2 2014			
exit		Next Reporting Quarter :	Q4 2014			
	Special Bulletin Message	Date Submission Begins for the Next Reporting Quarter :	10/01/2014			
	Messages:	Compliance Report Labelers are out of compliance with data reporting requirements. CMIS (12345) GENERAL CORPORATION (00021, 00007) MITPEX (00007) View Compliance Status				
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat.					
	I have reviewed the message E (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feuglat.					
	Ihave reviewed the message (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.					

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.

Medicare Pa	art B Average Sales Price	Home					
Home	Downloads: User Guide	s (PDF) File Upload Formats (zip)					
Compliance Summary Product Data	A COMPANY CONTRACTOR	Reporting Summary					
Add Product Data		Current Reporting Quarter :	Q3 2014				
Update Product		Current Submission Period Began :	07/01/2014				
Data		Days Remaining in the Current Submission Period :	14				
Product Data Upload	18	Closing Date for the Current Submission Period :	07/31/2014				
View Submitted	17 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	Pricing Quarter :	Q2 2014				
Drugs		Next Reporting Quarter :	Q4 2014				
Financial Data	Special Bulletin Message	Date Submission Begins for the Next Reporting Quarter :	10/01/2014				
Certification							
Re-statements	Messages:	Compliance Report					
Help	View All						
Exit	(2013-08-29) Lorem ipsum dolor sit amet, consoctetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.	Labelers are out of compliance with data reportin	ng requirements.				
	I have reviewed the message	E CMS (12345)	4				
	(2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.	GENERAL CORPORATION (00021, 00007) MIDEX (00007) 4					
	I have reviewed the message	View Compliance Status					
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.	•					

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

Medicare Pa	art B Average Sales Price	Add Product Data	Help						
Home	Reporting Period: Q3 2014								
Compliance Summary	I denotes required field								
Product Data	- denotes required neid								
Add Product Data	Add by NDC Add by Alternate ID								
Update Product Data	NDC1* Select	Manufacturer Name* Date of First Sale* Date of First Sale*							
Product Data Upload	NDC2*	Has Brand Name? Expiration Date of Final Lot Sold							
View Submitted Drugs	NDC3*	Generic Name* Select Date must be in MMOD/YYY format							
Financial Data									
Certification	Strength of Product*	Add Additional FDA Supplemental Numbers	*						
Re-statements	Volume Per Item*	FDA Application Number* FDA Supplemental Number FDA Approval Type*							
Help	Number of Items	EDA Einal Pre-Marketing Approval Date*							
Exit	per NDC*								
	Date must be in MMDDYYYY format								
	Save Reset								

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

Figure 4-3: Add Product Data – Alternate ID

Medicare Pa	art B Average Sales Price	Add Product Data	Help							
Home	Reporting Period: Q3 2014									
Compliance Summary	I denotes required field									
Product Data										
Add Product Data	Add by NDC Add by Alternate ID									
Update Product Data	Alternate ID*	Manufacturer Name* Date of First Sale*								
Product Data Upload		Has Brand Name?								
View Submitted Drugs		Generic Name* Select Date must be in MM/DD/YYYY format								
Financial Data										
Certification	Strength of Product*	Add Additional FDA Supplemental Numbers	*							
Re-statements	Volume Per Item*	FDA Application Number* FDA Supplemental Number FDA Approval Type*								
Help	Number of Items	Steed								
Exit	per Alternate ID*	FUA Final PTe-marketing Approval Date								
		Date must be in MM/DD/YYY format	*							
	Save Reset									

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

Table 4-1 Add Product Data Page Information

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

Name	User Action	Comments					
 Add new NDC1 (link) 	 Click the link to add a New NDC1. 	• Link displayed when the "Add by NDC" tab is selected.					
 Add by Existing NDC1 	 Click the link to enter an existing NDC1. 	Link is displayed when Add new NDC1 link is selected.					
– NDC2	 Enter the NDC2 in the field. 	NDC2 is a required field if Alternate ID is missing.NDC2 is a 4-digit numeric entry.					
– NDC3	 Enter the NDC3 in the field. 	NDC3 is a required field if Alternate ID is missing.NDC3 is a 2-digit numeric entry.					
- Alternate ID	 Enter the Alternate Product ID 	Alt ID is required if NDC is missing.					
 Manufacturer Name 	 Enter the name of the drug's manufacturer. 	 If a new manufacturer is entered, the ASP Application, the manufacturer's name will be marked 'Pending.' 					
 Brand Name 	 Enter the brand name of the drug in the field. 	• The Brand Name field is only displayed when the Has Brand Name? box is checked.					
		 Brand Name is required if the Has Brand Name? box is checked. 					
		• The Brand Name is limited to 250 characters.					
		The Brand Name field is optional.					
- Generic Name	 Select the Generic Name from the drop-down list. 	• The Generic Name is required.					
- Date of First	- Enter the date when the	• The Date of First Sale is required.					
Sale	drug was first available for sale.	• 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	 Enter the expiration date of 	• The date format is MM/DD/YYYY.					
Date of Final Lot Sold	the final lot that was sold. Scroll through the pop-up calendar for the desired date, or enter the date directly into the field.	The Expiration Date of Final Lot Sold field is optional.					
- Strength of	 Enter the Strength of 	The Strength of Product is required.					
Product	product in the field.	• The Strength of Product has a limit of 250 characters.					
– Volume Per	- Enter the Volume per Item in	• The Volume per Item is required.					
Item	the field.	• The Volume per Item has a limit of 250 characters.					

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

4.2 Upload Product Data – File Transfer

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

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

Medicare Pa	rt B Average Sales Price He	ome	
Home	Downloads: User Guides Welcome, ASPBOR!	(PDF) File Upload Formats (zip)	
Compliance Summary	all the second s		
Product Data		Reporting summary	
Add Product Data		Current Reporting Quarter :	Q3 2014
Update Product		Current Submission Period Began :	07/01/2014
Deta		Days Remaining in the Current Submission Period :	14
Product Data Upload		Closing Date for the Current Submission Period :	07/31/2014
View Submitted		Pricing Quarter :	Q2 2014
Drugs	Quarterly drug product and average sales price financial data can be submitted through online entry or Dirouch file upload. Please click to download the recurred file format for data upload.	Next Reporting Quarter :	Q4 2014
inancial Data	Files can then be uploaded to the respective sections found in Product Data and Financial Data.	Date Submission Begins for the Next Reporting Quarter :	10/01/2014
ertification			
te-statements	Messages:	Compliance Report	
ielp	View All		
Exit	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit, Suspendisse consectetur commodo urna, at moliis elit semper vitae. Praesent nec feugiat.	Labelers are out of compliance with data reportin	g requirements.
	E Thave reviewed the message	CMS (12345)	A
	(2013 00 02) Locom insum dolor sit amot consectator adiriscian ett. Sussendisse	GENERAL CORPORATION (00007, 00021)	
	consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat.	MIDEX (00007)	
	I have reviewed the message	View Compliance Status	
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feuglat.		

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

Medicare Pa	rt B Average Sales Price	Product Data Upload			
Home	Current Reporting Period: Q3 2014				
Compliance Summary	Browse for new or corrected product data		ר		
Product Data					
Add Product Data	Browse No file selected.				
Update Product Data	Click here for acceptable file formats				
Product Data Upload	- Obroan				
View Submitted Drugs					
Financial Data					
Certification					
Re-statements					
Help					
Exit					

- 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

Opening File Upload F	ormats.zip						
You have chosen to	open:						
🔍 File Upload Formats.zip							
which is: WinZip File (31.8 KB)							
from: http://20	9.251.176.37						
What should Firefox do with this file?							
Open with	WinZip (default)]					
Save File							
Do this <u>a</u> utor	natically for files like this from now on.						
	OK Cance						

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

ifite:	Name	Туре	Modified	Size	Ratio	Packed	Path
	■ financeTemplate.xls	Microsoft Of	7/26/2013 9:51 AM	30,208	78%	6,538	
	1 financeTemplatexIsx	Microsoft Of	7/26/2013 9:50 AM	11,418	27%	8,314	
	G 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	
	1 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	
							21 22
							8
							0-00-0
•	m						•

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.

	A	В	С	D	E	F	G	н	1	J	К	L	М	N	0	Р	Q	R	S
	Manufact	NDC1	NDC2	NDC3	Alternate	Generic	Brand	Strength	Volume Por Itom	Number	Expiratio	Date of	FDA	FDA	FDA	Addition	Addition	FDA	Addition
	Name					Name	name	Product	Fer item	Per NDC	Final Lot	Sale	on	on	Туре	Applicati	Applicati	Туре	Applicati
											Sold		Number	Supplem		on	on	Number	on
														Number		Number #1	Supplem	#1	Number #2
																	Number		
1	<u> </u>																#1		
2																			
3																			
4																			
5																			
6																			
7																			
8																			
9																			

Figure 4-8: Sample Product Data Template

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

- 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

Medicare P.	rt B Average Sales Price	Product Data Upload	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	Browse for new or corrected product data		ר
Product Data			
Add Product Data	Browse. No file selected.		
Update Product Data	Click here for acceptable file formats		
Product Data Upload	[
View Submitted Drugs			
Financial Data			
Certification			
Re-statements			
Help			
Ext			

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.

rigure + re. rieduot Bata opieda Result

Medicare Pa	art B Average S	ales Price	Proc	luct Da	ta Uplo	oad					Help
Home	Current Reporting	Period: Q3 2014									
Compliance Summary	Browse for r	ew or corrected product dat	ta								
Product Data Add Product Data	Browse No	file selected.									
Update Product Data	Click here for acceptable file formats Upload										
Product Data Upload											
View Submitted Drugs	Report of Transmitted Drugs via File Upload										
Financial Data	Upload Date 2014-07-16 14:29:10.0										
Certification			1 Out Of 1 Produ	ct Data has	theon Su	ccessfully	Savad				
Re-statements	T OUL OF T Product Joka mas been successfully saved.										
Help	Showing 1 Result. Previous First 1 Last Next										
Exit	Drug Identifier	Manufacturer 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 Type/App #/Supp #	FDA Approval Date	Status
	Insulin	AstraZeneca	insulin(Gluocyn)	25	1v	10	07/31/2013	05/30/2016	ANDA/ A123789 / B666777	01/01/2013	Uploaded-Success
	Showing 1 Result. Previous First 1 Last Next										

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.



Medicare Pa	are Part B Average Sales Price Product Data Upload Help											
Home	Current	Reporting Perio	od: Q3 2014									
Compliance Summary	Br	Browse for new or corrected product data										
Product Data Add Product Data	В	rowse.] No file se	lected.									
Update Product Data		k here for acceptabl	e file formats									
Product Data Upload	Uproad											
View Submitted Drugs	Report of Transmitted Drugs via File Upload											
Financial Data	Upload Da	ite:2014-07-17 09:2	1:50.0									
Certification				No Valid Data Pres	ent to be s	aved.Tota	l 1 druas ur	loaded.				
Re-statements												
Help	Showing	1 Result.		Prev	ous First	1 Last	Next					
Exit	Dn	ug Identifier	Manufacturer 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 Type/App #/Supp #	FDA Approval Date	Status
		Insulin	AstraZeneca	INSULIN(Gluocyn)	25	1v	10	07/31/2013	05/30/2016	/ A123789 / B666777	01/01/2013	FDA Approval Type Required.
	Showing	1 Result.		Prev	ous First	1 Last	Next					

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.

