

Medicare Part B Average Sales Price (ASP) Module

Certifier User Guide

Version 1.0 Date: March 15, 2024



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1. Purpose

The purpose of this user guide is to provide guidance and instructions to financial executives of drug manufacturing companies as they certify their federally required Medicare Part B drug Average Sales Price (ASP) data for the Centers for Medicare & Medicaid Services (CMS). CMS uses the Fee-for-Service Data Collection System (FFSDCS) to house various Fee-for-Schedule modules.

The ASP Data Collection System, referred to within this user guide as the ASP Module, is one of the modules under the FFSDCS system, and offers the following:

- Provides users with an online-based software application for automating the collection, editing, and processing of drug product pricing data drug manufacturers submit on a quarterly basis.
- Establishes a relationship between the manufacturers' reported data and the billing codes Medicare providers use to calculate a weighted average sales price for each billing code.
- Establishes prices for billing codes to determine payment limits of Part B drugs on certain Medicare claims.
- Eliminates data entry errors, data formatting errors, and incomplete submitted data, and greatly reduces the process cycle and resource time needed to provide the pricing to contractors through automation of the manually intensive processes.
- Accepts, stores, validates, and calculates drug pricing on Medicare Part B drug data received for the Center for Medicare Management (CMM) stakeholders.

Section 303 (b) and (c) of the <u>Medicare Modernization Act (MMA) of 2003</u> revised the payment methodology for the majority of Part B-covered drugs and biologicals that are not priced on a cost or prospective payment basis (hereafter referred to as drugs).

CMS applies the ASP methodology to the data drug manufacturers have submitted to the ASP Module. Per the MMA, ASP methodology determines the payment limit for these drugs. Local contractors calculate pricing for compounded drugs.



2. Logging in Using MFA

First time users must register and create an account in the <u>CMS Enterprise Portal</u>. Refer to the Resource Library on the <u>Education and Outreach page</u> to view the ASP Module Registration User Guide for registration steps.

Once registration is complete, follow these steps to log into the Module as a Certifier using Multi-Factor Authentication (MFA):

1. Navigate to the CMS Enterprise Portal main page.

The ASP Module Login Page opens. Refer to Figure 1.

Login	Login with PIV Card	
	CMS.gov Enterprise Portal	
Us	ser ID is a required field	
Pa	assword is a required field	
	I agree to the <u>Terms & Conditions</u>	5
	Login	
For Nee	got your <u>User ID</u> or your <u>Password</u> ? ed to <u>unlock</u> your account?	
	New User Registration	

Figure 1: Logging in Using MFA - ASP Module Login

- 2. Enter your login information into the required **User ID** and **Password** fields.
- 3. Click the **Terms & Conditions** hyperlink and review the text in the pop-up window; close the window to move on to the next step.
- 4. Review the terms and conditions and select the **I agree to the Terms & Conditions** checkbox.



Note: By selecting this checkbox, you certify that you read and consent to monitoring while accessing and using the ASP Module. The terms and conditions link provides additional hyperlinks to the HHS Rules of Behavior and the CMS Privacy Act Statement.

5. Click Login.

Note: If you forget your user ID or password, click the **Forgot your User ID or your Password?** hyperlink under the **Login** button and follow the provided instructions. If you still cannot access your account and need to unlock it, click the **Need to unlock your account?** hyperlink under **Login** button.

The Multi-Factor Authentication page opens. Refer to Figure 2.

	Multi- 1 more 5 your User egister	~		
	terprise Port ctor (A) Device in, also known as n make your logi er of protection t ce type to r		e (IVR)	<u>gistration</u>
Login with PIV Card	CMS.gov En Register Multi-Fa thentication (MFA) or Authentication (MFA), ca ire by providing an extra lay nd Password.	lect MFA Device	l <mark>ect MFA Device</mark> teractive Voice Respons nail xt Message (SMS) pogle Authenticator ta Verify	<u>New User Re</u>
Login	♥ I Aut Addii Facto secu ID an Sel	Sel	Sel Int Em Tex Go Ok	
1	0			

Figure 2: Logging in Using MFA - Select MFA Device Type Drop-Down

To ensure the security of high value data submitted to the ASP Module, you must authenticate your identity using an MFA process. The first time you attempt to log in, you must choose an authentication method. Users have various authentication options, including Interactive Voice Response (IVR), Email, Text Message (Short Message Service (SMS)), Google Authenticator and Okta Verify.



6. Click the **Select MFA Device** drop-down menu; select your preferred MFA device type from the list. Refer to *Figure 3*. Whenever you log back into the Module through this process, your preferred method of MFA reloads automatically.

Note: *Figure 3* demonstrates MFA registration using IVR as the selected option.

gin	Login with PIV Card	1
	CMS.gov Enterprise Por	tal
⊘ I Au	Register Multi–Factor thentication (MFA) Device	
Addi Facto secu ID ar Sel	ing an MFA code to your login, also known a or Authentication (MFA), can make your log ire by providing an extra layer of protection nd Password. ect the MFA device type to	as Multi- gin more h to your User register
Int	teractive Voice Response (IVR)	~
12		
The voice optic phor durit	IVR option will communicate your MFA Coo e message that will be sent directly to your on requires you to provide a valid ten (10) o ne number and (optional) extension that w ng login to obtain the MFA Code.	le through a phone. This Jigits U.S. ill be used
The l voice optic phor durin	IVR option will communicate your MFA Cod e message that will be sent directly to your on requires you to provide a valid ten (10) o ne number and (optional) extension that w ng login to obtain the MFA Code. ter Phone Number	le through a phone. This ligits U.S. ill be used
The l voice optio phor durin En	IVR option will communicate your MFA Cod e message that will be sent directly to your on requires you to provide a valid ten (10) o ne number and (optional) extension that w ng login to obtain the MFA Code. ter Phone Number ter Extension (Optional)	le through a phone. This digits U.S. ill be used
The l voice optic phor durin En	IVR option will communicate your MFA Cod e message that will be sent directly to your on requires you to provide a valid ten (10) of ne number and (optional) extension that w ng login to obtain the MFA Code. ter Phone Number ter Extension (Optional) Send MFA Code	le through a phone. This tigits U.S. ill be used

Figure 3: Logging in Using MFA - Multi-Factor Authentication - (IVR) Example

- 7. Enter your phone number in the **Phone Number** field; enter your extension in the **Extension** field, if necessary.
- 8. Click the **Send MFA Code** button to receive a six-digit code via your chosen contact method.



9. Record and enter the six-digit code you received into the **Enter MFA Code** field. Refer to *Figure 4*.

Login	Login with PIV Card
	CMS.gov Enterprise Portal
v	Multi-factor Authentication
In	teractive Voice Response (IVR)
Sen	nd To: xxx-xxx-1588
	MFA Code Sent
1	23456
	Verify
	Send MFA code automatically
30	Do not challenge me on this device for the next minutes
<u>Lea</u> Un	arn how to add MFA Devices beyond email able to Access MFA Device or MFA Code?
	<u>Cancel</u>

Figure 4: Logging in Using MFA - Multi-Factor Authentication - Verify MFA Code

10. Check the Send MFA code automatically and Do not challenge me on this device for the next 30 minutes checkboxes depending on your preference.

Note: If you need help, click the Learn how to add MFA Devices beyond email and Unable to Access MFA Devices or MFA Code? hyperlinks.

11. Click the **Verify** button to confirm your identity and enter the ASP Module.



The My Portal landing page opens. Refer to Figure 5.

My Portal	Add Application
	Previous Login: <u>View Login History</u>
Fee For Service Data Collection System(FFSDCS)-IMPLP	
Learn	how to add Multi-Factor Authentication (MFA) devices via My Profile in the Manage MFA Devices section.

Figure 5: My Portal Landing Page

Note: Other CMS applications you have access to may display on the **My Portal** landing page.

12. Click the Fee For Service Data Collection System (FFSDCS) box.

A Fee for Service Data Collection System (FFSDCS) drop-down menu opens. Refer to *Figure 6*.



