

**SUPPORTING STATEMENT FOR
SUPPLEMENTAL TO FORM CMS-2552-10
PAYMENT ADJUSTMENT FOR
ESTABLISHING AND MAINTAINING ACCESS TO
A BUFFER STOCK OF ESSENTIAL MEDICINES
(OMB# 0938-XXXX; CMS-10897)**

A. Background

CMS is requesting review and approval by the Office of Management and Budget (OMB) for this new collection, Supplemental to Form CMS-2552-10 Payment Adjustment for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines (supplemental form), as part of FY 2025 IPPS final rule. This supplemental form supports the policy goal to strengthen the resilience of medical supply chains, especially for pharmaceuticals and simple medical devices, a policy goal emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as a deliverable of President Biden’s Executive Order 14001 on “A Sustainable Public Health Supply Chain.” The supplemental form calculates a payment adjustment for an 1886(d) hospital for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for cost reporting periods beginning on or after October 1, 2024. A hospital eligible for the payment adjustment must complete this supplemental form and submit the form with its Medicare cost report that covers the same cost reporting period.

B. Justification

1. Need and Legal Basis

As described in the preamble to the FY 2025, Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System final rule, small, independent hospitals that incur additional resource costs to establish and maintain access to a 6-month buffer stock of one or more essential medicine(s) may receive an IPPS payment adjustment. This payment adjustment is made under the IPPS for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines under section 1886(d)(5)(I) of the Act. The Medicare cost reporting form CMS- 2552-10 (OMB #0938-0050) does not currently capture the necessary data to calculate this payment adjustment; therefore, hospitals need this supplemental worksheet to Form CMS- 2552-10 to calculate the payment adjustments for cost reporting periods beginning on or after October 1, 2024.

2. Information Users

The primary function of the supplemental form is to determine a payment adjustment for small, independent 1886(d) hospitals that establish and maintain access to a buffer stock of essential medicines. Each hospital submits the supplemental form with its Medicare cost report to its contractor for reimbursement determination. Section 1874A of the Act describes the functions of the contractor.

Hospitals must follow the principles of cost reimbursement, which require that hospitals maintain sufficient financial records and statistical data for proper determination of costs.

3. Use of Information Technology

CMS regulations at 42 CFR § 413.24(f)(4)(ii) require that each hospital submit an annual cost report to their contractor in a standard (ASCII) electronic cost report (ECR) format. The supplemental form must accompany the hospital's annual cost report for cost reporting periods beginning on or after October 1, 2024.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

CMS requires that all small, independent 1886(d) hospitals with fewer than 100 beds that are not part of a chain organization complete the supplemental form to receive the payment adjustment for establishing and maintaining at least a 6-month buffer stock of essential medicine(s). CMS designed this supplemental form with a view toward minimizing the reporting burden for all hospitals completing the form. CMS collects the form as infrequently as possible (annually) and only those data items necessary to determine the appropriate payment adjustment are required.

6. Less Frequent Collection

This supplemental form must accompany an eligible hospital's cost report, Form CMS-2552-10. Under the authority of 1861(v)(1)(F) of the Act, as defined in regulations at 42 CFR 413.20 and 413.24, CMS requires that each hospital submit the cost report on an annual basis with the reporting period based on the hospital's accounting period, which is generally 12 consecutive calendar months. A less frequent collection would adversely affect provider payments.

7. Special Circumstances

This information collection complies with all general information collection guidelines as described in 5 CFR 1320.6.

8. Federal Register Notice

A 30-day Federal Register notice of the FY 2025 IPPS/LTCH PPS final rule (RIN 0938-AV34, CMS-1808-P) published on August 28, 2024 (89 FR 68986).

9. Payments/Gifts to Respondents

CMS makes no payments or gifts to respondents for completion of this data collection. CMS issues claims payments for covered services provided to Medicare beneficiaries. These reports collect the data to determine accurate payments to a hospital. If the hospital fails to submit the cost report, the contractor imposes a penalty by suspending claims payments until the hospital submits the cost report. Once the hospital submits the cost report, the contractor releases the suspended payments. A hospital that submits the cost report timely experiences no interruption in claims payments.

