A. Background

This is a request for renewal of the emergency PRA approval of form CMS-2567, titled **"Statement of Deficiencies and Plan of Correction"** which is approved under OMB control number 0938-0391. The current OMB approval expires on 02/28/2022.

The form CMS-2567 is the legal, documentary basis for CMS's certification of a facility's compliance or noncompliance with the Medicare/Medicaid Conditions of Participation or Coverage, and the requirements for Nursing Home participation and CLIA certification. This form is used to state concisely and in a standard format whether or not any deficiencies were identified during the course of an inspection (survey), and if so, what each deficiency was and the evidence for it. It also provides a uniform format for providers, suppliers and CLIA laboratories to describe required plans to correct each deficiency. As of 2017, facilities are able to submit an electronic plan of correction as an option (see SC17-34-Formatting of Plans of Corrections), yet the attachment will be considered the official plan of correction under the form CMS-2567. This form facilitates analysis of deficiencies and plans of correction, and disclosure of information concerning deficiencies.

The form CMS-2567, titled "Statement of Deficiencies and Plan of Correction" is used by the State Survey Agency (SA) surveyors to document survey findings of compliance or noncompliance (deficiencies) resulting from inspection (survey) of Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) laboratories.

Beginning on October 1, 2021, the Accrediting Organizations (AOs) that accredit hospice programs will also use form CMS-2567 to document the findings of their Medicare hospice program surveys , as required by §407 of Consolidated Appropriations Act (CAA) of 2021. As of June 2021, there were three AOs with CMS-approved hospice accreditation programs. The AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

B. Justification

1. Need and Legal Basis

Section 1864(a) of the Social Security Act ("the Act") requires that the Secretary use State Survey Agencies (SAs) to conduct surveys to determine whether health care facilities meet Medicare, and CLIA participation requirements. The CMS-2567 form is the means by which the survey findings are documented. Section 1864(a) of the Act further requires that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The CMS-2567 form is the vehicle for this disclosure.

The CMS regulations at 42 CFR 488.18 require that SAs document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS-2567 form. Additionally, 42 CFR 488.26 and 488.28 further delineate how compliance findings must be recorded and that CMS prescribed forms must be used.

Additionally, Section 407 of CAA, 2021, amended Part A of Title XVIII of the Act at section 1822 establishing hospice program survey and enforcement requirements. This amendment, in part, requires the AOs that accredit hospice programs to include the form CMS-2567 to document the findings of their hospice program surveys. CMS has proposed conforming regulations through CMS-1747-P.

2. <u>Information Users</u>

The information from the CMS-2567 form is used by the SAs, and AOs that accredit hospice programs and CMS locations to document and certify compliance. It is also used by health care facilities to document their plan of correction. It is used by CMS, the States, AOs, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care provided by a facility and a facility's compliance with the applicable laws and regulations.

3. <u>Use of Information Technology</u>

This form is frequently produced in an automated fashion by the CMS Automated Survey Processing Environment (ASPEN) survey software. This automates the capture of survey data. AOs will also begin using this form and it may be incorporated into their proprietary electronic survey software.

4. Duplication of Efforts

This form elicits information not collected by any other means or form. There is no duplication of collection or information.

5. Small Business

These requirements do affect small businesses. However, this information collection is necessary for the businesses to participate in and receive Medicare or Medicaid reimbursement, or CLIA certification. These paperwork requirements are minimal and are necessary to meet the documentation and disclosure requirements of the law.

6. Less Frequent Collection

This information must be collected in conjunction with a facility survey. Survey frequency is prescribed by law for some facility types and by agency policy in other cases, in order to ensure quality of care. This information collection complies with the general guidelines in 5 CFR 1320.6.

7. Special Circumstances for Information Collection

There are no special circumstances associated with this information collection.

8. Federal Register and Outside Consultation

The 60-day Federal Register notice was published on October 22, 2021 (86 FR 58664). There was one comment received but it was out of the scope of the collection.

The 30-day Federal Register notice published on January 7, 2022 (87 FR 979).

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

This information contained in the CMS-2567 form is publicly disclosable. Identifiable data subject to the Privacy Act is not incorporated into the CMS-2567.

11. Sensitive Questions

There are no questions of a sensitive nature associated with the CMS-2567 form.

12. Estimation of Burden

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). The table below presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage for the person believed to perform tasks related to the completion and handling of the CMS-2567 form.

TABLE: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wages
Medical Secretaries and Administrative Assistants ¹	43-6013	\$18.75	\$18.75	\$37.50
Registered Nurse (RN) ²	29-1141	\$38.47	\$38.47	\$76.94
Medical Health Services Manager ³	11-9111	\$57.12	\$57.12	\$114.24

a. <u>Time & Cost Burden Related To Hospice Surveys Performed By The Accrediting Organization (AO) Surveyors.</u>

Beginning on October 1, 2021, AOs with CMS approved hospice programs will be required to use the CMS-2567 form to document their hospice program survey findings. At this time, only the AOs with hospice programs are required to use the form CMS-2567.

