

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

Medicare Part B Drug Average Sales Price (ASP)

User Manual

Version 2.3 01/12/23

Document Number: DCCA.CMS.ASP User Manual.V2.3

Contract Number: HHSM-500-2014-00445G

Disclosure StatementAccording to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-XXXX (Expires XX/XX/XXXX). The time required to complete this information collection is estimated to average [Insert Time (hours or minutes)] per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ****CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained.

Table of Contents

1.	Introc	uction	1
	1.1 1.2 1.3 1.4	What is the Medicare Part B Drug Average Sales Price (ASP) Application Purpose of the ASP Application ASP Business Process The user creates an output file to share with OIG, so they can complete A comparison studies. Updates with the Average Manufacturer Price (AMP provided by OIG are added to the drug pricing file to replace the ASP for some billing codes. ASP User Roles	1 2 ASP)
	1.5	ASP Reference Materials	_
2.	ASP /	pplication Access	3
	2.1 2.2	 ASP Data Collection Application Access Process	4 10 15 15 15 of 16
		2.2.4 Tier 4 Support	16
3.	ASP /	pplication Home Page	17
		pplication Home Page ge NDC1/ALT ID - Submitter	
4.	Mana		18
4.	Mana	ge NDC1/ALT ID - Submitter	18 23 23
4. 5.	Mana Comp 5.1 5.2	ge NDC1/ALT ID - Submitter liance Summary Submitter	18 23 28
4. 5.	Mana Comp 5.1 5.2	ge NDC1/ALT ID - Submitter liance Summary Submitter Certifier	18 23 23 28 34 34 39 45
4. 5. 6.	Mana Comp 5.1 5.2 Produ 6.1 6.2 6.3 6.4	ge NDC1/ALT ID - Submitter liance Summary Submitter Certifier ct Data Add Product Data Upload Product Data Upload Product Data	
4. 5. 6.	Mana Comp 5.1 5.2 Produ 6.1 6.2 6.3 6.4	ge NDC1/ALT ID - Submitter	
4. 5. 6.	Mana Comp 5.1 5.2 Produ 6.1 6.2 6.3 6.4 Finan 7.1 7.2	ge NDC1/ALT ID - Submitter	

10. Assu	mptions	
	Assumptions - Submitter Assumptions – Certifier	
11. Re-St	atements	68
	Add/Edit Restate Financial Data Upload Re-State Financial Data	
12. Drug	Certification	77
Appendi	x A: Record of Changes	79
Appendi	x B: Acronyms	80
Appendi	x C: Field Definitions	82

List of Figures

Figure 2-16: Multi-Factor Authentication Information
Figure 2-17: Register Your Phone, Computer, or Email Page
Figure 2-18: Successful MFA Registration Message14
Figure 2-19: Request Acknowledgement Page15
Figure 3-1: My Portal Home Page17
Figure 3-2: ASP Application Home Page – ASP Submitter
Figure 3-3: ASP Application Home Page – ASP Certifier
Figure 4-1: Manage NDC1/ALT ID Screen19
Figure 4-2: Manage NDC/ALT ID - Filter 19
Figure 4-3: Manage NDC/ALT ID – NDC1 Field Populated20
Figure 4-4: Manage NDC/ALT ID – NDC1 Saved Successfully
Figure 4-5: Manage NDC/ALT ID – ALT ID Field Populated
Figure 4-6: Manage NDC/ALT ID – ALT ID Saved Successfully
Figure 4-7: Manage NDC/ALT ID – Select NDCs/ALT IDs for Assignment
Figure 4-8: Manage NDC/ALT ID – NDC1/ALT ID Assigned Successfully
Figure 5-1: Compliance Summary Overview Page: Submitter
Figure 5-2: Manufacturer's Compliance Summary Report: Submitter
Figure 5-3: Compliance Summary: Submitter - Missing
Figure 5-4: Compliance Summary: Submitter – Add/Edit Financial Data
Figure 5-5: Compliance Summary: Submitter – Financial Data Saved Successfully 26
Figure 5-6: Compliance Summary: Submitter – Pending Certification
Figure 5-7: Compliance Summary: Submitter – Pending Restatement Certification 27
Figure 5-8: Compliance Summary: Submitter – Total Certification
Figure 5-9: Compliance Summary: Submitter – Total Restatement Certification
Figure 5-10: Compliance Summary: Submitter – Total New Drugs
Figure 5-11: Compliance Summary Overview Page: Certifier
Figure 5-12: Manufacturer's Compliance Summary Report: Certifier

Figure 5-13: Compliance Summary: Certifier - Missing	30
Figure 5-14: Compliance Summary: Certifier – Pending Certification	31
Figure 5-15: Compliance Summary: Certifier – Pending Restatement Certification	31
Figure 5-16: Compliance Summary: Certifier – Total Certification	32
Figure 5-17: Compliance Summary: Certifier – Total Restatement Certification	32
Figure 5-18: Compliance Summary: Certifier – Total New Drugs	33
Figure 6-1: Add Product Data Screen	34
Figure 6-2: Add Product Data – Fields Populated	36
Figure 6-3: Add Product Data – Product Submission Saved Successfully	37
Figure 6-4: Add Product Data – Add Fields by Alternate ID	39
Figure 6-5: Add Product Data – Product Submission Saved Successfully	39
Figure 6-6: Upload Product Data Screen	40
Figure 6-7: File Directory Window	40
Figure 6-8: Upload Product Data Browse Field Populated	40
Figure 6-9: Upload Product Data Saved Successfully	
Figure 6-10: Upload Product File	41
Figure 6-11: Upload Product Data Column Editing Dropdown	42
Figure 6-12: Upload Product Data Format Cells Window	42
Figure 6-13: Upload Product Data Format Cells Custom Editing Example	43
Figure 6-14: Upload Product Data Format Cells Custom Editing Example	44
Figure 6-15: Upload Product Data Format Cells Date Custom Editing Example	45
Figure 6-16: Update Product Data Screen	46
Figure 6-17: Update Product Data Screen, Update by NDC Tab Fields Populated	46
Figure 6-18: Update Product Data Screen – Update by NDC Saved Successfully	48
Figure 6-19: Update Product Data Screen – Update by Alternate ID Updated Successfully	49
Figure 6-20: View Submitted Drugs Screen	50

Figure 7-1: Add/Edit Financial Data Screen51
Figure 7-2: Add/Edit Financial Data Screen – Fields Populated52
Figure 7-3: Add/Edit Financial Data Screen – Financial Data Saved53
Figure 7-4: Add/Edit Financial Data Screen – Selected Financial Data53
Figure 7-5: Upload Financial Data Screen54
Figure 7-6: File Directory Window54
Figure 7-7: Upload Financial Data Browse Field Populated54
Figure 7-8: Upload Financial Data Saved Successfully55
Figure 7-9: Upload Financial Data File55
Figure 7-10: Upload Financial Data Column Editing Dropdown
Figure 7-11: Upload Financial Data Format Cells Number Editing56
Figure 7-12: Upload Financial Data Format Cells Number Custom Editing Example 57
Figure 7-13: Upload Financial Data Format Cells Number Editing Example58
Figure 8-1: Generate One Time Password (OTP) Screen59
Figure 8-2: Generate OTP – Please select the Manufacturer name*: Field Populated59
Figure 8-3: OTP Generated Successfully60
Figure 9-1: Verify One Time Password (OTP) Screen61
Figure 9-2: Verify OTP – Enter OTP provided by your data submitter*: Field Populated 61
Figure 9-3: Verify OTP – OTP Verified Message61
Figure 10-1: Assumptions Screen - Submitter62
Figure 10-2: Assumptions – For Reporting Period Field Populated
Figure 10-3: Assumptions – Comments Field Populated63
Figure 10-4: Assumptions Saved Successfully63
Figure 10-5: File Directory Window64
Figure 10-6: Assumptions Saved Successfully64
Figure 10-7: Assumptions Listed64

	65
Figure 10-9: Assumptions – For Reporting Period Field Populated	65
Figure 10-10: Assumptions – Comments Field Populated	65
Figure 10-11: Assumptions Saved Successfully	66
Figure 10-12: File Directory Window	66
Figure 10-13: Assumptions Saved Successfully	67
Figure 10-14: Assumptions Listed	67
Figure 11-1: Add/Edit Restate Financial Data Screen	68
Figure 11-2: Add/Edit Restate Financial Data – Select Re-Statement Period and Dru Identifier	
Figure 11-3: Add/Edit Restate Financial Data – Add/Edit Data	69
Figure 11-4: Add/Edit Restate Financial Data – Data Saved Successfully	70
Figure 11-5: Upload Restate Financial Data Screen	70
Figure 11-6: Upload Restate Financial Data Screen – Select Re-Statement Field Populated	71
Figure 11-7: File Directory Window	71
Figure 11-7: File Directory Window Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated	
	71
Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data	71 72
Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully	71 72 72
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File 	71 72 72 73
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File Figure 11-11: Upload Restate Financial Data Column Editing Dropdown 	71 72 72 73 74
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File Figure 11-11: Upload Restate Financial Data Column Editing Dropdown Figure 11-12: Upload Restate Financial Data Format Cells Number Editing Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing 	71 72 72 73 74 75
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File Figure 11-11: Upload Restate Financial Data Column Editing Dropdown Figure 11-12: Upload Restate Financial Data Format Cells Number Editing Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing Example Figure 11-14: Upload Restate Financial Data Screen – Re-Stated Financial Data 	71 72 72 73 74 75 76
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File Figure 11-11: Upload Restate Financial Data Column Editing Dropdown Figure 11-12: Upload Restate Financial Data Format Cells Number Editing Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing Example Figure 11-14: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully 	71 72 72 73 74 75 76 77
 Figure 11-8: Upload Restate Financial Data Screen – Browse Field Populated Figure 11-9: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully Figure 11-10: Upload Restate Financial Data File Figure 11-11: Upload Restate Financial Data Column Editing Dropdown Figure 11-12: Upload Restate Financial Data Format Cells Number Editing Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing Example Figure 11-14: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully 	71 72 72 73 74 75 76 77 77

Figure 12-4: Drug Information	Successfully Certified	. 78
-------------------------------	------------------------	------

1. Introduction

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

Section 303 (b) and (c) of the Medicare Modernization Act (MMA) of 2003 revised the payment methodology for the vast majority of Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs). Per the MMA, beginning January 01, 2005, the ASP methodology is used to determine the payment limit for these drugs. Pricing for compounded drugs is performed by the local contractor. Additionally, the ASP methodology is used to determine the payment limit for certain eligible outlier service drugs and biologicals under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS), as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS). In accordance with Section 11101 of the Inflation Reduction Act of 2022, CMS also uses the ASP methodology to establish the inflation adjusted beneficiary coinsurance and inflationary rebates for certain single source drugs and biologicals with prices increasing at a rate faster than the rate of inflation. The ASP methodology is based on guarterly data submitted to the Centers for Medicare and Medicaid Services (CMS) by drug manufacturers. CMS supplies the Medicare Fee-for-Service (FFS) claims processing contractors with the drug pricing files for Medicare Part B drugs on a quarterly basis.

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

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

1.2 Purpose of the ASP Application

The purpose of the ASP Application is to:

- Provide users with an Internet-based software application for automating the collection, editing and processing of drug product pricing data received from drug manufacturers on a quarterly basis
- Eliminate data entry errors, data formatting errors, incomplete submitted data and to greatly reduce the process cycle time and resource time needed to provide the pricing to contractors through automation of the manually intensive processes
- Accepts and stores Medicare Part B drug data received from manufacturers

1.3 ASP Business Process

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

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

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

If the drug manufacturer has a large amount of drug data to report to Medicare, they may decide to submit their Medicare Part B ASP drug information by uploading their data via file transfer. In this case, the ASP drug data are entered into a formatted file that is in compliance with Medicare's specifications and it is uploaded. Along with the submission, the user can submit any pertinent information to share with CM regarding their drug product data submissions. The user can view and check their submitted file and resubmit, if necessary. If the file records do not meet the file transfer validations and edits, then they are rejected, and the drug manufacturer can resubmit the drug data through file transfer or enter it online. With both submission options, the drug manufacturer must certify the accuracy of the data at the time of submission in order for it to be accepted. Regardless, every instance a drug manufacturer submits data they must submit a drug certification along with their submission and they may submit multiple times within a submission time period. Once data have been submitted, the drug manufacturer can view all drug data certified in the current reporting period and view whether current and previous drug submissions are in compliance with the reporting requirements. With drug data corrections within the current reporting period, the user can correct the drug data via data entry or upload. If data needs to be reported after the quarter has ended, the drug manufacturer has the capability to report restated ASP data via upload or online for any reporting period (greater than or equal to Quarter 3 2018) to the ASP application at any time.

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

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

Once the drug manufacturer submits the Reporting Manufacturer data and it is successfully received by CM/Division of Data Analysis and Market-based Pricing (DDAMBP) 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/DDAMBP runs drug

submission reports. These reports include Impact Analysis Report, Management Reports and Manufacturer Reports.

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

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

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

1.5 ASP Reference Materials

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

- EIDM User Guide
- <u>ASP Data Reporting Templates</u>
- Contextual Help

Click on <u>EIDM Links</u> for any assistance with using the application and to view applicable videos

2. ASP Application Access

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

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

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

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

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

2.1 ASP Data Collection Application Access Process

ASP users with an existing CMS Portal username and password can skip Section 2.1.1 and continue on to Section 2.1.2 Requesting ASP Application Access. Users should allot up to 72 hours to receive access to the ASP Portal following the submission of a CMS Portal username and password and request for access to the ASP application.

2.1.1 Obtaining a CMS EIDM Username and Password

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

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

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

CMS.gov Enterprise Portal		📰 Find Your Application 🛛 Help 🔞 About 🔤 E-mail Alerts
		0
	CMS.gov Enterprise Portal	
	UserID	
1	Password	
	Agree to our <u>Terms & Conditions</u>	
11 marine	Login	
	Forgot your User ID or your Password?	
	New User Registration	

Figure 2-1: CMS Enterprise Portal Home Page

2. Click on the New User Registration button.

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

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



3. Select "FFSDCS: Fee-For-Service Data Collection System" from the dropdown list. The "Terms and Conditions" page opens, as shown in Figure 2-3.

Figure 2-3: Terms and Conditions Page

ep 1 of 3 - Select your application from the drop	down. You will then need to agree to the terms.	
FFDCS: Fee-For-Service Data Collection Sys	tem	~
Terms & Conditions		
OMB No. 0938-1236 Expiration Date: 04/30/2	017	
OMB No.0938-1236 Expiration Date: 04/30/201	7 (OMB Re-Certification Pending) Paperwork Reduction Act	
Consent to Monitoring		
	monitored. Unauthorized attempts to upload information and/or change information on this web site are str the Computer Fraud and Abuse Act of 1086 and Title 18 U.S.C. Soc 1001 and 1030. We encourage you to	-

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

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

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

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

2 of 3 - Please enter your personal a	and contact inform	mation.						
ields are required unless marked	'Optional'.							
Enter First Name	Enter Midd	lle Name (optional)	Enter Last Name			Suffix (op	tional)	~
Enter Social Security Number (optic	onal)	Birth Month 🔹 🗸	Birth Date	•	Birth Year	~		
Your Address US Based?								
Ves O No								
Enter Home Address #1			Enter Home Addr	ess #2 ((optional)			
Enter Home Address #1	State			ess #2 (i	optional)	Enter Zip	n+4 (optional)	
	State			ess #2 (optional)	Enter Zip	9+4 (optional)	
	State			ess #2 (optional)	Enter Zip	o+4 (optional)	
Enter City	State		enter Zip Code	ess #2 (optional)	Enter Zip	o+4 (optional)	
Enter City	State		enter Zip Code	ess #2 ((optional)	Enter Zip	o+4 (optional)	

Figure 2-4: Step #2: Register Your Information 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) and click on the **Next** button.

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

_	ser ID, Password	& Challenge Questions
Enter User ID		
Enter Password	Enter Confirm Password	
Select Challenge Question #1	~	Enter Challenge Question #1 Answer
Select Challenge Question #2	*	Enter Challenge Question #2 Answer
Select Challenge Question #3	~	Enter Challenge Question #3 Answer
Back	lext Cancel	

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

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

Note: The passwords must match before you can continue.

- 9. Select a Security Question from each of the three (3) dropdown lists for which the answer is known.
- 10. Enter the answers to the Security Questions in the corresponding "Answer" fields.

The fields populate as shown in Figure 2-6.