Medicare Pa	art B Average Sales Price	Home	
Home Compliance	Downloads: User Gi Welcome, ASPBOR!	ides (PDF) File Upload Formats (נעס)	
Summary Product Data Financial Data Add/5dit Financial Data Financial Data Upload Certification Re-statements Help	Special Bulletin Message	Reporting Summ. Current Reporting Quarter : Current Submission Period Began : Days Remaining in the Current Submission Period : Closing Date for the Current Submission Period : Pricing Quarter : Next Reporting Quarter : Date Submission Begins for the Next Reporting Quarter	C3 2014 07/01/2014 13 07/31/2014 02 2014 04 2014 13 01/31/2014
Exit	Messages: View AI • (2013-08-29) Lorem løsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Præsent nec feugiat. I have reviewed the message (2013-08-02) Lorem løsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Præsent nec feugiat. I have reviewed the message (2013-08-29) Lorem løsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Præsent nec feugiat.	Compliance Repr Labelers are out of compliance with d CMS (12345) GENERAL CORPORATION (00021) GSK (00652) View Compliance State	ata reporting requirements.

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.
| Medicare Pa | art B Average | e Sales Price | Add | l Or Edit Fina | ncial Data | | | Help |
|----------------------------|------------------|------------------------|----------------|-------------------|------------------|----------------|---------------------|-------------------|
| Home | Current Report | ing Period: Q3 2014 | | | | | | |
| Compliance
Summary | Drug Identifier: | Search | | | | | | |
| Product Data | Showing 1 - 20 | of 29 Results. | Prev | vious First 1, 2. | Last Next | | | |
| Financial Data | Drug Identifier | Generic (Brand Name) | Manufacturer's | Number of ASP | Wholesale | Number of Cap | Status | View Details |
| Add/Edit Financial
Data | | | ASP | units | Acquisition Cost | Units Excluded | 0510010 | Product Discontin |
| Financial Data | 00000-0000-01 | AMPDRUG1 | | | | | PENDING | Product Financial |
| Upload | 00000-9797-97 | AMPDRUG1 | | | | | PENDING | Product Financial |
| Certification | 00001-0000-03 | AMPDRUG1 | | | | | PENDING | Product Einancial |
| Re-statements | 00007-0000-02 | AMPDRUG1 | | | | | PENDING | Product Einancial |
| Help | 00007-5476-02 | AMPORI IC1 | | | | | PENDING | Product Einancial |
| Exit | 00001-0410-02 | | | | | | T ENDING | LIGHER LIGHER |
| | 00021-0000-06 | AMPDRUG1 | 2.000 | 2.000 | 16.000 | | SAVED | Product Financial |
| | 00033-0000-04 | AMPDRUG1 | | | | | PENDING | Product Einancial |
| | 00651-0000-05 | AMPDRUG1 | | | | | PENDING | Product Einancial |
| | 00552-0000-07 | AMPDRUG1 | 1235.369 | 4569.365 | 8656.334 | | SAVED | Product Einancial |
| | 10022-5678-11 | LEVSIN INJECTION | 11.333 | 22.333 | 44.333 | | CERTIFIED | Product Einancial |
| | 12345-4444-44 | AMPDRUG1 | 2456.898 | 2222.222 | 3333.333 | | RE-STATED CERTIFIED | Product Einancial |
| | 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 Einancial |
| | 51220-8292-00 | MUSEUM FORTE | 361.333 | 274.373 | 1236.396 | | RE-STATED CERTIFIED | Product Einancial |
| | 83278-0233-20 | DRUG465 | 0.000 | 0.000 | 84.250 | 2.000 | SAVED | Product Einancial |
| | 83278-7236-10 | DRUG465 | 22.995 | 1001.664 | 32.790 | 2.000 | SAVED | Product Einancial |
| | 83336-0775-01 | DRUG464 | 14.399 | 26700.963 | 35.000 | 2.000 | SAVED | Product Einancial |
| | 8533607009 | DRUG466 | 8.057 | 14794.647 | 23.260 | 2.000 | SAVED | Product Einancial |

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

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

Table 4-2	Add or Edit Financial Data Home Page Information
	Aud of Luit I mancial Data nome Fage mornation

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

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

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

Medicare Pa	art B Average Sa	les Price	Add Or Edit	Financial Da	ta			Help		
Home		FINANCIAL DATA SAVED								
Compliance Summary	Current Reporting F	Surrent Reporting Pariod: 03 2014								
Product Data										
Financial Data	Drug Identifier: 00000	Search								
Add/Edit Financial Data	Showing all 2 Results		Previous	First 1 Last Ne	xt					
Financial Data Upload	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	View Details		
Certification	00000-0000-01	AMPDRUG1	150.555	15.000	175.555	4.000	SAVED	Product Financial		
Re-statements	00000-9797-97	AMPDRUG1	25.125	3.000	30.125	1.000	SAVED	Product Einancial		
Help	Showing all 2 Results		Previous	First 1 Last Ne	xt					
Exit										
	Export: 🛄 🛄 🐻									
			0.000	Figure cial Data						
			Save	Financial Data						

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.

Medicare Pa	rt B Average Sales Price H	ome	
Home	Downloads: User Guides	(PDF) File Upload Formats (zip)	
Compliance Summary	Welcome, ASPBOR!		
Product Data		Reporting Summary	
inancial Data		Current Reporting Quarter :	03 2014
Add/Edit Financial		Current Submission Period Began :	07/01/2014
Data		Days Remaining in the Current Submission Period :	13
Financial Data	the set that since	Closing Date for the Current Submission Period :	07/31/2014
artification	1 10	Pricing Quarter :	Q2 2014
eruncation	Quarterly drug product and average sales price financial data can be submitted through online only or through file unload. Please dick to download the conjugation for data unload.	Next Reporting Quarter :	Q4 2014
e-statements	Files can then be uploaded to the respective sections found in 'Product Data' and 'Financial Data'	Date Submission Begins for the Next Reporting Quarter :	10/01/2014
ixit	Messages:	Compliance Report	
	View All • (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat. I have reviewed the message (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat.	CMS (12345) CMS (12345) GENERAL CORPORATION (00021) CSK (10052)	g requirements.
	I have reviewed the message (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitao. Praesent nec feugiat.	View Compliance Status	

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

Medicare Pa	art B Average Sales Price Financial Data Upload	<u>Help</u>
Home	Current Reporting Period: Q3 2014	
Compliance Summary	Browse for new or corrected financial data	
Product Data		
Financial Data	Browse. No file selected.	
Add/Edit Financial Data	Click here for acceptable file formats	
Financial Data Upload		
Certification		
Re-statements		
Help		
Exit		

- 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

Opening File Upload F	ormats.zip	.
You have chosen to	open:	
🛄 File Upload Fo	rmats.zip	
which is: Winz	Zip File (31.8 KB)	
from: http://2	09.251.176.37	
What should Firefor	x do with this file?	
Open with	WinZip (default)	
💿 Save File		
Do this auto	matically for files like this from now on.	
	OK Cancel	

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

ili	Name	Туре	Modified	Size	Ratio	Packed	Path
<u> </u>	IfinanceTemplate.xls	Microsoft Of	7/26/2013 9:51 AM	30,208	78%	6,538	
	financeTemplate.dsx	Microsoft Of	7/26/2013 9:50 AM	11,418	27%	8,314	
	G 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	
						17	
							A 23
							318
							- Ha
< 1				_	_	_	- F

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.

	А	В	С	D	E	F	G	н	1	J	К
	Manufact urer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Manufact urer's Average Sales	Number of ASP Units	Wholesal e Acquisiti on Cost	Number of CAP Units Excluded
1								Price			
2											
3											
4											
5											
6											
7											

Figure 4-19: Sample Financial Data Template

- 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

Medicare Pa	rt B Average Sales Price	Financial Data Upload	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	Browse for new or corrected financial data		Л
Product Data			
Financial Data	Browse. Finance Dataxis		
Add/Edit Financial Data	Click here for acceptable file formats		
Financial Data Upload			
Certification			
Re-statements			
Help			
Exit			

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

Medicare Pa	art B Av	verage Sales	Price Financial D	ata Upload				Help				
Home	Current	urrent Reporting Period: Q3 2014										
Compliance Summary	В	Browse for new or corrected financial data										
Product Data												
Financial Data		rowse. No file set	ected.									
Add/Edit Financial Data		pload	nie formats									
Financial Data Upload		,										
Certification	Report	of Transmitted D	rugs via File Upload									
Re-statements	Unload D											
Help	Opioad D	ale.2014-07-17 13.46										
Exit			1 Out Of 1 Financial Data h	as been Successfully	Saved.							
	Showing	n 1 Result	Previous First	t 1 Last Next								
	D	rug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status				
	00	0033-0000-04	AMPDRUG1	30.125	4.000	40.125	1.000	Uploaded- Success				
	Showing	g 1 Result.	Previous First	t 1 Last Next								

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

Figure	4-22:	Financial	Data U	Jpload –	Error

Medicare Pa	art B A	verage Sales	Price Financial Da	ta Upload				Help				
Home	Current	rrent Reporting Period: Q3 2014										
Compliance Summary	Br	Browse for new or corrected financial data										
Product Data Financial Data		Browse No file selected. Click here for acceptable file formats										
Data Financial Data Upload	U	pload										
Certification Re-statements	Report	of Transmitted Dr ate:2014-07-17 13:21	rugs via File Upload									
Help			No Valid Data Present to be s	aved.Total 1 drugs u	iploaded.							
	Showing	g 1 Result.	Previous First	t 1 Last Next								
	D	rug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status				
	9	8765-234-10	Lisinoprii(Zestrii)	45.250	5.000	50.500	3.00	No Product Data exists Number of Cap Units Excluded 999999999.999.				
	Showing	g 1 Result.	Previous First	1 Last Next								

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

4.5 View Submitted Drug Data

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

Perform the following steps to view submitted drug data:

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

Medicare Pa	nt B Average Sales Price	Home
Home Compliance	Downloads: User C	Suides (PDF) File Upload Formats (Sp)
Product Data Add Product Data Update Product Data Upload Product Data Upload View Submitted Drugs	Special Bulletin Message	Reporting Summary 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
Re-statements Help Exit	Messages: View All (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molits elit semper vitae. Praesent nec feugiat. I have reviewed the message	Compliance Report Compliance with data reporting requirements. ASTRAZENICA (90210)
	(2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat. I have reviewed the message (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse cossoctetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.	CMS (12345) GENERAL CORPORATION (00021) View Compliance Status

Figure 4-23: View Submitted Drugs Selection

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

Medicare P	art B Average Sales Pri	ce View:	Submitted Dru	ugs			Hel
Home	Current Reporting Period: G	3 2014					
Compliance Summary	Drug Identifier:	Search					
Product Data	Showing 1 - 20 of 28 Results	Previous	First 1 2 Last	Next			
Add Product Data	Orug Identifier	Generic (Brand Name)	Manufacturer's	Number of ASP	Wholesale	Number of Cap	Status
Update Product			ASP	units	Acquisition Cost	Units Excluded	
Data	00000-0000-01	AMPDRUG1	150.555	15.000	175.555	4.000	SAVED
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				1000.002			Section 2
Re-statements	00021-0000-06	AMPDRUG1	2.000	2.000	16.000		SAVED
Help	00033-0000-04	AMPDRUG1	30.125	4.000	40.125	1.000	SAVED
Exit	00552-0000-07	AMPDRUG1	1235.369	4569.365	8656.334		SAVED
	10022-5678-11	LEVSIN INJECTION	11.333	22.333	44.333		CERTIFIED
	12345-4444-44	AMPDRUG1	2456.898	2222.222	3333.333		RE-STATED CERTIFIED
	51009-0733-82	LINA HYDRCHLORIDE	22.333	374.373	566.333		CERTIFIED
	51093-0941-99	KANACITIRIC DYSPEPTASE	1211.333	2374.373	9555.333		RE-STATED CERTIFIED

Figure 4-24: View Submitted Drugs

3. Drug financial data and drug product data are displayed on this screen. This screen can be used to verify drug data for accuracy. Scroll through the list of drugs displayed on the View Submitted Drugs page in order to locate the drug(s) needing financial data added or updated, or enter the drug identifier in the **Drug Identifier** field and click **Search** to filter the results Click **Home** on the main menu bar to return to the Medicare Part B ASP Application home page.

