



Average Sales Price (ASP) Data Collection System Webinar

Certifier Training Session

March 2024

Welcome



Thank you for joining our webinar to preview the modernized ASP Data Collection System for Certifiers, which will be live on April 1, 2024.

- This session will be recorded and posted.
- Participants can submit questions via the chat feature.
- This is a one-hour session with time for questions at the end.



Speakers

- Katie Wilder, Contractor
- Resources
- Michelle Berman,
Contractor - System
Overview



Panelists

- Felicia Brown, CMS
- Kwan Saddler, CMS
- Suzanne Bromley, Contractor
- Brian Edwards, Contractor
- Jim Bullard, Contractor

Modernization Priorities



User Experience



New Technology



Stakeholder
Engagement and
Support



Data Quality



Resources

New!

CMS Education and Outreach Website

- User Guides
- FAQs
- Fact Sheets
- *and more to come!*

CMS.gov Centers for Medicare & Medicaid Services

About CMS | Newsroom | Data & Research

Medicare | Medicaid/CHIP | Marketplace & Private Insurance | Priorities | Training & Education

Medicare > Payment > All Fee-For-Service-Providers > Medicare Part B Drug Average Sales Price > ASP Education & Outreach

ASP Education & Outreach

All Fee-For-Service-Providers

- Home Health Agency (HHA) Center
- Hospice Center
- Shared Savings Program (SSP) / ACOs
- Hospital-Acquired Conditions (HAC)
- Physician bonuses in Health Professional Shortage Areas (HPSAs)
- Medicare Fee-for-Service 5010-D0

Medicare Part B Drug Average Sales Price

- ASP Reporting
- ASP Pricing Files
- ASP Billing Resources
- Vaccine Pricing
- ASP Regulations & Policy
- Discarded Drugs
- ASP Education & Outreach**
- Competitive acquisition

Newly Updated Average Sales Price (ASP) Data Collection System

On April 1, 2024, CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. These one hour sessions will provide a brief demo of the new system highlighting the new features and key changes and an opportunity for manufacturers to ask questions about the new system. We will have separate training sessions for Submitters and Certifiers and will offer two training dates for each audience. Sign up for the session that works best for you!

Submitter Training Sessions

- Tuesday, March 19, 2024, at 2:00 p.m. Eastern Standard Time (EST): [Zoom Registration Link](#)
- Thursday, March 21, 2024, at 2:00 p.m. EST: [Zoom Registration Link](#)

Certifier Training Sessions

- Tuesday, March 19, 2024, at 3:30 p.m. EST: [Zoom Registration Link](#)
- Thursday, March 21, 2024, at 3:30 p.m. EST: [Zoom Registration Link](#)

CMS collects Average Sales Price (ASP) data from manufacturers of Medicare Part B-covered drugs, biologicals, and related items, services, supplies, and products. Explore the resources below to learn more about the ASP data collection and payment limit calculation processes and other relevant topics.

Show Entries: 10 per page | Filter On: []

Showing 1-3 of 3 entries

| Date | Title | Description | Format |
|----------------------------|---|--|--------|
| 2024-01-31 | Keys to Submitting Skin Substitute Product Data | Helpful information for manufacturers of Skin Substitute products when submitting ASP data to CMS | PDF |
| 2024-01-31 | How to Prepare for the ASP Data Collection System Upgrade | A guide to help users prepare for the first time they log in to the new ASP Data Collection System | PDF |
| 2024-01-31 | What's New in the ASP Data Collection System | A guide to explain the key highlights and changes in the new ASP Data Collection System | PDF |



