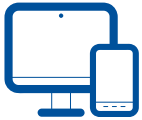




Manufacturers' Guide to Correcting Average Sales Price (ASP) Data Errors

Manufacturers of drugs and biologicals 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. The accuracy of data submitted to CMS is taken seriously in 1847A and CMS encourages manufacturers to submit corrected data if they identify an error.

Data Submission



- Manufacturers must submit ASP data for their drugs and biologicals payable under 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) or 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.
- As part of routine data analysis, CMS may also identify errors and will contact the manufacturer via electronic communication to request corrected data.

Data Correction



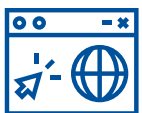
- Manufacturers must submit corrected data in the ASP Data Collection System as soon as they identify, or are notified by CMS of, an error.
- Manufacturers have until the 10th day of the month preceding the publication of the next quarter's ASP pricing files to submit corrected data without it being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

Impact Analysis



- If the manufacturer or CMS identifies that data need to be corrected after the ASP pricing files have 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 average sales price (ASP) payment limit(s) based on corrected data submitted by manufacturers of drugs and biologicals.
- If CMS determines a restatement is warranted based on the impact analysis, CMS will identify restated payment limits in the updated ASP pricing files with a note that indicates when an update to the file is made, e.g., April 2024.