5 Certifications

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

5.1 Certify Drug Data Online

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

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



Figure 5-1: Drug Certification Selection

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

Medicare Pa	rt B Average Sales Price		Drug	Certification					Help			
Home Compliance	Drug Data Pending Certificati	on for Reporting Period										
Product Data	Reporting Farinds: (2) 2014 😦 Beeck Options: Ching Size Preving Constanting 🙀 Manufacturer Hame (Ver All											
Financial Data		(kont)										
Certification	Bhowing 1-15 of 1.107 Results. Previous First 1, 2, 3, 4, 5, 6, 7, 8, 9, 10Last Next											
Assumptions	Drug identifier	Genetic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify			
Help	00660-1911-13	DR00549	2821.122	3090.868	2892.230		SAVED	Product Financial				
Ext	00660-3012-60	DR00618	165.802	7296.476	171.410		SAVED	Product Financial				
	00660-3075-19	DAOMO	303.721	63.524	313.790		SAVED	Product Financial				
	00660-3404-20	DRO0539	128,680	1765.216	132,960		SAVED	Protect Financial				
	00664-0062-07	DR:0029	96.863	72928.269	24.000		SAVED	Essant Enansial				
	00664-0952-11	DR00630	15.096	7254.942	23.250		SAVED	Protect Financial				
	00664-0952-15	D#00630	0.000	0.000	6.500		SAVED	Essent Energie				
	00664-0953-09	DR00833	19.654	826.119	25.000		SAVED	Protect Financial				
	00664-0953-11	D#00633	18.069	3444,425	31.250		SAVED	Essent Energie				
	00664-0953-13	DR00833	6.977	25494.615	9.750		SAVED	Protect Financial				
	00664-0953-15	DMG0633	8.532	125669.838	12.250		SAVED	Essaut Energie				
	00664-1120-06	DRO026	0.000	0.000	33.000		SAVED	Product Financial				
	00664-1177-02	DR00024	6.277	3193.391	28.000		SAVED	Essent Energie				
	00664-1177-04	DR60024	16.587	9147.334	37.500		SAVED	Product Financial				
	00664-1177-08	DRG0024	34.549	32193.854	75.000		SAVED	Essaut Energie				
	Showing 1 - 15 of 1,107 Results.	Prev	ious First 1, 2, 3,	4, 5, 6, 7, 8, 9, 10	Last Next							
		G	leset All Checked Drugs	Centry Selected Data	Centry All Data							

Figure 5-2: Drug Certification Home Page

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

Table 5-1	Select Certification Status Page Information
-----------	--

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

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

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

OR

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

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

Figure 5-3: Drug	Certification	Page – Pending
------------------	---------------	----------------

Medicare Pa	art B Average Sales Price		Drug	Certification					Help
Home									
Compliance Summary	Drug Data Pending Certificati	ion for Reporting Period Q3 2014							
Product Data	Reporting Period: Q3 2014 🜉 Sei	ect Option: Drug Data Pending Centrication 🕞 Manufacturer Name: Mex All					Drug identifier: (01548		
Financial Data				Submit					
Certification	Showing all 3 Results.		Previous	First 1 Last Next					
Drug Certification Assumptions	Drug identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certity
Re-statements									
Нир	01549-1749-60	DRG046	0.000	6.000	0.000		SAVED	Product Financial	
DAT	01549-2175-19	DRIGO#63	0.000	0.000	0.000		SA/ED	Product Financial	
	01549-6012-60	DRG046	16.810	9778.000	16.770		SAVED	Product Financial	
	Showing all 3 Results.		Previous	First 1 Last Next					
	+								P.
		C.	Reset All Checked Drugs	Centry Selected Data	Certify All Data				

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

Medicare P	art B Average Sales	Price				Drug	Certification						Help
Home Compliance Summary	Drug Data Pending Cer	lification for Reporti	ng Period Q3 2014									_	
Product Data Financial Data	Reporting Period: 0.0.2011	e] Sweet Option: [Drup :	Cata Percing Centrolation	 Manufacturer Nan 	MC VIEWAL		[Submit]			Drug i	dentifier: (210x8		
Certification	Showing all 3 Results.					Previou	s First 1 Last Next	1					
Assumptions	Drug identifier		Ceneto (B	rand Name)		Manufacturer's ASP	Number of ASP units	Wholesare Acquisition Cost	Number of I	Cep Units Ged	Status	Drug Details	Cettry
Heip	01548-1749-60		DA	20e98		0.000	0.000	0.000			SAIED	Product Financial	
Exit						Product Detail	s for Drug 01549-17	49-60					
		Manufacturer's Name	Generic (Brand Name)	Strength of Product	Volume per item	Number of flems per ND	CILIED Date of First Sei	Expiration Date of Fit	nai Lot Sold	FDA Approval Data	FDL Approval Typelipp #Bupp #	Status	
		ARUKA	DR00486	28 mg	100	1	04/03/2008			10151990	ANDA/A051099	24/50	
		19 S			:5			2013					Close
	01549-0175-19		DRI	30#63		0.000	0.000	0.000			SAVED	Eroout Francia	
	01548-6012-60		DR	20495		16.810	9775.000	16.770			SAVED	Etosal Etosat	0
	Showing all 3 Results.					Previou	s First 1 Last Next		_				
	e					Resist All Crecked Drugs	Certh Selected Data	Certify All Cata					

- 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

Medicare Pa	art B Average S	Sales Price			Drug C	ertificatior	ı				Help
Home											
Compliance Summary	Drug Data Pendin	g Certification fo	r Reporting Period								
Product Data	Reporting Period: 03	2014 Select Op	tion: Drug Data Pending	Certification	on 💌						
Financial Data	Manufacturer Name:	View All							Drug Ider	htifier:	
Certification						Submit					
Drug Certification	Showing 1 - 15 of	22 Results.			Previous Fin	st 1. 2 Last	Next				
Assumptions	Drug Identifier	Ge	neric (Brand Name)		Manufacturer's	Number of	Wholesale	Number of	Status	Drug Details	Certify
Re-statements					ASP	ASP units	Acquisition Cost	Cap Units Excluded			
Help	00000-0000-01		AMPDRUG1		150.555	15.000	175.555	4.000	SAVED	Product Financia	
Exit											
				F	inancial Detail	s for Drug 000	000-0000-01				
		Reporting Period	Manufacturer's ASP	Numbe	er of ASP units	Whole Sale Ac	quisition Cost	Number of C	ap Units Excluded	Status	
		Q2 2014	111.111	-	222 222	333.	333			CERTIFIED	
											<u>Close</u>

- 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

Data Certification Statement:
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.
I agree to the above certification Statement 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.

Medicare Pa	art B Average Sales Pric	e	Drug	Certification					Help
Home									
Compliance Summary	Drug Data Pending Certifica	ation for Reporting Period							
Product Data	Reporting Period: 03 2014 🗨 S	elect Option: Drug Data Pending Certification w Manufacturer Name: View All					Drug identifier; 14178		
Financial Data				Submit					
Certification	_								
Orug Certification			SOUT OF S1 Drug Produ	ct Data has been success	fully Certified.				
Assumptions	_								
Re-statements	Showing 1 - 15 of 28 Results.		Previous F	inst 1, 2Last No	ext				
нир	Drug identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition	Number of Cap Units	Status	Drug Details	Certity
Ext					Cost	Excluded			
	14178-0600-30	DRG0437	1929.550	9105.000	2156.180		SAVED	Product Financial	
	14178-0618-02	DRG0003	73.950	25733.000	91.890		SAVED	Product Emercial	
	14178-0618-03	DMG0004	23.230	6796.000	32.700		SAVED	Product Financial	
	14178-0618-10	DRG0003	262.820	6307.000	325.930		SAVED	Product Financial	
	14178-0631-02	DRG0047	0.000	0.000	0.000		SAVED	Product Financial	
	14178-0631-06	DRS0006	45.760	10129.000	81.520		SAVED	Product Financial	
	14178-0634-02	DMG0230	214,210	943.000	235.390		SAVED	Product Ethnoold	
	14178-0635-03	DMS0203	0.000	0.000	151.630		SAVED	Product Financial	
	14178-0635-04	DMG0203	125.100	459.000	151,630		SAVED	Product Eleancial	
	14178-0635-12	DRG0203	67.300	2709.000	80.410		SAVED	Product Financial	
	14178-0636-01	DMG0001	527.350	162.000	727.430		SAVED	Product Pinancial	
	14178-0636-02	DRG0001	0.000	0.000	96.650		SAVED	Product Financial	
	14178-0636-03	DRG0001	0.000	0.000	246.630		SAVED	Product Financial	
	14178-0636-05	DRG001	0.000	0.000	493,250		SAVED	Product Ethancial	
	14178-0645-12	DABG208	0.000	0.000	1973.000		SAVED	Product Financial	
	Showing 1 - 15 of 28 Results.		Previous F	rst 1, 2Last Ne	ext				
	*								÷.
				(
		U	Reset All Checked Drugs	Cent) Selected Data	Centry All Data				

Figure 5-8: Certification Confirmation Message

5.2 View Drug Data

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

5.2.1 View Drug Data Certified in the Reporting Period

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

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

Figure 5-9: Drug Data Certified This Period Option

Drug Data Pending Certification for Reporting Period		
Reporting Period: 03 2016 💭 Select Option: Drug Data Pending Centrication 💭 Manufacturer Name: View All		Drug identifier:
Drug Data Pending Certification Drug Data Centrales Inte Pendo Wer wit Drugs in Pendo	Submit	