Figure 6: My Portal Landing Page - FFSDCS Drop-down

13. Click the Average Sales Price (ASP) hyperlink.

A full-page statement displays, titled **ASP Data for Drugs and Biologics Covered Under Medicare Part B**. The statement details recent statutory requirements stated in the Social Security Act (the Act), and the <u>Consolidated Appropriations Act</u> (CAA),



2021. These requirements hold that manufacturers must report their ASP data to CMS with precision on a quarterly basis without errors or miscalculations. Refer to *Figure 7*.

CMS.go	V My Enterprise Portal	i≣ My Apps		E Will Will ASP Certifi▼	? <u>Help</u>	🕩 Log Out
Medicare P	art B Average Sales Price	Home				
Home	ASP Data for Drugs and Biologics Cove	ered Under Medicare Part B:				
Compliance Su Verify One Time	As part of our implementation of a new statutor sales price (ASP) data or may have only report new statutory requirement.	y requirement, CMS believes some manufacturers of drugs and biologi and ASP data for a subset of their applicable product line. This can inclu	cals payable under Medicare Par de repackagers. We request that	t B have not reported required ave you review your efforts in respons	erage e to this	number for
Certification Help	Section 1927(b)(3)(A)(iii)(1) of the Social Securi 401 of the Consolidated Appropriations Act (CA rebate agreement to report ASP information to 1842(0)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Physician Fee Schedule 2022 Final Rule (6	ty Act (the Act) requires manufacturers with a Medicaid drug rebate agr vA), 2021 amended section 1847A of the Act to add new section 1847A CMS for calendar quarters beginning on January 1, 2022, for drugs or 1 the Act, including items, services, supplies, and products that are payab 36 FR 64996).	eement to report ASP data as sp (f)(2) of the Act, which requires m biologicals payable under Medica ble under Part B as a drug or biologicals	ecified in section 1847A of the Act anufacturers without a Medicaid d are Part B and described in section ogical. This is discussed in further	. Section irug is detail in	, search s for improving net Explorer is
	Such manufacturers were to first report ASP da calculated by the manufacturer every calendar with provisions in section 1847A(f)(2) of the Acr Manufacturers are required to continue to repo	Ita to CMS for calendar quarters beginning on January 1, 2022. As statt quarter and submitted to CMS within 30 days of the close of the quarter tshould have done so no later than April 30, 2022 (within 30 days of the rt each quarter thereafter.	ed in 42 CFR ŧ 414.804, the 'm r.' Therefore, manufacturers first e close of the first quarter of 2022	anufacturer's average sales price r reporting ASP data to CMS in acc ?) for the July 2022 ASP Drug Prici	must be ordance ng File.	
	We are writing to you today to ask that you revi companies may be reporting only a subset of th identify from publicly available websites and pu	ew your efforts to meet this statutory obligation. This includes reviewing neir products for which ASP reporting is required, based on our review or ublic compendia.	g to ensure that all products are p of current lists of products, includi	properly reported. We believe that ing National Drug Codes, that we o	some can	
	Sections 1847A(d)(4)(B) and (C) of the Act app consistent with the civil money penalties found manufacturer has made a misrepresentation in misrepresentation was applied.	ly civil money penalties (CMPs) for failure to report timely and accurate at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with M the reporting of ASP data, a CMP of up to \$10,000 may be applied for	ASP data for manufacturers with edicaid drug rebate agreements. each price misrepresentation and	nout Medicaid drug rebate agreem If the Secretary determines that a d for each day in which the price	ents,	
	Please visit https://portal.cms.gov to register fo templates that must be used within the system. https://www.cms.gov/Medicare/Medicare-Fee-fr	r the ASP Data Collection System or login if you already have an accou . If you have any questions regarding the online portal system, please c or-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice or email Sec303	int. The User Guide can be found ontact asphelpdesk@dcca.com. ASPdata@cms.hhs.gov.	i in the links below as well as the of For additional information, please	lata visit	
	Thank you for your efforts in helping CMS to re	ceive all appropriate information as we work to improve the sustainabili	ty of the Medicare Part B Trust Fi	und.		
	Marla Durham					
	Director					
	vg		01	have read the above statement	Submit	

Figure 7: ASP Data for Drugs and Biologics Under Medicare Part B

14. Read the statement; select the **I have read the above statement** checkbox and click **Submit**.

The Medicare Part B Average Sales Price homepage opens. Refer to Figure 8.



\\$. gov My Enterprise Portal ≣ M	ly Apps			•	Jennifer	ASP Certifi▼	? <u>He</u>	elp 🕩 Lo
dicare Part B Average Sales Price				0	Help Desk	🛓 User Guide	(PDF)	Any Profile
TP Verification Compliance Summary Assumptions Drug Certification	on FAQ							
Welcome, Jennifer								Help
Reporting Summary Pricing Quarter: Q4 2023 Current Submission Period: 01/01/2024 - 01/30/2024 Days Remaining in the Current Submission Period: 0								
CMS Alerts		ASP Busi	ness Pro	ocess	Flow			
Validate Existing Product Data	î	Submitter	Certifier					
03/01/2024	_ [Submitter	Certifier					
With the updated data fields, there may be drug product data that will need additional when you log in for the first time. There is an alert box on this Welcome page with instru	review ictions							
on how to update all current product data. Please note, you may need to have prev submitted data available to reference when completing this task. You must complete th	viously is step	Submitter	Certifier					
before you can upload or enter new quarterly financial data into the system for th quarter only.	is first	(1) Authenti	cate using One-T	ime Passwo	ord (OTP)			
	- 1	2 Review S	ubmitted Financ	ial Data 🕕				
01/15/2023		3 Certify S	ubmitted Financi	ial Data				
On Tuesday, April 17, CMS will host a webinar on the Discarded Drug Refund. Durir webinar, CMS staff will discuss Section 90004 of the Infrastructure Investment and Jo (Pub, L, 117-58, November 15, 2021). Date: Tuesday, April 17 Time: 2:00 – 3:30 PM ET	ng this Ibs Act	The link to corner of to asphelpdo	the ASP Data Co he application so sk@dcca.com fo	ollection U creen. Pleas or technical	ser Guide is se contact t assistance.	s located in the u he ASP Helpdesl	upper rig < at	ht-hand
More information on this webinar opportunity can be found at: Discarded Drugs.	ļ	To return Price title	o this home pag at the top left of	e at any tim your screer	ne, click on 1 n.	he Medicare Pa	rt B Ave	rage Sales
<u>Go To OTP Verification</u> →								
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of 0921. The time required to complete this information collection is estimated to average 13 hours per resp the information collection. If you have comments concerning the accuracy of the time estimate(s) or sug 26-05, Baltimore, Maryland 21244-1850. CMS 10110 approval 08/31/2024.	information unless ponse, including the gestions for improv	it displays a valid OME e time to review instru ing this form, please w	control number. Th tions, search existin rite to: CMS, 7500 Se	e valid OMB c ng data resour ecurity Boulev	ontrol numbe rces, gather th vard, Attn: PRA	r for this informatio e data needed, and Reports Clearance	n collectio complete a Officer, Ma	n is 0938- and review il Stop C4-

Figure 8: Medicare Part B Average Sales Price Homepage



3. ASP Homepage Menu Tabs

The following sections describe the functionality of each menu tab on the ASP homepage, including **OTP Verification**, **Compliance Summary**, **Assumptions**, and **Drug Certification**.

3.1 One Time Password (OTP) Verification

Once the Submitter has completed and submitted product data, the Submitter must share the one-time password (OTP) with the Certifier to establish a relationship within the system. Note the following about OTPs:

- This step only occurs once as long as the people in both roles remain the same.
- A new OTP should only be generated if the person in either role changes.
- An OTP is valid for seven days. After seven days, the Submitter must generate a new OTP.
- Once the Submitter generates and provides the OTP to the Certifier, the Certifier must verify the OTP to continue.
- If the OTP is misplaced or lost, the Certifier must contact the Submitter to generate another OTP.

Follow these steps to verify the OTP:

1. From the Medicare Part B Average Sales Price homepage, click the **OTP Verification** tab.

The OTP Verification page opens. Refer to Figure 9.

