SUPPORTING STATEMENT FOR
SUPPLEMENTAL TO FORM CMS-2552-10
PAYMENT ADJUSTMENT FOR DOMESTIC
NIOSH-APPROVED SURGICAL N95 RESPIRATORS

A. Background

CMS is requesting expedited review and approval by the Office of Management and Budget (OMB) for this new collection, Supplemental to Form CMS-2552-10 Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators (supplemental form), proposed as part of CY2023 OPPS proposed rule. This supplemental form supports the policy goal of ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically-made PPE, 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 and/or a hospital paid for outpatient services under the hospital outpatient prospective payment system (OPPS) purchasing domestic NIOSH-approved surgical N95 respirators (domestic respirators) effective for cost reporting periods beginning on or after January 1, 2023. 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

On January 20, 2021, President Biden issued Executive Order (E.O.) 13987, titled "Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security" (86 FR 7019). This order launched a whole-of-government approach to combat the coronavirus disease 2019 (COVID-19) and prepare for future biological and pandemic threats. In March 2022, President Biden released the National COVID-19 Preparedness Plan that builds on the progress of the prior 13 months and lays out a roadmap to fight COVID-19 in the future. Both the ongoing threat of COVID-19 and the potential for future pandemics necessitate significant investments in pandemic preparedness.

Availability of personal protective equipment (PPE) in the health care sector is a critical component of this preparedness, and one that displayed significant weakness in the beginning of the COVID-19 pandemic. In spring of 2020, supply chains for PPE faced severe disruption due to lockdowns that limited production and unprecedented demand spikes across multiple industries. Supply of surgical N95 respirators—a specific type of filtering facepiece respirator used in clinical settings -- was one type of PPE that was strained in hospitals. Supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough surgical N95 respirators to protect health care workers. Prices for surgical N95 respirators soared, from an estimated $0.25–$0.40 range to $5.75 or even $12.00 in some cases. Unable to obtain surgical N95 respirators regulated by NIOSH, hospitals had to turn to KN95 respirators and other non-NIOSH-approved disposable respirators that were authorized under Emergency Use Authorization (EUA). Concerns were raised during the COVID-19 pandemic regarding counterfeit respirators. NIOSH evaluates and approves

surgical N95s to meet efficacy standards for air filtration and protection from fluid hazards present during medical procedures. KN95 respirators, on the other hand, are not regulated by NIOSH. KN95 respirators have faced particular counterfeit and quality risks -- with NIOSH finding that about 60% of KN95 respirators that it evaluated during the COVID-19 pandemic in 2020 and 2021 did not meet the particulate filter efficiency requirements that they intended to meet. Failure to meet these requirements compromises safety of health care personnel and patients.

Over the course of the pandemic, U.S. industry responded to the shortages and dramatically increased production of N95 respirators. Today, the majority of surgical N95 respirators purchased by hospitals are assembled in the U.S., and prices have returned to rates closer to $0.70 per respirator. However, risks remain to maintain preparedness for COVID-19 and future pandemics. It is important to maintain this level of domestic production for surgical N95 respirators, which provide the highest level of protection from particles when worn consistently and properly, protecting both health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material -- including the virus that causes COVID-19. Additionally, it is important as a long-term goal to ensure that a sufficient share of those surgical N95 respirators are wholly made in the U.S. -- that is, including raw materials and components. The COVID-19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays, can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID-19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance.

This policy goal -- ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE -- is 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." To help achieve this goal, the U.S. Government is committing to purchase wholly domestically-made PPE in line with new requirements in section 70953 of the Infrastructure Investment and Jobs Act. These new contract requirements stipulate that PPE purchased by covered departments must be wholly domestically-made -- that is, the products as well as their materials and components must be grown, reprocessed, reused, or produced in the U.S.