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

OR

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

5. Click the **Submit** button. The search results will be displayed, as shown in Figure 5-10.

Figure 5-10: Drug Data Certified This Period Results

Medicare P	art 8 Average Sales Price		Drug	Certification					Hei
Kome Compliance Summary	Drug Data Pending Certification for Re	porting Period Q3 2014							
Roduct Data	Reporting Period: [03:0012] Select Option:]	Drug Data Parating Centrology (1997) Manufacturer Name: V	Nev All	Subnit			Drug identifier: [14178		
Certification	Press 1 14 of 25 Dec. by		Bandara - B						
Drug Certification Assumptions	Drug Identifier	Generic (Brand Name)	Manufacturers A SP	Number of ABP units	Wholesale Acquisition Cost	Number of Cap Units. Excluded	Matus	Drug Dytets	Cette
Re-statements Help	14178-0803-30	CMG0437	1929 550	9105.000	2156.180		SAIED	Protect Financial	10
Ent	14175-0618-02	0%6000	73.960	26733.000	91.890	1	SAVED	Ecolut Energie	10
	14178-0618-05	D#90004	23 230	6796.000	32.700		SAVED	Erosust Erostate	
	14178-0618-10	DMG3003	262,520	6307.000	325 930		SA/ED	Ecolut Energie	
	14176-0031-02	0990347	6.000	0.000	0.000		SAVED	Etablist Energies	0
	14178-0631-06	DMSXXX	45.760	10129.000	81.820		SAVED	Ecoluti Energie	5
	14175-0634-02	DMG0000	214,210	943.000	235.390		SAVED	Protect Financial	
	14175-0635-03	049000	0.000	0.000	151.630		SAVED	Ecoluti Enerciei	5
	14175-0635-04	049000	125.100	458.000	151.630		SAVED	Ended Energie	0
	14178-0635-12	090000	67.300	2709.000	80.410		SAVED	Erodust Eronolat	10
	14178-0636-01	DMG0001	827.360	162,000	727.400		SAVED	Product Eleancial	10
	14178-0636-02	D#00001	0.000	0.000	98.650		SAVED	Product Strandiel	8
	14178-0636-03	DMG0001	0.000	0.000	246.630		SAIED	Erabet Eracole	
	14178-0836-08	DM00001	6.000	0.000	483 250		SAVED	Protest Energie	
	14178-0645-12	C/#G0208	0.000	0.000	1973.000		SAIED	Exclusi Energy	2

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

Drug Data Pending Certification for Reporting Period Q3 2014							
Reporting Period: 03 2014 💭 Select Option: Drug Data Pending Centification 💭 Manufacturer Name: View A	Al	Drug identifier: 14178					
Drug Data Pending Cestification Drug Data Cestified this Pendo Wate All Drugs In Pendo	Submit.						

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

OR

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

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

Figure 5-12:	View All	Drugs in	Period	Results	

Medicare P	art B Average Sales Price		Cen	tification Status				
ome omplance ummary	View All Drugs in Period for Reporting	Period Q3 2014						
voduct Data	Reporting Period: CO 2214 Select Option: V	Ves A3 Drugs IF Perios 🕞 Manufacturer Name: [V	18 AT			Drug ident	brec (sants	
Inancial Data				Submit				
ertification	Observation 1, 145 and 24 Dates date		Province P		2014 (¹			
Brug Certification Assumptions	Drug identifier	Generic (Brand Name)	Manufacturers ASP	Number of ASP Units	Wholesale Acquisition Cost	Number of Cap Units	status	View Details
te-statements	1 14178-0801-30	D#00051	0.000	0.000	3.580		CENTRED	Enskel Energy
nep Exit	14170-0601-06	DRIG0081	396.640	23671.000	472,410		CERTIFIED	Product Etrancial
77.	14178-0803-20	DMS0437	0.000	0.000	0.000		CERTIFIED	Product Prinancial
	14178-0605-30	DMS0437	1929-560	9105.000	2156.180		SAVED	Product Elmansial
	14175-0818-02	D#9000	73.950	28733.000	91.890		SAVED	Enolusi Einansiai
	14178-0818-00	D#(9000)	23.230	6796.000	32.700		SAVED	Enziel Enansiel
	14178-0818-10	D#9000	262,520	6307.000	325.630		SAVED	Ecolust Ecologia
	14170-0831-02	DM90347	0.000	0.000	0.000		SAVED	Product Eleanoid
	14178-0631-06	DMD0008	45.760	10129-000	51.520		SAVED	Protect Energie
	54178-0634-02	D#90230	214.210	943.000	235.390		54(6)	Prosed Energial
	14178-0635-03	DR90203	0.000	0.000	151,630		SAVED	Product Elitarical
	14178-0838-04	D#00000	125.100	459 000	101.630		SAIED	Ensue Energy
	54170-0635-12	DRG0200	67.300	2709-000	80,410		SAVED	Product Eliterated
	16178-0636-01	DMI00001	627.360	162.000	727,450		SAVED	Enous Energie
	14170-0006-02	D#(50001	0.000	0.000	96.650		SAVED	Product Etrancia

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.

Medicare Pa	art B Average Sales Price H	ome	
Home	Downloads: User Guides	(PDF) File Upload Formats (zip)	
Compliance Summary	Welcome, ASPBUR:		
Product Data		Reporting Summary	
Financial Data		Current Reporting Quarter :	Q3 2014
Certification	A The second second	Current Submission Period Began :	07/01/2014
Drug Certification		Days Remaining in the Current Submission Period :	9
Assumptions		Closing Date for the Current Submission Period :	07/31/2014
Re.stalements		Pricing Quarter :	Q2 2014
itele	Quarterly drug product and average sales price financial data can be submitted through online entry or through file upload. Please click to download the required file format for data upload.	Next Reporting Quarter :	Q4 2014
нер	Files can then be uploaded to the respective sections found in Product Data' and Financial Data'	Date Submission Begins for the Next Reporting Quarter :	10/01/2014
	Messages: Were All • (2013.08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat. • • 1 have reviewed the message •	Compliance Report Labelers are out of compliance with data reportin ASTRAZENICA (90210) CMS (12345) GENIFRAI CORPORATION (00021) * <u>View Compliance Status</u>	g requirements.

Figure 5-13: Certification Assumptions Selection

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

Figure 5-14: Certification Assumptions Page

Medicare Pa	are Part 8 Average Sales Price Assumptions	Help
Home	For Reporting Period: 00.3074	
Compliance Summary	Manufacturer Name: Select	
Product Data	Enter your assumptions / comments about a submission below Upload your assumptions document (doc, docx, bit, pdtia) Assumptions	
Financial Data		
Certification		
Orug Certification	aton	
Assumptions		
Re-statements	ta de la constancia de la	
Help		
Exit		
	(sont)	

- 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.
- The ASP Application allows assumptions to be submitted by entering them directly in the text box shown in Figure 5-14, or by uploading an attachment. Click the Upload your assumptions document (.doc, .docx, .txt, .pdf/A) tab to open the Certification Assumptions Page Upload.

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

Figure 5-15: Certification Assumptions Page -- Upload

Medicare Pa	Part B Average Sales Price Assumptions	Hele
Home Compliance	For Reporting Period: 00 2014	
Summary Product Data	Manufacturer Name: [Seed]	
Financial Data	True for anti-shore communication and characteristic and constrained for the formula standards	
Certification Drug Certification	Brown, to fire selected	
Assumptions		
Help	Sont	
Exit		

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

Figure 5-16: Certification Assumptions Saved

Medicare Pa	rt B Average Sales Price Assumptions	Help
Home	For Reporting Period: 00.0014	
Compliance Summary	Manufacturer Name: 0000 50.00	
Product Data		
Financial Data	Successfully saved Assumptions.	
Certification		
Drug Certification	Enteryour assumptions / comments about a submission below Upload your assumptions document (doc, docs, bt, pdts) Assumptions	
Assumptions		
Re-statements		
нер		
Ext		
	i.	
	(Anode)	

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



Medicare P	art B Average Sales Price	Assumptions		Help
Home	For Reporting Period: 02 2014			
Compliance Summary	Manufacturer Name: 00021 GENERAL CORPORATION			
Product Data	Enter your assumptions / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf/A)	Assumptions	
Financial Data		File Name	Upload Date	
Certification	Certificatio	n Assumption test file docx	2014-07-21 08:50:43.0	
Drug Certification	4		*	
Assumptions				
Re-statements				
Help				
Exit				

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

6 Re-statements

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

6.1 Restate Drug Financial Data – Online

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

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

Medicare Pa	art B Average Sales Price Ho	me	
Home	Downloads: User Guides I	PDF) File Upload Formats (2p)	
Compliance Summary	Trecome, AP BOR.		
Product Data		Reporting Summary	
Financial Data		Current Reporting Quarter :	Q3 2014
Certification		Current Submission Period Began :	07/01/2014
Re-statements		Days Remaining in the Current Submission Period :	9
Restate Online		Closing Date for the Current Submission Period :	07/31/2014
Destate Droduct	Contraction of the second s	Pricing Quarter :	Q2 2014
Data Upload	Quarterly drug product and average sales price financial data can be submitted through online entry or through file upload. Please click to download the required file format for data upload.	Next Reporting Quarter :	Q4 2014
Restate Financial Data Upload	Files can then be uploaded to the respective sections found in Product Data' and Financial Data'	Date Submission Begins for the Next Reporting Quarter :	10/01/2014
Help	Messages:	Compliance Report	
	View All • (2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat. I have reviewed the message (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat. I have reviewed the message (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat. I have reviewed the message	Labelers are out of compliance with data reporting ASTRAZENICA (90210) CMS (12345) GENERAL CORPORATION (90021)	g requirements.
	(2013-08-29) Lorem (psum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urne, at molis elit semper vitae. Praesent nec feugiat.	View Compliance Status	

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.