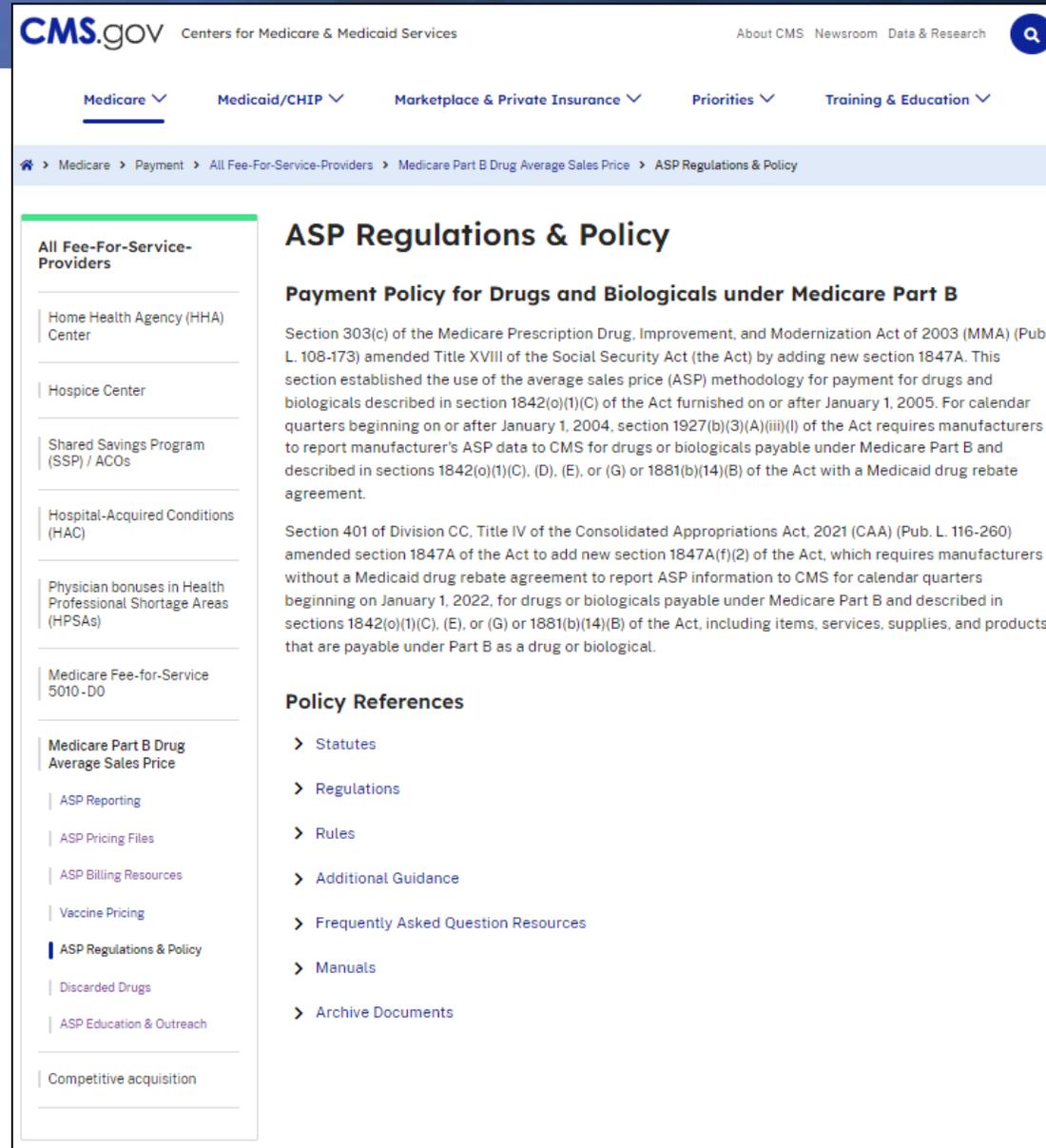
Policy Page

New Content!

[ASP Regulations and Policy Page](#)

One resource for all ASP-Related:

- Statutes
- Regulations
- Rules
- Guidance



The screenshot shows the CMS.gov website interface. At the top, there is a navigation bar with the CMS logo and the text "Centers for Medicare & Medicaid Services". To the right of the logo are links for "About CMS", "Newsroom", and "Data & Research". Below this is a secondary navigation bar with dropdown menus for "Medicare", "Medicaid/CHIP", "Marketplace & Private Insurance", "Priorities", and "Training & Education". A breadcrumb trail below the navigation bar reads: "Home > Medicare > Payment > All Fee-For-Service-Providers > Medicare Part B Drug Average Sales Price > ASP Regulations & Policy".

The main content area is titled "ASP Regulations & Policy". On the left side, there is a sidebar menu with the heading "All Fee-For-Service-Providers" and a list of categories: "Home Health Agency (HHA) Center", "Hospice Center", "Shared Savings Program (SSP) / ACOs", "Hospital-Acquired Conditions (HAC)", "Physician bonuses in Health Professional Shortage Areas (HPSAs)", "Medicare Fee-for-Service 5010 - DO", "Medicare Part B Drug Average Sales Price" (which is highlighted with a blue bar), "ASP Reporting", "ASP Pricing Files", "ASP Billing Resources", "Vaccine Pricing", "ASP Regulations & Policy" (which is highlighted with a blue bar), "Discarded Drugs", "ASP Education & Outreach", and "Competitive acquisition".

