

Supporting Statement – A

**Medicare Outpatient Prospective Payment System
(OPPS) Drug Acquisition Cost Survey**

(CMS-10931; OMB 0938-1487)

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Supporting Statement – Part A

Background

This is a request pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) to conduct a survey of the hospital acquisition costs for drugs paid separately under the Medicare Outpatient Prospective Payment System (OPPS).

The purpose of the survey is to assess the cost of certain specified covered outpatient drugs (SCODs), and drugs and biologicals CMS historically treats as SCODs, for consideration when proposing appropriate payment rates for hospitals paid under the OPPS.

The data collection captures the specific cost and utilization data for drugs that are furnished by a hospital paid under the OPPS.

To date, CMS has not surveyed all hospitals paid under the OPPS for these costs. The Comptroller General conducted a survey in 2004 and 2005, and CMS surveyed a subset of hospitals paid under the OPPS in 2020 (see the previously approved CMS-10709 (OMB 0938-1374) package at https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202008-0938-005). We are requesting a new approval for this collection, rather than a reinstatement of the previously approved collection, because we previously only surveyed certain hospitals paid under the OPPS, whereas now we are surveying all hospitals paid under the OPPS.

To facilitate this collection of data, we will be using the Medicare Fee-for-Service Data Collection System (FFSDCS). This is the main data system available to serve the needs of the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) in support of the collection and management of data related to Medicare Fee-for-Service (FFS) payment systems.

We are requesting new collection approval from OMB.

This new information collection request will be submitted to OMB for review under control number 0938-1487 (CMS-10931). The OMB control number will not be valid until formally approved by OMB.

A. Justification

Need and Legal Basis

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

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

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

³ *Id.* at 19.

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 OPPIs.

2. Information Users

CMS is exercising its statutory authority to survey hospital drug acquisition costs under section 1833(t)(14)(D)(ii) of the Act, and the agency may use the information collected to inform payment rates for drugs purchased by hospitals paid under the OPPIs. We intend for the survey to be completed in time for the survey results to be used to inform policy making, beginning with the CY 2027 OPPIs/ASC proposed rule.

3. Use of Information Technology

CMS intends to use the FFSDCS for electronically obtaining drug acquisition cost information for each SCOD, and drugs and biologicals CMS historically treats as SCODs, already acquired by the hospital over a one year period from July 1, 2024 through June 30, 2025, with the survey open January 1, 2026, through March 31, 2026. The entire survey, including any necessary respondent identification information, will be captured by FFSDCS which is a system operated by the CMS to gather and store data related to Medicare FFS payments. Hospitals may have familiarity with the system as it is primarily used to determine payment rates for services like laboratory tests through the Clinical Laboratory Fee Schedule where providers submit data on the services they provide to determine their payment amount; essentially, the FFSDCS is a platform to collect information on individual medical services billed under the FFS model. Hospitals may also have familiarity with the FFSDCS as hospital-based ambulance organizations may report in the Ground Ambulance Data Collection System (GADCS)(PRA-exempt), which is

⁴ *Id.* at 13.

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

another module in the FFSDCS. Additionally, the FFSDCS collects data from drug manufacturers to determine Average Sales Price (ASP) (OMB 0938-0921) which is a drug pricing model that refers to the average price a manufacturer charges for a drug after accounting for discounts and rebates.

4. Duplication of Efforts

This information collection does not duplicate any other effort, and the information cannot be obtained from any other source. The previously approved package (CMS-10709) is not sufficient to collect the required information as it only surveyed certain hospitals paid under the OPPI, whereas now we are surveying all hospitals paid under the OPPI for all discounts contributing to a hospital's net acquisition cost for a drug.

5. Small Businesses

Completion of the survey may affect small entities, such as small rural and urban hospitals. To minimize the burden, CMS has limited the specific information collected solely to the essential elements necessary to develop payment rates as statutorily authorized.

6. Less Frequent Collection

The survey is necessary to obtain acquisition cost data for use in setting payment rates for SCODs, and drugs and biologicals CMS historically treats as SCODs, acquired by hospitals paid under the OPPI. CMS believes that this survey will appropriately account for acquisition costs of drugs in Medicare and ensure that payment for these drugs is appropriate. As such, the collection of these data are essential. This survey will likely be conducted every four (4) years. We believe that this frequency will appropriately balance hospitals' burdens in completing the survey with ensuring that we capture the required data to inform payment rates under section 1833(t)(14)(D)(I)(ii) of the Act. However, this frequency is subject to revision based on the initial survey's results and other factors as appropriate. This time frame also aligns with the approximate guidance provided by GAO in their original report, which states that a survey should be conducted once or twice per decade.