CMS.gov My	Enterprise Portal			🗮 My Apps	
Medicare Part I	B Average Sales Price				
OTP Verification	Compliance Summary	Certification 🔫	FAQ		
← Back to Weld	ome page				
OTP Ver	rification				
Manufacturer N	ame (required)				
Begin typing the	manufacturer name to see name	mes for selection	TP Provided by Your Data	a Submitter (required)	_
					Verify

Figure 9: OTP Verification

2. In the **Manufacturer Name (required)** field, begin typing the manufacturer name to narrow down names for selection; select the appropriate manufacturer name. Refer to *Figure 10*.



CMS.gov My	Enterprise Portal				🔳 My Apps	
Medicare Part	B Average Sales Price	2				
OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ		
← Back to Weld	ome page					
OTP Ver	ification					
Manufacturer N Begin typing the	lame (required) manufacturer name to see na	mes for selection	OTP Provided by Your D	ata Submitte	er (required)	
теј		\mathbf{x}				Verify
(-				
Test Manf Nam	e impl	•				

Figure 10: OTP Verification - Manufacturer Name

3. Enter the OTP code from the Submitter in the **OTP Provided by Your Data Submitter** (required) field. Refer to *Figure 11*.

CMS.gov My	Enterprise Portal			🗮 My Apps	5
Medicare Part E	3 Average Sales Price				
OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ	
← Back to Welco	ome page				
OTP Ver	ification				
Manufacturer N	ame (required)				
Begin typing the	manufacturer name to see name	mes for selection	OTP Provided by Your D	ata Submitter (required)	
Test Manf Nam	ne impl	×	ecYa1RceQ7O9vUvDco2	FOA	Verify

Figure 11: OTP Verification - OTP Provided by Your Data Submitter

4. Click **Verify** to confirm the OTP.

A message displaying confirming you have successfully verified the OTP. Refer to *Figure 12*.



Enterprise Portal		🔳 Му Арј	os	
Average Sales Price	5			
Compliance Summary	Certification 🔫	FAQ		
ification				
rified for Manufacturer name	Test Manf Name impl an	d submitter Jennifer A	SP Submitter. You are permi	tted to certify data.
ame (required) manufacturer name to see na	ames for selection OT	P Provided by Your D	ata Submitter (required)	
	Enterprise Portal Average Sales Price Compliance Summary ome page ification rified for Manufacturer name ame (required) manufacturer name to see na	Enterprise Portal Average Sales Price Compliance Summary Certification ification ified for Manufacturer name Test Manf Name impl an me (required) manufacturer name to see names for selection	Enterprise Portal I I My App Average Sales Price Compliance Summary Certification ✓ FAQ ome page ification rified for Manufacturer name Test Manf Name impl and submitter Jennifer A ame (required) manufacturer name to see names for selection OTP Provided by Your D	Enterprise Portal Average Sales Price Compliance Summary Certification ▼ FAQ ome page ification rified for Manufacturer name Test Manf Name impl and submitter Jennifer ASP Submitter. You are perminanter (required) manufacturer name to see names for selection OTP Provided by Your Data Submitter (required)

Figure 12: OTP Verification Successful

3.2 Compliance Summary

The features in the **Compliance Summary** section allow drug manufacturers to determine if their products meet the current submission reporting requirements.

The **Compliance Summary** consists of the following sections:

- **Missing**: Displays drug products that are missing financial data for the selected reporting period.
- **Pending**: Displays drug products that are both pending certification and pending restatement certification, combined under one tab.
- **Certified**: Displays previously certified drug products for the selected reporting period.

Note: Financial data will be suppressed for prior quarters.

- New: Displays drug products with a first marketing date in the same reporting period.
- **Off Cycle**: Displays drug products added on or after the first day of the submission window of the current quarter.
- **Expired**: Displays drug products that have an expired date of final lot sold which is prior to the reporting period selected. A drug product that expired in an earlier quarter will continue to show in subsequent quarters.

Follow these steps to navigate the Compliance Summary section:

1. From the Medicare Part B Average Sales Price homepage, click the **Compliance Summary** tab.

The **Compliance Summary** page opens. The page displays the status for each submitted drug product regarding the drug manufacturer's compliance for the selected reporting period. The page automatically defaults to the **Missing** tab. Refer to *Figure 13*.

Note: *Figure 13* shows an alert message under **Reporting Period** stating that there are drug products in need of attention.



CMS.gov My	Enterprise Portal		🔳 My Apps	5		Jennifer ASP	Certifi 🔻 ? <u>Help</u>	e 🕩 <u>Log Out</u>
Medicare Part	3 Average Sales Pri	ice				🛛 Help Desk	User Guide (PDF)	My Profile
OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ				
← Back to Welc	ome page							
Comp	liance Sun	nmary						
comp	uance sun	innar y						
Reporting	Period (required)							
Q4 2023	~ >							
A Label	ers are out of compliance w	ith data reporting rec	uirements 20% of drugs are	certified out of 5 total	drugs (1 certified 0 Restate	ement Certified)		
U Laber		in dua reporting rec	faircriteria. 20 % of drags are			chiefe dertified,		
Missing 1	Pending 3	Certified 1	New 1 Off Cycle 1	Expired 1				
1 David Idea							Export to Exce	et
1 Drug Iden	itiners awaiting data entr	У	Reporting			Wholesale Acquisition	Average Wholesal	le
Drug Identif	ier Manufacturer N	lame	Period	Manufacturer's ASP	Number of ASP Units	Cost	Pric	:e
00010-1111-	11 Test Manf Name	impl	Q4 2023					*

Figure 13: Compliance Summary

Note: Click the **Reporting Period** (required) tab in the top left to scroll through previous quarters. Use the drop-down to navigate a previous quarter starting with the most recent, or the next quarter.

3.2.1 Missing

Follow these steps to review your data in the **Missing** tab of the **Compliance Summary**:

1. Under **Drug Identifiers waiting for data entry**, review and identify the missing financial information to address with the Submitter.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price** fields.

Note: Click the Export to Excel button to download all products under the Missing tab.

- 2. Inform the Submitter of any missing financial information to ensure the inclusion of all data collected in the Module.
- 3. Click the **Pending** tab to move on to the next page.

3.2.2 Pending

Follow these steps to review the **Pending** tab of the **Compliance Summary**:

1. From the default Compliance Summary page, click the **Pending** tab.

The Pending page displays. Refer to Figure 14.

S.gov My I	Enterprise Portal		III 1	My Apps			Jennifer ASP Cert	<u>ifi</u> ▼ ? <u>Help</u>	🕩 <u>Log O</u>
dicare Part B	Average Sales P	rice				0	Help Desk	er Guide (PDF)	y Profile
P Verification	Compliance Summa	ry Assumptions	s Drug Certificat	ion FAQ					
← Back to Welco	ome page								
Comp	liance Su	mmarv							
comp		ininar y							
Reporting F	Period (required)								
Q4 2023	~ 2								
		54 J			f = 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1 + 1		10.10.1		
	ers are out of compliance	with data reporting re	equirements. 20% of dri	ugs are certified out	of 5 total drugs. (1 cer	tified, 0 Restatemen	it Certified)		
Missing 1	Pending 3	Certified	New 1 Off Cy	cle 1 Expir	ed 1				
All Pendir	ng Certification O Per	nding Certification (O Pending Restatemer	nt Certification					
								🛓 Export to Excel	
3 Drug Iden	tifiers waiting for certif	ication/restatement	certification						
Drug Identifi	ier Manufacturer Na	Reporting me Period	Manufacturer's	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesal Pric	e Submitter Name	Action	
	11								
00000 0000 (7		61004567000.000	1224507000.000	£1004567000 000	\$1004FC7000.00	Will ASP Submitter,	Go to Certification \rightarrow	•
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Figure 14: Compliance Summary - All Pending Certification

The Module automatically selects the **All Pending Certification** radio button, and the page displays the drug identifiers waiting for certification/restatement certification.

Note: Click the Export to Excel button to download all products under the Pending tab.

2. Review the drug information under **Drug Identifiers Waiting for Certification/Restatement Certification**.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.

- 3. Under Action, click the Go to Certification hyperlink to navigate to Drug Certification. (Refer to Section 3.4 Drug Certification.)
- 4. Click the **Pending Certification** radio button to filter only for drugs pending certification. Refer to *Figure 15*.



