



Average Sales Price (ASP) Restatement Policy Overview

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](#).

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 biological products.

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 Medicare Part B Drug Payment Limit File 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 payment limit 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 are 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 Medicare Part B Drug Payment Limit File has 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 payment limit would result in a dollar change $\geq \pm \$1.00$ per billing unit.
- The revised payment limit would result in a percent change $\geq \pm 10.00$ percent.
- The total billing units billed under the HCPCS code in the 12 months preceding the current quarter $\geq 100,000$ HCPCS billing units.
- The estimated impact of change in the 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 criteria listed below:

- The revised payment limit would result in a dollar change $\geq \pm \$0.050$ per billing unit.
- The revised 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 payment limit should all affected claims be reprocessed with the corrected payment limit $\geq \pm \$50,000$ in total allowed payments.

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.