The main content area contains the following sections:

- Payment Policy for Drugs and Biologicals under Medicare Part B**

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act (the Act) by adding new section 1847A. This section established the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. For calendar quarters beginning on or after January 1, 2004, section 1927(b)(3)(A)(iii)(I) of the Act requires manufacturers to report manufacturer's ASP data to CMS for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (D), (E), or (G) or 1881(b)(14)(B) of the Act with a Medicaid drug rebate agreement.

Section 401 of Division CC, Title IV of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116-260) amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological.
- Policy References**
 - > Statutes
 - > Regulations
 - > Rules
 - > Additional Guidance
 - > Frequently Asked Question Resources
 - > Manuals
 - > Archive Documents

What's New?

- Key changes
- New features
- Additional context



WHAT'S NEW IN THE ASP DATA COLLECTION SYSTEM

CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. The full list of all added features and functionalities, along with other training resources, will be released with the launch of the new system, but here are some of the key highlights and notable changes coming in April!



MODERN PLATFORM

The new ASP Data Collection System is built on a modern platform which will allow CMS to easily add and expand system capabilities to pivot and respond to changing laws and regulations that affect Medicare Part B Drugs and payment limit calculations.



IMPROVED USER EXPERIENCE

The new system has clear screens, intuitive navigation, hover-over definitions, links to resources and much more to improve the user experience!



UPDATED DATA FIELDS

Data fields have been updated to eliminate data entry errors, standardize the data collected, and simplify the process for CMS to conduct data analysis and determine accurate calculations. Some updates include drop-down options instead of free-form text boxes when manually entering drug product data, and reorganized data fields such as two separate fields for strength and strength unit.



NEW DATA TEMPLATES

The product and financial data templates for your Medicare Part B Drugs have been updated to match the data collection fields in the new system and continue to provide an option to easily upload your data.



ONE LOCATION FOR FINANCIAL TASKS

In the new system, all Financial Data tasks, including restating financial data and adding data for prior quarters, are available in one location on the drop-down under the Financial Data menu.

How to Prepare

- Visit our Resource Library
- Gather New or Changed Drug Product Information
- Prepare to Validate Existing Product Data
- Use the New Templates



HOW TO PREPARE FOR THE ASP DATA COLLECTION SYSTEM UPGRADE

CMS will launch a newly updated Average Sales Price (ASP) Data Collection System designed on a modern platform to enhance the data collection and ASP payment limit calculation processes. The new system has clean screens, intuitive navigation, hover-over definitions, links to resources, and much more to improve the user experience. As we complete the final stages of preparation, there are some steps you can take to prepare your quarterly data for submission when the new system officially goes live in April!

VISIT OUR WEBSITE AND REVIEW NEW RESOURCES

Along with the ASP Data Collection System upgrade, CMS has also been working to build a library of resources for manufacturers and other stakeholders to learn more about the ASP data collection and payment limit calculation processes and other relevant topics. CMS will continue to build and expand our Education and Outreach library in the coming months but has posted some initial resources to support manufacturers through the transition to the new system. View our library at: <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-education-outreach>.

PLAN ADDITIONAL TIME FOR THE FIRST QUARTERLY DATA SUBMISSION

Validate Existing Product Data

With the new system and updated data fields, there may be drug product data that will need additional review when you log in to the new system for the first time. When the system is live, there will be an alert box on the home page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the new system for this first quarter only.

Gather New or Changed Drug Product Information

The new system includes an approval process for users to request new product information to be accepted into the system to minimize data entry errors. If you have new drug product information, such as a new National Drug Code (NDC) or Alternate ID, to enter since last quarter, or need to align an existing NDC to a new manufacturer, you will need to submit a request to have the data added to the new system. The approval process will be quick; however, there could be some initial delay due to an influx of requests with the launch of the new system.

Prepare your Data Using the New Templates

New templates have been created to match the newly configured ASP Data Collection System. Some data collection fields have been reorganized, such as having two separate fields for strength and strength unit. The product and financial templates have been updated to include these changes and are available now for you to prepare your data for an easy upload once the new system is live.

