



Average Sales Price (ASP) Restatement Policy Overview

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.

What is a Restatement?

The restatement of a Medicare Part B drug payment limit occurs when CMS revises previously published ASP payment limit(s) based on corrected data submitted by manufacturers of drugs and biologicals.

How is a Restatement Initiated?

Manufacturers or CMS may identify that previously submitted ASP data require revisions due to data entry mistakes, inaccuracies, or omissions of data, such as imprecise dosage or packaging descriptions. A restatement may be initiated when a manufacturer corrects previously submitted data in the ASP Data Collection System after the correction deadline has passed. As part of routine data investigations, CMS may also identify errors in the published ASP pricing files and will contact the manufacturer to request corrected data.

When will CMS Consider a Restatement?

To determine whether to issue a restatement, CMS assesses several conditions, including the timeframe in which corrected data are received and the impact the corrected data have on payment limits. If corrected data are received from manufacturers prior to publication of the quarter's ASP pricing files, CMS may implement a correction before the file is publicly released.

Pre-Publishing Timeframe: Correction

CMS and manufacturers may identify previously submitted ASP data that require revisions. CMS may recalculate payment limits for the current quarter if corrected data is received before the correction deadline, which is the 10th day of the month preceding the effective date of the payment limits.

If corrected data are received from manufacturers after the correction deadline or if the ASP pricing files have been published, CMS will analyze the impact of the corrected data on payment limits to determine if a restatement is needed based on two timeframes:

Current Quarter Post-Published Timeframe

CMS may identify an incorrect payment limit mid-quarter, after the files are published, and has the discretion to immediately restate it before the next quarter's files are published. Because restating payment limits in these circumstances imposes a substantial administrative burden on Medicare Administrative Contractors (MACs) to potentially reprocess claims and retest systems, CMS does so only when the price change would meet three or more of the following criteria:

- The revised ASP payment limit would result in a dollar change $\geq \pm \$1.00$ per billing unit.
- The revised ASP payment limit would result in a percent change $\geq \pm 10.00$ percent.
- The number of services billed under the Healthcare Common Procedure Coding System (HCPCS) code in the 12 months preceding the current quarter $\geq 100,000$ HCPCS billing units.
- The estimated impact of change in the ASP payment limit should all affected claims be reprocessed with the corrected payment limit $\geq \pm \$100,000$ in total allowed payments.

Limited Prior Quarter Restatement Timeframe

CMS may issue restatements for up to four previous quarters. Manufacturers have until the 30th day of the month after the end of the previous quarter to submit corrected data. If corrected data are not submitted by the deadline, or should further data investigation be required, any restatement could be delayed by a minimum of one quarter. CMS may initiate a restatement for a payment limit for one or more of the previous four quarters if the corrected data meet two or more of the following criteria:

- The revised ASP payment limit would result in a dollar change $\geq \pm \$.050$ per billing unit.
- The revised ASP payment limit would result in a percent change $\geq \pm 5.00$ percent.
- The number of services billed under the HCPCS code in the 12 months preceding the current quarter $\geq 50,000$ HCPCS billing units.
- The estimated impact of change in the ASP payment limit should all affected claims be reprocessed with the corrected payment limit $\geq \pm \$50,000$ in total allowed payments.

Should CMS restate a drug's payment limit, 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.

For more information visit: [CMS ASP Website](#)

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