Figure 2-6. 9	Ston #3.	Croato Ilso	r ID Dass	word & Ch	allongo Que	stions Page	Donulated
i iyure 2-0. ($JICP \pi J.$	Ulcale USe	п ір, газз		anenye wue	Suons raye	r upulateu

jan and a start and a start a		
Password	Confirm Password	
		Challenge Question #1 Answer
		Challenge Question #2 Answer
		~

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

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

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

Figure 2-7: Registration Summary Page

Registration Summary		
1990: Fee Fae Service Dels Goliection System	*	
I fields are required unless marked "Optional".		
Enter Middle Hanne (optione)	India (sptional)	
Enter Jacial Jaccarity Hamler (sptimal)		
Name Address II	Enter Hume Address 82 (optional)	
	Zip Carla Enter Zip+1 (optional)	
Conditions		
Para Ludar		
Tenned Codes Tenned		
	Caderage Quadro II Arease	
~	Calley (ada Blance	
~		
Subset User Cancel		

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

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

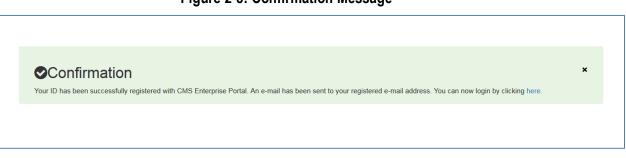


Figure 2-8: Confirmation Message

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

2.1.2 Requesting ASP Application Access

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

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

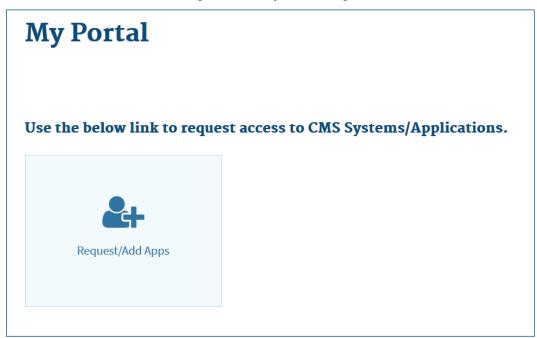
The CMS Enterprise Portal Home Page is shown in Figure 2-9.

A A A A A A A A A A A A A A A A A A A	Y
CMS.gov Enterprise Portal	
UserID	
Password	
Agree to our <u>Terms & Conditions</u>	1
Login	
Forgot your <u>User ID</u> or your <u>Password</u> ?	
New User Registration	

Figure 2-9: CMS Enterprise Portal Home Page

Enter your UserID and Password and click on the Login button.
 The "My Portal" page displays as shown in Figure 2-10.

Figure 2-10: My Portal Page



3. Click on Request/Add Apps.

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

Figure 2-11: Access Catalog Page

CMS.gov My Enterprise Portal						
Access Catalog Start typing	to filter apps	UEST ADMIN ROLE SHOW ALL	My Access			
ABC Test App ABC Test App for IMPL Help Desk Information 123-456-7590 SampleIMPL@cosinc.com	ACO-MS ACO-MS provides access to Shared Savings Program Accountable Care Orga More Help Desk Information 123-456-7890 SamelaTest@cssinc.com	FFSDCS The Fee for Service Data Collection System (FFSDCS) application collec More Help Desk Information 123-455-7890 SamoleIMPL@cosinc.com	You currently do not have access to any applications. Please use th access catalog to request access to the applications.	э		
Request Access BCRS Web The Benefits Coordination & Recovery System (BCRS) allows a user t More	Request Access Bundled Payments EFT Bundled Payments for Care Improvement Data File Transfer.	The CCIIO Enrollment Resolution and				
Help Desk Information 123-456-7980 SampleIMPL@cesinc.com	Help Desk Information 123-456-7890 SampleIMPL@ossinc.com	Reconciliation System (CERRS) supp More Help Desk Information 123-456-7690 SamcleIMPL@ossinc.com	My Pending Requests You do not have any pending requests at this time.			
Request Access	Request Access	Request Access				
The CMS WebEx (could offering consists of access to WebEx Training Cent More Help Desk Information 123-456-7890 SampleIMPL@cossinc.com	Access to this application is restricted to Trading Partners that exch More Help Desk Information 122-456-7800 SamoleIMPL@assinc.com	Connexion provides suppliers with secure online access to their Medica More Help Desk Information 123-456-7800 SampleIMPL@ossinc.com				
Request Access	Request Access DEX (Data Exchange) System	Request Access				
System) CO-OP Program Management System (CPMS) is	A system used to facilitate data sharing between and among State Medic More	sdfgsdf				

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

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

Figure 2-12: Request New System Access Page

My Access	Request New S	ystem Access
Request New System Access View and Manage My Access Annual Certification	establish credentials for Multi-F	e to request access. surance (LOA) and the role that you request access to, to satisfy system security requirements you may need to complete <u>Identity Verification,</u> actor Authentication (MFA), or change your password the next time you login to the system. This may require you to provide additional information as .If applicable, please note that your request cannot be fulfilled until Identity Verification is complete and Multi-Factor Authentication (MFA) is
	✤ System Description:	FFSDCS-The Fee for Service Data Colle
	* Role:	Select the Role
		Cancel

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

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

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

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

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

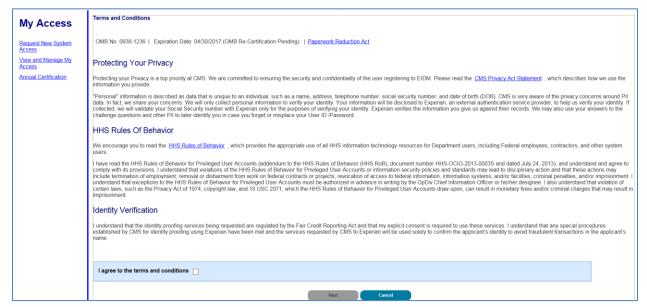
Figure 2-13: Identify Verification Page

My Access	Identity Verification
Request New System Access	To protect your privacy, you will need to complete Identity Verification successfully, before requesting access to the selected role. Below are a few items to keep in mind. • Ensure that you have entered your legal name, current home address, primary phone number, date of birth and E-mail address correctly. We will only collect personal
View and Manage My Access Annual Certification	information to verify your identity with Experian, an external Identity Verification provider. • Identity Verification involves Experian using information from your credit report to help confirm your identity. As a result, you may see an entry called a "soft inquiry" on your Experian credit report. Soft inquiries do not affect your credit score and you do not incur any charges related to them. • You may need to have access to your personal and credit report information, as the Experian application will pose questions to you, based on data in their files. For additional information, please see the Experian Consumer Assistance website -http://www.experian.com/help/
	If you elect to proceed now, you will be prompted with a Terms and Conditions statement that explains how your Personal Identifiable Information (PII) is used to confirm your identity. To continue this process, select 'Next'.
	Next Cancel

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

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

Figure 2-14: Terms and Conditions Page



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

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

Figure 2-15: Your Information Page

My Access	The diversity web to comp
Request time Sustain Access	Your Information
Viecand Manage IV Addess Annuel Certification	Deter prov legal het neres and de nares, as it may be regulard for blandly involution. For torus For torus Lase Neres Lase Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres Lose Neres
	Drie you Turul aldrea. In t will be seel for associations. - C-anal Addrease For white you Turul aldrea. - C-andrease Addrease
	Erner yur ful fulgi kadal asurity uvetar, sa ti nay las regulas for territy Verbackor bene Search Verba
	Come your date of both in MMISOUTYPY formed, and it may be required for Methodson Come of both Come of both
	B U.S. Nore Adjessed Orouge address Der post convert or med most here bei er spand for Sherity Verification. Anges Address Low Anges Address Low Convert of the Adjessed Adjesed Adjessed Adjessed Adjesed Adjessed Adj
	Deter yer annew yferen weter as it meg te segred fer Merley Verfiniten.
1	ter Const

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

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

CMS.gov My Enterprise Portal O Help O Help O La						
en reader mode Off Accessit	vility Settings					
My Access	Multi-Factor Authentication Information	1				
Request New System Access	To protect your privacy, you will need to add an additional level of security to your account. This will entail successfully registering your Phone,	Computer or E-mail, before continu	ing the role req	uest process.		
View and Manage My Access	To continue this process, please select 'Next'.					
Annual Certification	Next Cancel					

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

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

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

My Access	Register Your Phone, Computer, or E-mail			
Request New System Access Access Annual Certification	Adding a Security Code to your login also known as Multi-Factor Authentication (MFA) can make your login more secure by providing an extra layer of protection to your user name and password. You can associate the Security Code to your profile by registering your Phone, Computer or E-mail. Select the links below to find out more information about the options. > Phone/Tablet/PC/Laptop > Text Message Short Message Service (SMS) > Interactive Voice Response (IVR)			
	E-mail Please note that you are only allowed two attempts to register your MFA device. If you are unable to register your device within two attempts please log out, then log back in to try again.			
	Select the MFA Device Type that you want to use to login to secure applications from the dropdown menu below. * MFA Device Type: Select MFA Device Type			
	Next Cancel			

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

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

Figure 2-18: Successful MFA Registration Message

My Access	Register Your Phone, Computer, or E-mail You have successfully registered your Phone/Computer/E-mail to your user profile.
Request New System Access	ок
<u>View and Manage My</u> <u>Access</u>	
Annual Certification	

- 12. Click on the **OK** button.
 - A "Request Acknowledgement" screen displays as shown in Figure 2-19.

Figure 2-19: Request Acknowledgement Page

My Access	Request Acknowledgement
Request New System	Your request to access ASP using the ASP End User role has been successfully submitted.
Access	Your request id is : 2693343
View and Manage My Access	Use this number in all correspondence concerning this request. You will be contacted via E-mail after your request has been processed.
Annual Certification	ок

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

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

2.2 Points of Contact

2.2.1 Tier 1 Support – FFSDCS (ASP) Application Helpdesk

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

2.2.2 Tier 2 Support – CM Policy Support

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

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

• Remedy/SNOW Service Tickets

2.2.4 Tier 4 Support

• Data Center SR Workflow

3. ASP Application Home Page

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

After logging into the CMS Enterprise Portal (<u>https://portal.cms.gov/wps/portal/unauthportal/home/</u>), you will see your My Portal page.

Click on the Fee For Service Data Collection System (FFSDCS) icon to show the selections. Then click on the first link Average Sale Price (ASP) [Figure 3-2].

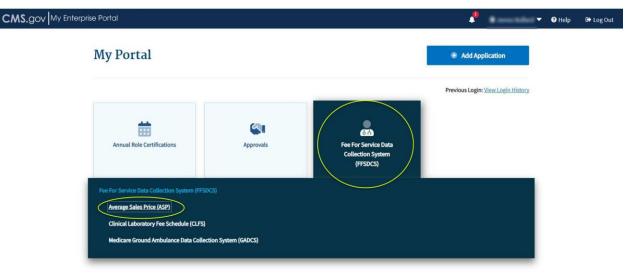


Figure 3-1: My Portal Home Page

If the user is new to the application, the user is placed directly into the Home page (for Submitter [Figure 3-2] or Certifier [Figure 3-33]).

Medicare Part B Av	verage Sales Price	Home		
Home	Welcome, Robert!		Downloads: Use	r Guide (PDF) File Upload Formats (zip
Compliance Summary				
llanage NDC1/ALT ID				
Product Data		Messages		
inancial Data		View All		
Generate One Time Password (OTP)				
ssumptions		ASP Business Process Flow	Reporting Sumr	nary
le-Statements		SUBMITTER	Pricing Quarter :	Q1 2019
lelp		Southing	Current Submission Period : Days Remaining in the Current Submission Period :	04/01/2019 - 05/01/2019
	Sabather	be Praduct Data Office (Inter Francel Data)	Currently Not Available please use Com	pliance Summary instead
		CERTIFIER		
	Centilier	Addrefation view (27)		
	Fe	or the best website experience, we recommend using the latest version of one of the following supported browsers: Chrome (version 49 or	greater), Firefox (version 10 or greater), or Internet Explorer 9.0 or greater	

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

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



4. Manage NDC1/ALT ID - Submitter

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

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

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

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

Medicare Part B Average Sales Pr	ice N	Nanage NDC1/ALT ID Help
Home		
Compliance Summary	NDC1/ALT ID Listings	Assigned NDC1/ALT ID Listings
Manage NDC1/ALT ID	Search/Filter:	
Product Data	01023	
Financial Data	38983 24241	
Generate One Time Password (OTP)	44333 44767 00658	Assign>>
Assumptions	00654 00653	
Re-Statements	00652 00651	
Help	00649 00648 00647 65600 65400 65400 65300 65200	
	Add New NDC1 O Add New ALT ID	
	NDC1:	
	Add	

Figure 4-1: Manage NDC1/ALT ID Screen

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

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

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

Medicare Part B Aver	age Sales Price	Manage NDC1/ALT ID Hereits Her	elp
Home			
Compliance Summary	NDC1/ALT ID Listings	Assigned NDC1/ALT ID Listings	
Manage NDC1/ALT ID	Search/Filter: 903		
Product Data	90371 903		
Financial Data	90375 90376		
Generate One Time Password (OTP)	90378 90385 90393	Assign>>	
Assumptions	90396		
Re-Statements			
Help			
	Add New NDC1 O Add New ALT ID		
	NDC1:		
	Add		

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

Note: the NDC1 must be 5 digits.

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

Medicare Part B Average Sales Price	М	lanage NDC1/ALT ID	<u>Help</u>
Home			
Compliance Summary	NDC1/ALT ID Listings	Assigned NDC1/ALT ID Listing	s
Manage NDC1/ALT ID	Search/Filter:		
Product Data	01023		
Financial Data	38983 24241		
Generate One Time Password (OTP)	44333 44767 00658	Assign>>	
Assumptions	00654 00653		
Re-Statements	00652 00651		
Help	00649 00648 00647 65800 65400 65300 65300	v	
	Add New NDC1 O Add New ALT ID		
	NDC1: 99999		
	Add		

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

4. Click on the **Add** button.

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

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

Medicare Part B Average Sales Pric	<u>e</u> M	lanage NDC1/ALT ID		H
Home				
Compliance Summary		99999 Successfully added.		
Manage NDC1/ALT ID				
Product Data				
Financial Data	NDC1/ALT ID Listings		Assigned NDC1/ALT ID Listings	
Generate One Time Password (OTP)	Search/Filter:			
Assumptions	99999 01023		<u>^</u>	
Re-Statements	38983 24241			
Help	44333 44767 00658 00654 00653 00652 00651 00649 00648 00648 00647 65800 65300	Assign>>	×	
	Add New NDC1 O Add New ALT ID NDC1:			
	Add			

5. To add an Alternate ID to the global list, click on the "Add New ALT ID" radio button and enter your new Alternate ID in the "ALT ID:" field.

Note: The ALT ID can be up to 23 alphanumeric characters including colon (:) period (.) and dash (-).

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

Medicare Part B Average Sales Price	Ma	anage NDC1/ALT ID		<u>Help</u>
Home				
Compliance Summary	NDC1/ALT ID Listings		Assigned NDC1/ALT ID Listings	
Manage NDC1/ALT ID	Search/Filter:			
Product Data	99999		A	
Financial Data	01023 38983			
Generate One Time Password (OTP)	24241 44333 44767	Assign>>		
Assumptions	00658 00654			
Re-Statements	00653 00652			
Help	00651 00649 00648 00647 65800 65400 65300 v			
	O Add New NDC1 ® Add New ALT ID ALT ID: (54321EDCBA) Add			

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

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

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

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

Medicare Part B Av	erage Sales Price	Manage NDC1/ALT ID	<u>Help</u>
Home			
Compliance Summary		54321EDCBA Successfully added.	
Manage NDC1/ALT ID		· · · · · · · · · · · · · · · · · · ·	
Product Data			
Financial Data	NDC1/ALT ID Listings	Assigned NDC1/ALT ID Listin	gs
Generate One Time Password (OTP)	Search/Filter:		
Assumptions	54321EDCBA ^		
Re-Statements	01023 38983		
Help	24241 44333 44767 00659 00654 00652 00652 00651 00649 00649 00647 65800 65400	Assign>>	
	Add New NDC1 O Add New AL NDC1:		
	Add		

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

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

Medicare Part B Average Sales Price	Ν	Manage NDC1/ALT ID		<u>Help</u>
Home				
Compliance Summary	NDC1/ALT ID Listings		Assigned NDC1/ALT ID Listings	
Manage NDC1/ALT ID	Search/Filter:			
Product Data	54321EDCBA		<u> </u>	
Financial Data	99999			
Generate One Time Password (OTP)	38983 24241 44333	Assign>>		
Assumptions	44767 00658			
Re-Statements Help	00654 00653 00652 00651 00649 00648 00647 65800			
	65400		v	
	Add New NDC1 O Add New ALT ID NDC1:			
	Add			

Fic	ure 4	-7:	Manage	NDC/AL	.T ID -	Select	NDCs/AL	T IDs	for A	Assian	iment
· · č	,				=						

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

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

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

Medicare Part B Aver	age Sales Price	Manage NDC1/ALT ID		Ŀ
Home				
Compliance Summary		Successfully assigned.		
Manage NDC1/ALT ID				
Product Data				
Financial Data	NDC1/ALT ID Listings		Assigned NDC1/ALT ID Listings	
Generate One Time Password (OTP)	Search/Filter:			
Assumptions	54321EDCBA ^		00658 ^	
Re-Statements	01023 38983		00653 00652	
Help	24241 44333 44767 65800 65500 65300 65500 65100 64900 64900 64900 64900 64900 64200 12345ABCDE 88888 ▼	Assign>>	00651 00649 00648 00647	
	NDC1:			

5. Compliance Summary

5.1 Submitter

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

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

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

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

Medicare Part B A	verage Sales Price Compliance Summary Overview	<u>Help</u>
Home		
Compliance Summary	Reporting Period *: 02 2019	
Manage NDC1/ALT ID	Manufacturer *: Select	
Product Data		
Financial Data	Drug Identifier:	
Generate One Time Password (OTP)	View Compliance Overview Detail	
Assumptions	Selected Quarter: Q2 2019	
Re-Statements	Labelers are out of compliance with data reporting requirements.	
Help	99% of drugs are certified out of 306 total drugs. (115 Certified, 190 Restatement Certified)	
	Missing 0	
	Pending Certification: 0	
	Pending Restatement Certification: 1	
	Total Certification: 115	
	Total Restatement Certification: 190	
	Total New Drugs: 3	

Figure 5-1: Compliance Summary Overview Page: Submitter

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

The summary results display for the selected manufacturer for the selected reporting period as shown in Figure 5-2.