User Guides



**Average Sales Price (ASP)
Registration User Guide**

Version 0.1
Date: January 22, 2024



**Medicare Part B Average Sales Price
(ASP) Module**

Certifier User Guide

Version 0.1
Date: January 22, 2024

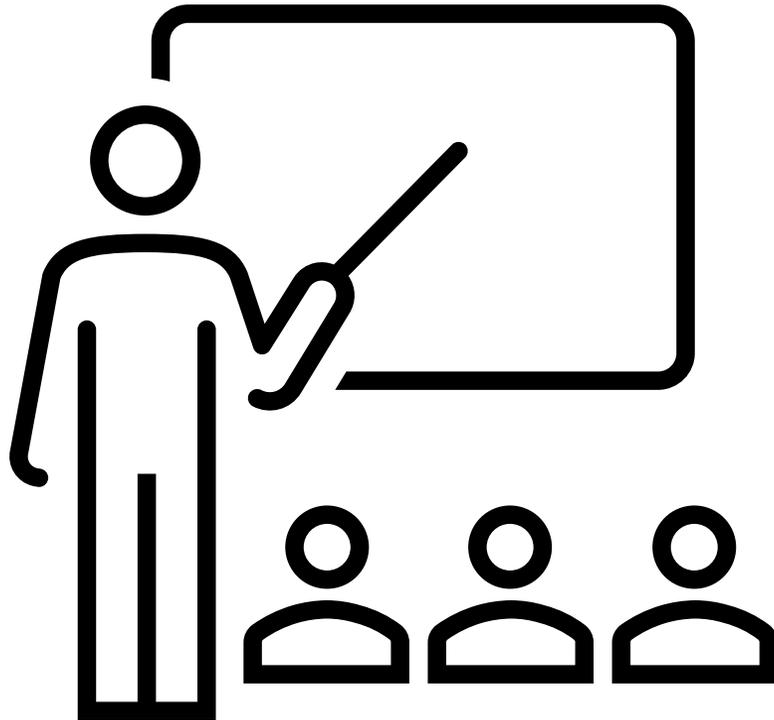


**Medicare Part B Average Sales Price
(ASP) Module**

Submitter User Guide

Version 0.1
Date: January 22, 2024

System Demonstration



The following slides present screenshots and an accompanying demo of the system.

Welcome Page



CMS.gov | My Enterprise Portal My Apps Michelle ASP Certifi... Help Log Out

Medicare Part B Average Sales Price Help Desk User Guide (PDF) My Profile

[OTP Verification](#) [Compliance Summary](#) [Assumptions](#) [Drug Certification](#) [FAQ](#)

Welcome, Michelle

Help

What's New **2**

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

Validate Existing Product Data

03/01/2024

With the updated data fields, there may be drug product data that will need additional review when you log in for the first time. There is an alert box on this Welcome page with instructions on how to update all current product data. Please note, you may need to have previously submitted data available to reference when completing this task. You must complete this step before you can upload or enter new quarterly financial data into the system for this first quarter only.

ASP Business Process Flow

Submitter **Certifier**

- 1 [Authenticate](#) using One-Time Password (OTP)
- 2 [Review](#) Submitted Financial Data **1**
- 3 [Certify](#) Submitted Financial Data

OTP Verification



[← Back to Welcome page](#)

OTP Verification

Manufacturer Name (required)

Begin typing the manufacturer name to see names for selection



OTP Provided by Your Data Submitter (required)

Verify

Compliance Summary



CMS.gov | My Enterprise Portal My Apps Michelle ASP Certifi... Help

Medicare Part B Average Sales Price

Help Desk | User Guide (PDF) | My

OTP Verification | **Compliance Summary** | Assumptions | Drug Certification | FAQ

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Compliance Summary

Reporting Period (required): Q4 2023

i Labelers are out of compliance with data reporting requirements. **33%** of drugs are certified out of **3** total drugs. (**1** certified, **0** Restatement Certified)

Missing **0** | **Pending 2** | Certified **1** | New **1** | Off Cycle **0** | Expired **0**

All Pending Certification Pending Certification Pending Restatement Certification

[Export to Excel](#)

2 Drug Identifiers waiting for certification/restatement certification

| Drug Identifier | Manufacturer Name | Reporting Period | Manufacturer's ASP | Number of ASP Units | Wholesale Acquisition Cost | Average Wholesale Price | Submitter Name | Action |
|-----------------|---------------------|------------------|--------------------|---------------------|----------------------------|-------------------------|-------------------------|---------------------------------------|
| 00000-0000-00 | Test Manf Name impl | Q4 2023 | \$123.000 | 456.000 | \$234.000 | | ASP Submitter, Michelle | Go to Certification → |
| 00000-0001-00 | Test Manf Name impl | Q4 2023 | \$12.000 | 34.000 | \$56.000 | | ASP Submitter, Michelle | Go to Certification → |

Assumptions

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Assumptions

✔ File upload has completed successfully.