MS.gov My	Enterprise Portal		III (My Apps		•	Jennifer ASP Cert	ifi ? <u>Help</u>	🕩 Log
ledicare Part E	3 Average Sales Pr	ice				0	Help Desk 🕹 Use	er Guide (PDF)	My Profile
OTP Verification	Compliance Summary	Assumptions	Drug Certificati	ion FAQ					
← Back to Welc	ome page								
Comp	liance Sur	nmarv							
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							
Reporting	Period (required)								
Q4 2023	~ >								
6 Labele	ers are out of compliance v	vith data reporting req	uirements. 20% of dru	ugs are certified out c	of 5 total drugs, (1 cer	tified 0 Restatement	Certified)		
0									
Missing 1	Pending 3	Certified	New 1 Off Cy	cle 1 Expire	ed 1				
O All Pendi	ng Certification 🔘 Pend	ding Certification C) Pending Restatemer	nt Certification					
								k Export to Excel	J
3 Drug Iden	tifiers awaiting Certifier	s action							
Drug Identif	fier Manufacturer Nan	Reporting ne Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price	Submitter Name	Action	
									_
99999-9999-1	99 Test Manf Name im	ipl Q4 2023	\$1234567890.000	1234567890.000	\$1234567890.000	\$1234567890.000	Will ASP Submitter, Will	Go to Certification →	*
99999-9999-	99 Test Manf Name im	pl Q4 2023	\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter, Jennifer	Go to Certification →	
xyz	Test Manf Name im	ipl Q4 2023	\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, Jennifer	Go to Certification \rightarrow	

Figure 15: Compliance Summary - Pending Certification

Note: Click the Export to Excel box to download all products under the Pending tab.

5. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.

- 6. Under Action, click the Go to Certification hyperlink to navigate to Drug Certification. (Refer to Section 3.4 Drug Certification.)
- 7. Click the **Pending Restatement Certification** radio button to filter only for drugs that are pending restatement certification. Refer to *Figure 16*.
- 8. Under Action, click the Go to Certification hyperlink to navigate to Drug Certification. (Refer to Section 3.4 Drug Certification.)



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OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ					
← Back to Welc	ome page								
Comp	liance Sun	ımary							
Reporting Q4 2023	Period (required)								
1 Label	ers are out of compliance wi	th data reporting requi	rements. 20% of drugs ar	re certified out of 5	i total drugs. (1 cer	tified, 0 Restateme	nt Certified)		
Missing 1	Pending 3	Certified 1 Ne	w 1 Off Cycle	1 Expired	1				
🔿 All Pendi	ng Certification O Pendi	ng Certification	Pending Restatement Cer	tification					
								🛓 Export to	Excel
0 Drug Ider	tifiers awaiting Certifier's	restatement action							
Drug Identii	fier Manufacturer Name	Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesa Pri	le ce Submitter Name	e Action	
			No	records available					

Figure 16: Compliance Summary - Pending Restatement Certification

Note: Click the Export to Excel box to download all products under the Pending tab.

9. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action** fields.

- 10. Under Action, click the Go to Certification hyperlink to navigate to Drug Certification. (Refer to Section 3.4 Drug Certification.)
- 11. Click the **Certified** tab to move on to the next page.

3.2.3 Certified

Follow these steps to review your data in the **Certified** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **Certified** tab.

The Certified page displays. Refer to Figure 17.



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dicare Part B	3 Average Sales Price	<u>e</u>				(😗 Help Desk	🛓 User Guid	e (PDF)	My Profile
TP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ						
← Back to Welc	ome page									
Comp	liance Sum	mary								
Reporting F	Period (required)									
1 Labele	ers are out of compliance with	data reporting requir	ements. 20% of drugs are	e certified out c	of 5 total drugs. (1 c	certified, 0 Restater	ment Certified)			
Missing	Pending 3 Cer	rtified 1 Nev	v 1 Off Cycle	Expire	ed 🚺					
All Certifi	ied 🔿 Certified 🔿 Resta	ated and Certified								
								E E	xport to Excel	
1 Drug Iden	tifiers certified/restated and	l certified								
Drug Identifi	ier Manufacturer Name	Re	porting Period	inufacturer's ASP	Number of ASP Units	Wholes Acquisition C	sale Average W Cost	/holesale Price Sub	omitter Name	
										-
xyz	Test Manf Name impl	Q	4 2023	\$123.450	123.450	\$123.	450	\$123.450 Will Will	l ASP Submitter,	*

Figure 17: Compliance Summary - Certified

The Module automatically selects the **All Certified** radio button, and the page displays the certified/restated drug identifiers.

Note: Click the Export to Excel button to download all products under the Certified tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

3. Click the **Certified** radio button to filter only for certified drugs. Refer to *Figure 18*.



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← <u>Back to Wel</u>	<u>come page</u>								
Comn	liance Sum	marv							
comp	dance Jum	inar y							
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Q 4 2023	~ 2								
	lers are out of compliance with	data reporting requ	uirements 20% of drue	as are certified out of	5 total drugs (1 cer	tified 0 Restatemen	t Certified)		
U Labe	iers are out or compliance with	ruata reporting requ		so are certified out of	o total drugs. (2 cer	unea, o restatemen	it certified,		
Missing 1	Pending 3 Ce	ertified 1 N	lew 1 Off Cyc	le 1 Expire	d 🚺				
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1 Drug Ide	ntifiers certified								
Drug Ident	ifier Manufacturer Name		Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholesale Acquisition Cost	Average Wholesale Price	Submitter Name	
хуг	Test Manf Name impl		Q4 2023	\$123.450	123.450	\$123.450	\$123.450	Will ASP Submitter, Will	•

Figure 18: Compliance Summary - Certified

Note: Click the Export to Excel button to download all products under the Certified tab.

4. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

5. Click the **Restated and Certified** radio button to filter only for certified drugs that were restated. Refer to *Figure 19*.



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Medicare Part	3 Average Sales Price	e				(🕜 Help Desk	🛓 User Guide	(PDF)	My Profile
OTP Verification	Compliance Summary	Assumptions	Drug Certificati	ion FAQ						
← Back to Weld	ome page									
Comp	liance Sum	mary								
Reporting Q4 2023	Period (required)									
1 Label	ers are out of compliance with	n data reporting req	quirements. 20% of dru	ugs are certified out	of 5 total drugs. (1 d	certified, 0 Restaten	nent Certified)			
Missing 1	Pending 3 Ce	artified 1	New 1 Off Cy	cle 1 Expin	red 1					
O All Certif	ied 🔘 Certified 🔘 Rest	ated and Certified								
0 Drug Ider	ntifiers restated and certified	d						Exp	port to Excel	
Drug Identif	fier Manufacturer Name		Reporting Period	Manufacturer's ASP	Number of ASP Units	Wholes Acquisition C	ale Average W ost	holesale Price Subn	nitter Name	_
				No records available						•

Figure 19: Compliance Summary - Restated and Certified

Note: Click the Export to Excel button to download all products under the Certified tab.

6. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

7. Click the **New** tab to move on to the next page.

3.2.4 New

Follow these steps to review data in the **New** tab of the **Compliance Summary**:

1. From the default **Compliance Summary** page, click the **New** tab.

The New page displays. Refer to Figure 20.



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OTP Ver	ification	Compliance Summary	Assumptio	ns Drug	g Certification	FAQ						
← <u></u>	Back to Welcon	ne page										
C	ompli	iance Sun	nmary									
٢	Reporting Pe	riod (required)										
	1 Labelers	are out of compliance w	ith data reporting	requirements	. 20% of drugs are co	ertified out of 5 total dr	rugs. (1 certified,0 Res	statem	ent Certified)			
	Missing 1	Pending 3	Certified 1	New 1	Off Cycle 1	Expired 1						
	1 Drug Identii	fiers whose First Market	ing Date resides i	in the Report	ing Period					🛓 Exp	oort to Exce	ı
	Drug Identifier	r Manufacturer N	ame		Reporting Period	Manufacturer's AS	SP Number of ASP U	nits	Whole Acquisition	sale Averag Cost	e Wholesal Pric	e e
	00010-1111-11	Test Manf Name	impl									

Figure 20: Compliance Summary - New

Note: Click the Export to Excel button to download all products under the New tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

3. Click the **Off Cycle** tab to move on to the next page.

3.2.5 Off Cycle

Follow these steps to review data in the Off Cycle tab of the Compliance Summary:

1. From the default **Compliance Summary** page, click the **Off Cycle** tab.

The Off Cycle page displays. Refer to Figure 21.