Medicare Part B A	verage Sales Price Compliance Summary Overview	<u>Help</u>
Home		
Compliance Summary	Reporting Period *: Q2 2019	
Manage NDC1/ALT ID	Manufacturer *: RWH9	
Product Data		
Financial Data	Drug Identifier:	
Generate One Time Password (OTP)	View Compliance Overview Detail	
Assumptions	Selected Quarter: Q2 2019	
Re-Statements		
Help	Labelers are out of compliance with data reporting requirements.	
	95% of drugs are certified out of 320 total drugs.	
	(115 Certified, 190 Restatement Certified)	
	Missing 12	
	Pending Certification: 2	
	Pending Restatement Certification: 1	
	Total Certification: 115	
	Total Restatement Certification: 190	
	Total New Drugs: 4	

Figure 5-2: Manufacturer's Compliance Summary Report: Submitter

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

- Missing (go to step 3)
- Pending Certification (go to Step 6)
- Pending Restatement Certification (go to Step 8)
- Total Certification (go to Step 10)
- Total Restatement Certification (go to Step 12)
- Total New Drugs (go to Step 14)
- 3. To view drugs that are not compliant because the financial data for the drug have not been submitted, click on the **Missing** panel.

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

	verage Sales Price		Cor	npliance Summ	ary Overviev	v			Hel
ome									
ompliance Summary	Reporting Period *: Q2 2019								
anage NDC1/ALT ID									
oduct Data	Manufacturer *: Select		*						
nancial Data	Drug Identifier:								
enerate One Time ssword (OTP)	View Compliance Overview Detail								
sumptions	Selected Quarter: Q2 2019								
Statements	Labelers are out of compliance v	with data reporting requirements							
lp									
	95% of drugs are certified out of	320 total drugs.							
	(115 Certified, 190 Restatement Certified)								
	Missing 12								
	Missing 12 Showing 1 - 10 of 12 results.			Previous First 1,	2Last Next				^
	Showing 1 - 10 of 12 results. Drug Identifier	Reporting Period	ASP	Previous First 1, ASP Units	2Last Next WAC	CAP Units	Status	Resolve	^
	Showing 1 - 10 of 12 results.	Reporting Period Q2 2019	ASP			CAP Units	Status PENDING	Resolve Resolve	^
	Showing 1 - 10 of 12 results. Drug Identifier		ASP			CAP Units			^
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56	Q2 2019	ASP			CAP Units	PENDING	Resolve	^^
	Showing 1 - 10 of 12 results. Drug Identifier 7/777-1234-56 7/7777-2222-88	Q2 2019 Q2 2019	ASP			CAP Units	PENDING	Resolve Resolve	^
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-2222-88 77777-2345-01	Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING	Resolve Resolve Resolve	^
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-2234-501 77777-3356-02	Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING PENDING	Resolve Resolve Resolve Resolve	>
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-234-501 77777-3345-01 77777-3359-22	Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING PENDING	Resolve Resolve Resolve Resolve	• •
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-2234-501 77777-3356-02	Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING PENDING	Resolve Resolve Resolve Resolve	×
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-2234-501 77777-2345-01 77777-3359-22 c Pending Certification: 2	Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING PENDING	Resolve Resolve Resolve Resolve	> *
	Showing 1 - 10 of 12 results. Drug Identifier 77777-1234-56 77777-222-88 77777-2345-501 77777-3359-22 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019 Q2 2019	ASP			CAP Units	PENDING PENDING PENDING PENDING	Resolve Resolve Resolve Resolve) ^

Figure 5-3: Compliance Summary: Submitter - Missing

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

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

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

Note: If the reporting period selected is not the current reporting period, the "Add/Edit Restate Financial Data" screen displays.

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

Medicare Part B A	verage Sales Pric	erage Sales Price Add/Edit Financial Data									
Home											
Compliance Summary											
Manage NDC1/ALT ID		Please resolve NDC/Alt ID:77777-1234-56									
Product Data											
Financial Data	Data being subm	ta being submitted for: Q2 2019									
Add/Edit Financial Data	Drug Identifier:	Drug Identifier Search									
Upload Financial Data											
Generate One Time	Showing 1 result. Previous First 1 Last Next										
Password (OTP)	Drug Identifie	r	Generic (Brand Name)	Manufacturer's	Number of ASP	Wholesale	Number of Cap	Status	View Details		
Assumptions				ASP*	units*	Acquisition Cost*	Units Excluded				
Re-Statements	77777-1234-5	6 0.9%	NACL 500ML VIAFLO UK NP					PENDING	Product		
Help	Showing 1 result.			Previo	us First 1 Last Ne	xt					
				Expo	ort : CSV 🎽 🝌						
	¢			Si	ave Financial Data						

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

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

Medicare Part B A	verage Sales Price Add/Edit Financial Data									<u>He</u>	
Home											
Compliance Summary		Financial data saved									
Manage NDC1/ALT ID											
Product Data											
Financial Data	Data being submitte	Data being submitted for: Q2 2019									
Add/Edit Financial Data	Drug Identifier:		Search								
Upload Financial Data	Showing 1 result.			Previous	First 1 Last Next						
Generate One Time Password (OTP)	Drug Identifier		Generic (Brand Name)	Manufacturer's	Number of ASP	Wholesale	Number of Cap	Status	View Detail	ls	
Assumptions	77777-1234-56		0 9% NACL 500ML VIAFLO UK NP	ASP*	444.555	Acquisition Cost*	Units Excluded	SAVED	Product		
Re-Statements	Showing 1 result.										
Help	choning ribbun.										
	<.			Export							
	Export 🚾 🐃 🛵										

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

6. To view drugs that have saved financial data, but whose certifications are pending, click on the **Pending Certification** panel from the "Compliance Summary Overview" screen.

The "Pending Certification" report displays, as shown in Figure 5-6.

Figure 5-6: Co	ompliance S	Summary:	Submitter -	Pending	Certification
J		· · · ·		J	

Medicare Part B A	werage Sales Price	Com	pliance Summar	y Overview			He		
Home									
Compliance Summary Manage NDC1/ALT ID	Reporting Period *: Q2 2019								
Product Data	Manufacturer *: Select	Ŧ							
Financial Data	Drug Identifier:								
Generate One Time Password (OTP)	View Compliance Overview Detail								
Assumptions	Selected Quarter: Q2 2019								
Re-Statements	total and a second state of the second state o								
Help	Labelers are out of compliance with data repo								
	95% of drugs are certified out of 320 total dru	gs.							
	(HS Certified, H9 Restatement Certified)								
	Missing 11								
	Pending Certification: 3								
	Showing all 3 results.		Previous First 1 La	st Next			^		
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status		
	77777-0123-11	Q2 2019	333.444	444.555	555.666	222.333	SAVED		
	77777-1234-01	Q2 2019	333.333	444.444	555.555	222.222	SAVED		
	77777-1234-56	Q2 2019	333.333	444.555	555.666	222.333	SAVED		
	Showing all 3 results.		Previous First 1 La	st Next					
							× .		
	-								
	Pending Restatement Certification: 1								
	Total Certification: 115								
	Total Restatement Certification: 190								
	Total New Drugs: 4								

- 7. Click on the **Pending Certification** panel to hide the drug information that is pending certification.
- 8. To view drugs that have saved financial data that were restated but whose certifications are pending, click on the **Pending Restatement Certification** panel from the "Compliance Summary Overview" page.

The "Pending Restatement Certification" report displays, as shown in Figure 5-7.

Medicare Part B A	verage Sales Price		Compliance S	Summary Overvie	W			<u>Help</u>	
Home									
Compliance Summary									
Manage NDC1/ALT ID	Reporting Period *: Q2 2019								
Product Data	Manufacturer *: Select	•							
Financial Data	Drug Identifier:								
Generate One Time Password (OTP)	View Compliance Overview Detail								
Assumptions	Selected Quarter: Q2 2019								
Re-Statements									
Help	Labelers are out of compliance with data	reporting requirements.							
	95% of drugs are certified out of 320 tota	l drugs.							
	(115 Cartified, 110 Restatement Certified)								
	Missing 11								
	Pending Certification: 3								
	Pending Restatement Certification: 1								
	Showing 1 result.		Pre	ious First 1 Last Next					
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status		
	00710-0543-01	Q2 2019	142.592	14450.000	143.250		RESTATE SAVED		
	Showing 1 result.		Pre	ious First 1 Last Next					
	¢							>	
	Total Certification: 115								
	Total Restatement Certification: 190								
	Total New Drugs: 4								

Figure 5-7: Compliance Summary: Submitter – Pending Restatement Certification

- 9. Click on the **Pending Restatement Certification** panel to hide the drug information that is pending restatement certification.
- 10. To view drugs that have been certified during the selected reporting period, click on the **Total Certification** panel from the "Compliance Summary Overview" page.

The "Total Certification" report displays, as shown in Figure 5-8.

Figure 5-8: Compliance Summary: Submitter – Total Certification

Medicare Part B A	Average Sales Price	Com	pliance Summ	ary Overview			<u>!</u>			
Home										
Compliance Summary	Reporting Period *: Q2 2019									
Manage NDC1/ALT ID										
Product Data	Manufacturer *: Select	•								
inancial Data	Drug Identifier:									
Generate One Time Password (OTP)	View Compliance Overview Detail									
Assumptions	Selected Quarter: Q2 2019									
e-Statements										
Help	Labelers are out of compliance with data report	ing requirements.								
	95% of drugs are certified out of 320 total drugs	i.								
	(115 Certified, 100 Restatement Certified)									
	Missing 11									
	Pending Certification: 3									
	Pending Restatement Certification: 1									
	Total Certification: 115									
	Showing 1 - 10 of 115 results.			5, 7, 8, 9, 10Last Next						
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status			
	01023-0014-01	Q2 2019					CERTIFIED			
	01023-0014-50	Q2 2019					CERTIFIED			
	01023-0315-53	Q2 2019					CERTIFIED			
	01023-0315-93	Q2 2019					CERTIFIED			
	01002 0244 52	02.0040			1		CEDTRIED			
	<									
	Total Restatement Certification: 190									

- 11. Click on the **Total Certification** panel to hide the certified drug information.
- 12. To view the information for drugs that have been restated and certified, click on the **Total Restatement Certification** panel from the "Compliance Summary Overview" page.

The "Total Restatement Certification" report displays, as shown in Figure 5-9.

Medicare Part B A	verage Sales Price		Complia	nce Summary O	verview		
lome							
ompliance Summary Ianage NDC1/ALT ID	Reporting Period *: Q2 2019						
roduct Data	Manufacturer *: Select	*					
nancial Data	Drug Identifier:	1					
enerate One Time assword (OTP)	View Compliance Overview Detail						
ssumptions	Selected Quarter: Q2 2019						
-Statements							
elp	Labelers are out of compliance with	data reporting requirements.					
	95% of drugs are certified out of 320	total drugs.					
	(115 Certified, 190 Restatement Certified)						
	Missing 11						
	Pending Certification: 3						
	Pending Restatement Certification: 1						
	Total Certification: 115						
	Total Restatement Certification: 190						
	Showing 1 - 10 of 190 results.		Previous Fit	st 1, 2, 3, 4, 5, 6, 7, 8, 9, 1	0Last Next		
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status
	00699-3025-02	Q2 2019	14.880	11056.000	25.880		RE-STATED CERTIFIED
	00699-3026-02	Q2 2019	19.624	6905.000	28.980		RE-STATED CERTIFIED
	00699-3027-02	Q2 2019	9.934	46566.000	14.490		RE-STATED CERTIFIED
	00699-3028-02	Q2 2019	12.026	55030.000	18.110		RE-STATED CERTIFIED
	00000 2724 44	02 2010	27.004	2222 000	20.050		

Figure 5-9: Compliance Summary: Submitter – Total Restatement Certification

- 13. Click on the Total Restatement Certification panel to hide the certified drug information.
- 14. To view the product and financial information for new drugs that have been certified or saved, click on the **Total New Drugs** panel.

The "Total New Drugs" report displays, as shown in Figure 5-10.

Figure 5-10: Compliance Summary: Submitter – Total New Drugs

Medicare Part B A	verage Sales Price		Compliar	nce Summary Ov	erview		He			
Home Compliance Summary Manage NDC1/ALT ID Product Data Financial Data Genorate One Time Password (OTP) Assumptions Re-Statements Help	Reporting Period *: 02 2019 Manufacturer *: Seed Drug Identifier: View Compliance Overview Detail Selected Quarter: 02 2019 Labelers are out of compliance with dat 95% of drugs are certified out of 320 tot.									
	95% or drugs are certified out or 320 tot. (115 Certified, 190 Restatement Certified) Missing 11	a arugs.								
	Pending Certification: 3 Pending Restatement Certification: 1									
	Total Certification: 115 Total Restatement Certification: 190									
	Total New Drugs: 4			Previous First 1 Last Nex						
	Showing all 4 results. Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status			
	38983-9999-99	Q2 2019					CERTIFIED			
	38983-9999-99	Q2 2019					RE-STATED CERTIFIED			
	50000-5454-54	Q2 2019	4.444	55.555	4.444		RE-STATED CERTIFIED			
	77777-2222-88	Q2 2019					PENDING			

5.2 Certifier

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

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

The "Compliance Summary Overview" page displays.

Note: The "Compliance Summary Overview" screen lists the compliance summary for all manufacturers assigned as a default, as shown in Figure 5-11.

Medicare Part B A	verage Sales Price Compliance Summary Overview	Help
Home		
Compliance Summary	Reporting Period *: 012019	
Verify One Time Password (OTP)	Manufacturer*: Select •	
Certification	Drug Identifier:	
Help	View Compliance Overview Detail	
	Selected Quarter: Q1 2019 Labelers are out of compliance with data reporting requirements. 7% of drugs are certified out of 177 total drugs. (2 Certified, 10 Restatement Certified)	
	Missing 17	
	Pending Certification: 7	
	Pending Restatement Certification: 141	
	Total Certification: 2	
	Total Restatement Certification: 10	
	Total New Drugs: 11	

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

The summary results display for the selected manufacturer for the selected reporting period, as shown in Figure 5-12.

Medicare Part B A	Average Sales Price Compliance Summary Overview	<u>Help</u>
Home		
Compliance Summary	Reporting Period *: Q1 2019	
Verify One Time Password (OTP)	Manufacturer *: ABC	
Certification	Drug Identifier:	
Help	View Compliance Overview Detail	
	Selected Quarter: Q1 2019 Labeler is out of compliance with data reporting requirements. 50% of drugs are certified out of 10 total drugs. (2 Certified, 3 Restatement Certified) Missing 1	
	Pending Certification: 3	
	Pending Restatement Certification: 1	
	Total Certification: 2	
	Total Restatement Certification: 3	
	Total New Drugs: 2	

Figure 5-12: Manufacturer's Compliance Summary Report: Certifier

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

Drugs that are listed in the panels are:

- Missing (go to Step 3)
- Pending Certification (go to Step 6)
- Pending Restatement Certification (go to Step 8)
- Total Certification (go to Step 10)
- Total Restatement Certification (go to Step 12)
- Total New Drugs (go to Step 13)
- 3. To view drugs that are not compliant because the financial data for the drug have not been submitted, click on the **Missing** panel.

The "Missing" report displays with the status of "PENDING," as shown in Figure 5-13.

Medicare Part B A	verage Sales Price	Com	pliance Su	Immary Over	view		<u>Helj</u>	
Home								
Compliance Summary	Reporting Period *: Q1 2019 -							
Verify One Time Password (OTP)	Manufacturer *: ABC		Ŧ					
Certification	Drug Identifier:							
Help	View Compliance Overview Detail							
	Selected Quarter: Q1 2019 Labeler is out of compliance with data reporting requirements. 50% of drugs are certified out of 10 total drugs. (2 Certified, 3 Restatement Certified)							
	Showing 1 result. Previous First 1 Last Next							
	Drug Identifier Reporting Period ASP ASP Units WAC CAP Units Str							
	00999-3456-01	Q1 2019					PENDING	
	Showing 1 result.	I	Previo	us First 1 Last Next		1		

Figure 5-13: Compliance Summary: Certifier - Missing

- 4. Click on the **Missing** panel to hide the drug information that needs financial data.
- 5. To view drugs that have saved financial data but whose certifications are pending, click on the **Pending Certification** panel from the "Compliance Summary Overview" screen.

The "Pending Certification" report displays, as shown in Figure 5-14.

Medicare Part B Av	verage Sales Price	с	ompliance Su	ummary Over	view		<u> </u>	Help		
Home										
Compliance Summary Verify One Time	Reporting Period *: Q1 2019									
Password (OTP)	Manufacturer *: ABC		*							
Certification	Drug Identifier:									
Help	View Compliance Overview Detail									
	Selected Quarter: 01 2019 Labeler is out of compliance with data reporting requirements. 50% of drugs are certified out of 10 total drugs. (2 Certified, 3 Restatement Certified) Missing 1 Pending Certification: 3									
	Showing all 3 results.	Burnardan Burlad		us First 1 Last Next		615 U.S.	Status			
	Drug Identifier 00999-3333-11	Q1 2019	ASP 44.333	ASP Units 33.221	WAC 55.444	CAP Units	SAVED			
	00999-3333-66	Q1 2019	45.222	54.333	66.222		SAVED			
	00999-5123-22	Q1 2019	33.222	44.111	55.111	44.333	SAVED			
	00999-6789-59	Q1 2019	206.430	21812.820	241.520		SAVED			
	00999-7890-01	01 2019	2739 250	76487 840	2818 750		SAVED			

Figure 5-14: Compliance Summary: Certifier – Pending Certification

- 6. Click on the **Pending Certification** panel to hide the drug information that is pending certification.
- 7. To view drugs that have saved financial data that were restated but whose certifications are pending, click on the **Pending Restatement Certification** panel from the "Compliance Summary Overview" page.

