



Manufacturers' Guide to Correcting Average Sales Price (ASP) Data Errors

Manufacturers of drugs and biological products separately payable under Medicare Part B must report accurate Average Sales Price (ASP) data to CMS, as described in sections 1927(b)(3), 1847A(c), and 1847A(f) of the Social Security Act and in regulation at [42 CFR 414 Subpart J](#). Ensuring the accuracy of submitted data is a key requirement under 1847(A) and manufacturers are strongly encouraged to submit corrected data if any errors are identified.

Data Submission



- Manufacturers must submit ASP data for their drugs and biological products payable under Medicare Part B in the ASP Data Collection System by the 30th day of the month following the end of the quarter.
- The manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or designee, must review and confirm the accuracy of the submitted ASP data.

Error Identification



- After submission, manufacturers may notice mistakes in reported ASP data due to data entry, inaccuracies, or omissions of data, such as imprecise dosage or packaging descriptions, etc.
- As a part of routine data analysis, CMS may also identify errors and will contact the manufacturer via electronic communication to request corrected data.

Data Correction



- Manufacturers must submit corrected data in the ASP Data Collection System as soon as they identify, or are notified by CMS of, an error.
- Manufacturers have until the 10th day of the month preceding the publication of the next quarter's Medicare Part B Drug Payment Limit File to submit corrected data without it being considered a restatement.

Impact Analysis



- If the manufacturer or CMS identifies that data need to be corrected after the Payment Limit File has been published, CMS will assess whether the impact of the corrected payment limit meets the criteria to justify a restatement on a future pricing file.
- The criteria against which CMS evaluates corrected data include, but are not limited to, significant dollar or percentage changes to the payment limit and the estimated impact on total payments as a result of the revised payment limit.

ASP Pricing Restatement



- The restatement of a Medicare Part B drug payment limit occurs when CMS revises previously published payment limit(s) based on corrected data submitted by manufacturers of drugs and biological products.
- If CMS determines a restatement is warranted based on the impact analysis, CMS will note the updated payment limits in the Payment Limit File, including the date of the update.
- Additional information about the Restatement Policy can be found in the Restatement Overview Fact Sheet on the ASP Education and Outreach Resource page.

For more information visit the [Medicare Part B Drug ASP website](#).

Contact us at sec303aspdata@cms.hhs.gov.

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