Medicare Pa	art B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	Indate Einancial Data Indate Droduct Data	Add New Devoluet	
Product Data	oposte Pinancial Data Oposte Product Data	Add New Product	
Financial Data	Select Re-Statement Period: Select		
Certification			
Re-statements			
Restate Online			
Restate Product Data Upload			
Restate Financial Data Upload			
Help			
Exit			

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

Medicare Pa	rt B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	Hedate Financial Data Hindate Product Data Add New Product		
Product Data			
Financial Data	Select Re-Statement Period: 03 2014 -		
Certification	For Reporting Period Q3 2014		
Re-statements	Search/Filter;	Drugs Selected for Re-Statement	
Restate Online	00007-5476-02 AMPDRUG1	Add>>	
Restate Product Data Upload	00651-0000-05/AMPDRUG1 10022-5678-11:LEVSIN INJECTION	Add All >>	
Restate Financial Data Upload	12345-4444-44.AMPDRUG1 51009-0733-82:LINA HYDROHLORIDE 81093-0941-99 KANACITERIC DVSPEPTASE	<< Remove All	
Help		Submit Re-Statement List	
Exit			

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

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

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

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

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

Medicare Pa	rt B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: 03 2014		
Compliance Summary			
Product Data	update Financia Data Optiate Fronct Data Add How Product		
Financial Data	Select Re-Statement Period: 03 2014 💌		
Certification	For Reporting Period Q3 2014		
Re-statements	Search Filter:	Drugs Selected for Re-Statement	
Restate Online	00007-5476-02-4480084424	Add>>	
Restate Product	00551-0000-05-AMPORUG1	Add All >>	
Restate Financial Data Upload	12345-4444-44 MIPDRUG1 51009-0733-82 LINA HYDRCHLORIDE 51009-0733-82 LINA HYDRCHLORIDE 51009-0733-82 LINA HYDRCHLORIDE	<< Remove Al	
Help		Submit Re-Statement List	
Exit			

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

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

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

Medicare Pa	rt B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: 03 2014		
Compliance Summary	Hedde Financial Data Hode Deduct Data Add How Devolut		
Product Data	upuare rimancias basa upuare product basa Auto new product		
Financial Data	Select Re-Statement Period: 03 2014		
Certification	For Reporting Period Q3 2014		
Re-statements	Search/Filter;	Drugs Selected for Re-Statement	
Restate Online	STATE AND ADDRESS	Add>> Dopport 6176 Add United Topport	
Restate Product Data Upload	51090-0733-82-LINA HYDRCHLORIDE 51093-0941-99 KANACITIRIC DYSPEPTASE	Add Al >> 00051-0000 05 AMPCRUG 1 << Remove 10022-5578-11 LEVSIN INJECTION	
Restate Financial Data Upload	83278-0233-00:08/UG485 83278-7015.th DenicLase	<< Remove All	
Help		Submit Re-Statement List	
Exit			

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

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

			Review Re-	Statement List:			
Showin	ng all 3 Results.		Previous Fi	rst 1 Last Nex	t		
	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
8	<u>10022-5678-11</u>	LEVSIN INJECTION	11.333	22.333	44.333		CERTIFIED
Showin	ng all 3 Results.		Previous Fi	rst 1 Last Nex	t		

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.

Name	User Action	Comments
 Manufacturer's 	 Enter or update the 	• The Manufacturer's ASP is a required field.
ASP	Manufacturer's ASP in the 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	 Enter the number of ASP 	• The Number of ASP Units is a required field.
ASP Units	Units in the 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	 Enter the Wholesale 	• The WAC is a required field.
Acquisition Cost	Acquisition Cost (WAC) in the 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 	 Enter the number of CAP unites excluded 	• The Number of CAP Units Excluded is an optional field.
Excluded		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).

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

- 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.

	IT B Average Sales Price		Restate	Online			
Home	Current Reporting Period: Q3 2	2014					
Compliance Summary							
Product Data	Update Financial Data Update F	Product Data Add New Product					
inancial Data	Select Re-Statement Period:	03 2014					
ertification	For Reporting Period Q3 201	14					
te-statements	SourchEllor					Drugs Selected for Re	Statement
Restate Online	1924E-4444-44-400P	1		Add>>	00007	5476-02 AMPORISO1	
Restate Product Data Upload	51009-0733-82 LINA 51093-0941-99 KANA	HYDRCHLORIDE ACITIRIC DYSPEPTASE	A(Id All >> Remove	00651- 10022-	0000-05 AMPORUG1 5678-11 LEVSIN INJECT	ION
Restate Financial Data Upload	83278-0233-20.DRU 83278-0233-20.DRU 83278-7236-35.DRU	G465 CARR	<< R	temove All			
lelp			Submit Re	-Statement List			
			Finance	Data Saved.			
	Showing all 3 Results		Finance Previous Fi	Data Saved. rst 1 Last Nex	at		
	Showing all 3 Results. Drug Identifier	Generic (Brand Name)	Finance Previous Fi Manufacturer's ASP	Data Saved. rst 1 Last Nex Number of ASP units	t Wholesale Acquisition Cost	Number of CAP Units Excluded	Status
	Showing all 3 Results. Drug Mentifier	Generic (Brand Name) AMPDRUG1	Finance Previous Fi Manufacturer's ASP [12:350	Data Saved. rst 1 Last Nex Number of ASP units [12.000	t Wholesale Acquisition Cost 15000	Number of CAP Units Excluded	Status RESTATE SAVED
	Showing all 3 Results. Drug Mentifier Initial 00007-5476-02 Initial 00551-0000-05	Generic (Brand Name) AMPDRUG1 AMPDRUG1	Finance Previous Fi Manufacturer's ASP [12:350 [22:000	Data Saved. rst 1 Last Nex Number of ASP units [12.000 [15.000	t Wholesale Acquisition Cost 15 000 25 000	Number of CAP Units Excluded	Status RESTATE SAVED RESTATE SAVED
	Showing all 3 Results. Drug Mentifier III 00007-5476-02 III 00051-0000-05 III 10022-5678-11	Generic (Brand Name) AMPDRUG1 AMPDRUG1 LEVSIN INJECTION	Finance Previous Fi Manufacturer's ASP [12:350 [22:000 [11:333 [11:333	Data Saved. rst 1 Last New Number of ASP units 12000 (15.000 (22.333	t Wholesale Acquisition Cost [15:000 [25:000 [44.333]	Number of CAP Units Excluded [1.000 [1.000	Status RESTATE SAVED RESTATE SAVED RESTATE SAVED
	Showing all 3 Results. Drug Mentifier Drug Mentifier D0007-5476-02 D0051-0000-05 D0022-5678-11 Showing all 3 Results.	Generic (Brand Name) AMPDRUG1 AMPDRUG1 LEVSIN INJECTION	Finance Previous Fi Manufacturer's ASP [12:350 [22:000 [22:000 [11:333 Previous Fi	Data Saved. rst 1 Last Nex Number of ASP units 12 200 (15 000 (22 333 rst 1 Last Nex	t Wholesale Acquisition Cost [15.000 [25.000 [44.333] t	Number of CAP Units Excluded [1.000 [1.000 [1.000	Status RESTATE SAVED RESTATE SAVED RESTATE SAVED
	Showing all 3 Results. Drug Mentifier Drug Drug Drug Drug Drug Drug Drug Drug	Generic (Brand Name) AMPDRUG1 AMPDRUG1 LEVSIN INJECTION	Finance Previous Fi Manufacturer's ASP [12:350 [22:000 [11:333 [11:333] Previous Fi	Data Saved. Ist 1 Last Nex Number of ASP units [12 000 [15 000 [22 333 Ist 1 Last Nex]	t Mbolesale Acquisition Cost [55.000 [44.333] t	Number of CAP Units Excluded [1.000 [1.000	Status RESTATE SAVED RESTATE SAVED RESTATE SAVED
	Showing all 3 Results. Drug Mentifier Drug Drug Drug Drug Drug Drug Drug Drug	Generic (Brand Name) AMPDRUG1 AMPDRUG1 LEVSIN INJECTION	Finance Previous Fi Manufacturer's ASP [12:350 [22:000 [11:333 Previous Fi Export	Data Saved. Ist 1 Last Nex Number of ASP units Ist 000 Ist 000 Ist 1 Last Nex Image: Nex	t Acquisition Cost [55:000 [44:333] t	Number of CAP Units Excluded 1 000 1 000 1 000	Status RESTATE SAVED RESTATE SAVED RESTATE SAVED

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.

Medicare Pa	irt 8 Average Sales Price	ome		
Home	Downloads User Guides	(POF) File Upload Formata (20)		
Compliance Summary	Welcome, ASPBOR!			
Product Data		Reporting Summary		
Financial Data		Current Reporting Quarter :	03 2014	
entification		Current Submission Period Began :	07/01/2014	
e-statements		Days Remaining in the Current Submission Period :		
Restate Online	the set of the system	Closing Date for the Current Submission Period :	07/31/2014	
	7 7 7 10	Pricing Quarter :	02 2014	
Deta Upicad	Quarterly drug product and average sales price financial data can be submitted through online arthres: Toposts Ne attended (Please click) In description the construct the format for side option of	Next Reporting Quarter :	G4 2014	
Restate Financial Data Upload	First can then be uploaded to the respective sections found in Product Data' and Financial Data'	Date Submission Begins for the Next Reporting Quarter :	10/01/2014	
ielp	Messages:	Compliance Report		
ait	Constant of Consta	Labelers are out of compliance with data reportin	g requirements.	
	I have reviewed the message	CMS (12345)	13	
	(2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendinse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feuglat.	GENERAL CORPORATION (00071)		
	Ihave reviewed the message	View Compliance Status		
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendinse consectetur commodo urna, at mollis elit semper vitae. Praesent nec feugiat.			

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

Medicare Pa	urt B Average Sales Price	Re	state Online	Help
Home	Current Reporting Period: Q3 2014			
Compliance Summary				
Product Data	Update Financial Data Update Produ	Data Add New Product		
Financial Data	Select Re-Statement Period: Se	A 💌		
Certification				
Re-statements				
Restate Online				
Restate Product Data Upload				
Restate Financial Data Upload				
Help				
Exit				

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

Figure 6	6-10:	Restate	Online –	Product	Data
----------	-------	---------	----------	---------	------

Medicare Pa	rt B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	He date Generated Bates He date Bendust Bates Add How Residual		
Product Data	update Pinancial Data Update Product Data Add New Product		_
Financial Data	Select Re-Statement Period: 03 2014 💌		
Certification	For Reporting Period Q3 2014		
Re-statements	Search/Filter:	Drugs Selected for Re-Statement	
Restate Online	00007-5476-02 AMPDRUG1	Add>>	
Restate Product Data Upload	00651-0000-05:AMPDRUG1 10022-5678-11:LEVSIN INJECTION	Add All >>	
Restate Financial Data Upload	12345-4444-442AMPORUG1 51009-0733-821L0A HYDRCHLORIDE 51003-0041-09-KANACITIRIC DYSPEPTASE	<< Remove All	
Help		Submit Re-Statement List	
Exit			

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

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

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

Name	User Action	Comments
< <remove< td=""><td> Click <<remove remove<br="" to="">the selected drugs from the Drugs Selected for Re- Statement field.</remove> </td><td>• N/A</td></remove<>	 Click <<remove remove<br="" to="">the selected drugs from the Drugs Selected for Re- Statement field.</remove> 	• N/A
– << Remove All	 Click <<remove all="" to<br="">remove all drugs from the the Drugs Selected for Re- Statement field.</remove> 	• 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

Medicare Pa	rt B Average Sales Price		Restate Online		Help
Home	Current Reporting Period: Q3 2014				
Compliance Summary	Indate Enancial Data Indate Product Data	Add New Dreduct			
Product Data		HUN HER FILMEL			
Financial Data	Select Re-Statement Period: 03 2014				
Certification	For Reporting Period Q3 2014				
Re-statements	Search Filter:	_		Drugs Selected for Re-Statement	
Restate Online	00007-5475-02-MIRDRUG1		Add>>		
Restate Product	00651-0000-05-AMPDRUG1	1	Add All >>		
Data opicad	12345-4444-44 AMPDRUG1		<< Remove		
Restate Financial Data Upload	51009-0733-82 LINA HYDRCHLORIDE 51003-0041-00 KANACITIRIC DVSPEPT	1495 ·	<< Remove All	*	
Help			Submit Re-Statement List		
Exit					

