McDermott Will & Schulte

Medicare OPPS drug acquisition cost survey: Navigating Risks and Benefits of Responding

January 22, 2026

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Agenda

OPPS Drug Payment: Background
History and framework

OPPS Drug Acquisition Cost Survey: In-Depth
Structure, scope, and data requirements

Practical Considerations
Confidentiality, compliance risk, and potential reimbursement and enforcement implications

Questions and Discussion

OPPS drug payment: background

HISTORY AND FRAMEWORK

Statutory framework for OPPS drug payment

Medicare Part B pays for certain drugs furnished by hospital outpatient departments under the Outpatient Prospective Payment System (OPPS).

Under a federal law enacted in 2003, beginning in 2006, CMS must pay for drugs under OPPS at Average Acquisition Cost (AAC), relying on hospital acquisition cost survey data

If no survey data is available, CMS must use the rate methodology used under the Medicare Physician Fee Schedule, currently Average Sales Price (ASP) plus 6 percent

Budget neutrality

Adjustments to drug payments under OPPS are required to be "budget neutral"

- A **reduction** in payment for one item or service will **increase** payment for all other items and services
- An increase in payment for one item or service will **decrease** payment for all other items and services

If the payment methodology for drugs increases or decreases payment for drugs, payment for all other items and services will have a corresponding increase or decrease

Any "savings" generated by payment reductions for drugs would increase OPPS payments for all other items and services

Budget neutrality adjustments affect each hospital and beneficiary differently, depending on their outpatient services offerings/consumption

- A beneficiary who receives only hospital outpatient services and no hospital outpatient drugs would pay more if drug payment rates were reduced

Historical use of hospital acquisition cost data

Congress required the Government Accountability Office (GAO) to conduct hospital acquisition cost surveys in 2004 and 2005.

- The surveys are required to "have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost" of each drug
- CMS ultimately declined to rely on the GAO data when setting OPPS payment rates.

CMS instead concluded that ASP data was more current, more comprehensive, and more administratively feasible

- Since 2006, CMS has paid for most drugs under OPPS at ASP plus a percentage
- Currently ASP plus six percent

340B litigation as context

In 2018, CMS reduced OPPS payment rates for 340B drugs to ASP minus 22.5%, without conducting an acquisition cost survey.

- CMS reasoned that its authority to "calculate and adjust" drug payments "as necessary" under the ASP methodology gives CMS "broad discretion to adjust payments for drugs," and the reduction reflected the lower bound estimate of the average minimum discount on 340B drugs.

The Supreme Court held CMS's action unlawful, emphasizing that:

- CMS did not conduct a survey of hospitals' acquisition costs as required by the Statute.
- ASP methodology did not authorize CMS to vary payment rates by hospital group.

This decision provides important context for CMS's renewed focus on conducting an acquisition cost survey.