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Comp	liance Sum	marv						
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Reporting	Period (required)							
< Q4 2023	~ 2							
f Labele	ers are out of compliance with	data reporting requir	ements. 20% of drugs are	certified out of 5 total	drugs. (1 certified, 0 Restat	ement Certified)		
J								
Missing 1	Pending 3 Cer	rtified 1 New	w 1 Off Cycle 1	Expired 1				
							<u> </u>	
1 New Drug	Identifiers with neutial finan	sial data required					🛓 Exp	ort to Excel
Drug Identif	ier Manufacture	r Name	Reporting	Period	Wholesale Acquisit	ion Cost	Average Who	olesale Price
							-	
00000-9999-	11 Test Manf Nar	ne impl	Q4 2023		\$1	1000.000		*

Figure 21: Compliance Summary - Off Cycle

Note: Click the **Export to Excel** button to download all products under the **Off Cycle** tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name**, and includes **Reporting Period**, **Wholesale Acquisition Cost**, and **Average Wholesale Price**.

3. Click the **Expired** tab to move on to the next page.

3.2.6 Expired

Follow these steps to review data in the Expired tab of the Compliance Summary:

1. From the default **Compliance Summary** page, click the **Expired** tab.

The **Expired** page displays. Refer to *Figure 22*.



CMS.gov M	y Enterprise Portal		🔳 My Apps	5	A	I <u>Jennifer ASF</u>	<u>Certifi</u> ▼ ? <u>He</u>	<u>lp</u> 🕩 <u>Log Out</u>
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OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ				
← Back to We	lcome page							
Com	oliance Sun	nmary						
Reportir	g Period (required)							
Q4 2023	~ >							
🚺 Lab	elers are out of compliance w	ith data reporting re	quirements. 20% of drugs are	certified out of 5 total d	rugs. (1 certified,0 Restaten	nent Certified)		
Missing	Pending 3	Certified	New 1 Off Cycle 1	Expired 1				
							🛓 Export to Ex	cel
1 Drug ld	entifiers whose Expiration I	Date has passed						
Drug Ider	tifier Manufacturer	Name			First Marketing Da	Expire Sold	ration Date of Final Lot	
00010-00	0-00 Test Manf Nan	ne impl			03/20/2023	09/0	1/2023	•

Figure 22: Compliance Summary - Expired

Note: Click the Export to Excel button to download all products under the Expired tab.

2. Review the submitted drug information.

The Module organizes the full list by **Drug Identifier** and **Manufacturer Name** and includes **First Marketing Date** and **Expiration Date of Final Lost Sold**.

3.3 Assumptions

Drug manufacturers can submit comments regarding their certifications to CMS. Manufacturers may submit these comments for either the current or prior reporting periods.

Follow these steps to submit certification assumptions to CMS:

1. From the **Medicare Part B Average Sales Price** homepage, click the **Assumptions** tab.

The **Assumptions** page opens and defaults to the current quarter and year. Refer to *Figure 23*.



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licare Part B Ave	erage Sales Price					🕜 Help Desk 🛃 🛓	User Guide (PDI	F) My Prot
Verification Co	mpliance Summary	Assumptions	Drug Certification	FAQ				
← Back to Welcome p	bage							
Assumpt	tions							
Reporting Period	d (required)							
Q 4 2023	~ >	_						
Q4 2023	or Upload Assumption	File						
Q4 2023	or Upload Assumption	File					Exp	ort to Excel
Q4 2023 Create Assumption Saved Files	or Upload Assumption	File					🛓 Exp	ort to Excel
Q4 2023 Q4 2023 Create Assumption Saved Files File Name	or Upload Assumption	File File Description	Manufacturer	Name	Date Saved	Saved By	Actions	ort to Excel
Q4 2023 Create Assumption Saved Files File Name	vor Upload Assumption	File File Description	Manufacturer	Name	Date Saved	Saved By	Actions	ort to Excel
Q4 2023 Create Assumption Saved Files File Name Assumption Test File do	or Upload Assumption	File File Description Description of File	Manufacturer Test Manf Nam	Name e impl	Date Saved	Saved By ASP Submitter, Jennifer (submitter)	Actions	ort to Excel
Q4 2023 Create Assumption Saved Files File Name Assumption Test File.dc user_entry_assumption mpl 2024 03 1314 02	Control Upload Assumption	File File Description Description of File This is a short description is a sample	Manufacturer Test Manf Nam 1. This Test Manf Nam	Name e impl	Date Saved 2024-03-13 14:07 PM 2024-03-13 14:02 PM	Saved By ASP Submitter, Jennifer (submitter) ASP Submitter, Jennifer (submitter)	Actions	ort to Excel

Figure 23: Assumptions

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Use the drop-down menu to navigate to a previous quarter starting with the most recent quarter.

Note: Click the **Export to Excel** box to download all products under the **Assumptions** tab.

3.3.1 Create Assumption

Follow these steps to create an assumption:

1. Click the Create Assumption or Upload Assumption File button.

The **Create Assumption or Upload Assumption File** window displays. The Module automatically defaults to the **Create Assumption** radio button with a **Manufacturer Name (required)** drop-down menu and empty **Short Description** and **Text for Assumption file** fields. Refer to *Figure 24*.



Create Assumption or Upload Assumption Fi	ile × <u>Close</u>
Create Assumption O Upload Assumption File	
Manufacturer Name (required)	
- Select - V	
Short Description	
	1.
500 characters left	
Text for Assumption file (required)	
5000 characters left	11
Sa	ve Cancel

Figure 24: Assumptions - Create Assumption or Upload Assumption File

- 2. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** dropdown menu to expand the list and select the manufacturer name.
- 3. Complete the **Short Description** and **Text for Assumption file** fields.

Note: The **Short Description** field is optional and allows for 500 characters of text to provide a summary of the complete assumption you are submitting to CMS. The **Text for Assumption file** field is required and allows for 5000 characters to provide as much detail as possible related to the selected period's financial submission.

4. Click the Save button.

A message displays confirming you have successfully created your **Assumption**. Refer to *Figure 25*.



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edicare Part B Average Sales Price				🛛 Help Desk	User Guide (PDF)
TP Verification Compliance Summary Assu	umptions Drug Certification	FAQ			
← Back to Welcome page					
Assumptions					
File upload has completed successfully.					
Reporting Period (required)					
Create Assumption or Upload Assumption File					
Saved Files					🛓 Export to Excel
File Name	File Description	Manufacturer Name	Date Saved	Saved By	Actions
user entry assumptions test manf name impl 2024 01 1610 53 03.txt		Test Manf Name impl	2024-01-16 10:53 AM	Will ASP Certifier, Will (certifier)	Delete
ProductDataTemplate (1) (1),xlsx	Short description of the Assumption File.	Test Manf Name impl	2024-01-12 16:41 PM	Will ASP Submitter, Will (submitter)	
user entry assumptions test manf name impl 2024 01 1216 40 05.txt	Short description of your assumption.	Test Manf Name impl	2024-01-12 16:40 PM	Will ASP Submitter, Will (submitter)	
ProductDataTemplate (1).xlsx	Lorem ipsum dolor sit amet, consectetur adipiscin Read More	Test Manf Name impl	2024-01-11 17:01 PM	Will ASP Certifier, Will (certifier)	Delete
user entry assumptions test manf name impl 2024 01 11 17 00 50.txt	Lorem ipsum dolor sit amet, consectetur adipiscin <u>Read More</u>	Test Manf Name impl	2024-01-11 17:00 PM	Will ASP Certifier, Will (certifier)	Delete

Figure 25: New Assumption Successfully Created

3.3.2 Upload Assumption File

Follow these steps to upload an assumption file to the Module:

1. Click the **Create Assumption or Upload Assumption File** tab.

The **Create Assumption or Upload Assumption File** window displays. The Module automatically defaults to the **Create Assumption** radio button.

2. Select the Upload Assumption File radio button.

A **Manufacturer Name (required)** drop-down menu and empty **File Description** field display. Refer to *Figure 26*.