The "Pending Restatement Certification" report displays, as shown in Figure 5-15.

Figure 5-15: Compliance	e Summarv: Certifier	– Pending Restatement Certification
J		

Medicare Part B A	verage Sales Price	C	ompliance Su	ummary Over	view			Help	
Home									
Compliance Summary	Reporting Period *: Q1 2019								
Verify One Time Password (OTP)	Manufacturer *: ABC		¥						
Certification	Drug Identifier:								
Help	View Compliance Overview Detail								
	Selected Quarter: Q1 2019 Labeler Is out of compliance with data reporting requirements. 50% of drugs are certified out of 10 total drugs. (2 Certified, 3 Restatement Certified) Missing 1 Pending Certification: 3 Pending Certification: 1								
	Showing 1 result.	1	1	us First 1 Last Next	1	1	1		
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status	4	
	00999-2222-22	Q1 2019	555.556	666.666	777.777	888.888	RESTATE SAVED		
	66995-0018-20	Q1 2019	18.940	49050.000	29.000		RESTATE SAVED		
	66995-0022-01	Q1 2019	45.540	385.000	46.470		RESTATE SAVED		
	66995-0039-28	Q1 2019	37.630	79397.000	75.370		RESTATE SAVED		

- 8. Click on the **Pending Restatement Certification** panel to hide the drug information that is pending restatement certification
- 9. To view drugs that have been certified during the selected reporting period, click on the **Total Certification** panel from the "Compliance Summary Overview" page.

The "Total Certification" report displays, as shown in Figure 5-16.

Medicare Part B A	verage Sales Price	Com	pliance Sum	mary Overview			Hel			
Home										
Compliance Summary	Reporting Period *: Q1 2019									
Verify One Time Password (OTP)	Manufacturer *: ABC									
Certification	Drug Identifier:									
Help	View Compliance Overview Detail									
	Selected Quarter: 01 2019 Labeler is out of compliance with data reporting requirements. 50%, of drugs are certified out of 10 total drugs. (2 Certified, 3 Restatement Certified) Missing 1 Pending Certification: 3 Pending Restatement Certification: 1 Total Certification: 2									
	Showing all 2 results.			First 1 Last Next						
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status			
	00999-1234-01	Q1 2019	6444.545	19639.020	773.100		CERTIFIED			
	00999-4567-01	Q1 2019	104.650	3211566.740	130.000		CERTIFIED			
	Showing all 2 results.		Previous F	First 1 Last Next						

Figure 5-16: Compliance Summary: Certifier – Total Certification

- 10. Click on the **Total Certification** panel to hide the certified drug information.
- 11. To view the information for drugs that have been restated and certified, click on the **Total Restatement Certification** panel from the "Compliance Summary Overview" page.

The "Total Restatement Certification" report displays, as shown in Figure 5-17.

Figure 5-17:	Compliance S	Summary: Certifier -	- Total Restatement Certification
--------------	--------------	----------------------	-----------------------------------

Medicare Part B A	verage Sales Price		Compliand	e Summary (Overview		
Home Compliance Summary Verify One Time Password (OTP)	Manufacturer *: ABC Drug Identifier: View Compliance Overview Detail		*				
Certification Help	Selected Quarter: Q1 2019						
	Labeler is out of compliance 50% of drugs are certified ou (2 Certified, 3 Restatement Certified Missing 1 Pending Certification: 3 Pending Restatement Certifica Total Certification: 2 Total Restatement Certification	tion: 1	ts.				
	Showing all 3 results.			Previous First 1 Last	Next)
	Drug Identifier	Reporting Period	ASP	ASP Units	WAC	CAP Units	Status
	00999-0123-11	Q1 2019	545.370	224.880	111.222	0.000	RE-STATED CERTIFIED
	00999-2345-01	Q1 2019	111.222	90.100	148.190		RE-STATED CERTIFIED
	00999-5678-17	Q1 2019	17.180	329708.240	42.000	222.333	RE-STATED CERTIFIED
	66995-0003-02	Q1 2019	16.130	17678.000	18.290		RE-STATED CERTIFIED
	66995-0005-01	O1 2019	33 380	3370 000	38 540		RE-STATED CERTIFIED

- 12. Click on the **Total Restatement Certification** panel to hide the certified drug information.
- To view the product and financial information for new drugs that have been certified or saved, click on the Total New Drugs panel from the "Compliance Summary Overview" page.

The "Total New Drugs" report displays, as shown in Figure 5-18.

Figure 5-18: Compliance Summary: Certifier – Total New Drugs

Medicare Part B A	verage Sales Price		Complian	ce Summary O	verview		Н
Home Compliance Summary Verify One Time Password (OTP) Certification Help	Reporting Period *: 02 2019 w Manufacturer *: Seat Drug Identifier: View Compliance Oveniew Detail	•					
	Selected Quarter: Q2 2019 Labelers are out of compliance with in 97% of drugs are certified out of 77 tr (72 certified, 2 Restatement Certified) Missing 0 Pending Certification: 1 Pending Restatement Certification: 1						
	Total Certification: 73 Total Certification: 73 Total Restatement Certification: 2 Total New Drugs: 3 Showing all 3 results. Drug Identifier	Reporting Period	ASP	Previous First 1 Last Ne: ASP Units	xt WAC	CAP Units	Status)
	38983-9999-99	Q2 2019 Q2 2019	55.555	55.555	55.555	55.555	CERTIFIED RE-STATED CERTIFIED
	38983-9999-99 Showing all 3 results.	Q2 2019		Previous First 1 Last Ne:			CERTIFIED

14. Click on the **Total New Drugs** panel to hide the certified drug information.

6. Product Data

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

6.1 Add Product Data

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

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

The "Add Product Data" screen displays, as shown in Figure 6-1.

Medicare Part B A	verage Sales Price	Add Product Data	<u>Help</u>
Home			
Compliance Summary	* denotes required field		
Manage NDC1/ALT ID	Add by NDC Add by Alternate ID		
Product Data	NDC1* Select	Manufacturer Name* Date of First Sale*	
Add Product Data	NDC2*	Date must be in MM/DD/YYYY format	
Update Product Data		Expiration Date of Final Lot Sold	
Upload Product Data	NDC3*	Has Brand Name? Date must be in MM/DD/YYYY format	
View Submitted Drugs		Generic Name* Select Generic Name *	
Financial Data			
Generate One Time Password (OTP)			
Assumptions	Strength of the Product*	Add New FDA Application Numbers	
Re-Statements		FDA Approval Date" FDA Approval Type"	
Help	Volume per Item*	Select *	
	Number of Items per NDC*	Date must be in MM/DD/YYYY format FDA Application Number/Registration Number*	
		Save	

Figure 6-1: Add Product Data Screen

 To add fields by NDC, select the "Add by NDC" tab and use the following requirements: Note: To add fields by Alternate ID, go to step 4.

NDC1: dropdown

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

NDC2: numeric required 4-digit entry

NDC3: numeric required 2-digit entry
Manufacturer Name: required limited to 250 characters
Note: When entering Product Data for the same Manufacturer more than once, be sure that the spelling is the same each time for that Manufacturer. If data were entered through "Upload Product Data," the spelling must match that as well.
Has Brand Name?: checkbox optional
Brand Name: field is only displayed if the "Has Brand Name?" box is checked required if "Has Brand Name?" box is checked limited to 250 characters
Generic Name: dropdown list required
New Generic Name: displayed only if selecting "Add New Generic Name" from the "Generic Name" dropdown list required limited to 250 characters
Date of First Sale: MM/DD/YYYY format required cannot occur before the FDA approval date must occur prior to the "Current Reporting Period" start date
Expiration Date of Final Lot Sold: MM/DD/YYYY format optional
Strength of the Product: required limited to 500 characters
Volume Per Item: required limited to 250 characters
Number of Items per NDC: numeric required limited to 9 digits and 2 decimal places
FDA Approval Date: required MM/DD/YYYY format must be prior to "Current Reporting Period" start date

FDA Application Num	ber/Registration N	umber:	required alphanumeric up to 10 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link
FDA Approval Type:	required dropdown list		
		can hav	ll characters ve up to 2 more optional entries by J on the "Add New Application

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

Medicare Part B A	verage Sales Price	Add Product Data	<u>Help</u>
Home Compliance Summary	* denotes required field		
Manage NDC1/ALT ID Product Data Add Product Data Update Product Data Upload Product Data View Submitted Drugs Financial Data	Add by NDC Add by Alternate ID NDC1* 66666 NDC2* 2222 NDC3* 44	Manufacturer Name* TEST - New Manufacturer Test - New Manufacturer Has Brand Name? Generic Name* 0 9% NACL 250ML VIAFLO UK NP *	06/01/2019
Generate One Time Password (OTP) Assumptions Re-Statements Help	Strength of the Product* 1000 Volume per Item* 10 Number of Items per NDC*	Add New FDA Application Numbers FDA Approval Date* G5/05/2019 Date must be in MMDD0YYYY format FDA Application Number/Registration Number* [4444 Save	

Figure 6-2: Add Product Data – Fields Populated

3. Click on the **Save** button.

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

Medicare Part B A	verage Sales Price	Add Product Data	<u>Help</u>
Home			
Compliance Summary		66666-2222-44 product data has been saved successfully.	
Manage NDC1/ALT ID			
Product Data			
Add Product Data			
Update Product Data	* denotes required field		
Upload Product Data	Add by NDC Add by Alternate ID		
View Submitted Drugs	NDC1* Select	Manufacturer Name*	Date of First Sale"
Financial Data	NDC2*		Date must be in MM/DD/YYYY format
Generate One Time Password (OTP)	NDC3*	Has Brand Name?	Expiration Date of Final Lot Sold Date must be in MM/DD/YYYY format
Assumptions		Generic Name* Select Generic Name *	
Re-Statements			
Help			
	Strength of the Product'	Add New FDA Application Numbers	
	Volume per item*	FDA Approval Date" FDA Approval Type" Date must be in MMDD/YYYY format	
	Number of Items per NDC*	FDA Application Number/Registration FDA Application Supplement Number'	umber:
		Save	

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

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

Alternate ID: required dropdown

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

Manufacturer Name: required limited to 250 characters

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

- Has Brand Name?: checkbox optional
- Brand Name: field is only displayed if the "Has Brand Name?" box is checked required if "Has Brand Name?" box is checked limited to 250 characters
- Generic Name: dropdown list required
- New Generic Name: only displayed when selecting "Add New Generic Name" from the "Generic Name" dropdown list required limited to 250 characters

Date of First Sale:	numeric cannot occur befo	(Y format ir before the FDA approval date prior to the "Current Reporting Period" start date					
Expiration Date of		I/DD/YYYY format ional					
Strength of the Pro	duct: required limited to 50	0 characters					
Volume Per Item:	required limited to 250 chara	acters					
Number of Items p		neric uired to 9 digits allowed and 2 decimal places					
FDA Approval Date	MM/DD/YYYY fo	ormat "Current Reporting Period" start date					
FDA Application N	umber/Registration	Number: optional alphanumeric up to 10 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link					
FDA Approval Type	e: optional dropdown list						
FDA Application So	upplement Number:	alphanumeric optional up to 9 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link					

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

Medicare Part B A	verage Sales Price	Add Product Data	Help
Home			
Compliance Summary	* denotes required field		
Manage NDC1/ALT ID	Add by NDC Add by Alternate ID		
Product Data	Alternate ID* 5432AMDC *	Manufacturer Name" Date of First Sale"	5/05/2018
Add Product Data	543200DC *	TEST - Manufacturer Name by Alternate ID Date must be in MM/DD/YYYY format	1032010
Update Product Data		Expiration Date of Final Lot Sold	
Upload Product Data		Date must be in MMDD/YYYY format	
View Submitted Drugs		Generic Name* 0 9% NACL 250ML VIAFLO UK NP *	
Financial Data			
Generate One Time Password (OTP)			
Assumptions	Strength of the Product"	Add New FDA Application Numbers	
Re-Statements	1000	FDA Approval Date FDA Approval Type	
Help		Select *	
	Volume per Item*	Date must be in MM/DD/YYYY format	
	100	FDA Application Number/Registration Number FDA Application Supplement Number	
	Number of items per Alternate ID* 1.00		
		Save	

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

5. Click on the Save button.

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

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

Medicare Part B A	werage Sales Price	Add Pro	duct Data		<u>Help</u>
Home Compliance Summary Manage NDC1/ALT ID		5432AMDC product	t data has been saved successfully.		
Product Data Add Product Data Update Product Data Upload Product Data View Submitted Drugs Financial Data Generate One Time Password (OTP) Assumptions Re-Statements Help	* denotes required field Add by NDC Add by Alternate ID NDC1* Select NDC2* NDC3*	• Manufacturer Name* Has Brand Name? Generic Name*	Select Generic Name	Date of First Sale* Date must be in MMDD/YYYY format Expiration Date of Final Lot Sold Date must be in MMDD/YYYY format	
	Strength of the Product* Volume per Item* Number of Items per NDC*	Add New FDA Application Numbers FDA Approval Date* Date must be in MMDD0/YYYY format FDA Application Number/Registration Number*	FDA Approval Type* Select FDA Application Supplement Save	Number	

6.2 Upload Product Data

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

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

The "Upload Product Data" screen displays, as shown in Figure 6-6.

Figure 6-6: Upload Product Data Screen

Medicare Part B A	rerage Sales Price Upload Product Data	Help
Home		
Compliance Summary		
Manage NDC1/ALT ID	Refresh	
Product Data	Last three uploaded files	
Add Product Data	No data exists.	
Update Product Data		
Upload Product Data	s Browse for new or corrected product data	>
View Submitted Drugs	brows to new or conected product data	
Financial Data	Browse No file selected.	
Generate One Time	Click here for acceptable file formats	
Password (OTP)	Upload	
Assumptions		
Re-Statements		
Help		

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

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

Figure 6-7: File Directory Window

Financial Data_Test	7/2/2018 11:52 AM	Microsoft Excel Comma Separated Values File	8 KB
Product Data_Test	4/16/2018 3:43 PM	Microsoft Excel Comma Separated Values File	13 KB

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

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

Figure 6-8: Upload Product Data Browse Field Populated

Medicare Part B A	verage Sales Price Upload Product Data	<u>Hel</u> j
Home		
Compliance Summary		
Manage NDC1/ALT ID	Refresh	
Product Data	Last three uploaded files	
Add Product Data	No data exists.	
Update Product Data		
Upload Product Data	C Browse for new or corrected product data	>
View Submitted Drugs		
Financial Data	Browse Product Data_Test1.csv	
Generate One Time	Click here for acceptable file formats	
Password (OTP)	Upload	
Assumptions		
Re-Statements		
Help		

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

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

Note: ASP offers a "Refresh" button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say "Processing." If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say "Completed."

Medicare Part B Avera	ige Sales Price			Սբ	load Product I	Data										He
Home																
Compliance Summary Manage NDC1/ALT ID	Refesh															
Product Data	Last three uploaded files												_			_
Add Product Data	File Name		Upload Type		Upload Date					Statu				Re	eporting Period	
Ipdate Product Data	Product Data_Text2.c		PRODUCT		2019-10-31 15:51					Comple					Q3 2019	
Upload Product Data	Product Date _ Text2.c		PRODUCT		2019-09-12 11:07					Comple			_		Q2 2019	_
View Submitted Drugs	Product Data Test3.c	<u>av</u>	PRODUCT		2019-09-12 11:05	5:58.0				Validation	errors				Q2 2019	
inancial Data	c															A
lenerate One Time lassword (OTP)	Browse for new or corrected product data															
ssumptions	Browse No file selected.															
e-Statements	Click here for acceptable file formats															
elp	Upload															
	port of Transmitted Drugs via File Upload			8 out of 1	8 product data has been sav	ved success	fully.									
s	rowing all 8 results.				Previous First 1 Last											
	Drug identifier	Manufactu	irer Name	Generic (Brand N		Strength of Product	Volume per Item	Number of Items per NDC/AltD	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval Type	FDA App #	FDA Supp #	FDA Approval Date	Status	
	66666-1234-01	TEST - NEW MA	ANUFACTURER	DR00032		2 mg/ml	5 ml	1.00	02/01/2005		BLA	103575	5110	12/16/2003	Data Uploaded	
	66666-2345-01	TEST - NEW MA	ANUFACTURER	DR00544		200 MG	1	1.00	05/16/1996		NDA	20509	70	05/15/1998	Data Uploaded	
	66666-3456-01	66656-3456-01 TEST - NEW MANUFACTURER		DR00544		1 GM	1	1.00	05/16/1996		NDA	20509	70	05/15/1998	Data Uploaded	
	66666-4567-01	TEST - NEW MA	ANUFACTURER	DRG0245	1	00units/ml	10 ml	1.00	07/15/1998		NDA	20563	128	06/14/1996	Data Uploaded	
	66666-6678-17	TEST - NEW MA	ANUFACTURER	DRG0248	1	00units/ml	3 ml	1.00	01/04/2010		NDA	20563	128	06/14/1996	Data Uploaded	
	66666-6789-59	TEST - NEW MA	ANUFACTURER	DRG0245	1	00units/ml	3 ml	5.00	08/02/2000		NDA	20563	128	06/14/1996	Data Uploaded	
	66666-7890-01	TEST - NEW MANUFACTURER		DRG0579		500 mg	1	1.00	02/13/2004		NDA	21462	40	02/04/2004	Data Uploaded	
	66666-0123-11	00000-0123-11 TEST - NEW MANUFACTURER				210 MG	1	1.00	03/01/2010		NDA	22173	14	12/11/2009	Data Uploaded	
8	rowing all 8 results.				Previous First 1 Last Export : 📷 🏁 🎽											

Figure 6-9: Upload	Product Data	Saved Successfully
--------------------	--------------	--------------------

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

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 0. To be certain of file column formatting, click on the "Click here for acceptable file formats" link, or follow the criteria below.