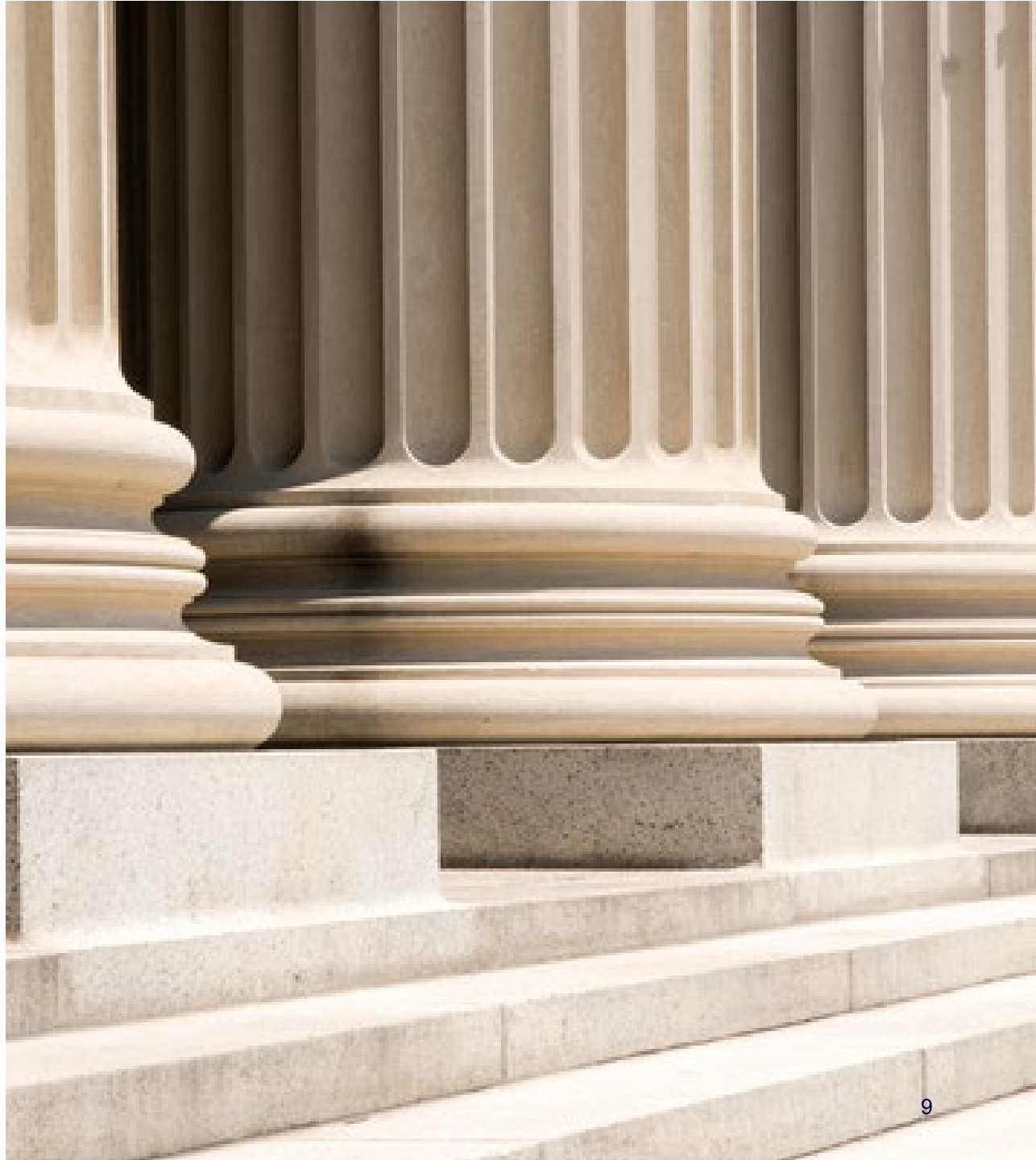
CMS conducted a survey of 340B hospitals in 2020, but ultimately opted to continue to pay 340B hospitals at ASP plus six percent.

Drug pricing executive order

On April 15, 2025, the White House issued an executive order, entitled, “Lowering Drug Prices by Once Again Putting Americans First.”

The EO required the Secretary of Health and Human Services (Secretary) to publish in the Federal Register, within 180 days, a plan to conduct a survey to determine hospital acquisition costs for covered outpatient drugs at hospital outpatient departments.

Following the survey, the Secretary must propose adjustments to align Medicare payment with the cost of acquisition.



CY 2026 OPPS final rule: survey announcement

In the CY 2026 OPPS Final Rule, CMS announced that it will conduct a hospital outpatient drug acquisition cost survey across **all hospitals paid under OPPS** to collect data intended to "inform policymaking."

Key features of the survey include:

Drug acquisition period: July 1, 2024-June 30, 2025	Data collection period: January 1 through March 31, 2026

CMS indicated that future rulemaking would take place before the survey data is used for ratesetting

But, suggested that the data may be used beginning with CY 2027 OPPS payment rates.