Create Assumption or Upload Assumption File	X Close
O Create Assumption 🔘 Upload Assumption File	
Manufacturer Name (required)	
- Select - V	
File Description	4
500 characters left	

Figure 26: Upload Assumption File

3. From the **Manufacturer Name (required)** drop-down menu, click the **-Select-** dropdown menu to expand the list and select the manufacturer name.

As you select your manufacturer name, additional fields display on the screen. Refer to *Figure 27*.



• • • • • •		
Create Assumption	Upload Assumption File	
Manufacturer Name (r	equired)	
Test Manf Name impl	~	
]
		li
500 characters left		
500 characters left Supported File Forma format(.doc) Show m	ats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (.docx), Word old
500 characters left Supported File Forma format(.doc) Show m File (required)	ats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (.docx), Word old
500 characters left Supported File Forma format(.doc) Show m File (required) Maximum File Size is 1	ats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (nore	.docx), Word old
500 characters left Supported File Forma format(.doc) Show m File (required) Maximum File Size is 1	ats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (nore LOOMB	.docx), Word old
500 characters left Supported File Forma format(.doc) <u>Show m</u> File (required) Maximum File Size is 1	ats: Text(.txt), PDF(.pdf), Excel(.xlsx), Word (nore 100MB Select file or drag file here	.docx), Word old

Figure 27: Upload Assumption File - Expanded Fields

4. In the **File Description** field, enter your assumption about a data submission. You have 500 characters of total text to comment about your submission in this section.

Note: Click the **Show More** tab to display all **Supported File Formats** available in the Module for you to use in your **Assumption File** upload.

5. Click **Select File** to browse your desktop and upload your **Assumption File** to the Module. You may also drag your **Assumption File** into the **Select File** box. Refer to *Figure 28*.



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← Back t	Realized access	Assumption Test File	3/13/2024 2:05 PM	Microsoft Wor	d D 12					
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Create	Pictures									
	Videos Y	<			>					
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			Upload from mobile	Open	Cancel					
Saved F			401 characters left			}	4			
File Nam	ne	File	491 Characters len					aved By Acti	ins	
			Supported File Formats: Te	kt(.txt), PDF(.pdf),	Excel(.xlsx), \	Nord (.docx), W	ord old			_
			format(.doc) Show more							
			File (required)					SP Submitter Jennifer		
Assump	tion Test File.docx	Des	rite (requirea)					ubmittor)		

Figure 28: Upload Assumption File - Uploading Files From Desktop

A download bar displays as your file uploads. A message opens to confirm you have successfully uploaded your assumption file. Refer to *Figure 29*.

S.gov My E	interprise Portal			📰 My Apps		A 0	Will Will ASP Certifi	• ? <u>Help</u>
licare Part B	Average Sales Price					🛛 Help (Desk 🛃 User Guid	e (PDF)
P Verification	Compliance Summary	Assumptions	Drug Certification	FAQ				
← Back to Welco	me page							
Assum	ptions							
	-							
S File up	load has completed successfu	uy.						
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< Q4 202	3 ~ >							
Create Assump	ption or Upload Assumption	File						
								Export to Excel
Saved Files								
File Name		File Descript	tion	Manufacturer Name	Date Saved	Saved By	Actions	
user entry assur 01 16 10 53 03	mptions test manf name impl : Ltxt	2024		Test Manf Name impl	2024-01-16 10:53 AM	Will ASP Certifier, Will (certifier	Delete	
ProductDataTem	plate (1) (1),xlsx	Short descrip	ption of the Assumption File.	Test Manf Name impl	2024-01-12 16:41 PM	Will ASP Submitter, Will (submitter)		
<u>user entry assu</u> 01 12 16 40 05	mptions test manf name impl : i.txt	2024 Short descrip	ption of your assumption.	Test Manf Name impl	2024-01-12 16:40 PM	Will ASP Submitter, Will (submitter)		
ProductDataTem	plate.(1).xlsx	Lorem ipsun adipiscin	n dolor sit amet, consectetur Read More	Test Manf Name impl	2024-01-11 17:01 PM	Will ASP Certifier, Will (certifier	Delete	
user entry assu	mations test mont some ined	and Kanadiana						

Figure 29: Upload Assumption File - Successfully Added

3.4 Drug Certification

Drug certification is the process in which a drug manufacturer certifies the accuracy of submitted drug data. This process marks data for immediate certification or pending certification to be



completed later. Selection may include one drug product item, a list of drugs, or all items pending certification for a manufacturer.

The Submitter gathers the required quarterly drug data and submits it to the Module. Once the Submitter has successfully submitted the data, they will notify the Certifier to log in to the system to review and certify their submission.

Follow these steps to certify drug product data:

1. From the Medicare Part B Average Sales Price homepage, select **Drug Certification** tab from the **Certification** tab. Refer to *Figure 30*.

CMS.gov My	Enterprise Portal				🗮 My Apps
Medicare Part I	3 Average Sales Price	2			
OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ	

Figure 30: Certification - Drop-down

The Drug Certification page opens. Refer to Figure 31.

Medicare Par	Iedicare Part B Average Sales Price									
OTP Verification	Compliance Summary	Assumptions	Drug Certification	FAQ						
← Back to the Drug Ce Reporting Per < Q1 2023	Welcome page ertification iod (required) Manufa Selection 	cturer Name (require	ed)							

Figure 31: Drug Certification

Note: Click the **Reporting Period** (required) tab in the top left to scroll through previous quarters. Use the drop-down menu to navigate to a previous quarter starting with the most recent quarter.

2. Click the **-Select-** box under **Manufacturer Name (required)** to expand the list. Refer to *Figure 32*.



CMS.gov My En	terprise Portal		і≣ му	y Apps			Jennifer AS	<u>P Certifi</u> …▼	? <u>Help</u>	🕩 <u>Log Out</u>
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OTP Verification	Compliance Summar	y Assumptions	Drug Certificatio	n FAQ						
← Back to Welcom	e page									
Drug Cert	tification									
Reporting Per	iod (required)	Manufacturer Name (re	quired)							
< Q4 2023	~ >	- Select -			^					
		🗸 - Select -								
Drug Data Pend	ling Certification	Test Manf Name impl								
					* denotes product data	has been modified betwe	en current and prior qua	arter. 🛓 Expo	ort to Excel	
Drug Identifie	rs awaiting Certifier's	action								
		Mar	nufacturer's Nu	mber of ASP	Wholesale Acquisition Cost*	Average Wholesale				
Drug Ident	titier Generic Nam	e	•		•		Submitter's Name	Action		
				No records avail	able					

Figure 32: Drug Certification - Manufacturer Name

3. Select the appropriate manufacturer name.

The page displays two new radio buttons asking you to confirm if you are certifying as a direct employee or contractor. Refer to *Figure 33*.

CMS.gov My Enterprise Portal	≣ Му Аррз	♠ <u></u>
Medicare Part B Average Sales Price		🕒 Help Desk 🖉 🖢 User Guide (PDF)
OTP Verification Compliance Summary	Assumptions Drug Certification FAQ	
← Back to Welcome page Drug Certification		
Reporting Period (required) Man	Ifacturer Name (required) Manf Name impl	
Please confirm the manufacturer's ad Confirm button.	dress and certifier's email below are correct before proceeding. If they are inc	correct, Please edit them and save your changes before clicking the
Are you a contractor or a direct employee of the	manufacturer?	
O Direct Employee O Contractor		

Figure 33: Drug Certification - Direct Employee or Contractor

Note: In the updated ASP Data Collection System, CMS requests verification of your contact information prior to certifying data.

The following sections describe how to complete the drug certification process as a direct employee or contractor.



3.4.1 Direct Employee

Follow these steps to complete the drug certification process as a direct employee:

1. Click the **Direct Employee** radio button.

New fields display asking for more information about the manufacturer's address and contact information.

- 2. Enter or select the required information as follows:
 - a. Enter the street address in the Street Address (required) field.
 - b. Enter the street address in the Street Address Line 2 (optional) field, if necessary.
 - c. Enter the city in the **City (required)** field.
 - d. Enter the state in the State (required) field.
 - e. Enter the ZIP code in the **ZIP Code (required)** field.
 - f. Enter the name in the Name (required) field.
 - g. Enter the email address in the Email Address (required) field.
 - h. Enter the phone number in the Phone Number (required) field.
- 3. Click the **Edit** button under **Manufacturer's Address and Certifier's Contact Info** if you need to correct information already populated in a field. Refer to *Figure 34*.

