Published on *The National Law Review* https://natlawreview.com

The 2025 Final Hospital Outpatient Prospective Payment System and Physician Fee Schedule Rules: What Pharma Stakeholders Need to Know

Article By:

Stephanie Trunk

Shoshana Golden

This past July, we reported on the Centers for Medicare & Medicaid Services (CMS) release of the 2025 proposed Hospital Outpatient Prospective Payment System (HOPPS) and Physician Fee Schedule (PFS) rules. CMS has now released the 2025 final rules, though they will not be published in the Federal Register for several more weeks.

Our alert on CMS' release can be found here.

The HOPPS final rule can be found here, with a high-level summary in the CMS fact sheet available here.

The PFS final rule can be found here, with the companion CMS fact sheet available here.

Both rules are effective January 1, 2025.

Below is an overview of the relevant provisions for pharmaceutical manufacturers and the pharma community.

Hospital Outpatient Prospective Payment System Final Rule

Under the HOPPS final rule, there are several regulatory changes for stakeholders to note for 2025:

- Representing a slight increase from the proposed rule, the final rule updates HOPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.9% based on the projected hospital market basket percentage increase of 3.4%, reduced by a 0.5% productivity adjustment.
- The final rule tracks with the proposed rule in implementing a packaging threshold (to

establish a separate payment amount for certain drugs and biologicals above the threshold) for calendar year 2025 set at $140 per day, with the caveat that it will be set at $630 per day for diagnostic radiopharmaceuticals.
- Separately reimbursed drugs and biologics administered in the hospital outpatient setting reimbursement will remain at Average Sales Price (ASP) +6% (4.3% after sequestration) or Wholesale Acquisition Cost (WAC) +3% if there is not an established ASP. For biosimilars, CMS has set reimbursement at ASP +8% of the reference product's ASP during the first five years in accordance with the Inflation Reduction Act of 2022 (IRA) mandate.

Physician Fee Schedule Final Rule

CMS finalized numerous changes to this year's PFS rule as explained below.

Implementing the IRA-Mandated Medicare Prescription Drug Inflation Rebate Program

As we have previously explained, the IRA established new requirements under which drug companies must pay inflation rebates if they raise their prices for certain Medicare Part B and Part D drugs faster than the rate of inflation.

As part of the 2025 PFS final rule, CMS has codified policies established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and Medicare Part D Drug Inflation Rebate Program, including the process to seek a rebate reduction for a drug in shortage, likely to be in shortage, or in the event of a severe supply chain disruption.

Under the PFS final rule:

- In response to strong objections in comments to the proposed PFS rule, CMS will not finalize the estimation methodology to remove 340B units from the total number of units used to calculate the total rebate amount for a Part D rebatable drug for the applicable period that begins on October 1, 2025. Instead, CMS will explore avenues for excluding 340B units starting January 1, 2026, through the establishment of a Medicare Part D claims data repository. CMS finalized its proposal to remove 340B units from the total number of units used to calculate the total rebate amount for a Part B rebatable drug utilizing dates of service from entities that are 340B Covered Entities listed in the Health Resources and Services Administration Office of Pharmacy Affairs Information System as participating in the 340 program. CMS will also exclude units billed with the "JG" or "TB" modifiers, which indicate that the drugs administered or dispensed were purchased under the 340B program.
- For Part D rebatable drugs first sold on or after October 1, 2021, CMS clarifies the benchmark period is the first full calendar year of sales. For a Part D rebatable drug missing manufacturer reported Average Manufacturer Price (AMP) data during this time, the benchmark period is the first calendar year in which at least one quarter of AMP is available for the applicable Part D rebatable drug at the National Drug Code-9 level.
- For Part B rebatable drugs first being sold in the calendar quarter starting July 1, 2021, and thereafter, the baseline ASP will be the third full calendar quarter of sales after the drug is billed under a specific Healthcare Common Procedure Coding System code and not under a not otherwise classified or miscellaneous code.
- CMS established the method and process for reconciliation of a rebate amount for Part B and Part D rebatable drugs, including the circumstances that may trigger such a reconciliation. The final rule provides for two reconciliations for rebates on Part D rebatable drugs. The two reconciliations are between 12 months and 36 months after the issuance of the final Rebate

Report from CMS, while only one reconciliation for rebates on Part B rebatable drugs.
- CMS clarified rebate calculations for Part B and Part D rebatable drugs in specific circumstances, including exclusion of Part B units of single-dose container or single-use package drugs subject to discarded drug refunds.
- CMS established a civil monetary penalty process for when a manufacturer of a Part B rebatable drug or Part D rebatable drug fails to pay the rebate amount in full by the payment deadline for such drug, applicable calendar quarter, or applicable period, respectively.