OPPS drug acquisition cost survey: in-depth

STRUCTURE, SCOPE, AND DATA REQUIREMENTS

Hospitals subject to the survey

All hospitals that were paid under OPPS during the surveyed period are subject to the survey

OPPS applies to all hospitals except the following:

- Hospitals providing only inpatient services
- Critical Access Hospitals
- Indian Health Service and Tribal hospitals
- Hospitals in certain US Territories
- Maryland hospitals paid under the Total Cost of Care Model

The survey:

- Applies regardless of whether a hospital participates in the 340B Drug Pricing Program;
- Includes both 340B and non-340B drug purchases;
- Is not limited by hospital size, ownership, or geographic location

Required NDC-level data elements

CMS requires hospitals to report detailed acquisition cost information at the 11-digit National Drug Code (NDC) level.

CMS has identified the 11-digit NDCs for which data is to be provided

For each 11-digit NDC, hospitals is expected to report:	Total units purchased for non-340B drugs;
	Total units purchased for 340B drugs;
	Total net acquisition cost for non-340B drugs;
	Total net acquisition cost for 340B drugs.

Definition of net acquisition cost

CMS expects hospitals to include all applicable discounts, rebates, and price concessions when calculating net acquisition cost.

- Discounts applied directly to individual invoices or NDCs
- Prompt pay discounts
- Wholesaler discounts
- Other discounts

Calculating GPO discounts and rebates

For discounts not attributable to individual NDCs, hospitals are instructed to:

- Indicate whether such discounts exist for the reporting time period
- Identify the relevant GPO, if applicable
- Report the total dollar amount of all non-NDC based discounts for the reporting period in the “Price Concessions” tab in the survey

Practical considerations

CONFIDENTIALITY, COMPLIANCE RISK, AND POTENTIAL REIMBURSEMENT AND ENFORCEMENT IMPLICATIONS

CMS position on hospital participation

CMS has stated that it interprets the statute as imposing an obligation on hospitals to respond to the survey, notwithstanding the statute's silence as to enforcement/enforcement penalties

CMS nonetheless suggests that hospital participation is expected

Hospital associations have asked CMS to clarify that participation is not required by law

Confidentiality and data use

CMS has stated that it will make the reported data available within the Department of Health and Human Services, including its agencies and their contractors and representatives, and the Executive Office of the President

CMS has indicated that individual hospital information will be kept confidential “to the full extent permitted by law,” suggesting that disclosure via FOIA or other avenues may occur

CMS anticipates that aggregate data may be disclosed in rulemaking

Uncertainty

- How many hospitals will respond to the survey
- Which types of hospitals will respond to the survey
- Whether the data will be statistically significant
- If and how CMS may use or attempt to use the data
- If and how CMS will group hospitals for rate setting
- Whether and what CMS actions related to the use or disclosure of the reported data may be challenged in litigation
- The outcome of any litigation challenging CMS actions

Risks for non-response

CMS has suggested that non-response could:

- Indicate that a hospital's acquisition costs are minimal or lower than peers;
- Justify the use of proxy data from similar responding hospitals;
- Support packaging of drugs into associated services;
- Inform future payment policy decisions.

Hospitals have further expressed concerns that non-response could:

- Result in enforcement of laws outside of the statute establishing the survey (e.g., False Claims Act)
- Cause reputational harm if the fact of non-response is disclosed
- Antagonize government regulators, resulting in scrutiny of other operations/programs
- Suggest that the hospital is not "cooperative" with government request
- Be inconsistent with organizational culture/policies
- Weaken a potential future claim that the data is statically invalid for rate setting

Risks for response

Hospitals have expressed concerns that responding could pose risks as well, such as:	Reducing their drug reimbursement rate based average acquisition costs
	Comparison against other pricing data sources
	Scrutiny or enforcement action as to inconsistent data reporting
	Data being made publicly available
	Data being used by other payors for rate-setting purposes

Hospitals have also identified staffing or data limitations that make it impossible/impracticable to respond to the survey in precisely the manner that CMS has requested

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Questions?

Thank you