7. Special Circumstances

We are not requesting original documents of any kind. Furthermore, we are not requiring respondents to retain any records other than what hospitals already retain for drug acquisition. The information collected via this survey tool is intended to be analyzed for suitability in determining payment amounts for drugs paid under the Medicare OPPI. This collection will not require the use of statistical data classification or other large-scale data sorting procedures. The Secretary was given the authority to do this collection and collect this type of data under the law at section 1833(t)(14)(D)(ii). CMS will maintain the

confidentiality of any drug pricing respondents submit as proprietary or confidential to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice displayed on 07/15/2025 and published as part of the CY 2026 OPPS/ASC notice of proposed rulemaking on 07/17/2025 (90 FR 33476).

The CY 2026 OPPS/ASC final rule published on 11/25/2025 in the Federal Register (90 FR 53448).

9. Payments/Gifts to Respondents

No payments or gifts are made to respondents. The acquisition cost data received as a result of respondents' completion of the survey is intended to be used to inform policy making beginning with the CY 2027 OPPS/ASC proposed rule.

10. Confidentiality

CMS pledges privacy to the extent required by law.

Only the Department of Health and Human Services (HHS) and relevant component agencies, their contractors and representatives, and the Executive Office of the President (EOP), and CMS and their contractor(s) will have access to these data. In accordance with section 1833(t)(14)(A)(iii)(I) of the Act, the agency plans to use the data collected to determine acquisition costs for SCODs, and drugs and biologicals CMS historically treats as SCODs. Following the collection of data and its analysis, the aggregate results of the survey will be considered when determining proposed payment rates. The proposed payment rates and calculations with aggregate data could appear in notice and comment rulemaking; however, the confidentiality of individual hospitals and proprietary information would be maintained to the extent permitted by law.

11. Sensitive Questions

To the extent that acquisition prices for certain SCODs, and drugs and biologicals CMS historically treats as SCODs, are deemed sensitive and/or confidential, we do not intend to make such prices available in an individually identifiable manner. As noted in section 10 above, we pledge confidentiality to the extent required by law. Acquisition cost data collected through a survey is directed by sections 1833(t)(14)(A)(iii)(I) and 1833(t)(14)(D)(ii) of the Social Security Act. CMS is authorized to obtain the data to inform payment for drugs paid under the OPPS.

12. Burden Estimates (Hours & Wages)

To derive average costs, we used data from the Occupational Employment and Wage Statistics ([Hospital-Specific Wages](#)) for all salary estimates. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage for providers that are responsible for completing the survey.

We estimated 80.5 hours to complete the survey by aggregating time from the four roles that are most likely to be responsible. These roles are described below:

- A **Top Executive** (11-1000) will likely review the survey request and designate a Submitter prior to survey distribution.
- A **Pharmacy Technician** (29-1051) will likely register for the module and apply to fill out the survey. Once the survey is distributed, the Pharmacy Technician reviews the survey. Then, the Pharmacy Technician requests data from suppliers, and/or pulls data from internal systems, ensures data are in the appropriate format, manually enters data OR uploads data into system, reviews data, makes corrections as needed, and certifies data.
- A **Lawyer** (23-1011) will likely review the survey request, the survey, and requirements for compliance.
- A **Pharmacist** (29-2052) will likely review the survey request and data that are pulled by the Pharmacy Technician.

Table 1. Salary Estimates for Providers Completing the Survey

Average Hourly Rate Analysis	Hours per Response	BLS Cost per Hour (\$)	Cost Per Hour with Overhead & Fringes (\$)	Cost per Response (\$)
Top Executives (11-1000) / POC	0.5	116.99	233.98	116.99
Lawyers (23-1011) / General Council	1	108.36	216.72	216.72
Pharmacist (29-1051) / Pharmacy Director	8	70.94	141.88	1,135.04

Pharmacy Technicians (29-2052) / Pharmacy Buyer	71	25.2	50.4	3,578.40
			Total Annual Cost Per Response:	\$5,047.15
			Total Estimated Cost Across all Survey Responses:	\$5,047.15 * 4,500 hospitals = \$22,712,175

We have adjusted our employee hourly wage estimates by a factor of 100 percent to account for fringe benefits and overhead costs. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Table 2. Hourly Burden Estimates for the Survey

Potential Respondents	Respondent #	Total Responses	Burden per Response	Total Annual Burden (hours)
Hospitals	4,500	1	80.50	362,250

Information Collection Instruments/Instructions

We have included with this package the following:

A. An Example of the survey collection instrument, consisting of an Excel File Template.

This file outlines the specific data elements that will be required for the survey, including which NDCs we intend to include in the drug acquisition cost survey. These NDCs were gathered by analyzing the drugs and biologicals that were separately payable under the OPPI during the survey period of July 1, 2024 through June 30, 2025. This is the time-period we are surveying for hospital drug acquisition costs. This 12-month time period aligns with GAO's 12-month survey period for their original study of July 1, 2003, through June 30, 2004. This time period also provides a 6 month window between the end of the survey period and the start of the survey submission window to ensure adequate time for all rebates, discounts, and price concessions to be finalized, so they can be incorporated into the NDC acquisition costs submitted by hospitals.