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

A	1	>	< 🗸	<i>f</i> _x Ma	nufacture	er's Name															
4	А	В	с	D	E	F	G H	1		ј к	L	м	N	0	Р	Q	R	S	т	U	v
1	Manufact	NDC1	NDC2	NDC3	Alternate	el Generic N	Brand Nar Strength	c Volume	P Num	iber o Expiratio	n Date of Firs	FDA Appli I	FDA Appli	FDA App	re Addition	na Additio	na Additio	na Additiona	a FDA Approval D	ate	
2	ELC	647	7140	1		DRG0032	2 mg/ml	5 ml		1	2/1/2005	103575	5110	BLA					12/16/2003		
3	ELC	647	7501	1		DRG0544	200 MG		1	1	5/16/1996	20509	70	NDA					5/15/1996		
ŧ	ELC	647	7502	1		DRG0544	1 GM		1	1	5/16/1996	20509	70	NDA					5/15/1996		
5	ELC	647	7510	1		DRG0245	100units/	'i 10 ml		1	7/15/1996	20563	126	NDA					6/14/1996		
5	ELC	647	7510	17		DRG0245	100units	r 3 ml		1	1/4/2010	20563	126	NDA					6/14/1996		
7	ELC	647	7516	59		DRG0245	100units,	r 3 ml		5	8/2/2000	20563	126	NDA					6/14/1996		
3	ELC	647	7623	1		DRG0579	500 mg		1	1	2/13/2004	21462	40	NDA					2/4/2004		
9	ELC	647	7635	11		DRG0294	210 MG		1	1	3/1/2010	22173	14	NDA					12/11/2009		
0	ELC	647	7636	11		DRG0294	300 MG		1	1	3/1/2010	22173	14	NDA					12/11/2009		
1	ELC	647	7637	11		DRG0294	405 MG		1	1	3/1/2010	22173	14	NDA					12/11/2009		
2	ELC	647	7640	1		DRG0579	100 mg		1	1	1/10/2008	21462	40	NDA					2/4/2004		
3	ELC	647	8031	1		DRG0216	1 mg		1	1	2/22/1999	20928	44	NDA					9/11/1998		
4	ELC	647	8215	1		DRG0246	100units,	'i 10 ml		1	7/1/1983	18780	138	NDA					10/28/1982		
5	ELC	647	8215	17		DRG0246	100units,	13 ml		1	1/4/2010	18780	138	NDA					10/28/1982		
6	ELC	647	8215	91		DRG0246	100units,	'i 10 ml		1	8/16/2010	18780	138	NDA					10/28/1982		
7	ELC	647	8315	17		DRG0246	100units,	r 3 ml		1	7/12/2010	18781	124	NDA					7/1/1983		
8	ELC	647	8501	1		DRG0246	500 units	/ 20 ml		1	12/11/1996	18780	138	NDA					10/28/1982		
9	ELC	647	8725	59		DRG0245	100units,	r 3 ml		5	11/9/1998	20563	126	NDA					6/14/1996		
0	BMSC	648	293	5		DRG0384	40mg/ml		1	1	9/30/1990	14901		NDA					2/1/1965		
1	BMSC	648	293	20		DRG0384	40mg/ml		5	1	9/30/1990	14901		NDA					2/1/1965		
2	BMSC	648	293	28		DRG0384	40mg/ml	1	0	1	9/30/1990	14901		NDA					2/1/1965		
3	BMSC	648	371	13		DRG0074	250mg		1	1	6/27/2011	125288		BLA					6/15/2011		
4	BMSC	648	494	20		DRG0384	10mg/ml		5	1	9/30/1990	12041		NDA					1/4/1960		
5	BMSC	648	2187	10		DRG0031	250mg		1	1	2/9/2006	125118		BLA					12/23/2005		
6	BMSC	648	2327	11		DRG0563	5mg/ml	1	0	1	4/6/2011	125377		BLA					3/25/2011		
7	BMSC	648	2328	22		DRG0563	5mg/ml	4	10	1	4/6/2011	125377		BLA					3/25/2011		
8	GNTHI	649	188	9		DRG0232	3MG/3M		0	1	3/2/2006	21858		NDA					1/6/2006		
9	GNTHI	649	191	9		DRG0233	3MG/3M		0	1	3/2/2006	21859		NDA					1/6/2006		
0	GNTHI	649	259	1		DRG0465	250 MG.	2	0	100	6/12/1995	50722		NDA					5/3/1995		
1	GNTHI	649	259	5		DRG0465	250 MG.	2	0	1440	6/12/1995	50722		NDA					5/3/1995		
2	GNTHI	649	259	43		DRG0465	250 MG.	:	0	500	6/12/1995	50722		NDA					5/3/1995		
3	GNTHI	649	260	1		DRG0465	500MG T/	4	0	100	8/12/1997	50723		NDA					6/19/1997		
4	GNTHI	649	260	43		DRG0465	500MG T	4	0	500	8/12/1997	50723		NDA					6/19/1997		
5	GNTHI	649	261	29		DRG0465	175ML M	L	0	175	5/10/1999	50759		NDA					10/1/1998		
6	GNTHI	649	1100	20		DRG0489	150 MG T		0	60	5/15/1998	20896		NDA					4/30/1998		
	GNTHI	649	1101	50		DRG0489	500MG T		0	120	5/15/1998	20896		NDA					4/30/1998		

Figure 6-10: Upload Product File

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

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

Α	В		C	n	E	F	
Manufact	NDC1	፠	Cu <u>t</u>		Alternate	Generic N	Bra
ELC	6	Ē	<u>С</u> ору			DRG0032	
ELC	6	ĥ	Paste Op	tions:		DRG0544	
ELC	6		ھ			DRG0544	
ELC	6					DRG0245	
ELC	6		Paste Spe	ecial		DRG0245	
ELC	6		Insert			DRG0245	
ELC	6		-			DRG0579	
ELC	6		<u>D</u> elete			DRG0294	
ELC	6		Clear Co	ntents		DRG0294	
ELC	6	8- 0-	Format C	ells		DRG0294	
ELC	6		Column	2		DRG0579	
ELC	6			<u>vv</u> latn		DRG0216	
ELC	6		<u>H</u> ide			DRG0246	
ELC	6		<u>U</u> nhide			DRG0246	
ELC	64	4/	8215	9	1	DRG0246	
ELC	64	47	8315	1	7	DRG0246	
FLC	6/	17	8501		1	DRG0246	

Figure 6-11: Upload Product Data Column Editing Dropdown

7. Select "Format Cells."

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

								TEAL
Format Cells						?	\times	e & Cen
Number	Alignment	Font	Border	Fill	Protection			e a cen
Category:								
General Number Currency Accounting Date Time Percentage Fraction Scientific Text Special Custom	used for gener	Use Negativ 1234.1 (1234.2) (1234.3) (1234.3)	1 places: 2 1000 Separat e numbers: 0 0 0) 0)		ounting offer s	pecialized formatti	ing for	l rolume ml ml ml
monetary va	alue.							0 ml ml
								0 ml
								ml
					OK	Car	ncel	.0 ml
9 ELC	647	8725	59		DRG0245		0units/r	3 ml
0 BMSC	648	3 293	5		DRG0384	40	mg/ml	

Figure 6-12: Upload Product Data Format Cells Window

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

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

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

Format Cells						?	×	e & Cente	r • \$ •
Number	Alignment	Font	Border	Fill	Protection				5
Category:									100
General Number Currency		Samp NDC						1	J
Accounting		<u>T</u> ype:						/olume P	Number o
Date Time		00000						ml	1
Percentage		Gener	al				^	1	1
Fraction Scientific		0						1	1
Text		#,##0						0 ml	1
Special Custom		#,##0	.00 _);(#,##0)					ml	1
Custom			_);[Red](#,##0)				ml	5
			.00_);(#,##0.00					1	1
			.00_);[Red](#,# 0_);(\$#,##0)	#0.00)				1	1
		\$#,##	0_);[Red](\$#,#	#0)			~	1	1
		\sim				Delete		1	1
								1	1
Type the nu	mber format co	de, using on	e of the existir	ng codes as a	starting point.			1	1
								.0 ml	1
								ml ^L	र्षे 1
								.0 ml	1
								ml	1
					OK	Cance	91	.0 ml	1
ELC	647	8725			DRG0245		nits/r	3 ml	5
BMSC	648	293	5 5	5	DRG0384	40m	g/ml	1	1

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

Note: For the Number of Items Per NDC column, select "Number" ensure the "Decimal places" field is set to 2, and then click on the **OK** button. Repeat from Step 6 for any other column changes, as shown in Figure 6-14.

Format Cells						?	×		
Number Alignment	Font	Border	Fill	Protection					
General Number Currency Accounting Date Time Percentage Fraction Scientific	Decimal	er of Items I places: 2 000 Separa e numbers:	-						
Text Special Custom	1234.10 (1234.10 (1234.10	D)					×		
Number is used for gene formatting for monetary		y of numbe	rs. Currer	ncy and Accou	unting offer sp OK		ncel		

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

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

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

ormat Cells						?	×			
Number	Alignment	Font	Border	Fill	Protection					
<u>C</u> ategory: General Number Currency		∧ Sam	ple e of First Sale							
Accounting Date Time			mm/dd/yyyy							
Percentage Fraction Scientific Text		\$#,## \$#,##	\$#,##0_);(\$#,##0) \$#,##0_];(Red](\$#,##0) \$#,##0.00_);(\$#,##0.00) \$#,##0.00_];(Red](\$#,##0.00)							
Special Custom		0% 0.009 0.008	6 E+00	.,,						
		##0.(# ?/? # ??/	??							
		~	YYYY			<u>D</u> elete	·	0		
ype the nur	nber format	code, using o	ne of the existi	ng codes as a	a starting point.					
						_				
	.00units/r	2 ml	5		ок 11/9/1998	20563	126			

Figure 6-15: Upload Product Data Format Cells Date Custom Editing Example

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

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

Note: Any time that you have to retrieve a file to edit, you will have to perform Steps 0 through 8 again, before you resave the file.

6.3 Update Product Data

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

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

The "Update Product Data" screen displays with the current reporting period showing, as shown in Figure 6-16.

Figure 6-16: Update Product Data S	Screen
------------------------------------	--------

Medicare Part B A	verage Sales Price		Update F	Product Data		<u>Help</u>
Home						
Compliance Summary	* denotes required field					
Manage NDC1/ALT ID						
Product Data	Update by NDC Update by Alternate ID		Manufacturer Name*		Date of First Sale*	
Add Product Data	Select Drug Identifier Select	*			Date must be in MM/DD/YYYY format	
Update Product Data			Has Brand Name?		Expiration Date of Final Lot Sold	
Upload Product Data			Generic Name*	Select Generic Name	Date must be in MM/DD/YYYY format	
View Submitted Drugs						
Financial Data						
Generate One Time Password (OTP)	Strength of the Product*	Add New FDA Ap	polication Numbers			
Assumptions		FDA Approva	I Date"	FDA Approval Type"		
Re-Statements	Volume Per Item*	Date must be in N	1M/DD/YYYY format	Select *		
Help		FDA Applicat	ion Number/Registration	FDA Application Supplement N	umber	
	Number of Items per NDC*					
				UPDATE		

- To update fields by NDC, select the "Update by NDC" tab.
 Note: To update fields by Alternate ID, go to step 6.
- 3. Select Drug Identifier: dropdown menu required

All of the fields automatically populate, as shown in Figure 6-17.

Figure 6-17: Update Product Data Screen, Update by NDC Tab Fields Populated

Medicare Part B A	verage Sales Price	Update Product Data	<u>Help</u>
Home			
Compliance Summary	* denotes required field		
Manage NDC1/ALT ID	Update by NDC Update by Alternate ID	Manufacturer Name* TEST - NEW MANUFACTURER Date of First Sale*	06/01/2019
Product Data		Date must be in MM/DD/YYYY format	000002010
Add Product Data	Select Drug Identifier* 66666-2222-44	Expiration Date of Final Lot Sold	
Update Product Data		Generic Name* 0 9% NACL 250ML VIAFLO UK NP	
Upload Product Data			
View Submitted Drugs			
Financial Data	Strength of the Product*	Add New FDA Application Numbers	
Generate One Time Password (OTP)	1000	FDA Approval Date" FDA Approval Type"	
Assumptions		05/05/2019 510(K) * Date must be in MMDD/YYYY format	
Re-Statements	Volume Per Item*	FDA Application Number/Registration Number* FDA Application Supplement Number	
Help	10		
	Number of Items per NDC* 2.00		
		UPDATE	

4. Make any updates using the following criteria.

Has Brand Name?: checkbox optional

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

Generic Name: dropdown list required

New Generic Name: displayed only if selecting "Add New Generic Name" from the "Generic Name" dropdown list required limited to 250 characters Date of First Sale: MM/DD/YYYY format required cannot occur before the FDA approval date must occur prior to the "Current Reporting Period" start date Expiration Date of Final Lot Sold: MM/DD/YYYY format optional Strength of the Product: required limited to 500 characters Volume Per Item: required limited to 250 characters Number of Items per NDC: numeric required limited to 9 digits and 2 decimal places FDA Approval Date: required MM/DD/YYYY format must be prior to "Current Reporting Period" start date FDA Application Number/Registration Number: required alphanumeric up to 10 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link FDA Approval Type: required dropdown list FDA Application Supplement Number: optional alphanumeric up to 9 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link

The fields populate with the entered data.

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

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

Medicare Part B A	verage Sales Price Update Product Data	<u>Help</u>
Home		
Compliance Summary	66666-222-44 Product updated successfully.	
Manage NDC1/ALT ID		
Product Data		
Add Product Data	* denotes required field	
Update Product Data	- denotes required nerd	
Upload Product Data	Update by NDC Update by Alternate ID	
View Submitted Drugs	Select Drug Identifier' 66665-222-44 Manufacturer Name* TEST - NEW MANUFACTURER Date of First Sale* 06/01/2019	
Financial Data	Has Brand Name?	-
Generate One Time Password (OTP)	Generic Name* 0 9% NACL 250ML VIAFLO UK NP Expiration Date of Final Lot Sold Date must be in MMDD/YYYY format	
Assumptions		
Re-Statements		_
Help	Strength of the Add New FDA Application Numbers Product*	
	1000 FDA Approval Date* FDA Approval Type* 05:05/2019 510(K) *	
	Volume Per Item* Date must be in MM/DD/YYY format	
	10 FDA Application Number' FDA Application Supplement Number 4444	
	Number of Items 2.00 2.00	
	UPDATE	

Figure 6-18: Update Product Data Screen – Update by NDC Saved Successfully

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

Has Brand Name?: checkbox optional Brand Name: field is only displayed if "Has Brand Name?" box is checked required if "Has Brand Name?" box is checked limited to 250 characters Generic Name: dropdown list required New Generic Name: only displayed when selecting "Add New Generic Name" from the "Generic Name" dropdown list required limited to 250 characters Date of First Sale: MM/DD/YYYY format required cannot occur before the FDA approval date must occur prior to the "Current Reporting Period" start date Expiration Date of Final Lot Sold: MM/DD/YYYY format optional Strength of the Product: required limited to 500 characters Volume Per Item: required limited to 250 characters

Number of Items per	re	equired	s and 2 decimal places
FDA Approval Date:	optional MM/DD/YYYY must be prior t		Reporting Period" start date
FDA Application Num	nber/Registratio	n Number:	optional alphanumeric up to 10 characters can have up to 2 more optional entries by clicking on the "Add New Application Numbers" link
FDA Approval Type:	optional dropdown list		
FDA Application Sup		alphanu up to 9 c can hav	meric characters e up to 2 more optional entries by on the "Add New Application

The fields populate with the entered data.

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

The screen displays the confirmation that the product submission has been saved, as shown in Figure 6-19.

Figure 6-19: Update Product Data Screen – Update by Alternate ID Updated Success	sfully
----------------------------------------------------------------------------------	--------

Medicare Part B A	verage Sales Prio	ce		Update	Product Data			<u>Help</u>			
Home											
Compliance Summary		6432AMDC Product updated successfully.									
Manage NDC1/ALT ID											
Product Data											
Add Product Data	* denotes required fi	-14									
Update Product Data	a denotes required to	eiu									
Upload Product Data	Update by NDC	Update by Alternate ID									
View Submitted Drugs	Alternate ID*	5432AMDC		Manufacturer Name*	TEST - MANUFACTURER NAME BY ALTEI	Date of First Sale*	05/05/2018				
Financial Data		043248800		Has Brand Name?		Date must be in MM/DD/YYYY format		_			
Generate One Time Password (OTP)				Generic Name*	0 9% NACL 250ML VIAFLO UK *	Expiration Date of Final Lot Sold Date must be in MM/DD/YYYY format					
Assumptions											
Re-Statements											
Help	Strength of the Product* 1000 Volume Per Item 100 Number of Items per Alternate ID*	200	Add New FDA App FDA Approval Date must be in MI FDA Applicatio	Date M/DD/YYYY format	FDA Approval Type Select * FDA Application Supplement Num	ber					
					UPDATE						

6.4 View Submitted Drugs

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

Perform the following steps to view submitted drug data:

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

The "View Submitted Drugs" window displays, as shown in Figure 6-20.