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Please confirm the manufactor Confirm button.	ucturer's address and o	certifier's email below are correct b	efore proceedin	g. If they are incorrect, Pl	ease edit th	em and save y	our changes before	clicking the	
Are you a contractor or a direct empl	oyee of the manufactu	irer?							
Direct Employee O Cont	ractor								
	actor								
Manufacturer's Address									
Street Address (required)									
321 Main St.									
Street Address 2									
City (required)	State (required)	ZIP Code (required)							
MyCity	AA 🗸 🗸	12121							
		Edit							
Certifier's Contact Info									
Name (required)]							
Email Address (required)]							
JenniferSmith@DrugManufactur	er.com								
Phone Number (required)									
999-867-5309									
I confirm the accuracy of the info	rmation provided abo	ve.							
Confirm									

Figure 34: Drug Certification - Direct Employee - Fields Populated

4. Once you complete the fields, select the I confirm the accuracy of the information provided above checkbox; click Confirm and Save.

A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to *Figure 35*.



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Figure 35: Drug Certification - Direct Employee Confirmation

3.4.2 Contractor

Follow these steps to complete the drug certification process as a contractor:

1. Click the **Contractor** radio button.

New fields display asking for more information about the manufacturer's address, your manufacturer's point of contact (POC), and your contact information.

- 2. Enter or select the required information as follows:
 - a. Enter the street address in the Street Address (required) field.
 - b. Enter the street address in the Street Address Line 2 (optional) field, if necessary.
 - c. Enter the city in the **City (required)** field.
 - d. Enter the state in the State (required) field.
 - e. Enter the ZIP code in the **ZIP Code (required)** field.
 - f. Enter the point of contact name in the **Point of Contact's Name (required)** field.
 - g. Enter the point of contact email address in the **Point of Contact's Email Address** (required) field.
 - h. Enter the point of contact phone number in the **Point of Contact's Phone Number** (required) field.
 - i. Enter the certifier name in the Certifier's Name (required) field.
 - j. Enter the certifier email address in the **Certifier's Email Address (required)** field.
 - k. Enter the certifier phone number in the Certifier's Phone Number (required) field.



3. Click the **Edit** button under **Manufacturer's Address**, **Point of Contact Info**, and **Certifier's Contact Info** if you need to correct information already populated in a field. Refer to *Figure 36*.

Chrone Address (see ised)		
235 East 42nd Street		
Street Address line 2		
City (required)	State (required)	ZIP Code (requ
New York	NY 🗢	10017
		C
Point of Contact Info		
Name (required)		
John Doe		
Email Address (required)		
john.doe@pfizer.com		
Phone Number (required)		
410-555-1234		
		(
Certifier's Contact Info		
Name (required)		
Jane Doe		
Email Address (required)		
jane.doe@contractor.com		
Phone Number (required)		
410-555-5678		
		ſ

Figure 36: Drug Certification - Contractor - Fields Populated

4. Once you complete the fields, select the I confirm the accuracy of the information provided above checkbox; click Confirm and Save.

A message displays confirming you have successfully confirmed the manufacturer's address and certifier's email address. Refer to *Figure 37*.



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Figure 37: Drug Certification - Contractor Confirmation

3.4.3 Drug Data Pending Certification

Follow these steps to complete the drug data certification process and certify your products:

1. Confirm that your preferred drug product is selected under **Manufacturer Name** (required) field on the Drug Certification homepage. Refer to *Figure 37* and *Figure 38*.

Note: Click the **Reporting Period (required)** tab in the top left to scroll through previous quarters. Use the drop-down to navigate a previous quarter starting with the most recent quarter.

The Module displays the **Drug Data Pending Certification** tab by default. (Click the tab if the Module does not automatically open the page to the default setting.)

This page also lists all drug products by **Drug Identifier** and **Generic Name** as well as **Manufacturer's ASP**, **Number of ASP Units**, **Wholesale Acquisition Cost**, **Average Wholesale Price**, and **Action**. Refer to *Figure 38*.



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99999-	9999-99* GENERICA		\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter,	Certify	*
Pro	duct Info								
Bran	nd Name: No Data hber of Items per NDC/Alt ID: 30	Strengt Package	h of Product: 10 % (GM/A) Type: SINGLE DOSE	CTIVATION)	Volume per Item: 1 First Marketing Dat	1 Capsule :e: 01/01/2023			
Expi	ration Date of Final Lot Sold: N of First Sale for this Product: (o Data FDA App 02/01/2023 FDA App	roval Date: 12/31/2022 lication Number: 000001	L	FDA Approval Type FDA Application Su	: ANDA pplement Number: 00	01		
— xyz*	GENERICA		\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, Jennifer	Certify	
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Figure 38: Drug Data Pending Certification

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

- Click the plus symbol on each row of the table to expand each product's information and view additional drug product fields, such as Brand Name, First Marketing Date, Volume per Item, and all other information the Submitter previously reported. Refer to *Figure 38*.
- 3. Select the drug product and click the **Certify** box to open a new Data Certification Statement. Refer to *Figure 39*.



e		
Data Cert	ification Statement	× <u>Close</u>
I certify that the Product and Fir complete, and o faith. I understa Medicare reimb	reported Average Sales Prices were ca ancial information and statements ma current to the best of my knowledge ar nd that information contained in this s ursement purposes.	alculated accurately and that all ade in the submission are true, nd belief and are made in good submission may be used for
I agree to t	he above certification statement.	
		Cancel Certify Data
DAC	Şaa'111 153'42P	299.111
	Figure 39: Data Certification S	Statement

4. Read the statement; select the I agree to the above certification statement checkbox and select **Certify Data** to confirm approval of the submitted data.

A message displays confirming you have successfully certified the drug data. Refer to *Figure 40*.



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Drug Identi	fiers awaiting Certifier's a	ction							
					Wholesale				
		Ма	nufacturer's	Number of ASP	Acquisition Cost*	Average Wholesale	1978-199-19-01		
Drug Id	entifier Generic Name		ASP	Units U	U	Price	Submitter's Name	Action	
+ xvz*	GENERICA		\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter,	Certify	-
							Jennifer		

Figure 40: Data Certification - Confirmation Message

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

5. Continue this process for each individual drug product until all your products have been certified. Click **Certify All** to certify all products at the same time.

3.4.4 All Drugs in Period

Follow these steps to review all drug products and biologicals for the current reporting period:

1. From the **Drug Certification** homepage, click the **All Drugs in Period** tab.

The All Drugs in Period page opens. Refer to Figure 41.



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+ 99999-	999-99* GENERICA		\$0.000	30.000	\$1500.000	\$500.000	ASP Submitter, Jennifer	Certified	•
+ xyz*	GENERICA		\$5000.000	500.000	\$10000.000	\$1000.000	ASP Submitter, Jennifer	Awaiting Certification	

Figure 41: Drug Certification - All Drugs in Period

This page lists all drug products the Submitter entered for the current reporting period. The Module organizes the full list by **Drug Identifier and Generic Name**, the **Manufacturer's ASP**, the Number of ASP Units, the Wholesale Acquisition Cost, the Average Wholesale Price, and Status.

Note: Click the **Export to Excel** box to download the information on this page into an Excel file.

- 2. Click the plus symbol on each row of the table to expand each product's information and view additional Drug Product data fields, such as **Brand Name, First Marketing Date, Volume per Item,** and all other information the Submitter previously reported.
- 3. Review the information for accuracy.
- 4. Return to the **Compliance Summary** tab to review your certified products after they have undergone drug certification. Refer to *Section 3.2.3 Certified*.



4. Technical Support Contact Information

Contact the FFSDCS (ASP) Application Helpdesk for issues such as:

- Account unlock
- Password reset
- Registration process questions
- System availability escalations

Table 1 provides contact information for technical support.

Table 1: Technical Support Contacts

Email Address	Phone Number	Hours
ASPHelpDesk@dcca.com	1-844-876- 0765	9:00 a.m. to 6:00 p.m. Eastern Standard Time (EST), Monday through Friday



Appendix A: Field Definitions

Table 2 provides an overview of field definitions for this document.