There are 3 AOs that have CMS approved hospice programs. We estimate that these 3 AOs together perform approximately 1,448 hospice program surveys per year. The chart below shows the estimated number of hospice program surveys performed annually by these 3 AOs.

Accrediting Organization	Number of Surveys Hospice Performed Annually	
СНАР	585 surveys	
ACHC	291 surveys	
TJC	572 surveys	
Total	1,448 surveys	

The information that is documented on the CMS-2567 form is collected during the course of the survey. We estimate that *each* hospice program survey takes approximately two days (**16 hours**).

¹ https://www.bls.gov/oes/current/oes436013.htm

² https://www.bls.gov/oes/current/oes291141.htm

³ https://www.bls.gov/oes/current/oes119111.htm

We further estimate that the total time burden *across all* AO hospice program surveys would be **23,168 hours.**

• 1,448 surveys x 16 hours per survey = 23,168 hours

AO surveyors are typically Registered Nurses (RNs). According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a RN is \$38.47. This wage, adjusted for the employers overhead and fringe benefits, would be **\$76.94**.

We estimate that the cost burden to *each* AO with a hospice program *per each survey* would be **\$1,231.**

• 16 hours x \$76.94 per hour = \$1,231.04

We further estimate that the total annual cost burden *across all* 1,448 AO hospice program surveys performed by the 3 AOs would be **\$1,782,546**.

• 23,168 hours per all surveys x \$76.94 per hour = \$1,782,546

b. <u>Time & Cost Burden Related to Surveys Performed by the State Survey Agency (SA)</u> Surveyors.

The SAs perform approximately 64,500 surveys per year of all types and programs. We estimate that *each* SA survey takes approximately 2 days (**16 hours**).

We also estimate that the total annual time burden *across all* SA surveys would be **1,032,000 hours.**

• 64,500 surveys x 16 hours per survey = 1,032,000 hours

Most SA surveyors are also Registered Nurses (RNs). As stated above, the adjusted mean hourly wage for an RN is **\$76.94**.

We estimate that the cost burden for *each* SA_survey would be **\$1,231**

• 16 hours per survey x \$76.94 per hour = \$1,231

We also estimate that the total annual cost burden *across all* SA surveys would be **\$79,402,080.**

• 1,032,000 hours per all surveys x \$76.94 per hour = \$79,402,080

c. Time & Cost Burden Related to Completion of Form CMS-2567 by the AOs and SAs

We estimate that it takes approximately 110 minutes (1.83 hours) for each CMS-2567 form to be completed. Between the AOs and the SA, we estimate that there would be a total of **65,948 forms** CMS-2567 completed annually.

• 1,448 AO surveys + 64,500 SA surveys = 65,948 CMS-2567 forms annually

We also estimate that the total annual time burden for the completion of *all* 65,948 forms CMS-2567 per year would be **120,905 hours**

- 110 minutes x 65,948 surveys = 7,254,280 minutes
- 7,254,280 minutes divided by 60 min. per hour = 120,905 hours

We believe that the CMS-2567 forms are completed by the lead surveyor, who may hold a management position at the State Survey Agency or AO. We further believe that this person's job would fall under the U.S. Bureau of Labor Statistic job category of "Medical and Health Services Manager."

According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical and Health Services Manager is \$57.12. This wage, adjusted for the employer's fringe benefits and overhead, would be \$114.24.

We estimate the cost burden for the completion *of each* CMS-2567 form to be \$209.44.

Step 1:

• 110 minutes divided by 60 min. per hour = 1 hours and 50 minutes

Step 2:

• 1-hour x \$114.24 = \$114.24 (for 1 hour)

<u>Step 3:</u>

- \$114.24 divided by 60 minutes = \$1.904 per minute
- \$1.904 per minute x 50 minutes = \$95.20 (for 50 min.)

Step 4:

• \$114.24 + \$95.20 = \$209.44

We further estimate that the cost burden for the completion for *all* 65,948 form CMS-2567 per year would be **\$13,812,187.**

• 120,905 hours x \$114.24 per hour = \$13,812,187

d. Time & Cost Burden Related to Record Keeping for the CMS-2567 Form

As stated above, we estimate that the AOs perform **1,448** hospice surveys annually. We also estimate that the SAs perform 64,500 surveys annually. This equates to **65,948 responses annually**.

• 1,448 AO surveys + 64,500 SA surveys = 65,948 total surveys

We estimate that it will take approximately **10 minutes** to perform the record keeping tasks related to *each* CMS-2567 form. These record keeping tasks include generating the form electronically, preparing a cover letter to send the form CMS-2567 to the facility, and emailing the completed form CMS-2567 to the facility.

We estimate that the total annual time burden related to the record keeping tasks *for all* CMS-2567 forms completed annually would be **10,991 hours**

- 10 minutes per form x 65,948 CMS-2567 forms per year = 659,480 minutes
- 659,480 minutes divided by 60 min. per hour = 10,991 hours per *all* forms CMS-2567 per b year

We believe that these record keeping tasks are performed by a person at the at the SA or AO with a job that falls under the U.S. Bureau of Labor Statistics' job category of Medical Secretary and Administrative Assistants. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Secretary is \$18.75. This wage, adjusted for the employer's fringe benefits and overhead, would be **\$37.50**.