Medicare Part B A	verage Sales Price	View Su	bmitted Dru	igs			<u>Help</u>
Home							
Compliance Summary	Data being submitted for:	Q1 2019					
Manage NDC1/ALT ID	Drug Identifier:	Search					
Product Data							
Add Product Data	Showing all 4 results.		Previous First 1 Last	Next]
Update Product Data	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status
Upload Product Data	32334-9029-11	CINACALCET (Sensipar®)					PENDING
View Submitted Drugs							
Financial Data	32334-9029-22	CINACALCET (Sensipar®)					PENDING
Generate One Time Password (OTP)	32334-9029-22	0 9% NACL 250ML VIAFLO UK NP					PENDING
	32334-9029-33	CINACALCET (Sensipar®)					PENDING
Assumptions			Denter First ditert				
Re-Statements	Showing all 4 results.		Previous First 1 Last	-]
Help			Export : 🔤 🏪 🎴				

Figure 6-20: View Submitted Drugs Screen

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

7. Financial Data

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

7.1 Add/Edit Financial Data

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

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

The "Add/Edit Financial Data" page displays a listing of the drugs, as shown in Figure 7-1.

Home											
Compliance Summary	Data being submitted f	or: Q1 2019									
Manage NDC1/ALT ID	Drug Identifier:	Search									
Product Data	Showing all 4 results.		Previo	us First 1 Last N	ext						
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					
Upload Financial Data	32334-9029-11	CINACALCET (Sensipar®)					PENDING	Product			
enerate One Time assword (OTP)	32334-9029-22	CINACALCET (Sensipar®)					PENDING	Product			
Assumptions	32334-9029-22	0 9% NACL 250ML VIAFLO UK NP					PENDING	Product			
Re-Statements	32334-9029-33	CINACALCET (Sensipar®)					PENDING	Product			
Help	Showing all 4 results.		Previo	us First 1 Last N	ext	· ,					
			Expo	rt : ன 🐃 💌							
	Export: 🔤 🎬 🌽										

Figure 7-1: Add/Edit Financial Data Screen

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

Manufacturer's ASP: numeric

Must have three decimal places (i.e., XXXXXXXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000

Number of ASP units: numeric must have three decimal places (i.e., XXXXXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000 Wholesale Acquisition Cost: numeric must have three decimal places (i.e., XXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000
Number of Cap Units Excluded: optional numeric must have three decimal places (i.e., XXXXXXXXX). can be a positive number or be equal to 0.000

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

ome										
ompliance Summary	Data being submitted for: Q1 2019									
lanage NDC1/ALT ID	Drug Identifier:	Search								
roduct Data	Showing all 4 results.		Previo	us First 1 Last N	ext					
inancial 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				
Upload Financial Data	32334-9029-11	CINACALCET (Sensipar®)	12.222	90.222	13.999	12.222	PENDING	Product		
enerate One Time assword (OTP)	32334-9029-22	CINACALCET (Sensipar®)					PENDING	Product		
ssumptions	32334-9029-22	0 9% NACL 250ML VIAFLO UK NP					PENDING	Product		
e-Statements	32334-9029-33	CINACALCET (Sensipar®)					PENDING	Product		
Help	Showing all 4 results. Previous First 1 Last Next									

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

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

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

Home										
Compliance Summary			Fin	ancial data saved						
Manage NDC1/ALT ID	1									
Product Data										
Financial Data	Data being submitted f	or: Q1 2019								
Add/Edit Financial Data	Drug Identifier:	Search								
Upload Financial Data	Showing all 4 results. Previous First 1 Last Next									
Generate One Time Password (OTP)	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP*	Number of ASP units*	Wholesale Acquisition Cost*	Number of Cap Units Excluded	Status	View Details		
	0000 4 0000 44	CINACALCET (Sensipar®)	12.222	90.222	13.999	12.222	SAVED	Product		
Assumptions	32334-9029-11		10.000							
	32334-9029-22	CINACALCET (Sensipar®)					PENDING	Product		
Re-Statements							PENDING	Product Product		
Re-Statements	32334-9029-22	CINACALCET (Sensipar®)						and the second second		
Re-Statements	32334-9029-22 32334-9029-22	CINACALCET (Sensipar®) 0 9% NACL 250ML VIAFLO UK NP		us First 1 Last N	ext		PENDING	Product		
Assumptions Re-Statements Help	32334-9029-22 32334-9029-22 32334-9029-33	CINACALCET (Sensipar®) 0 9% NACL 250ML VIAFLO UK NP	Previo	us First 1 Last N	2017		PENDING	Product		

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

5. To view the product data for the Drug Identifier, click on the "Product" link in the "View Details" tab.

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

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

Medicare Part B A	Average Sales Pric	ie.			Add/	Edit Fir	anc	ial Dat	ta					He
lome														
ompliance Summary	Data being subm	itted for: Q1 2	019											
Manage NDC1/ALT ID	Drug Identifier:													
roduct Data	Showing all 4 results.				Previous First 1 Last Next									
nancial Data	Drug Identifier Generic (Brand Nat		I Name)	M	anufacturer's		per of ASP	Wholesale	Number of Cap Status		View Details			
Add/Edit Financial Data					ASP*	1	units*	Acquisition Cost*	Units Exclud	ed				
Jpload Financial Data	32334-9029-11		CINACALCET (S	ensipar®)		12.222		90.222	13.999	12.222	SA	AVED		Product
enerate One Time assword (OTP)					F	Product Detai	ls for D	Irug 32334-	-9029-11					_
ssumptions	1	Manufacturer's Name	Generic (Brand Name)	Strength of Product	Volume per Item	S	100000000	Date of First Sale	Expiration Date of Final Lot Sold	FDA Approval	FDA Approval	FDA App #	FDA Supp	
e-Statements	1	Harris	(Brand Hame)	Troduct	periten	pernoor	Alub	That Gule		Date	Туре	- PP #	#	
elp	1	TEM INC	CINACALCET (Sensipar®)	60 mg/per tablet	12.12	6		11/13/2016		11/11/2016	NDA	6666	0	
								I						Clos
	32334-9029-22		CINACALCET (S	ensipar®)							PEN	NDING		Product
	32334-9029-22	0.99	% NACL 250ML V	IAFLO UK NP	C						PEN	NDING		Product
	32334-9029-33		CINACALCET (S	ensipar®)	C						PEN	NDING		Product
	Showing all 4 results					Previo	us First	1 Last Ne	xt					
						Expo	rt : csv							
	+						10	ncial Data						

7.2 Upload Financial Data

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

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

The "Upload Financial Data" screen displays, as shown in Figure 7-5.

Figure 7-5: Upload Financial Data Screen

Medicare Part B A	verage Sales Price Upload Financial Data	<u>Hel</u> r
Home		
Compliance Summary	Data being submitted for: Q1 2019	
Manage NDC1/ALT ID		
Product Data		
Financial Data	Refresh	
Add/Edit Financial Data	Last three uploaded files	
Upload Financial Data	No data exists.	
Generate One Time Password (OTP)		
Assumptions	C Browse for new or corrected financial data	>
Re-Statements	Browse No file selected	
Help	Calcioner for acceptation file formats	
	Upload	

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

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

Figure 7-6: File Directory Window

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

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

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

Medicare Part B A	verag	ye Sales Price Upload Financial Data	<u>Help</u>
Home			
Compliance Summary	Data	a being submitted for: Q1 2019	
Manage NDC1/ALT ID			
Product Data			
Financial Data		Refresh	
Add/Edit Financial Data		Last three uploaded files	
Upload Financial Data		No data exists.	
Generate One Time Password (OTP)			
Assumptions		Browse for new or corrected financial data	>
Re-Statements		Browse., Financial Data, Test1 csv	
Help		Click here for acceptable file formats	
		Uproad	

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

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

Note: ASP offers a "Refresh" button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say "Processing." If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say "Completed."

	verage Sales Price		Upload Financial Data				<u>H</u>
ome							
ompliance Summary	Refresh						
anage NDC1/ALT ID	Last three uploaded files						
oduct Data	File N	ame Upload Type	Upload Date		Status	Reporting Peri	iod
nancial Data	Einancial Dat	a_Test1.csy FINANCIAL	2019-05-23 14:30:42.0		Completed	Q1 2019	
dd/Edit Financial Data	< Browse for new or correct	ed financial data					>
pload Financial Data	browse for new or correct						
enerate One Time ssword (OTP)	Browse No file selected. Click here for acceptable file formation	<u>#15</u>					
sumptions	Upload						
-Statements							
Ip	Report of Transmitted Drugs via	File Upload					
	Upload Date:2019-05-23 14:30:42.0						
	Upload Date:2019-05-23 14:30:42.0						
	Upload Date:2019-05-23 14:30:42.0	9	147 out of 158 financial data has been saved succ	essfully.			
	Upload Date 2019-05-23 14 30 42.0 Data being submitted for: Q1 201	9		-]
	Upload Date 2019-05-23 14 30-42.0 Data being submitted for: Q1 201 Showing 1 - 20 of 158 results.	9 9	Previous First 1, 2, 3, 4, 5, 6, 7, 8Last	Next]
	Upload Date 2019-05-23 14 30 42.0 Data being submitted for: Q1 201	9		Next	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status
	Upload Date 2019-05-23 14 30-42.0 Data being submitted for: Q1 201 Showing 1 - 20 of 158 results.	9 9	Previous First 1, 2, 3, 4, 5, 6, 7, 8Last	Next			
	Upioad Date 2019-05-23 14:30 42 0 Data being submitted for: Q1 201 Showing 1 - 20 of 168 results. Drug Identifier	9 Generic (Brand Hame)	Previous First 1, 2, 3, 4, 5, 6, 7, 6Last Manufacturer's AS	Next P Number of ASP units	Cost	Excluded	Both NDC and Alterna ID are present.
	Upioad Date 2019-05-23 14-30 42 0 Data being submitted for: Q1 201 Showing 1 - 20 of 150 results Drug Identifier 66995-7516-59	9 Generic (Brand Name) DR02245	Previous First 1, 2, 3, 4, 5, 6, 7, 8 - Last Manufacturer's AS 151.511	Next P Number of ASP units 21612.820	Cost 241.520	Excluded	Both NDC and Alterna ID are present. Both NDC and Alterna

Figure 7-8: Upload Financial Data Saved Successfully	Figure 7-8: Uplo	ad Financial	I Data Saved	d Successfully
------------------------------------------------------	------------------	--------------	--------------	----------------

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

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

5. Open the "Upload Financial" file, as shown in Figure 7-9.

2	Δ	в	с	D	E	F	G	н			к	L.	м	N	0
1	Manufacti		NDC2	NDC3		Generic N								IN	0
2	ELC	647	7140			DRG0032	brund real		19639.02	773.1	tumber of	cup onne	JEXCIUGED		
3	ELC	647	7501			DRG0544		145.23	90.1	148.19					
4	ELC	647	7502			DRG0544				5.23E+09					
5	ELC	647	7510			DRG0245		104.65	3.21E+09	130					
6	ELC	647	7510			DRG0245		17.18		39					
7	ELC	647	7516		73287278			206.43	21812.82	241.52	44949				
8	ELC	647	7623			DRG0579		2739.25	76487.84	2818.75					
9	ELC	647	7635	11		DRG0294		545.37	224.88	556.5	0				
10	ELC				G*2372	DRG0294		779.1	2197.76	795	-1				
11	ELC	647	7637	11		DRG0294		1051.13	1512.29	1073.25	2				
	ELC	647	7640	1		DRG0579		546.94	-7	563.75	hh				
13	ELC	647	8031	1		DRG0216		135.75	213207.3	138.98					
14	ELC	647	8215	1		DRG0246		46.12	229545.6	70.4					
15	ELC				92382727	DRG0246		4.66	455360.2	21.12	1E+09				
16	ELC	647	8215	91		DRG0246		17.69	0	18.15					
17	ELC	647	8315	17		DRG0246		6.01	76992.82						
18	ELC	647	8501			DRG0246		565.89	79204.13	704					
19	ELC	647	8725	59		DRG0245		0	0	207.85					
20	BMSC	648	293	5		DRG0384		8.042	781947.7	8.55					
21	BMSC	648		20		DRG0384		39.447	148675.6	43.39					
22	BMSC	648	293	28		DRG0384		0	236581.5	64.8					
23	BMSC	648	371	13		DRG0074		897.76	2657.74	923					
24	BMSC					DRG0384		9.767	142772.6	11.04					
25	BMSC	648	2187	10	G8329828	DRG0031		528.256	275517.5	595.74					
26	BMSC	648	2327	11		DRG0563		5904.116	4150.718	6000					
27	BMSC	648	2328	22		DRG0563		23616.52	0	24000					
28	GNTHI	649	188	9		DRG0232		0	0	439.16					
29	GNTHI	649	191	9		DRG0233		428.789	5110	439.16					
30	GNTHI	649	259	1		DRG0465		0	26631	439.16					
31	GNTHI	649	259	5		DRG0465		7648.63	181	7942.81					
32	GNTHI	649	259	43		DRG0465		2647.225	1682	7942.81					
33	GNTHI	649	260	1		DRG0465		1061.597	18168	1103.17					
34	GNTHI	649	260	43		DRG0465		5275.052	1461	5515.84					
35	GNTHI	649	261	29		DRG0465		882.067	11362	908.85					
36	GNTHI	649	1100	20		DRG0489		502.218	6880	527.72					
37	GNTHI	649	1101	50		DRG0489		3341.122	54671	3517.67					
20	GNITHI	649	1101	75		DPG0499		0	0	2517.67					

Figure 7-9: Upload Financial Data File

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

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

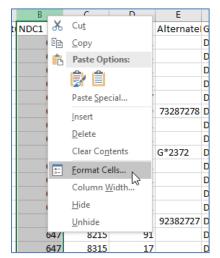


Figure 7-10: Upload Financial Data Column Editing Dropdown

7. Select "Format Cells."

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

ormat Cell	s						? ×	e & Cente	r
Number	Alignment	Font	Border	Fill	Protection			e a cente	
<u>C</u> ategory:								-	
General		Sampl	e						
Number Currency		NDC1						1.1	
Accountin	9	Decimal	places: 2	+				Jumber o	v
Time			1000 Separato					19639.02	
Percentag	e		e numbers:	A ()				90.1	
Fraction Scientific		-1234.1						398.71	İ.
Text		1234.10					\sim	3.21E+09	
Special Custom		(1234.1						329708.2	
custom		(1234.1	0)					21812.82	
								76487.84	
								224.88	
								2197.76	
		\sim					~	1512.29	
								-7	
Number is monetary v		al display of nu	imbers. Curre	ncy and Ac	counting offer spec	ialized for	matting for	213207.3	
monetary	/alue.							229545.6	
								455360.2	
								0	
					ОК		Cancel	76992.82	
								79204.13	
ELC	647		59		DRG0245		0	0	
BMSC	648		5		DRG0384		8.042	781947.7	
BMSC	648		20		DRG0384		39.447	148675.6	

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

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

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

ormat Cells	;					?	\times		
Number	Alignment	Font	Border	Fill	Protection			e & Center	
Category:									5
General		Samp	e						
Number		NDC						-	
Currency		NDC						1	
Accounting Date	1	<u>Type</u> :						Jumber o	Wh
Time		00000						19639.02	
Percentage	2	Genera	al				^	90.1	
Fraction Scientific		0						398.71	5.2
Text		0.00						3.21E+09	5.4
Special		#,##0.	00				_		
Custom);(#,##0)					329708.2	
);[Red](#,##0) 00):(#,##0.00)					21812.82	
			00_);(#,##0.00) 00_);[Red](#,##					76487.84	2
)_);(\$#,##0)	,				224.88	
		\$#,##()_);[Red](\$#,##	0)			~	2197.76	
		~				Delete		1512.29	1
						genete		-7	
Type the nu	mber format c	ode, using one	of the existing	codes as	a starting point.			213207.3	
								229545.6	
								455360.2	
								400000.2	
								76992.82	
					ОК	Cance	el de la companya de	79204.13	
-									
ELC	647				DRG0245		0	0	
BMSC	648	293	5		DRG0384		8.042	781947.7	

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

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

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

	- 17			- AY 3 -	GIM 147	and the state	1		T
F	ormat Cells							? ×	.00 Cor
	Number	Alignment	Font	Border	Fill	Protection			Form
	<u>Category:</u> General Number Currency Accounting Date Time Percentage Fraction Scientific Text Special Custom	used for genei	Decim. Us Negat 1234. (1234 (1234	al places: e 1000 Separa ive numbers: .210 210 .210) .210)	itor (,)	vice	ecialized for	matting for	L Cap Units
						ОК		Cancel	
25	59)	DRG0245		0	0	207.85		
93	5	5	DRG0384		8.042	781947.7	8.55		
	20)	DRG0384		39,447	148675.6	43.39		