The federal government's procurement of wholly domestically-made PPE will help achieve the above policy goal. However, the U.S. Government alone cannot sustain the necessary level of production. As outlined in the previously mentioned National Strategy for a Resilient Public Health Supply Chain, the U.S. Government is only one small part of the market for PPE. Hospitals are the primary purchasers and users of medical PPE, including surgical N95 respirators. Sustaining a strong domestic industrial base for PPE in order to be prepared for future pandemics or COVID-19-driven surges and protect Americans' health during such times, therefore, requires hospitals' support.

2. Information Users

The primary function of the supplemental form is to determine a payment adjustment for an 1886(d) hospital and/or a hospital paid for outpatient services under the hospital OPPS purchasing domestic respirators. 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 January 1, 2023.

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 all 1886(d) hospitals and all hospitals paid for outpatient services under the hospital OPPS, regardless of size, to complete the supplemental form. 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 impede the annual rate setting process and 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

The 60-day Federal Register notice was part of the proposed rule(CMS-1772-P; RIN 0938-AU82) that published on July 26, 2022 (87 FR 44502).

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 hospital facilities (as of 5/5/2022)		4,662
Hours burden per facility to complete the cost report:	.50	
Number of hours of reporting	10	
Number of hours of recordkeeping	45	
Total hours burden (4,662 facilities x .50 hours)	2,331	
Cost per hospital		$18.92
Total annual cost estimate ($18.92 x 4,662 hospitals)		$87,637
Total annual cost estimate (rounded)		$87,640

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.

The number of respondents, calculated as 3,240, includes the number of Medicare certified 1886(d) hospitals eligible for the payment adjustment under Part A and Part B (excluding 30 Indian Health Services Hospitals excluded from the Part B payment adjustment as they are paid under an all-inclusive rate for Part B services) plus 1,422 additional hospitals paid for outpatient services under the hospital OPPS for a total population of 4,662 hospitals.

Burden hours for each hospital estimate the time required (number of hours) to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Supplemental to Form CMS-2552-10. The total number of hospitals required to file the Supplemental to Form CMS-2552-10 annually is 4,662, which includes the 3,240 Medicare certified 1886(d) hospitals plus 1,442 additional hospitals paid for outpatient services under the hospital OPPS (per System for Tracking Audit and Reimbursement (STAR), an internal CMS data system maintained by the Office of Financial Management

(OFM). We estimate the average burden hours per facility as 0.50 hours, an average per provider of 0.45 hours for recordkeeping and 0.10 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: 4,662 hospitals multiplied by 0.50 hours per hospital equals 2,331 annual burden hours.

The 0.45 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 0.10 hours for reporting include accounting and audit professionals' activities. Based on the most recent Bureau of Labor Statistics (BLS) in its 2021 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 $21.70. We added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $43.40 ($21.70 plus $21.70) and multiplied it by 0.25 hours, to determine the annual recordkeeping costs per hospital to be $10.85 ($43.40 per hour multiplied by 0.25 hours).

The mean hourly wage for Category 13-2011 www.bls.gov/oes/current/oes132011.htm (accounting and audit professionals) is $40.37. We added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $80.74 ($40.37 plus $40.37) and multiplied it by 0.10 hours, to determine the annual reporting costs per hospital to be $8.07 ($80.74 per hour multiplied by 0.10 hours).

We calculated the total average annual cost per hospital of $18.92 by adding the recordkeeping costs of $10.85 plus the reporting costs of $8.07. We estimated the total annual cost to be $87,637 ($18.92 cost per hospital multiplied by 4,632 hospitals), rounded to $87,640.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Annual cost to MACs: MACs processing information on the forms based on estimates provided by OFM	$173,700
Annual cost to CMS: Total Federal cost	$0
	$173,700

15. Changes to Burden

The Supplemental to Form CMS-2552-10 is a new information collection.

16. Publication/Tabulation Dates

Each 1886(d) hospital and/or hospital paid for outpatient services under the hospital OPPS 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 Healthcare Provider Cost Reporting Information System (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.