For the NDCs included in the template, we excluded radiopharmaceutical NDCs from our list of NDCs. Radiopharmaceuticals are unique products with various forms in which they can be purchased. These unique characteristics were acknowledged by GAO in the original survey. GAO collected information, and analyzed data, for radiopharmaceuticals separately from other drugs. They specifically acknowledged, with regard to radiopharmaceuticals, that “their complex nature as compared with drugs poses challenges for collecting and interpreting cost data.”⁶ We believe due to these unique characteristics, we should not include radiopharmaceuticals in the survey at this time. This will also reduce hospital reporting burden.

Additionally, we excluded NDCs that were obsolete during the survey timeframe, and we only included NDCs for which there was a payment made under the OPPS during the survey period. Consequently, we did not include NDCs for which payment would typically be packaged under the OPPS. By reducing the number of NDCs, this also helps reduce hospital burden and ensures we are asking for only the most necessary data. We can use a hospital’s OPPS billing patterns to approximate the NDCs, and their associated volume, that would have been purchased during the survey time-period to ensure the approximate accuracy of a hospital’s submission to CMS.

CMS is also creating a web portal in the FFSDCS where survey respondents can submit their data. Hospitals have the option to download an Excel template similar to the one included in this package, fill out the required fields, and then upload the template to the web portal. Hospitals can also directly enter their survey data into the web portal itself, which will follow the same layout as the provided Excel template. Additionally, the web portal will check for common submission errors, such as including units purchased but not acquisition costs, and alert the submitter to the error before the final submission.

Once the submitter has uploaded or entered the required data, then they must officially submit that data to CMS and attest to the validity, integrity, and completeness of the data being submitted.

- B. **Survey Instruction Sheet:** The instructions for completing the survey that will be provided to hospitals. Included in the Excel File Template is a tab that contains instructions, including relevant terms and definitions, on how to fill out the survey. These instructions will also be available in the FFSDCS web portal.
- C. **OPPS Drug Acquisition Cost Survey Website:** A new CMS webpage has been created within the Medicare Hospital OPPS website (<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey>)

⁶ <https://www.gao.gov/new.items/d06372.pdf> at page 10.

to serve as a central hub for information and resources for hospitals as they learn more about the process required to submit this data to CMS.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The cost to the Federal Government to build and design the data collection system for the new module in the FFSDCS that will facilitate the collection of drug cost information to collect cost information, and analyze the information submitted through that system is estimated as follows:

We estimate the total cost to the Federal Government through direct costs incurred by government FTEs and contractor support.

Government FTE Cost Estimate:

Using the *WASHINGTON-BALTIMORE-ARLINGTON, DC-MD-VA-WV-PA LOCALITY – 2025* pay, we calculated an average hour rate of \$144.48, which is an hourly rate of \$72.24 doubled to include fringe benefits.

GS-12 (step 5): \$55.07

GS-13 (step 5): \$65.48

GS-14 (step 5): \$77.38

GS-15 (step 5): \$91.02

Average Rate (equally weighted): $\$72.24 \text{ per hour} * 2 = \144.48 per hour .

$\$144.48 \text{ per hour} * 3,000 \text{ hours} = \text{approximately } \$435,000 \text{ annualized for Government FTEs.}$

Government Contracting Cost Estimate:

There will be contractual cost to the development of survey specific module to the existing electronic reporting system. These costs are confidential in preparation for contract negotiations; however, we provide a general estimate of the costs associated with contractor support for the development of this data collection as well as the associated data analysis.

Annualized Contractor Support: \$1,700,000.

Total annualized estimated cost to the government:

Approximate annualized for Government FTEs + Annualized Contractor Support
\$435,000 + \$1,700,000 = \$2,135,000.

15. Changes to Burden

No changes to burden. This is a new collection.

16. Publication/Tabulation Dates

In accordance with section 1833(t)(14)(A)(iii)(I), the agency plans to use the data collected to determine acquisition costs for SCODs, and drugs and biologicals CMS historically treats as SCODs, based on data submission to the FFSDCS. Following the collection of data and its analysis, the results of the survey will be considered in determining proposed payment rates, which would be subject to notice and comment rulemaking. We intend for the survey to be completed in time for the survey results to be used to inform policymaking beginning with the CY 2027 OPPI/ASC proposed rule.

We do not plan to post the raw survey data publicly. We may provide aggregated or deidentified statistics in conjunction with any proposed payment rates we propose in future rulemaking based on survey data.

17. Expiration Date

CMS will display the expiration date and OMB control number on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

This new information collection request will be submitted to OMB for review under control number 0938-1487 (CMS-10931). The OMB control number will not be valid until formally approved by OMB.

18. Certification Statement

There are no exceptions to the certification statement.