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

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

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

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

8. Generate One Time Password (OTP) - Submitter

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

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

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

Medicare Part B A	Generate One Time Password (OTP)	Help
Home	Please select the Manufacturer Name": Select	
Compliance Summary	Generate One Time Password (OTP)	
Manage NDC1/ALT ID		
Product Data	All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier. Please click below to generate a one-time password (OTP) and share this with your data certifier. Upon accessing the system to certify your manufacturer's data, they will be asked for this	
Financial Data	password to verify their identity.	
Generate One Time Password (OTP)	Generate One Time Password (OTP)	
Assumptions		
Re-Statements		
Help		

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

2. Select a Manufacturer name from the "Please select the Manufacturer Name*:" dropdown list.

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

Figure 8-2: Generate	OTP - Please	select the Manu	ifacturer name*·	Field Populated
i igule 0-2. Generale		Select the Manu	nacturer name .	i leiu i opulateu

Medicare Part B A	werage Sales Price Generate One Time Password (OTP)	<u>Help</u>
Home	Please select the Manufacturer Name" : ELC *	
Compliance Summary	Generate One Time Password (OTP)	
Manage NDC1/ALT ID		
Product Data	All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier. Please click below to generate a one-time password (OTP) and share this with your data certifier. Upon accessing the system to certify your manufacturer's data, they will be asked for this	
Financial Data	password to verify their identity.	
Generate One Time Password (OTP)	Generate One Time Password (OTP)	
Assumptions		
Re-Statements		
Help		

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

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

Medicare Part B A	verage Sales Price Generate One Time Password (OTP)	Help						
Home								
Compliance Summary	Generated OTP successfully. Expires 11/12/2018.							
Manage NDC1/ALT ID								
Product Data	Please select the Manufacturer Name* : ELC							
Financial Data	Constate One Time Descured (OTD)							
Generate One Time Password (OTP)	All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier.	Generate One Time Password (OTP) All ASP submissions by an authorized submitter to CMS must be certified by an authorized certifier.						
Assumptions	Please click below to generate a one-time password (OTP) and share this with your data certifier. Upon accessing the system to certify your manufacturer's data, they will be asked for thi password to verify their identity.	S						
Re-Statements	Generate One Time Password (OTP)							
Help	irtj1t8MSzy1iQz4xecr7A							
	One Time Password expires on 11/12/2018							

Figure 8-3: OTP Generated Successfully

9. Verify OTP - Certifier

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

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

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





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

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

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



3. Click on the Verify button.

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

Figure 9-3: Verify OTP – OTP Verified Message

Medicare Part B A	verage Sales Price	Verify One Time Password (OTP)	<u>Help</u>
Home			
Verify One Time Password (OTP)		OTP verified for Manufacturer name YWLT and submitter TULIM HOGGARD. You are permitted to certify data.	
Certification			
Help	Enter OTP provided by y	our data submitter * : Venty	

10. Assumptions

10.1 Assumptions - Submitter

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

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

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

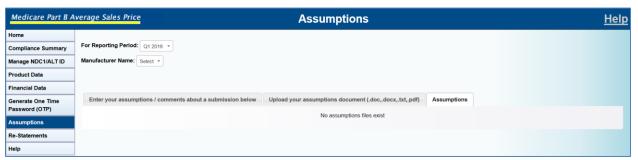


Figure 10-1: Assumptions Screen - Submitter

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

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

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

Medicare Part B A	verage Sales Price	Assumptions				
Home						
Compliance Summary	For Reporting Period: Q1 2019 *					
Manage NDC1/ALT ID	Manufacturer Name: YWLT *					
Product Data						
Financial Data						
Generate One Time	Enter your assumptions / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions			
Password (OTP)		No assumptions files exist				
Assumptions						
Re-Statements						
Help						

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

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

Medicare Part B A	verage Sales Price Assumptions	<u>Help</u>
Home		
Compliance Summary	For Reporting Period: Q1 2019 *	
Manage NDC1/ALT ID	Manufacturer Name: VWLT *	
Product Data		
Financial Data		
Generate One Time Password (OTP)	Enter your assumptions / comments about a submission below Upload your assumptions document (.doc,.docx,.txt,.pdf) Assumptions	
Assumptions	This is an assumptions/comments test.	
Re-Statements		
Help		
	Submit	

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

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

Figure 10-4: Assumptions Saved Successfully

Medicare Part B A	verage Sales Pric	Assumptions	<u>Help</u>
Home			
Compliance Summary	For Reporting Period	d: Q1 2019 *	
Manage NDC1/ALT ID	Manufacturer Name:	YWLT *	
Product Data			
Financial Data		Successfully saved assumptions.	
Generate One Time Password (OTP)		סעכפיסונווין אמיפע מסטווואטעווא.	
Assumptions			
Re-Statements	Enter your assum	nptions / comments about a submission below Upload your assumptions document (.doc,.docx,.txt,.pdf) Assumptions	
Help			
		Submit	

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

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

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

Figure 10-5: File Directory Window

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

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



Medicare Part B A	Average Sales Price Assumptions	<u>Help</u>
Home		
Compliance Summary	For Reporting Period: Q1 2019 +	
Manage NDC1/ALT ID	Manufacturer Name: YWLT *	
Product Data		
Financial Data	Successfully saved assumptions.	
Generate One Time Password (OTP)	Successituity saved assumptions.	
Assumptions		
Re-Statements	Enter your assumptions / comments about a submission below Upload your assumptions document (.doc,.docx,.txt,.pdf) Assumptions	
Help		
	Browse No file selected.	

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

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

Figure 10-7: Assumptions Listed

Medicare Part B A	verage Sales Price		Assumptions			
Home						
Compliance Summary	For Reporting Period: Q1 2019 T					
Manage NDC1/ALT ID	Manufacturer Name: YWLT *					
Product Data						
Financial Data						
Generate One Time	Enter your assumptions / com	ments about a submission below	Upload your assumptions document (.doo	c,.docx,.txt,.pdf)	Assumpti	ons
Password (OTP)			File Name	Upload D	ate	File Uploaded User
Assumptions		USER ENTRY ASSUME	PTIONS 2019-03-28 11:53:23.493	03/28/2019 1	1:53:24	TULIM HOGGARD
Re-Statements		Ass	umptions.docx	03/28/2019 1	1:54:07	TULIM HOGGARD
Help		<				

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

10.2 Assumptions – Certifier

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

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

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

Figure 10-8: Assumptions Screen - Certifier

Medicare Part B A	verage Sales Price	Assumptions	
Home			
Verify One Time Password (OTP)	For Reporting Period: Q1 2019 -		
Certification	Manufacturer Name: Select *		
Drug Certification			
Assumptions	Enter your assumptions / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions
Help		No assumptions files exis	st

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

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



Medicare Part B A	verage Sales Price	Assumptions		
Home				
Verify One Time	For Reporting Period: Q1 2019 *			
Password (OTP)	Manufacturer Name: YWLT *			
Certification				
Drug Certification				
Assumptions	Enter your assumptions / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions	
Help				
		No assumptions files exi	xist	

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

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

Figure 10-10: Assumptions – Comments Field Populated

Medicare Part B A	verage Sales Price	Assumptions		<u>Help</u>
Home				
Verify One Time Password (OTP)	For Reporting Period: Q1 2019 *			
Certification	Manufacturer Name: YWLT *			
Drug Certification				
Assumptions	Enter your assumptions / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions	
Help				
	The	is an assumptions/comments test message.		
		Submit		

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

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

Medicare Part B A	Average Sales Price		Assumptions		<u>Help</u>
Home Verify One Time Password (OTP) Certification	For Reporting Period:				
Drug Certification Assumptions Help			Successfully saved assu	imptions.	
	Enter your assumpti	ons / comments about a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions	
			Submit		

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

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

Figure 10-12: File Directory Window

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

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

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

Figure 10-13: Assumptions Saved Successfully

Medicare Part B A	verage Sales Price	Assumptions	<u>Help</u>
Home			
Verify One Time	For Reporting Period:	Q1 2019 •	
Password (OTP)	Manufacturer Name: Y	WIT -	
Certification			
Drug Certification			
Assumptions		Successfully saved assumptions.	
Help			
	F -1	ons / comments about a submission below Upload your assumptions document (.doc,.docx,.txt,.pdf) Assumptions	
	Enter your assumption	upload your assumptions document (.doc.,docx,.txt.,pdf) Assumptions	
		Browse No file selected.	
		Submit	

7. To view assumptions that have been added select a Manufacturer Name and select the "Assumptions" tab.

The added assumptions are listed, as shown in Figure 10-14.

Figure 10-14: Assumptions Listed

Medicare Part B A	verage Sales Price	rage Sales Price Assumptions						ĺ
Home Verify One Time Password (OTP)	For Reporting Period: Q1 2019 * Manufacturer Name: YWLT *							
Certification Drug Certification Assumptions								
Help	Enter your assumptions / comments abo	but a submission below	Upload your assumptions document (.doc,.docx,.txt,.pdf)	Assumptions	ad Date	File Uploaded User		
	-	USER ENT	IRY ASSUMPTIONS_2019-03-27_11-20.36.82 Assumptions.docx	03/27/20	019 11:20:37 019 11:22:17	GARRY SOBBERS GARRY SOBBERS		
	<					>		

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

11. Re-Statements

11.1 Add/Edit Restate Financial Data

The ASP application provides the drug manufacturers the ability to restate Medicare Part B drug financial data to CMS. Perform the following steps to restate the drug financial data manually using the online data entry process.

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

The "Add/Edit Restate Financial Data" screen displays, as shown in Figure 11-1.

Medicare Part B A	verage Sales Price Add/Edit Restate Financial Data	<u>Help</u>
Home		
Compliance Summary	Select Re-Statement Period: Select	
Manage NDC1/ALT ID		
Product Data		
Financial Data		
Generate One Time Password (OTP)		
Assumptions		
Re-Statements		
Add/Edit Restate Financial Data		
Upload Restate Financial Data		
Help		

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

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

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

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

Medicare Part B A	verage Sales Price	Add/Ed	it Restate	Financial	Data			Hel
Home								
Compliance Summary	Select Re-Statement Period:	01 2019						
Manage NDC1/ALT ID								
Product Data	For Reporting Period Q1 201	9						
Financial Data	Please select the Drug Identifier* :	66666-2222-44 *						
Generate One Time Password (OTP)	Review Re-Statement List:							
Assumptions								
Re-Statements	Drug Identifier	Generic (Brand Name)	Manufacturer's	Number of ASP	Wholesale	Number of Cap	Status	
Add/Edit Restate Financial Data			ASP*	units*	Acquisition Cost*	Units Excluded		
Upload Restate Financial	66666-2222-44	0 9% NACL 250ML VIAFLO UK NP					PENDING	
Data								

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

Manufacturer's ASP: numeric must have three decimal places (i.e., XXXXXXXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000 Number of ASP units: numeric must have three decimal places (i.e., XXXXXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000 Wholesale Acquisition Cost: numeric must have three decimal places (i.e., XXXXXXXXXXXXXXXXXXX). can be a positive number, a negative number, or be equal to 0.000 Number of Cap Units Excluded: optional numeric must have three decimal places (i.e., XXXXXXXXXXXXXXX). can be a positive number or be equal to 0.000

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

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

Medicare Part B Average Sales Price		Add/Ed	Add/Edit Restate Financial Data					
Home								
Compliance Summary	Select Re-Statement Period:	01 2019 *						
Manage NDC1/ALT ID								
Product Data	For Reporting Period Q1 201							
Financial Data	Please select the Drug Identifier* :	66666-2222-44 *						
Generate One Time Password (OTP)	Review Re-Statement List:							
Assumptions								
Re-Statements	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP*	Number of ASP units*	Wholesale Acquisition	Number of Cap Units Excluded	Status	
Add/Edit Restate Financial Data			AJF	units	Cost*	Units Excluded		
Upload Restate Financial	66666-2222-44	0 9% NACL 250ML VIAFLO UK NP	111.111	222 222	444.444	333.333	PENDING	
Data				Re-State				
Help				110-01010				

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

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

Medicare Part B Av	erage Sales Price	Add/Ed	lit Restate	Financial	Data		Hel
Home							
Compliance Summary	Select Re-Statement Period:	01 2019 *					
Manage NDC1/ALT ID							
Product Data	For Reporting Period Q1 201	9					
Financial Data	Please select the Drug Identifier* :	66666-2222-44 *					
Generate One Time Password (OTP)	Review Re-Statement List:						
Assumptions							
Re-Statements			Finan	cial data saved			
Add/Edit Restate Financial Data							
Upload Restate Financial Data	Drug Identifier	Generic (Brand Name)	Manufacturer's	Number of ASP	Wholesale	Number of Cap	Status
Help			ASP*	units*	Acquisition Cost*	Units Excluded	
	<u>66666-2222-44</u>	0 9% NACL 250ML VIAFLO UK NP	111.111	222.222	444.444	333.333	RESTATE SAVED
				Re-State			

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

11.2 Upload Re-State Financial Data

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

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

The "Upload Restate Financial Data" screen displays, as shown in Figure 11-5.

Figure 11-5: Upload Restate Financial Data Screen	
---------------------------------------------------	--

Medicare Part B A	erage Sales Price Upload Restate Financial Data	Hel
Home		
Compliance Summary	Select Re-Statement Period: SELECT	
Manage NDC1/ALT ID		
Product Data		
Financial Data	Refresh	
Generate One Time Password (OTP)	Last three uploaded files	
Assumptions	No data exists.	
Re-Statements		,
Add/Edit Restate Financial Data	Browse for Re-Statement Financial Data File	
Upload Restate Financial Data	Browse No file selected.	
Help	Click here for acceptable file formats Uplead	

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

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

Medicare Part B A	verage Sales Price	Upload R	estate Financial Data			
Home						
Compliance Summary	Select Re-Statement Period: Q1 2019					
Manage NDC1/ALT ID						
Product Data						
Financial Data	Refresh					
Senerate One Time	Last three uploaded files					
Password (OTP)	File Name	Upload Type	Upload Date	Status	Reporting Period	
ssumptions	Product Data_Test1.csy	RESTATE FINANCIAL	2019-05-23 14:39:04.0	Invalid file format.	Q1 2019	
le-Statements	<					>
Add/Edit Restate Financial Data	Browse for Re-Statement Financial Data File					
Financial Data Upload Restate	Browse for Re-Statement Financial Data File Browse No file selected.					

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

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

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

Figure 11-7: File Directory Window

×a	Financial Data_Test	7/2/2018 11:52 AM	Microsoft Excel Comma Separated Values File	
×a,	Product Data_Test	4/16/2018 3:43 PM	Microsoft Excel Comma Separated Values File	

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

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

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

Medicare Part B A	verage Sales Price	Upload R	estate Financial Data			
iome						
Compliance Summary	Select Re-Statement Period: 01 2019					
lanage NDC1/ALT ID						
Product Data						
inancial Data	Refresh					
Generate One Time Password (OTP)	Last three uploaded files					
ssumptions	File Name	Upload Type	Upload Date	Status	Reporting Period	
e-Statements	Product Data_Test1.csv	RESTATE FINANCIAL	2019-05-23 14:39:04.0	Invalid file format.	Q1 2019	
Add/Edit Restate Financial Data	Browse for Re-Statement Financial Data File					
	Browse for Re-Statement Financial Data File Browse Financial Data_Test1.csv Click here for acceptable file formats					

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

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

Note: ASP offers a "Refresh" button for times when an upload takes longer to process; the system will notify you to come back later while the status for the upload will say "Processing." If you want to know if the upload finished processing, you would click on the **Refresh** button and the system will give the current status of the upload. When the upload is finished, the status will say "Completed."

Medicare Part B A	verage Sales Price		Upload R	estate Financial Data				Ŀ
Home								
Compliance Summary								
Manage NDC1/ALT ID	Select Re-Statement Period: Q1 201	3 ~						
Product Data								
inancial Data	Refresh							
Generate One Time Password (OTP)	Last three uploaded files							
Assumptions	File Nan	10	Upload Type	Upload Date		Status	Reporting P	Period
Re-Statements	Financial Data_	Test1.csv	RESTATE FINANCIAL	2019-05-23 14:43:52.0		Completed	Q1 201	9
Add/Edit Restate Financial Data	Product Data_1	lest1.csv	RESTATE FINANCIAL	2019-05-23 14:39:04.0		Invalid file format.	Q1 201	9
Upload Restate Financial Data felp	Browse for Re-Statement Find Browse. No file selected. Click here for acceptable file format Upload Report of Transmitted Drugs via File Upload Date 2015-05-23 14.43 52.0 Data being submitted for: Q1 2019	2						
			147 out of 158	financial data has been saved successful	lly.			
	Showing 1 - 20 of 158 results.		Previous F	irst 1, 2, 3, 4, 5, 6, 7, 8Last Next				
	Drug Identifier		Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status
	66995-0555-01		DRG0265	18.210	3090.000	18.610		Data Uploaded
	66995-0555-02		DRG0265	68.850	14505.000	70.380		Data Uploaded
	66995-0626-01		DRG0153	188.470	1967.000	202.010		Data Uploaded
	66995-0698-01		DRG0361	14.730	84937.000	21.380		Data Uploaded
	66995.0758.01		DDG0361	9.080	51412 000	11 290		Date Unloaded

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

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

Note: If there are errors in uploading the document where leading zeros are removed from the NDC and date field values, the file will need to be edited and certain columns reformatted. To do this, open your file and continue with Step 6. To be certain of file column formatting, click on the "Click here for acceptable file formats" link, or follow the criteria below.