Table 2: Field Definitions

Column/Field Name	Format	Allowed/Sample Values	Required/Optional	Notes
Manufacturer Name	Alphanumeric	Maximum of 250 characters	Required	 When entering product data for the same Manufacturer more than once, be sure the spelling matches. Special characters (comma, dash, period) allowed.
NDC1	5-digit number	e.g., 12345	Required	 First segment of the National Drug Code (NDC) that identifies the labeler. Products that do not have a NDC should only use the Alternate ID column. Not required if the product has an Alternate ID. Leading zero allowed.
NDC2	4-digit number	e.g., 1234	Required	 Not required if the product has an Alternate ID. The NDC2 is the sixth through the ninth digits of the 11-digit NDC that identifies the product.
NDC3	2-digit number	e.g., 12	Required	 Not required if the product has an Alternate ID. The NDC3 is the last two digits of the 11-digit NDC that identify the package size.
Alternate ID	alphanumeric	maximum of 23 characters	Required	 Not required if the product has an NDC. Must match product ID exactly as listed publicly on the manufacturer's website. Special characters (colon, dash, period) allowed.
Alternate ID Website URL	NA	e.g., http://www.medicare.gov	NA	Must have http:// or https:// prefix.



Column/Field Name	Format	Allowed/Sample Values	Required/Optional	Notes
Brand Name	Alphanumeric	Maximum of 250 characters	Optional	Enter strength and package size in their respective fields unless it is a part of the registered brand name.
Generic Name	Alphanumeric	Maximum of 250 characters	Required	Refer to valid values in Generic Name.
Volume Per Item	Numeric	NA	Required	For Alternate ID, report the volume amount in one item. (For instance, enter 10 for 10 ml in one vial, and enter 1 for powders, sheets, or patches.)
Unit for Volume per Item	NA	NA	NA	See valid value in Unit of Volume per Item. For example, for Alternate ID, select EACH for powders, sheets, or patches.
Number of Items Per NDC or Alternate ID	Numeric	Maximum of 9 digits and 2 decimal places	Required	• For NDCs: Indicates the number units within the NDC package (for instance, enter 5 for 5 vials in a package).
				 For Alternate IDs: Indicates the number of units within the Alternate ID. (for instance, enter 5 for 5 grafts in a package).
Package Type	Alphanumeric	2 characters	Required	Enter SD, MD, or NA. (SD = Single dose, MD = Multi dose, NA = Not Applicable)
Strength	Numeric	e.g., 300	Required	NA
Unit for Strength	NA	NA	NA	See valid values in Unit for Strength
FDA Application Number/Registration	Alphanumeric	Maximum of 6 characters	Required	Enter FDA Application Number for NDCs and Registration Number for Alternate IDs.
Number				 Enter Facility Registration Number for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).
FDA Application Supplement Number	Alphanumeric	Maximum of 9 characters	Optional	NA



Column/Field Name	Format	Allowed/Sample Values	Required/Optional	Notes
Additional FDA Application Number #1	Alphanumeric	Maximum of 6 characters	Optional	NA
Additional FDA Application Supplement Number #1	Alphanumeric	Maximum of 9 characters	Optional	NA
Additional FDA Application Number #2	Alphanumeric	Maximum of 6 characters	Optional	NA
Additional FDA Application Supplement Number #2	Alphanumeric	Maximum of 9 characters	Optional	NA
FDA Approval/Registration Date	MM/DD/YYYY	e.g., 01/01/2023	Required	Must be prior to the current submission period start date.
FDA Approval Type	NA	NA	Required	Refer to valid values in FDA Approval Type.
First Marketing Date	MM/DD/YYYY	e.g., 01/01/2023	Required	 Must be on or after the FDA Approval Date. Must be prior to the current submission period start date. If the date is after the current submission period start date, it must be submitted as an off-cycle submission. NDC: For drugs marketed under an FDA-approved application (e.g., Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), New Drug Application (NDA)), the earliest date the drug was first marketed under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the First Marketing Date should be equal to the First Marketing Date of the original product.



Column/Field Name	Format	Allowed/Sample Values	Required/Optional	Notes
First Marketing Date (continued)	MM/DD/YYYY	e.g., 01/01/2023	Required	• Alternate ID: For products marketed under an FDA-approved application/registration (e.g., 510(k), HCT/P, Premarket Approval (PMA)), the earliest date the product was first marketed under the application/registration number by any labeler. If a product was purchased or otherwise acquired from another labeler, the date should be equal to the First Marketing Date of the original product.
Date of First Sale for this Product	MM/DD/YYYY	e.g., 01/01/2023	Required	 Must be after the First Marketing Date. Must be prior to the current submission reporting period start date unless it is an off- cycle submission. NDC: The date of first sale of individual NDCs. Alternate ID: The date of first sale of individual Alternate IDs.



Appendix B: Revision History

Table 3 provides a revision history for this document.

Table 3: Revision History

Version Number	Date	Author/Editor	Description of Change
1.0	03/15/2024	Index Analytics/DCCA	Initial version of ASP Data Collection System Certifier User Guide



Appendix C: Glossary

Table 4 presents a list of terms, acronyms, and definitions in this document.

Table 4: Glossary

Expanded Form	Acronym/Term	Definition
510(k)	NA	A 510(k) submission is the mechanism through which the majority of medical devices obtain U.S. marketing clearance. Such devices include catheters, contact lenses, and absorbable sutures.
Abbreviated New Drug Application	ANDA	An ANDA is an application for a U.S. generic drug approval for an existing licensed medication or approved drug. Authorized generics do not require ANDAs.
Average Sales Price	ASP	ASP refers to the price at which an organization typically sells a certain class of good or service. CMS uses manufacturer- reported ASPs, based on manufacturers' actual quarterly drug sales, to calculate provider payment amounts for these drugs. Federal law defines the price.
Biologics License Application	BLA	A BLA is used to request permission to introduce or deliver a biologic product into interstate commerce.
Center for Medicare Management	СММ	The CMM oversees the fee-for-service Medicare program.
Centers for Medicare & Medicaid Services	CMS	CMS is a federal agency within the U.S. Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program, and health insurance portability standards.
Consolidated Appropriations Act, 2021	CAA	The CAA establishes protections for consumers related to surprise billing and transparency in health care. The No Surprises Act (NSA) is part of the CAA.
Eastern Standard Time	EST	EST is the standard time in the 5th time zone west of Greenwich, reckoned at the 75th meridian. This time zone is in the eastern part of the United States.
Fee-for-Service Data Collection System	FFSDCS	The FFSDCS is an instrument to collect cost, revenue, utilization, and other information for FFS claims.
Human Cells, Tissues, and Cellular Products	HCT/P	HCT/Ps include human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient. The FDA Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps.
Interactive Voice Response	IVR	IVR is a technology that allows a computer to detect voice and DTMF keypad inputs.



Expanded Form	Acronym/Term	Definition
Medicare	NA	Medicare is the federal system of health insurance for people over 65 years of age and for certain younger people with disabilities.
Medicare Part B	NA	Medicare Part B is the part of Medicare that covers doctor services, outpatient hospital care, and other medical services that Part A does not cover such as physical and occupational therapy, X-rays, medical equipment, or limited ambulance service.
Multifactor Authentication	MFA	MFA is a security system that implements more than one form of authentication to verify the legitimacy of a transaction.
National Drug Code	NDC	The NDC is a code set that identifies the vendor (manufacturer), product, and package size of all drugs and biologics the FDA recognizes.
New Drug Application	NDA	An NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical drug for sale and marketing.
Okta	NA	Okta is an enterprise-grade, identity management service, built for the cloud, but compatible with many on-premises applications.
One-Time Password	OTP	An OTP is a password that is valid for only one login session or transaction.
Point of Contact	POC	The POC identifies the key person or group serving as the coordinator on a given project.
Premarket Approval	PMA	PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Such devices include implants, ventilators, and pacemakers.
Short Message Service	SMS	SMS is a text messaging service component of phone, web, or mobile communication systems. It uses standardized communication protocols to allow fixed-line or mobile phone devices to exchange short text messages.
Social Security Act	SSA	The SSA is a law that provides income to retired workers aged 65 or older.



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