

To: Jamie Wilson
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)

From: William N. Parham III
Office of Strategic Operations and Regulatory Affairs (OSORA)
Centers for Medicare and Medicaid Services (CMS)

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Subject: Non-Substantive Change Request – Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey (OMB No: 0938-1487; CMS-10931)

This memo requests approval of a non-substantive change to the approved information collection titled Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey (OMB No: 0938-1487; CMS-10931).

BACKGROUND

Under Medicare's Outpatient Prospective Payment System (OPPS), and pursuant to section 1833(t) of the Social Security Act, the Secretary pays hospitals for outpatient services at predetermined rates based on the average cost that hospitals incur for certain services. Paragraph (14) directs the Secretary on how to calculate, review, and adjust payment rates for SCODs.

In particular, subparagraph (A)(iii) directs the Secretary of HHS to set payment rates based on either (I) the drug's average acquisition cost, which may vary by hospital group, as determined by the Secretary taking into account certain hospital cost survey data under subparagraph (D)(ii), or (II) if hospital cost acquisition data are not available, the average sales price of the drug, with certain adjustments by the Secretary. (*See* 42 U.S.C. §1395l(t)(14)(A)(iii).)

The Secretary has not collected hospital cost acquisition data under subparagraph (D)(ii), and so has generally set the default payment rate for most SCODs, and non-SCODs, at the average sales price plus six percent under subparagraph (A)(II). The Secretary set that rate in calendar year 2006 based on two surveys of hospital drug acquisition costs that the statute required the Comptroller General to conduct in 2004 and 2005. (*See* 42 U.S.C. §1395l(t)(14)(D)(i).)

The statute does not envision that the Secretary will rely on surveys from 2004 and 2005 to set payment rates for SCODs forever. As noted, subdivision (A)(iii)(I) authorizes the Secretary to set payment rates based on a drug's average acquisition cost if he has cost survey data under paragraph (D). And the statute required that the Comptroller General use his experience conducting cost acquisition surveys in 2004 and 2005 to make recommendations to the Secretary about what methodology he should use to conduct future cost acquisition surveys and how often he should conduct them. (*See id.* at (t)(14)(D)(i)(II).)

The Government Accountability Office (GAO) accordingly prepared reports in October 2005¹ and April 2006² that included recommendations for the Secretary regarding the frequency and methodology for subsequent cost acquisition surveys. To ensure that Medicare payments for SCOD products were based on sufficiently accurate data, GAO recommended that the Secretary of Health and Human Services “validate, on an occasional basis, manufacturers’ reported drug ASPs as a measure of hospitals’ acquisition costs using a survey of hospitals or other method that CMS determines to be similarly accurate and efficient.”³ While GAO recognized that collecting current, accurate drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO recommended that CMS conduct a streamlined survey “once or twice per decade” because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS.⁴ To better approximate hospitals’ acquisition costs of SCODs, GAO also recommended that CMS (1) reconsider the level of proposed payment rates for drug SCODs, in relation to survey data on average purchase price, the role of rebates in determining acquisition costs, and the desirability of setting payment rates for SCODs at average acquisition costs and (2) collect information on ASP components and ASP by purchaser type to validate the reasonableness of reported ASPs as a measure of hospital acquisition costs.⁵

On April 15, 2025, President Trump signed Executive Order (E.O.) 14273, “Lowering Drug Prices by Once Again Putting Americans First.” Section 5 of the E.O., “Appropriately Accounting for Acquisition Costs of Drugs in Medicare,” directs the Secretary of HHS to publish in the Federal Register a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments.

Accordingly, under section 1833(t)(14)(D)(ii) of the Act and consistent with E.O. 14273, CMS will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPDS.

OVERVIEW OF REQUESTED CHANGES

The Division of Outpatient Care in the Hospital and Ambulatory Policy Group of the Center for Medicare (CM) is requesting to make the following non-substantive edits to the currently approved information collection request. The following changes have no impact on the currently approved burden for this information collection. No data elements have been added or removed. All of the non-substantive edits being requested are to remediate errors in the original OMB submission package received by OIRA on November 25, 2025.

- Agency Tracking No

¹ <https://www.gao.gov/assets/gao-06-17r.pdf>

² <https://www.gao.gov/new.items/d06372.pdf>

³ *Id.* at 19.

⁴ *Id.* at 13.

⁵ <https://www.gao.gov/assets/gao-06-17r.pdf> at 13-14.

- o During the OMB submission process, CMS uses this data field to list the program under which the information collection falls. The original OMB submission incorrectly listed the Centers for Clinical Standards and Quality (CCSQ).
- o With this non-substantive change request, CMS is revising the “Agency Tracking No.” data field to list CM.
- Obligation to Respond
 - o The information collection request was submitted with the incorrect box checked in the “Obligation to Respond” field. It was erroneously submitted with the “Voluntary” box checked.
 - o With this non-substantive change request, CMS is revising the “Obligation to Respond” to “Required to obtain or retain benefits” as discussed in the final rule.
 - In the final rule that published November 25, 2025, (90 FR 53448) and titled Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Rating; Hospital Price Transparency; and Notice of Closure of a Teaching Hospital and Opportunity To Apply for Available Slots rulemaking documents for the CY 2026 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1834-FC), CMS referred to the obligation to respond to the survey as required. For example, in response to comments, CMS stated: “Response: We are not treating any hospital type or group differently for purposes of conducting this survey. **All hospitals paid under the OPSS are required to respond to the survey.** We note that Critical Access Hospitals are not included in the survey pool since they are not paid under the OPSS.”(90 FR 53760) Additionally, in response to comment CMS discusses the “...obligations on both the Secretary to design such a survey and on hospitals generally to respond to the survey...” CMS concludes that response to comment by stating: “The lack of a response to this **required survey** is still meaningful data to CMS which can be taken into consideration to inform future payment rates in future rulemaking.” (90 FR 53764). Finally, when summarizing the proposal for CY 2026, CMS states: “After consideration of public comments, we are finalizing our proposal outlining our intent to conduct a **required OPSS drug acquisition cost survey** to all hospitals paid under the OPSS, pending final approval from OMB.” (90 FR 53766).
 - Additionally, in Supporting Statement B when CMS describes the respondent universe of the survey, CMS states: “All hospitals paid under the OPSS are required to respond to this survey.” Additional similar references are throughout the PRA submission.
 - Finally, in the CMS rollout of the CY 2026 OPSS/ASC final rule with comment period, CMS stated: “CMS will be conducting a **required survey** by early CY 2026 on the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPSS.”⁶

⁶ <https://www.cms.gov/newsroom/fact-sheets/calendar-year-2026-hospital-outpatient-prospective-payment-system-opss-ambulatory-surgical-center>

- The intent regarding a hospital's obligation to respond to the survey was clear and communicated through a variety of methods as described.