6. Open the "Upload Financial" file, as shown in Figure 11-10.

1	А	В	с	D	E	F	G	н	1.1	J	К	L	M	N	0
1	Manufact		NDC2	NDC3				Manufacti							_
2	ELC	647	7140			DRG0032			19639.02	773.1					
3	ELC	647	7501	1		DRG0544		145.23	90.1	148.19					
4	ELC	647	7502	1		DRG0544			398.71	5.23E+09					
5	ELC	647	7510	1		DRG0245		104.65	3.21E+09	130					
6	ELC	647	7510	17		DRG0245		17.18	329708.2	39					
7	ELC	647	7516	59	73287278	DRG0245		206.43	21812.82	241.52	44949				
8	ELC	647	7623	1		DRG0579		2739.25	76487.84	2818.75					
9	ELC	647	7635	11		DRG0294		545.37	224.88	556.5	0				
10	ELC				G*2372	DRG0294		779.1	2197.76	795	-1				
11	ELC	647	7637	11		DRG0294		1051.13	1512.29	1073.25	2				
12	ELC	647	7640	1		DRG0579		546.94	-7	563.75	hh				
13	ELC	647	8031	1		DRG0216		135.75	213207.3	138.98					
14	ELC	647	8215	1		DRG0246		46.12	229545.6	70.4					
15	ELC				92382727	DRG0246		4.66	455360.2	21.12	1E+09				
16	ELC	647	8215	91		DRG0246		17.69	0	18.15					
17	ELC	647	8315	17		DRG0246		6.01	76992.82						
18	ELC	647	8501			DRG0246		565.89	79204.13	704					
19	ELC	647	8725	59		DRG0245		0	0	207.85					
20	BMSC	648	293	5		DRG0384		8.042	781947.7	8.55					
21	BMSC	648		20		DRG0384		39.447	148675.6	43.39					
22	BMSC	648	293	28		DRG0384		0	236581.5	64.8					
23	BMSC	648	371	13		DRG0074		897.76	2657.74	923					
24	BMSC					DRG0384		9.767	142772.6	11.04					
25	BMSC	648	2187	10	G8329828	DRG0031		528.256	275517.5	595.74					
26	BMSC	648	2327	11		DRG0563		5904.116	4150.718	6000					
27	BMSC	648	2328	22		DRG0563		23616.52	0	24000					
28	GNTHI	649	188	9		DRG0232		0	0	439.16					
29	GNTHI	649	191	9		DRG0233		428.789	5110	439.16					
30	GNTHI	649	259	1		DRG0465		0	26631	439.16					
31	GNTHI	649	259	5		DRG0465		7648.63	181	7942.81					
32	GNTHI	649	259	43		DRG0465		2647.225	1682	7942.81					
33	GNTHI	649	260	1		DRG0465		1061.597	18168	1103.17					
34	GNTHI	649	260	43		DRG0465		5275.052	1461	5515.84					
35	GNTHI	649	261	29		DRG0465		882.067	11362	908.85					
36	GNTHI	649	1100	20		DRG0489		502.218	6880	527.72					
37	GNTHI	649	1101	50		DRG0489		3341.122	54671	3517.67					
20	GNITHI	649	1101	75		DPG0490		0	0	2517.67					

Figure 11-10: Upload Restate Financial Data File

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

The "Column Editing" dropdown displays, as shown in Figure 11-11.

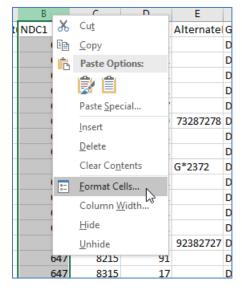


Figure 11-11: Upload Restate Financial Data Column Editing Dropdown

8. Select "Format Cells."

The "Format Cells" window displays, as shown in Figure 11-12.

ormat Cells	;						? ×	e & Cente	er -
Number	Alignment	Font	Border	Fill	Protection			e or cente	
Category:									
General Number Currency		 Sampl NDC1 							
Accounting	1	Decimal	places: 2	* *				Jumber o	h W
Date Time			1000 Separato					19639.02	
Percentage Fraction	•	Negativ	e numbers:					90.1	
Scientific		-1234.1	0				~	398.71	5
Text		1234.10						3.21E+09	
Special Custom		(1234.1						329708.2	
		(12341)	0)					21812.82	
								76487.84	
								224.88	
								2197.76	
		~					~	1512.29	
								-7	
		l display of nu	imbers. Currer	ncy and Aco	counting offer speci	alized for	matting for	213207.3	
monetary va	alue.							229545.6	
								455360.2	
								0	
								76992.82	
					ОК		Cancel	79204.13	
ELC	647	8725	59		DRG0245		0	0	
BMSC	648	293	5		DRG0384		8.042	781947.7	
BMSC	648		20		DRG0384		39,447	148675.6	

Figure 11-12: Upload Restate Financial Data Format Cells Number Editing

9. Make the following changes as shown in Figure 11-13 and Figure 11-14, in the "Type" field according to the below criteria:

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

- NDC1: Type 5 0s (00000), click on the **OK** button, and repeat from Step 7 for any other column changes
- NDC2: Type 4 0s (0000), click on the **OK** button, and repeat from Step 6 for any other column changes
- NDC3: Type 2 0s (00), click on the **OK** button, and repeat from Step 6 for any other column changes

Example:

ormat Cells						?	×	e & Cente	
Number	Alignment	Font	Border	Fill	Protection			e a Cente	1 *
	ragance	, one	border						5
Category: General Number Currency Accounting Date Time Percentage Fraction Scientific Text Special Custom		#,##0_ #,##0. #,##0. \$#,##0	al) #0.00)			~	l Jumber of 19639.02 90.1 398.71 3.21E+09 329708.2 21812.82 76487.84 224.88 2197.76	1 5.2 2 28
		~	2.1	-,		Delete		1512.29	
Type the nur	mber format co	ode, using one	of the existin	g codes as	a starting point.			213207.3	1
				-				229545.6	
								455360.2	
								0	
						_		76992.82	
					ОК	Cance	el 🛛	79204.13	
ELC	647	8725	59		DRG0245		0	0	2
BMSC	648				DRG0384		8.042	781947.7	
			_						

Figure 11-13: Upload Restate Financial Data Format Cells Number Custom Editing Example

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

- Manufacturer's Average Sales Price: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 6 for any other column changes
- Number of ASP Units: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 6 for any other column changes
- Wholesale Acquisition Cost: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes
- Number of CAP Units Excluded: Change the number of decimal places to "3," click on the **OK** button, and repeat from Step 7 for any other column changes

_	- 13					and the set	C.e.e.	a seal			
Fo	ormat Cells							?	×	.00. →.0	Con
	Number	Alignment	Font	Border	Fill	Protection				5	Forn
	<u>Category:</u> General Number Currency Accounting Date Time Percentage Fraction Scientific Text Special Custom		Decim	al places: e 1000 Separa ive numbers: .210 210 .210)		ice			^	L Cap U	Jnits
	monetary va	lue.		numbers. Cur	rency and Acco	ОК		Cance			
25	59		DRG0245		0	0	207.8				
93	5		DRG0384		8.042		8.5	-			
	20		DRG0384		39.447	148675.6	43.3	9			

Figure 11-14: Upload Restate Financial Data Screen – Re-Stated Financial Data Successfully

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

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

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

12. Drug Certification

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

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

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

The "Drug Certification" screen displays, as shown in Figure 12-1.

Figure 12-1: Drug Certification Screen

	verage Sales Price		Drug Cer	tification					Hel
ome									
erify One Time	Choose a reporting period Certifying Data for: Q1 2019	I and a certification status Select Option: Drug data pending certification Manufacturer N	ame: View All	×					
ertification	Drug Identifier:								
Drug Certification	-								
Assumptions				Submit					
elp	** denotes product data has been	n modified between current and prior quarter							
	Showing all 3 results.		Previous	First 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	Drug Details	Certify
	66995-0003-02	DRG0361	444.444	333.333	555.555	111.111	SAVED	Product	
	66995-0003-02 66995-0005-01	DRG0361 DRG0231	444.444		555.555	111.111 222.222	SAVED SAVED	Product Product	
				333.333					

2. Select a Reporting Period from the dropdown list, a certification status, the manufacturer name (optional), and the drug identifier (optional), and click on the **Submit** button.

The status for the drug information displays as "SAVED," as shown in Figure 12-2.

Figure 12-2: Selected Drugs to be Certified

Medicare Part B Av	verage Sales Price		Drug Cer	tification					Help
Home Verify One Time Password (OTP) Certification Drug Certification	Choose a reporting period and a certification status Certifying Data for: O1 2010 Select Option: Drug data pending certification Manufacturer Name: MAUREEN TEST Drug Identifier: 66995								
Assumptions		Submit							
Help	** denotes product data has been modified between current and prior quarter								
	Showing all 3 results. Previous First 1 Last Next								
	Drug Identifier	Generic (Brand Name)	Manufacturer's ASP	Number of ASP units	Wholesale Acquisition Cost	Number of Cap Units Excluded	Status	Drug Details	Certify
	66995-0003-02	DRG0361	444.444	333.333	555.555	111.111	SAVED	Product	
	66995-0005-01	DRG0231	555.555	444.444	666.666	222.222	SAVED	Product	
	66995-0011-03	DRG0231	666.666	555.555	777.777	333.333	SAVED	Product	
	Showing at 3 results. Previous First 1 Last Next								
	¢	Reset	All Checked Drugs	Certify Selected Data	a Certify All Data				>

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

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

Figure 12-3: Data Certification Statement

Dete Certification Statement
Data Certification Statement:
I certify that the reported Average Sales Prices were calculated accurately and that all Product and Financial information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.
Please agree to data certification statement
□ I agree to the above certification statement
Proceed to Certify Data

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

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

Figure 12-4: Drug Information Successfully Certified

Medicare Part B A	verage Sales Price	Drug Certification	<u>Help</u>
Home			
Verify One Time	Choose a reporting p	period and a certification status	
Password (OTP)	Certifying Data for: Q1	2019 🗹 Select Option: Drug data pending certification 🤟 Manufacturer Name: MAUREEN TEST 🗸	
Certification	Drug Identifier: 66995		
Drug Certification			
Assumptions		Submit	
Help			
		3 out of 3 drug product data has been successfully certified.	
	** denotes product data ha	as been modified between current and prior quarter	
		No data exists for this period.	

Appendix A: Record of Changes

Table A-1: Record of Changes

Version Number	Date	Author/Owner	Description of Change
1.0	03/23/2018	Maureen Campbell	Initial Release
1.1	04/26/2018	Maureen Campbell	Section 4.1: Add Product Data - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," "FDA Approval Date," and "Alternate ID."
1.1	04/26/2018	Maureen Campbell	Section 4.3: Update Product Data - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," "FDA Approval Date," and "Alternate ID."
1.1	04/26/2018	Maureen Campbell	Section 7.1: Restate Online - Increased the requirements for "Strength of the Product" from 250 characters to 500 characters; made changes for requirements for "FDA Application Number," "FDA Approval Type," and "FDA Approval Date."
2.0	3/28/2019	Maureen Campbell	Globally: Changes to reflect changes in the application for Release 9
2.1	5/29/2019	Maureen Campbell	Section 5: Compliance Summary – Submitter – replaced section; Globally: changed FDA Application Number requirements from 9 digits to 10 digits; replaced most screenshots to reflect the absence of reporting period on the screens. Added Note about the Refresh button when uploading files. Increase Manufacture ASP and WAC digits increased from 6 to 10. Added Compliance Summary – Certifier and Assumptions – Certifier sections.
2.2	01/10/2023	Felicia Brown	Section 1 and 2.1: revised language
2.3	01/12/2023	Jenn Palmer	Added Appendix C, updated formatting, Added Figure 3-1 and corresponding instructions.

Appendix B: Acronyms

Table B-1: Acronyms

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

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

Appendix C: Field Definitions

1. Table 1 contains the field definitions for drugs and biologicals reported on the NDC or CMS-specified unit level.

Most ASP reporting is done at the NDC level where the ASP corresponds to the amount of drug represented by that NDC. However, for a limited number of products, reporting at the NDC unit level is not appropriate and must be done at a CMS-specified unit level. A list of such drug products is maintained on the CMS website at: <u>http://www.cms.gov/McrPartBDrugAvgSalesPrice/</u>. For these drugs and biologicals,

manufacturers will still submit ASP sales data for an NDC, but will do so on an ASP unit level specified in this list.

Field Name	Field Definition
Manufacturer's Name	The reporting manufacturer's name.
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC or UPC number) used when an 11 digit NDC is not available.
Manufacturer's Average Sales Price	ASP for a corresponding ASP unit rounded to 3 or more decimal places.
Number of ASP Units	The number of ASP units sold.
Wholesale Acquisition Cost (WAC)	The WAC for a corresponding ASP unit in effect on the last day of the reporting period. WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.

Table C-1: Field Definitions for Drugs and Biologicals

Field Name	Field Definition
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.
Strength of the Product	The dosage strength of one item (e.g.: 250 mg tablet, 20 mg/ml solution, 1 IU).
Volume Per Item	The amount in one item (ex: 10 ml in one vial, or 500 tablets in one bottle).
Number of Items Per NDC	The number of items in the 11-digit NDC (ex: if an NDC packaged as a box contains 4 vials, the number of items per NDC is 4).
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means the manufacturer will not make sales of that NDC to any purchaser.
Date of First Sale	Report for NDCs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).
FDA Application Supplement Number	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application	
Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA	
Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration (FDA).
FDA Final Pre- Marketing Approval Date	This is the original date that the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).
FDA Approval Type	The type of FDA approval for the product.
Description of FDA Approval Type	If Other was specified in the column 'FDA Approval Type,' please specify the type.

2. Table 2 contains the field definitions for dermal grafting products.

Some dermal grafting products are not assigned an NDC. Instead, manufacturers identify them using product codes, which can be catalog numbers, Universal Product Codes (UPCs), or other unique identifiers. If an NDC is not available, the UPC or other unique identifier must be entered in the field "Alternate ID". Manufacturers may not convert a UPC or other alternative identifier to an NDC format by adding zeros or removing numbers. Additionally, where the strength of a dermal grafting product must be described in units of area, manufacturers must report in units of square centimeters. Dermal grafting products that are sold in customized or irregularly shaped sheets must be quantified and reported using square centimeters. Other units of measure such as "square inches", "each", "sheet", etc are not acceptable. Dermal grafting products that are sold in powder, foam, or liquid form must be quantified and reported in metric measures such as grams, milligrams, or milliliters.

Field Name	Field Definition
Manufacturer's Name	The reporting manufacturer's name.
11-Digit National Drug Code (NDC1)	The NDC1 is the first 5 digits of the 11 digit National Drug Code that identifies the labeler. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC2)	The NDC2 is the sixth through the ninth digits of the 11 digit National Drug Code that identifies the product. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
11-Digit National Drug Code (NDC3)	The NDC3 is the last 2 digits of the 11 digit National Drug Code that identifies the package size. The 11 digit NDC consists of the NDC1, NDC2, and NDC3, which identifies the labeler, product, and package size.
Alternate ID	Numeric or alphanumeric alternate identifier (ex: an NHRIC number or UPC) used when an 11 digit NDC is not available.
Manufacturer's Average Sales Price	ASP rounded to 3 or more decimal places. Report the ASP per package, as identified by the NDC or alternate ID (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the ASP per box of five).
Number of ASP Units	Report the number of packages sold (ex: for an NDC or Alternate ID that represents a box of five 2 cm x 3cm grafts, report the number of boxes sold).

Table C-2: Field Definitions for Dermal Grafting Products

Field Name	Field Definition
	The WAC in effect on the last day of the reporting period. Report the WAC per package.
Wholesale Acquisition Cost (WAC)	WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.
Name of Drug or Biological	The trade or brand name of the product or the active ingredient name.
Strength of the Product	For products sold in sheets: the total square centimeters in one item (ex: a 6cm x 8cm item is 48 sq cm).
Volume Per Item	Use this field for dermal grafting products that are reported in units of volume, for example liquids. Report the volume amount in one item, include the metric unit of measurement, such as cc or ml. Enter "1" for powders and sheets.
Number of Items Per NDC	The number of items in the 11-digit NDC or Alternative ID (ex: for an NDC or Alternate ID that has 5 grafts in a package, the number of items per NDC is 5).
Expiration Date of Final Lot Sold	The expiration date of the final lot sold must be reported to CMS once at the end of utilization of the NDC or Alternate ID when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means the manufacturer will not make sales of that NDC or Alternate ID to any purchaser.
Date of First Sale	Report for NDCs/Alternate IDs first sold on or after 04/01/2006. Report at least once and no later than with the first ASP report.
Number of CAP Units Excluded	Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.
FDA Application Number	The application number assigned by the Food and Drug Administration (FDA).
FDA Application Supplement Number	The application supplement number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Number #1	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #1	The application supplement number assigned by the Food and Drug Administration (FDA).

Field Name	Field Definition
Additional FDA Application Number #2	The application number assigned by the Food and Drug Administration (FDA).
Additional FDA Application Supplement Number #2	The application supplement number assigned by the Food and Drug Administration (FDA).
FDA Final Pre- Marketing Approval Date	This is the original date the FDA granted approval for the drug (NDA), biological (BLA), or pre-marketing application (PMA).
FDA Approval Type	The type of FDA approval for the product.