We estimate that the total cost burden for the record keeping for *each* form CMS-2567 would be **\$6.25**.

- \$37.50 per hour divided by 60 min per hour = \$0.625 per minute
- \$0.625 per minute x 10 minutes = \$6.25

We further estimate that the total cost burden for the record keeping for *all* 67,396 forms CMS-2567 completed annually would be **\$412.163**.

• 10,991 hours x \$37.50 = \$412,163

e. Summary of Burden Related to the Form CMS-2567

We estimate the total *time burden* associated with the completion of *each* CMS-2567 form would be as follows:

•	Time for record keeping TOTAL TIME	0.166 hours 18.000 hours
	Time to complete the form CMS-2567	1.833 hours
•	Time to complete each SA or AO hospice program survey	16.00 hours

We estimate the total *time burden* associated with the completion of *all* CMS-2567 forms annually would be as follows:

	TOTAL TIME	1,187,064 hours
•	Time for all record keeping related to CMS-2567 forms annually	10,991 hours
•	Time to complete all CMS-2567 forms annually	120,905 hours
•	Time to complete all SA surveys annually	1,032,000 hours
•	Time to complete all AO hospice program surveys annually	23,168 hours

We estimate the total *cost burden* associated with the completion of *each* CMS-2567 form would be as follows:

	TOTAL Time Burden	\$1,446.69	
•	Cost for record keeping for each form CMS-2567	\$	6.25
•	Cost to complete each form CMS-2567	\$ 20	9.44
•	Cost to complete each SA or AO hospice program survey	\$1,2	31.00

We estimate the total *cost burden* associated with the completion of *all* CMS-2567 forms would be as follows:

	TOTAL Cost Burden	\$95,408,976
•	Cost for record keeping associated with the CMS-2567 annually	\$ 412,163
•	Cost to complete all CMS-2567 forms annually	\$13,812,187
•	Cost to complete all SA surveys annually	\$79,402,080
•	Cost to complete all AO hospice surveys annually	\$ 1,782,546

Note: While facilities are provided with the opportunity to reflect plans of corrections as an attachment (SC17-34), this does not decrease the time and cost burden associated with competition of the form CMS-2567 and Plan of Correction.

13. Annualized Cost of Burden

Other than the annual cost and time burden stated above, there are no additional annualized costs associated with this collection.

14. Cost to the Federal Government

There are no costs to the federal government.

15. Program Changes / Burden Changes

The table below shows the changes in burden that have occurred since the last PRA package submission.

	Tasks	Total Requested	Due to Adjustment in OPDIV/Office Estimate	Currently Approved
a.	Annual responses for CMS-2567	65,948 responses	0 responses	65,948 responses
b.	Time burden <i>across all</i> AOs hospice surveys performed annually	23,168 hours	0 hours	23,168 hours
c.	Time burden <i>across all</i> SA surveys completed annually	1,032,000 hours	-23,168 hours	1,055,168 hours
d.	Time burden for completion of all CMS-2567 form annually	120,905 hours	0 hours	120,905 hours
e.	Time burden for record keeping associated with all SAs & AOs annually	10,991 hours	0 hours	10,991 hours
f.	One-Time Time burden for AOs incorporation of the form CMS- 2567 into proprietary electronic documentation systems	0 hours	-144 hours	144 hours
g.	Cost burden across all AOs to perform hospice surveys	\$1,782,546	\$ 0	\$1,782,546
h.	Cost burden <i>across all</i> SAs to complete all surveys	\$79,402,080	- \$1,782,546	\$81,184,626
i.	Cost burden for completion of all forms CMS-2567 annually	\$13,812,187	<mark>+</mark> \$423,167	\$13,389,020
j.	Cost burden for record keeping across all forms CMS-2567 completed annually	\$412,163	<mark>+</mark> \$9,673	\$402,490
k.	One-Time cost burden for AOs incorporation of the form CMS- 2567 into proprietary electronic documentation systems	\$0	- \$13,940	\$13,940

Total Responses	65,948 responses	0 responses	65,948 responses
Total Hour Burden	1,187,064 hours	-23,312 hours	1,210,376 hours
Total Cost Burden	\$95,408,976	-\$1,363,646	\$96,772,622

The total number of responses have stayed the same. However, the total annual time burden has decreased by 23,312 hours, and the total annual cost burden has decreased by \$1,349,706.

In the previous PRA package a one-time cost and time burden added for the time required for the AOs to incorporate the CMS-2567 format into their proprietary electronic documentation systems. As this was a one-time burden, we have not included this time and cost burden in this PRA package.

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. OMB Expiration Date

CMS will display the expiration date on the CMS-2567 form.

18. <u>Certification Statement</u>

There are no exceptions to the certification statement.

19. Collections of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.