10. Confidentiality

Confidentiality is not assured. This supplemental form must accompany the hospital's cost report. Cost reports are subject to disclosure under the Freedom of Information Act.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Cost)

Number of estimated eligible hospital facilities (as of 7/11/2024)		500
Hours burden per facility to complete the cost report	1.00	
Number of hours of reporting	.60	
Number of hours of recordkeeping	.40	
Total hours burden (500 facilities x 1.00 hours)	500	
Cost per hospital		\$71.45
Total annual cost estimate (\$71.45 x 500 hospitals, rounded)		\$35,725

Only when the standardized definitions, accounting, statistics, and reporting practices defined in 42 CFR 413.20(a) are not already maintained by the provider on a fiscal basis does CMS estimate additional burden for the required recordkeeping and reporting.

Burden hours estimates the time required (number of hours) for each respondent to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Supplemental to Form CMS-2552-10. The number of respondents consists of the number of small, independent Medicare certified 1886(d) hospitals eligible for the payment adjustment under Part A. The total number of small, independent hospitals required to file the Supplemental to Form CMS-2552-10 annually, as determined in the FY 2025 IPPS final rule is 500. We estimate the average burden hours per respondent as 1.00 hour, an average per provider of 0.40 hours for recordkeeping and 0.60 hours for reporting. We recognize this average varies depending on the provider size and complexity. We invite public comment on the hours estimate as well as the staffing requirements utilized to compile and complete the supplemental form.

We calculated the annual burden hours as follows: 500 hospitals multiplied by 1.00 hour per hospital equals 500 annual burden hours.

The 0.40 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 0.60 hours for reporting include accounting and audit professionals' activities. Based on the most recent Bureau of Labor Statistics (BLS) in its 2023 Occupation Outlook Handbook, the mean hourly wage for Category 43-3031 <https://www.bls.gov/oes/current/oes433031.htm> (bookkeeping, accounting and auditing clerks) is \$23.84. We added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to \$47.68 (\$23.84 plus \$23.84) and multiplied it by 0.40 hours, to determine the annual recordkeeping costs per hospital

to be \$19.07 (\$47.68 per hour multiplied by 0.40 hours).

The mean hourly wage for Category 13-2011 www.bls.gov/oes/current/oes132011.htm (accounting and audit professionals) is \$43.65. We added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to \$87.30 (\$43.65 plus \$43.65) and multiplied it by 0.60 hours, to determine the annual reporting costs per hospital to be \$52.38 (\$87.30 per hour multiplied by 0.60 hours).

We calculated the total average annual cost per hospital of \$71.45 by adding the recordkeeping costs of \$19.07 plus the reporting costs of \$52.38. We estimated the total annual cost to be \$35,725 (\$71.45 cost per hospital multiplied by 500 hospitals).

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

<u>Annual cost to MACs:</u> MACs processing information on the forms based on estimates provided by the CMS Office of Financial Management	\$87,300
<u>Annual cost to CMS:</u>	<u>\$0</u>
Total Federal cost	<u>\$87,300</u>

Burden to the Federal Government consist of an estimated 2 hours for the MAC to accept, review, validate, establish interim payments, and finalize the Essential Medicines worksheet data. The total number of small, independent hospitals required to file the Supplemental to Form CMS-2552-10 annually, as estimated in the FY 2025 IPPS final rule is 500. We calculated the annual burden hours as follows: 500 hospitals multiplied by 2 hours per hospital equals 1,000 annual burden hours.

The CMS Office of Financial Management estimated the costs to the Federal Government using the mean hourly wage for Category 13-2011 www.bls.gov/oes/current/oes132011.htm (accounting and audit professionals) of \$43.65. They added 100% of the mean hourly wage to account for fringe benefits and overhead costs, resulting in an hourly rate of \$87.30 (\$43.65 plus \$43.65). The hourly rate of \$87.30 was multiplied by the 1,000 hours, to determine the annual costs to the Federal Government of \$87,300.

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

Each small, independent 1886(d) hospital must submit the Supplemental to Form CMS-2552-10 with its cost report Form CMS-2552-10 in which the hospital reports the payment adjustment calculated on the Supplemental to Form CMS-2552-10. CMS maintains the cost report data, which will include the payment adjustment, in the HCRIS. The HCRIS data supports CMS's

reimbursement policymaking, congressional studies, legislative health care reimbursement initiatives, Medicare profit margin analysis, market basket weight updates, and public data requirements. CMS publishes the HCRIS dataset for public access and use at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/>.

17. Expiration Date

CMS will display the expiration date on the data collection instrument in the upper right corner.

18. Certification Statement

There are no exceptions to the certification statement.

C. Statistical Methods

There are no statistical methods involved in this collection.