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

Medicare Pa	art B Average Sales Price	Restate Online	Help
Home	Current Reporting Period: Q3 2014		
Compliance Summary	Indate Seascial Data Indata Product Data Add New Product		
Product Data			
Financial Data	Select Re-Statement Period: Q3 2014		
Certification	For Reporting Period Q3 2014		
Re-statements	Search/Filter:	Drugs Selected for Re-Statement	
Restate Online		Add>> 00002.6426.022.009.00124	-
Restate Product	51009-0733-821 INA HYDRCHLORIDE	Add A&>> 00651-0000-05 AMPDRUG1	
Data Upload	51090-0941-99:KANACITIRIC DYSPEPTASE 51220-0292-0040 JSEUM FORTE	<< Remove 1002225078511115050/ENLEGTION	
Restate Financial Data Upload	83278-0233-20 DRUG465 83278-7236-50 DRUG465	<< Remove All	•
Help		Submit Re-Statement List	
Exit			

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

Medicare Pa	rt B Average Sales Price	Restate Online	Help	
Home	Current Reporting Period: Q3 2014			
Compliance Summary				
Product Data	Update Pinancial Data Update Product Data Add New Product			
Financial Data	Select Re-Statement Period: 03 2014 💌			
Certification	For Reporting Period Q3 2014			
Re-statements	Search/Filter;	Drugs Selected for Re-Statement		
Restate Online	12345-4444-44-AMPORTIG1	Add>> 00007-5475-02-AMPORUG1 +		
Restate Product Data Upload	51009-0733-82:LINA HYDRCHLORIDE 51093-0941-99:KANACITIRIC DYSPEPTASE	Add All >> 00851-0000-05/AMPDRUG1 << Remove 10022-5678-111.EVSIN INJECTION		
Restate Financial Data Upload	51220-8292-003MUSEUM FORTE 48278-0233-20:DRUG465 82278-7228-10:DRUG465	<< Remove All		
Help		Submit Re-Statement List		
Exit				
	Update Product Data for Drug Identifier: 00007-5476-02AMPDRUG1			
	Update Product Data for Drug Identifier: 00651-0000-05AMPORUG1			
	Update Product Data for Drug Identifier: 10022-5678-11-LEVSIN INJECTIO	N		

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

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

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

Update Product Data for Drug Identifier: 0000	Update Product Data for Drug Identifier: 00007-5476-02AMPDRUG1					
* denotes required field	* denotes required field					
Drug Identifier: 00007-5478-02	Manufacturer Name* STANFORD Has Brand Name? Generic Name* AMPDRUG1	Date of First Sale* 01/01/2013 Expiration Date of Final Lot Sold				
Strength of Product* 100 Volume Per Item* 1 Number of Items per NDC* 2	Add Additional FDA Supplemental Numbers FDA Application Number* FDA Supplemental Number [1111 [2222 FDA Final Pre-Marketing Approval Date* [12/28/2012]	FDA Approval Type* ANDA 💌				
UPDATE						

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

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

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

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

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

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

Update Product	Data for Drug Identifier: 000	007-5476-02AM	PDRUG1							
	Product data for 00007-5476-02 has been saved									
* denotes requ	red field									
Drug Identifier	00007-5476-02		Manufacturer Name* STANFOR Has Brand Name? Generic Name* AMPDRU	D G1	Date of First Sale* Expiration Date of Final Lot Sold	01/01/2013				
Strength of Product* Volume Per Item* Number of Items per NDC	300 1 2	Add Additiona FDA Applicat 1111 FDA Final Pro	FDA Supplemental Numbers on Number* F 2 -Marketing Approval Date* 12/2	DA Supplemental Number 222 8/2012	FDA Approval Type* (ANDA 💌				
	UPDATE									

Figure 6-15: Re-stated Product Data Saved

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

6.3 Add New Product – Re-statement Tab

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

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

CMS XLC

Medicare Pa	rt B Average Sales Price	Restate Online		Help							
Home	Current Reporting Period: Q3 2014										
Compliance Summary	Update Financial Data Update Product Data Add New Product										
Product Data											
Financial Data	Select Re-Statement Period: 02 2014 💌										
Certification	Reporting Period: Q2 2014										
Re-statements											
Restate Online	* denotes required field										
Restate Product Data Upload											
Restate Financial Data Upload	Add by NDC Add by Alternate ID NDC1* Select Add new NDC1	Manufacturer Name*	Date of First Sale*								
Exit	NDC2*	Has Brand Name?	Expiration Date of Final Lot Sold Date must be in MMDDYYYY format	_							
	Strength of Product* Add Additional Volume Per Item* FDA Applicati Number of Items FDA Final Pre Date must be in 1	EDA Supplemental Numbers On Number* FDA Supplemental Number Marketing Approval Date* MMDD/YYYY Iomat	FDA Approval Type*	*							
		Save Reset									

Figure 6-16: Restate Online – Add New Product

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

6.4 Restate Financial Data – File Upload

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

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

Medicare Pa	art B Average Sales Price Ho	ne	
Home Compliance	Downloads: User Guides (F Welcome, ASPBOR!	DE) Eile Upload Formats (20)	
Product Data Financial Data	Contraction of the second	Reporting Summary Current Reporting Quarter :	Q3 2014
Certification Re-statements		Current Submission Period Began : Days Remaining in the Current Submission Period :	07/01/2014 8
Restate Online Restate Product	10-	Closing Date for the Current Submission Period : Pricing Quarter :	07/31/2014 Q2 2014
Data Upload Restate Financial Data Upload	Continue only produce and precise same pick with the doubted of the required the optimized in the optimized of the pick of the	Next Reporting Quarter : Date Submission Begins for the Next Reporting Quarter :	Q4 2014 10/01/2014
Help Exit	Messages:	Compliance Report Example and the state of the	g requirements.
	Thave reviewed the message (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at moliis elit semper vitae. Praesent nec feuglat. Thave reviewed the message	ASTRAZENICA (90210) CMS (12345) CENERAL CORPORATION (00021)	•
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feugiat	VIEW COMPLIANCE STATUS	

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

Medicare Pa	Part B Average Sales Price Restate Financial Data Upload	Help							
Home	Current Reporting Period: 03 2014								
Compliance Summary	lect Re-Statement Period: SELECT								
Product Data									
Financial Data	Browse for Re-statement Financial Data File								
Certification	Browse No file selected.								
Re-statements	Click here for acceptable file formats								
Restate Online	Upload								
Restate Product Data Upload	A								
Restate Financial Data Upload									
Help									
Exit									

- 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

Opening File Upload Formats.zip	
You have chosen to open:	
🛄 File Upload Formats.zip	
which is: WinZip File (31.8 KB)	
from: http://209.251.176.37	
What should Firefox do with this file?	
Open with WinZip (default)	•
Save File	
Do this <u>a</u> utomatically for files like this from now on.	
ОК	Cancel

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

ImanceTemplate.ds Microsoft Of 7/26/2013 9-51 AM 30,208 78% 6,538 ImanceTemplate.dsx Microsoft Of 7/26/2013 9-50 AM 11,418 27% 8,314 ImanceTemplate.csv Microsoft Of 7/26/2013 4-22 PM 184 26% 137 ImanceTemplate.csv Microsoft Of 7/26/2013 10.01 AM 528 57% 226 ImanceTemplate.dsx Microsoft Of 7/26/2013 10.01 AM 134.08 24% 10,170 ImanceTemplate.dsx Microsoft Of 7/26/2013 10.01 AM 27,648 78% 6,212	ili	Name	Туре	Modified	Size	Ratio	Packed	Path
Microsoft Of 7/26/2013 9:50 AM 11,418 27% 8,314 GranceTemplate.sv ProductTemplate.six productTemplate.als Microsoft Of 7/1/2013 4:22 PM 184 26% 137 Microsoft Of 7/26/2013 1:01 AH 13,408 24% 10,170 Microsoft Of 7/26/2013 10:01 AM 27,648 78% 6,212 Microsoft Of 7/26/2013 10:01 AM 27,648 78% 6,212		🗃 financeTemplate.xls	Microsoft Of	7/26/2013 9:51 AM	30,208	78%	6,538	
Image: Symposized constraints Microsoft Of 7/1/2013 4:22 PM 184 26% 137 Image: Symposized constraints Microsoft Of 6/26/2013 4:14 PM 528 57% 226 Image: Symposized constraints Microsoft Of 7/26/2013 10:01 AM 13;408 24% 10;170 Image: Symposized constraints Microsoft Of 7/26/2013 10:01 AM 13;408 24% 6,212		InanceTemplate.xlsx	Microsoft Of	7/26/2013 9:50 AM	11,418	27%	8,314	
Image: SproductTemplate.csv Microsoft Of 6/26/2013 4:14 PM 528 57% 226 Image: SproductTemplate.six Microsoft Of 7/26/2013 10:01 AM 13,408 24% 10,170 Image: SproductTemplate.six Microsoft Of 7/26/2013 10:01 AM 27,648 78% 6,212		SinanceTemplate.csv	Microsoft Of	7/1/2013 4:22 PM	184	26%	137	
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		SproductTemplate.csv	Microsoft Of	6/26/2013 4:14 PM	528	57%	226	
Image: ProductTemplate.xls Microsoft Of 7/26/2013 10:01 AM 27,648 78% 6,212		🗐 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	
								21 25
								8
								三 芬
								0-0-0

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

	А	В	С	D	E	F	G	н	1	J	К
	Manufact urer's Name	NDC1	NDC2	NDC3	Alternate ID	Generic Name	Brand Name	Manufact urer's Average Sales	Number of ASP Units	Wholesal e Acquisiti on Cost	Number of CAP Units Excluded
1								Price			
2											
3											
4											
5											
б											
7											

Figure 6-21: Sample Financial Data Template

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

Figure	6-22:	Restate	Financial	Data	Upload –	File to	be U	ploaded
i igui c	·	neotate	i manoiai	Dutu	opiouu	1 110 10		picadca

Medicare Pa	art B Average Sales Price Restate Financial Data Upload	Help								
Home	Current Reporting Period: 03 2014									
Compliance Summary	lect Re-Statement Period: Q2 2014									
Product Data										
Financial Data	Browse for Re-statement Financial Data File									
Certification	Browse. Finance Data.ds									
Re-statements	Click here for acceptable file formats									
Restate Online	Upload									
Restate Product Data Upload		_								
Restate Financial Data Upload										
Help										
Exit										

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

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

Medicare Pa	Medicare Part B Average Sales Price				I Data Upload	ł			Help			
Home	Current	urrent Reporting Period: Q3 2014										
Compliance Summary	Select R	Select Re-Statement Period: 02 2014										
Product Data			Financial Data Sila									
Financial Data	Вго	wse for Re-stati	iment Financial Data File									
Certification	B	rowse. No file set	ected.									
Re-statements	Clic	k here for acceptable	file formats									
Restate Online	Up	load										
Restate Product Data Upload												
Restate Financial Data Upload	Report o	of Transmitted Dr	rugs via File Upload									
Help	Opload Da	101.2014-07-22 00.57	.49.0									
Exit			1 Out Of 1	1 Financial Data has	s been Successfully	Saved.						
	Showing	1 Result.		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			
	00033-0000-04 AMPDRUG1				30.125	4.000	40.125	1.000	Uploaded- Success			
	Showing 1 Result. Previous First 1 Last Next											

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

Medicare P	art B Average Sales Price	Restate F	inancial Data Uploa	d			Heli
Home	Current Reporting Period: Q3 :	2014					
Compliance Summary	Select Re-Statement Period:	2 2014 💌					
Product Data							1
Financial Data	Browse for Re-statement Financial Data File						
Certification	Browse No file selected. Click here for acceptable file formats						
Re-statements							
Restate Online	Upload Report of Transmitted Drugs via File Upload Upload Date 2014-07-22 09:00:41.0						
Restate Product Data Upload							
Restate Financial Data Upload							
Help							
Exit	No Valid Data Present to be saved.Total 1 drugs uploaded.						
	Showing 1 Result. 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
	98765-234-10	Lisinopril(Zestril)	45.250	5.000	50.500	3.00	No Product Data exists Number of Cap Units Excluded 9999999999.999.
	Showing 1 Result.	Prev	ious First 1 Last Next				

- 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.