Reporting Period (required)

< >

[Create Assumption or Upload Assumption File](#)

[↓ Export to Excel](#)

Saved Files

| File Name | File Description | Manufacturer Name | Date Saved | Saved By | Actions |
|---|---|---------------------|---------------------|--|------------------------|
| user_entry_assumptions_test_manf_name_i mpl_2024_01_09_16_54_29.txt | akdjfei djewiwj jdioiwej jflskwejeic jakdj kweic | Test Manf Name impl | 2024-01-09 16:54 PM | ASP Certifier, Jennifer (certifier) | Delete |

Confirm Contact Information

[← Back to Welcome page](#)

Drug Certification

Reporting Period (required) **Manufacturer Name** (required)

Q4 2023 Test Manf Name

⚠ Please confirm the manufacturer's address and certifier's email below are correct before proceeding. If they are incorrect

Are you a contractor or a direct employee of the manufacturer?

Direct Employee Contractor

Manufacturer's Address

Street Address (required)
321 Main St.

Street Address 2

City (required) **State** (required) **ZIP Code** (required)

- Select -

Certifier's Contact Info

Name (required)
Jane Doe

Email Address (required)
jane.doe@dot.com

Phone Number (required)
212-222-2333

I confirm the accuracy of the information provided above.

Confirm

Drug Certification



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Drug Certification

Reporting Period (required)

Manufacturer Name (required)

Q4 2023

Test Manf Name impl

Drug Data Pending Certification

All Drugs in Period

* denotes product data has been modified between current and prior quarter.

[Export to Excel](#)

[Certify All](#)

Drug Identifiers awaiting Certifier's action

| Drug Identifier | Generic Name | Manufacturer's ASP* | Number of ASP Units* | Wholesale Acquisition Cost* | Average Wholesale Price | Submitter's Name | Action |
|---|--------------|---------------------|----------------------|-----------------------------|-------------------------|-------------------------|-------------------------|
| <input type="text"/> | | | | | | | |
| <input type="checkbox"/> 00000-0000-00* | GENERICA | \$123.000 | 456.000 | \$234.000 | | ASP Submitter, Michelle | Certify |

Product Info

Brand Name: No Data

Number of Items per NDC/Alt ID: 1

Expiration Date of Final Lot Sold: No Data

Date of First Sale for this Product: 08/10/2023

Strength of Product: 20 MG

Package Type: SINGLE DOSE

FDA Approval Date: 08/01/2023

FDA Application Number: T98765

Volume per Item: 1 Ampule

First Marketing Date: 08/05/2023

FDA Approval Type: ANDA

FDA Application Supplement Number: No Data



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FAQ

This information will be updated to address the most frequently asked questions regarding the ASP Data Collection System.

For questions regarding policy, process, calculation, and the publication of ASP pricing files, please refer to the FAQ document posted on the [CMS ASP Education and Outreach](#) page.

⌵ Expand All

⌶ Collapse All

What is the difference between an NDC1 and an Alternate ID?



What is a unit of a drug?



For the purposes of ASP data submissions, the term "unit" (defined at section 1847A(b)(2)(B) and codified at 42 CFR 414.802) means the product represented by the 11-digit NDC, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a NDC varies. Note that the definition of "unit" is different than the term "billing unit" (defined in section 1847A(b)(6)(B) of the Act), which means the identifiable quantity associated with the billing and payment code.

I submitted my data, now what do I do?



Help Desk Contact Information

Phone: +1 (844) 876-0765

Email: asphelpdesk@dcca.com

Hours: Monday - Friday, 9am - 6pm EST

Closing Remarks

- [Education and Outreach Page](#)
- **Technical Support**
 - ASPHelpDesk@dcca.com
 - 1-844-876-0765
 - 9:00 a.m. through 6:00 p.m., Eastern Standard Time (EST), Monday through Friday
- **Feedback and Other Questions**
 - sec303aspdata@cms.hhs.gov

