Medicare Part B
Instructions for Reasonable Assumptions in Reporting of Manufacturer's ASP

CMS permits manufacturers to make "reasonable assumptions" that are consistent with statute and regulation when they calculate the manufacturer's average sales price (ASP). Defined under 42 CFR § 414.802 and § 414.804, CMS will require manufacturers to document and submit their assumptions for quarterly sales beginning January 1, 2026 (reflected in ASP data reported to CMS not later than April 30, 2026).

Submission Method
Manufacturers will submit their reasonable assumptions via the ASP Data Collection System. Technical assistance will also be made available. Reasonable assumptions are due by January 30, April 30, July 30, and October 30 every year along with the applicable ASP data submitted to the portal.

Follow these steps to upload an assumption file to the Module:
1. Click the Upload Assumption File tab.
2. Select the Upload Assumption File radio button. A Manufacturer Name (required) drop-down menu and empty File Description field display.
3. From the Manufacturer Name (required) drop-down menu, click the -Select- dropdown menu to expand the list and select the manufacturer name.
4. 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.

Reasonable Assumptions
Manufacturers must provide all required information below in the form fields. If you do not have reasonable assumptions for a particular area, put "N/A" in the box. If you have additional verbiage for any of the areas below, attach a cover letter when submitting this form.

Bona Fide Service Fees	Response Format
Provide an overview of contractual arrangements that the submitting	*Text (1000-character count limit)*

manufacturer has with entities for which it pays a bona fide service fee(s) as well as the fair market value analysis for service arrangements each time an arrangement is issued or renewed.

Bundled Sales	Response Format
Provide an overview of bundled sale arrangements and the discount reallocation for each arrangement.	*Text (1000-character count limit)*

Price Concessions and Discounts	Response Format
Provide list and overview of price concessions and discounts (e.g., lagged, non-lagged, stacked, prompt pay) for products or transactions.	*Text (1000-character count limit)*

Reporting of Products with Zero, Negative, or False Positive ASPs	Response Format
Confirm how you will report products with zero, negative, or false positive ASPs.	*Text (1000-character count limit)*

Sales Excluded from Best Price	Response Format
Confirm how you will report sales excluded from Medicaid Best Price.	*Text (1000-character count limit)*

Time Value of Money	Response Format
Confirm how you factor the time value of money in the ASP calculation.	*Text (1000-character count limit)*

Free Goods Not Contingent on a Purchase Requirement	Response Format
Provide a review of any free goods not contingent on a purchase requirement, including but not	*Text (1000-character count limit)*

limited to coupons, copay assistance programs, vouchers and free goods, and patient assistance programs.	

Value-Based Purchasing Arrangements	Response Format
Confirm how you account for any value-based purchasing arrangements in the ASP calculation.	*Text (1000-character count limit)*

Sales to 340B Covered Entities	Response Format
Confirm how sales to 340B covered entities are considered in the ASP calculation.	*Text (1000-character count limit)*

Returned Goods	Response Format
Confirm how returned goods will be treated in the ASP calculation.	*Text (1000-character count limit)*

Billing Corrections	Response Format
Confirm how you process transactional issues that may require a credit or rebill.	*Text (1000-character count limit)*

Other Reasonable Assumptions	Response Format
If you have additional reasonable assumptions to report, include those here.	*Text (1000-character count limit)*