As we explained previously, inflation rebates began accruing on Part B drug utilization in 2023, and CMS will invoice manufacturers for any inflation rebates due on a Part B drug's utilization by September 30, 2025. For calendar quarters in 2025 and beyond, CMS will invoice manufacturers six months after the end of the applicable quarter. Inflation rebates began accruing on Part D utilization as of October 1, 2022, and CMS will invoice for the applicable periods beginning October 1, 2022, and October 1, 2023, no later than December 31, 2025. For periods beginning October 1, 2024, and beyond, CMS will invoice manufacturers no later than nine months after the end of the applicable period (12 months from October 1 to September 30).

Drugs and Biologics Paid Under Medicare Part B: Single-Dose and Single-Use Refunds

Section 90004 of the Infrastructure Investment and Jobs Act of 2021 requires manufacturers of single-dose or single-use vials reimbursed under Medicare Part B to pay a rebate on discarded amounts above a 10% threshold. Over the last several years, CMS has finalized numerous policies to implement this section.

In the 2025 PFS final rule, CMS has finalized clarifications to certain already-implemented policies, such as (1) excluding drugs for which payment has been made under Part B for fewer than 18 months from the definition of "refundable single-dose container" or "single-use package drug," and (2) identifying "single-dose containers" or "single-use package drugs."

The 18-month exclusion runs from the date of the first product sale reported to CMS with one exception. To the extent the date of first sale did not adequately approximate the first date of a Medicare Part B payment for the product under an applicable National Coverage Determination, CMS may select a date more reflective of Medicare Part B's first payment and coverage of the product.

CMS has finalized clarifications for certain single-dose or single-use products approved prior to the US Food and Drug Administration's (FDA) guidance issued in October 2018 addressing single-patient use containers. Specifically, some drugs approved prior to the October 2018 FDA guidance do not include the package type terms and explicit discard statements. CMS identified digoxin, oxytocin, diphenhydramine, and phenobarbital as being single-use despite not having the single-use package type or discard statements in their labels. CMS has now finalized the definition of single-use to include injectable drugs with a labeled volume of 2mL or less that lack the package type terms or discard statements on their labels. CMS also finalized including ampules in the single-use definition even if the products lack the package type terms or discard statements in their FDA-approved product labels.

CMS has additionally finalized requiring that the JW modifier be used if a billing supplier is not administering a drug, but there is an amount of the single-dose or single-use drug discarded during the preparation process before supplying the drug to the patient.

Finally, CMS has finalized that skin substitutes will not be included in the identification of refundable

drugs for the calendar quarters in 2025.

ASP Approach When Negative or Zero ASP Data Is Reported to CMS

CMS has finalized the approach to how it will calculate payment limits when manufacturers report negative or zero ASP. In doing so, CMS has finalized the policy that negative and zero ASP data be considered “not available” under section 1847A(c)(5)(B) of the Social Security Act. The determination of a payment limit when ASP data is not available will vary based on certain factors, such as whether the drug is single-source or multiple source, whether the ASP for some but not all National Drug Codes (NDCs) is negative or zero, and whether the applications for all NDCs for a billing or payment code have a marketing status of discontinued.

For a single-source drug, if the ASP for only some of the NDCs is negative or zero, only the positive ASPs and units will be used to calculate the ASP-based reimbursement. For a single-source drug, if the ASP for all NDCs is negative or zero, the last positive ASP will be used to establish reimbursement (i.e., a carry forward). CMS will substitute the current or previous quarter WAC for ASP to the extent lower than the last positive ASP.

For biosimilars for which the ASP for some — but not all NDCs — is negative or zero, CMS will calculate the payment limit using the positive manufacturer’s ASP data reported for the biosimilar. For a biosimilar for which the ASP for all NDCs is negative or zero, CMS will set the payment limit equal to the sum of the volume-weighted average of the most recently available positive manufacturer’s ASP data from a previous quarter +6% (or +8% for a qualifying biosimilar biological) of the amount determined for the reference biological product for the given quarter. Of note, CMS backed away from its proposal to calculate reimbursement for a biosimilar in such instance based on the ASP data of other biosimilars with the same reference product (even though such biosimilars have their own codes).

Payment for Radiopharmaceuticals in a Physician’s Office

In the final rule, CMS has clarified that, for radiopharmaceuticals furnished in a setting other than a hospital outpatient department, Medicare Administrative Contractors shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. CMS stated that such methodology may include, but is not limited to, the use of invoice-based pricing.

National Law Review, Volume XIV, Number 326