Medicare P	art B Average Sales Price Ho	me			
Home Compliance Summary	Downloads: User Guides II Welcome, ASPBOR!	PDF) File Upload Formats (zip)			
Product Data Financial Data		Reporting Summary Current Reporting Quarter :	Q3 2014		
Certification Re-statements		Current Submission Period Began : Days Remaining in the Current Submission Period :	07/01/2014 8		
Restate Online Restate Product	Quarterly drug product and average sales price financial data can be submitted through online	Closing Date for the Current Submission Period : Pricing Quarter : Next Reporting Quarter :	07/31/2014 Q2 2014 Q4 2014		
Restate Financial Data Upload	entry or through file upload. Please click 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.	Date Submission Begins for the Next Reporting Quarter :	10/01/2014		
Help Exit	Messages:	Compliance Report Compliance Report Example are out of compliance with data reporting requirements.			
	Thave reviewed the message (2013-08-02) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at molis elit semper vitae. Praesent nec feuglat. There reviewed the message	ASTRAZENICA (90210) CMS (12345) GENERAL CORPORATION (00021) View Compliance Statua			
	(2013-08-29) Lorem ipsum dolor sit amet, consectetur adipiscing elit. Suspendisse consectetur commodo urna, at modis elit semper vitae. Praesent nec feugiat.				

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

Medicare Pa	Int B Average Sales Price Restate Product Data Upload	Help				
Home	Current Reporting Period: 03 2014					
Compliance Summary	Select Re-Statement Period: SELECT					
Product Data						
Financial Data	Browse for Restatement product data					
Certification	Browse. No file selected.					
Re-statements	Click here for acceptable file formats					
Restate Online	Upload					
Restate Product Data Upload						
Restate Financial Data Upload						
Help						
Exit						

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

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

Figure 6-27: Attachment Uploadzip File					
Opening File Upload Formate	s.zip				
You have chosen to open:					
File Upload Formats.	zip				
which is: WinZip File	which is: WinZip File (31.8 KB)				
from: http://209.251.	176.37				
What should Firefox do wi	ith this file?				
Open with WinZ	ip (default) 👻				
Save File					
Do this <u>a</u> utomatica	illy for files like this from now on.				
	OK Cancel				

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

n de	Name	Туре	Modified	Size	Ratio	Packed	Path
[S financeTemplate.ds	Microsoft Of	7/26/2013 9:51 AM	30,208	78%	6,538	
	financeTemplate.dsx	Microsoft Of	7/26/2013 9:50 AM	11,418	27%	8,314	
	SinanceTemplate.csv	Microsoft Of	7/1/2013 4:22 PM	184	26%	137	
	SproductTemplate.csv	Microsoft Of	6/26/2013 4:14 PM	528	57%	226	
	1 productTemplate.dsx	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	
							3
							3 8
							S A Sa
< 1	* · · · · · · · · · · · · · · · · · · ·						

Figure 6-28: Acceptable File Format Templates

6. Click any one of Product Template files to open a product data template. A sample template is shown in Figure 6-29.
| | A | В | С | D | E | F | G | н | 1 | J | К | L | м | N | 0 | Р | Q | R | S |
|---|----------------------------|------|------|------|-----------|-----------------|---------------|-------------------------------|--------------------|-------------------------------|---|--------------------------|----------------------------------|--|-------------------------|---|---|---|---|
| 1 | Manufact
urer's
Name | NDC1 | NDC2 | NDC3 | Alternate | Generic
Name | Brand
Name | Strength
of the
Product | Volume
Per Item | Number
of Items
Per NDC | Expiratio
n Date of
Final Lot
Sold | Date of
First
Sale | FDA
Applicati
on
Number | FDA
Applicati
on
Supplem
ent
Number | FDA
Approval
Type | Addition
al FDA
Applicati
on
Number
#1 | Addition
al FDA
Applicati
on
Supplem
ent
Number
#1 | FDA
Approval
Type
Number
#1 | Addition
al FDA
Applicati
on
Number
#2 |
| 2 | - | | | | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | | | | | |
| 5 | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | | | | | |

Figure 6-29: Sample Product Data Template

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

- 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.

Medicare Pa	rt B Average Sales Price Restate Product Data Upload	Help
Home	Current Reporting Period: 03 2014	
Compliance Summary	Select Re-Statement Period: 02 2014	
Product Data		
Financial Data	Browse for Restatement product data	
Certification	Browse_ 03 2013 Product Data xis	
Re-statements	Click here for acceptable file formate	
Restate Online	Upload	
Restate Product Data Upload		
Restate Financial Data Upload		
Help		
Exit		

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.

Medicare Pa	art B Av	verage Sales	Price	Restate	Produc	t Data	Upload					Help
Home	Current	Reporting Perio	od: Q3 2014									
Compliance Summary	Select F	Re-Statement Pe	riod: 02 2014 💌									
Product Data												
Financial Data	Br	owse for Restate	ement product data									
Certification		rowse No file se	lected.									
Re-statements	Clic	k here for acceptab	le file formats									
Restate Online	U	pload	â									
Restate Product Data Upload												
Restate Financial Data Upload	Report	of Transmitted D	orugs via File Upload									
Help	Upload D	ate:2014-07-22 09:1	0.41.0									
Exit				1 Out Of 1 Produ	ict Data has	s been Su	ccessfully	Saved.				
	Showing	g 1 Result.		Prev	ious First	1 Last	Next					
	Dr	Drug Identifier Manufacturer Name Generic (Brand Name) Strength Volume Number of per of Items First Sale Date of Approval Approval Product Item per First Sale Straute Strength Volume Number Ot Bate of Approval Approval Approval Approval Status Strength Volume Number Ot Bate of								Status		
		Insulin	AstraZeneca	insulin(Gluocyn)	25	tv	10	07/31/2013	05/30/2016	ANDA/ A123789 / B666777	01/01/2013	Uploaded-Success
	Showing	g 1 Result.		Prev	ious First	1 Last	Next					

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

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

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

Medicare Pa	rt B Av	erage Sales	Price	Restate I	Product	Data	Upload					Help
Home	Current	Reporting Perio	od: Q3 2014									
Compliance Summary	Select R	e-Statement Pe	riod: 02 2014 💌									
Product Data												
Financial Data	Bro	wse for Restate	ement product data									
Certification	B	rowse. No file se	lected.									
Re-statements	Clic	k here for acceptabl	e file formats									
Restate Online	Up	Upload										
Restate Product Data Upload												
Restate Financial Data Upload	Report o	of Transmitted D	rugs via File Upload									
Help	Oproad De	0.2014-07-22 00.1	a.av.v									
Exit				No Valid Data Pres	ent to be sa	aved.Tota	l 1 drugs up	loaded.				
	Showing	1 Result.		Previ	ous First	1 Last	Next					
	Dn	ig Identifier	Manufacturer Name	Generic (Brand Name)	Strength	Volume	Number	Date of	Expiration	FDA	FDA	Status
		of per of items First Sale Date of Approval Approval Product Item per First Sale Date of Approval Approval Product Sale Date of Approval #SuperApp Date										
		Insulin	AstraZeneca	INSULIN(Gluocyn)	28	1v	10	07/31/2013	05/30/2016	/ A123789 / B666777	01/01/2013	FDA Approval Type Required.
	Showing	1 Result.		Previ	ous First	1 Last	Next					

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

7 Compliance

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

7.1 Compliance Summary Overview

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

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

Medicare Pa	Compliance Summary Overview	Help
Home	Reporting Period: 03 2014 💽	
Compliance Summary	Manufacturer: Select	
Product Data	View Compliance Overview Detail	
Financial Data		
Certification	Selected Quarter: Q3 2014 Prior Quarter: Q2 2014 Prior Quarter: Q1 2014	
Re-statements	All Manufacturers	
Help		
Exit	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	
	Total New Drugs: 20	

Figure 7-1: Compliance Summary Overview

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

 Table 7-1
 Select Certification Status Page Information

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

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

 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

Medicare Pa	art B Average Sale:	s Price	Complian	ice Summary Overview	v	E	Help
Home	Reporting Period:	Q3 2014 💌					
Compliance Summary	Manufacturer:	PSTI CORP. (8533607009)		×			
Product Data	View Compliance Overview	/ Detail					
Financial Data							-
Certification	Selected Quarter: Q3 201	14 Prior Quarter: Q2 2014	Prior Quarter: Q1 2014				_
Re-statements			P	STI CORP. (8533607009)			
Help							
Exit			Labelers are out of cor	mpliance with data reporting	requirements.		
			0% of drugs	are certified out of 1 total dr	ugs.		
			(0 Ce	rtified, 0 Restatement Certified)			
	Missing: 0						
	Pending Certificatio	an: 1					3
	Pending Restateme	ant Certification: 0					
	Total Certified: 0						
	Total Restatement C	Certified: 0					
	Total New Drugs: 1						

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

7.2 Compliance Overview

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

7.2.1 Missing Drugs

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

Medicare Pa	art B Average Sales	Price	Comp	liance Sun	nmary Overv	iew			Help		
Home	Reporting Period: 03	2014 💌									
Compliance Summary	Manufacturer: Sei	Compliance Summary Overview Raip Compliance Summary Overview Raip Compliance Summary Overview Compliance Summary O									
Product Data	View Compliance Overview De	Intring Period: 03 2014 Intring Period: 03 2014 Intring Period: 04 2014 Intring Period: 04 2014 Intring Period: 04 2014 Intring Prior Quarter: 02 2014 Prior Quarter: 01 2014 Intring Prior Quarter: 02 2014 Prior Quarter: 02 2014 Intring Prior Quarter: 02 2014 Prior Quarter: 02 2014 Intring Prior Quarter: 02 2014 Prior Quarter: 02 2014 Intring Prior									
Financial Data		Ing Period: 03.2014 inturer: Select impliance Overview Detail ted Quarter: Q3.2014 Prior Quarter: Q2.2014 Prior Quarter: Q1.2014 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 Drue Mediatifier: Rescription Deriod: ASD Holds: MAC CAB Holds: Status: Rescale Compliance Cab Holds: CAB H									
Certification	Selected Quarter: Q3 2014	Q3 2014 Prior Quarter: Q2 2014 Prior Quarter: Q1 2014 All Manufacturers									
Re-statements		All Manufacturers Labelers are out of compliance with data reporting requirements.									
Help		All Manufacturers Labelers are out of compliance with data reporting requirements.									
Exit		Labelers are out of compliance with data reporting requirements.									
			20% of dr	ugs are certif	ied out of 30 to	tal drugs.					
				(3 Certified, 3 Re	statement Certified)						
	Missing: 1										
	Drug Identifier	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. 20% of drugs are certified out of 30 total drugs. (3 Certified, 3 Restatement Certified) Missing: 1 Drug Identifier Reporting Period ASP ASP Units VMAC CAP Units Status Resolve Asp (Secolve) Insulin Q3 2014 Image: Colspan="4">Image: Colspan="4">Colspan= 4									
	Manufacturer: Select View Compliance Overview Detail Selected Quarter: Q3 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 Drug Identifier Reporting Period ASP ASP Missing: 1 PENDING					Resolve					
		View Compliance Overview Detail Selected Quarter: Q3 2014 Prior Quarter: Q1 2014 All Manufactu Labelers are out of compliance with d 20% of drugs are certified ou (3 Certified, 3 Restatement Missing: 1 Orug Identifier Reporting Period ASP ASP Units Insulin Q3 2014									

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
		- ···· ,		

Medicare Pa	art B Avera	ige Sales	Price	Add Or Ed	it Financial D	ata				Help	
Home				Please re:	olve NDC/Alt ID:Insu	ılin					
Compliance Summary	Current Rep	orting Peri	od: Q3 2014								
Product Data											
Financial Data	Drug Identifier:	rug Identifier: Insulin Search									
Add/Edit Financial Data	Showing 1 R	esult.		Previous	First 1 Last N	lext					
Financial Data Upload	Drug Ide	entifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	View	Details	
Certification	Insu	ilin	INSULIN (Gluocyn)					PENDING	Product	Financial	
Re-statements	Showing 1 R	esult.		Previous	First 1 Last N	lext					
Help											
Exit	4 Export. Control Cont									÷	
	Save Financial Data										

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.

Medicare Pa	art B Average Sales P	rice	Comp	oliance Sun	nmary Over	view			Help			
Home	Reporting Period: 03.2	014 💌										
Compliance Summary	Manufacturer: Sele	d										
Product Data	View Compliance Overview Det	ail										
Financial Data	Selected Ouerdee 03 2014	Drive Owardon 02 2014	Drive Quarters O1 2	044								
Certification	Selected Quarter, Q5 2014	Prior Quarter, Q2 2014	Phot Quarter, Q120	014								
Re-statements			All Manufacturers									
Help			I shelere are out of compliance with data reporting requirements									
Exit			Lessiers are out o			and redenement						
			20% of dr	20% of drugs are certified out of 30 total drugs.								
				(a certified, a ro								
	Missing: 1											
	Pending Certification: 2)										
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status	Resolve	Â.			
	00000-0000-01	Q3 2014	333.333	333.333	333.333	333.333	SAVED	Resolve	8			
	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	-			
	<		00.00F		10.105			<u> </u>	7			
	Pending Restatement C	ertification: 3										
	Total Certified: 3											
	Total Restatement Certi	fied: 3										
	Total New Drugs: 20											

Figure 7-5: Compliance Summary Overview—Pending Certifications

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

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

Medicare Pa	art B Average :	Sales Price	Drug C	ertificatior	n				Help		
Home											
Compliance Summary	Drug Data Pendin	ng Certification for Reporting Period Q3 2014									
Product Data	Reporting Period:	3 2014 Select Option: Drug Data Pending Certification	on 💌						_		
Financial Data	Manufacturer Name:	STP (00000)					 Drug Ide 	ntifier: 00000-0000-01			
Certification				Submit							
Re-statements											
Help		Please resolve NDC/Alt ID:00000-0000-01									
Exit											
	Showing 1 Result.		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	Drug Details	Certify		
	00000-0000-01	AMPDRUG1	333.333	333.333	333.333	333.333	SAVED	Product Einancial			
	Showing 1 Result.		Previous	First 1 Last	Next						
	<								÷		
		Reset All C	hecked Drugs	Certify Selected D	Data Confirm	All Data					

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 P	art B Average Sales	Price	Comp	oliance Sun	nmary Over	view			Help
Home	Reporting Period:	3 2014 💌							
Compliance Summary	Manufacturer:	elect							
Product Data	View Compliance Overview	Detail							
Financial Data			1						
Certification	Selected Quarter: Q3 201	4 Prior Quarter: Q2 2014	Prior Quarter: Q1 2	014					
Re-statements				All Man	ufacturers				
Help									
Exit]		Labelers are out o	of compliance	with data repo	rting requiremen	its.		
			20% of d	rugs are certif	fied out of 30 to	otal drugs.			
				(3 Certified, 3 Re	statement Certified	1)			
	Missing: 1								
	Pending Certification	n: 20							
	Pending Restatemen	t Certification: 3							
	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:	1				_
	1								
	,								,
	Total Certified: 3								
	Total Restatement C	ertified: 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.

Medicare Pa	art B Average	Sales Price	Drug C	ertificatior	ı				Help		
Home Compliance Summary Product Data Financial Data Certification	Drug Data Pendi Reporting Period:	Drug Data Pending Certification for Reporting Period Q3 2014 Reporting Period: 23 2014 Select Option: Drug Data Pending Certification Course International Certification Co									
Re-statements Help Exit	Please resolve NDC/ARI0:10022-5678-11										
	Showing 1 Result	t.	Previous	First 1 Last	Next		<i></i>				
	Drug Identifier	Generic (Brand Name)	ASP	ASP units	Acquisition Cost	Cap Units Excluded	Status	Drug Details	Certify		
	10022-5678-11	LEVSIN INJECTION	11.333	22.333	44.333	1.000	SAVED	Product Financial			
	Showing 1 Result	t	Previous	First 1 Last	Next						
	< Reset All Checked Drugs Certify Selected Data Confirm All Data										

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

Medicare P	art B Average Sales Price	e	Complianc	e Summary Overvi	iew			Help
Home	Reporting Period: 03 2014	•						
Compliance Summary	Manufacturer: Select							
Product Data	View Compliance Overview Detail							
Financial Data	1	37						
Certification	Selected Quarter: Q3 2014 Pr	rior Quarter: Q2 2014	Prior Quarter: Q1 2014					
Re-statements]			All Manufacturers				
Help								
Exit		La	belers are out of com	bliance with data report	ing requirements.			
			20% of drugs a	e certified out of 30 tot	al drugs.			
			(3 Certi	hed, 3 Restatement Certified)				
	Missing: 1							
	Pending Certification: 20							
	Pending Restatement Certific	cation: 3						
	Total Certified: 3							
	Drug Identifier	Reporting Po	rriod ASP	ASP Units	WAC	CAP Units	Status	^
	51009-0733-82	Q3 2014	22.33	3 374.373	566.333		CERTIFIED	
	83278-7236-10	Q3 2014	22.99	5 1001.664	32.790	2.000	CERTIFIED	-
	GG100	Q3 2014	41.95	5 1262.533	120.000	2.000	CERTIFIED	-
			Exp	ort : 🔤 🎦				_
	4							*
	Total Restatement Certified:	3						
	Total New Drugs: 20							

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.

Medicare P	art B Average Sales P	rice	Compliar	nce Summary	Overview			Help		
Home	Reporting Period: 032	014 💌								
Compliance Summary	Manufacturer: Sele	d								
Product Data	View Compliance Overview Deb	ail								
Financial Data	l	· · · · · · · · · · · · · · · · · · ·								
Certification	Selected Quarter: Q3 2014	Prior Quarter: Q2 2014	Prior Quarter: Q1 2014							
Re-statements				All Manufactur	ers					
Help			holose are out of co	malianae with data	to repeting require	iner ente				
Exit		La	belers are out or co	mpliance with da	ita reporting req	uirements.				
			20% of drugs	are certified out	t of 30 total drugs	6.				
			0.0	rtified 3 Restatemen	t Certified)					
			() ()	i unea, o restatemen	n corumou)					
	Missing: 1									
	Pending Certification: 20)								
	Pending Restatement Co	ertification: 3								
	Total Certified: 3									
	Total Restatement Certil	fied: 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:									
	<i>ϵ</i>							÷ .		
	Total New Drugs: 20									

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

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

7.2.6 Total New Drugs

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

Medicare Pa	art B Average Sales Pr	ice	Complia	nce Summary	Overview			Help
Home	Reporting Period: 03 20	14 💌						
Compliance Summary	Manufacturer: Select			•				
Product Data	View Compliance Overview Detail	4						
Financial Data		D-1	- 0 01 0011					
Certification	Selected Quarter: Q3 2014	Phor Quarter: Q2 2014 Pho	r Quarter: Q1 2014					
Re-statements				All Manufacture	ers			
Help		Labo						
Exit		Labe	iers are out of co	ompliance with da	ta reporting req	uirements.		
			20% of drugs	s are certified out	of 30 total drug	ı.		
			(3 C	ertified, 3 Restatemen	t Certified)			
	Missing: 1							
	Pending Certification: 20							
	Pending Restatement Ce	rtification: 3						
	Total Certified: 3							
	Total Restatement Certifi	ed: 3						
	Total New Drugs: 20							
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status	4
	10022-5678-11	Q3 2014	11.333	22.333	44.333	1.000	RESTATE SAVED	8
	12345-4444-44	Q3 2014	2456.898	2222.222	3333.333		RE-STATED CERTIFIED	
	51009-0733-82	Q3 2014	22.333	374.373	566.333		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	

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 P	art B Average Sales Pri	ice	Complia	nce Summary	Overview			Help
Home	Reporting Period: 03201	4						
Compliance Summary	Manufacturer: Select							
Product Data	View Compliance Overview Detail							
Financial Data		Drive Overstein 02 2014	0.000	1				
Certification	Selected Quarter: Q3 2014	Phor Quarter: QZ 2014 Pric	r Quarter: Q1 2014					
Re-statements				All Manufacture	ers			
Help		Labe	ers are out of co	mpliance with da	ta reporting reg	uirements.		
Exit]	2404			an reporting req			
			20% of drugs	are certified out	of 30 total drug	5.		
			(3 Ce	ertified, 3 Restatemen	t Certified)			
	Missing: 1							
	Pending Certification: 20							
	Pending Restatement Cert	tification: 3						
	Total Certified: 3							
	Total Restatement Certifie	d: 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 : 🔽 🏪	4			

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

Opening ASPCSV.csv	
You have chosen to open:	
SPCSV.csv	
which is: Microsoft Office Excel Comma Separated Values File (775 bj from: http://aspweb.dcca.com	
What should Firefox do with this file?	
Open with Microsoft Office Excel (default)	
Save File	
Do this automatically for files like this from now on.	
OK Cancel	

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.

	А	В	С	D	E	F	G	н
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								

Figure 7-	14: CSV	Export	Option
-----------	---------	--------	--------

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	123458.777	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	123458.777	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