

**Supporting Statement for
Statement of Deficiencies and Plan of Correction (CMS-2567)**

A. Background

This is a request to revise form CMS-2567, titled “**Statement of Deficiencies And Plan of Correction**” which is approved with OMB control number 0938-0391. The current OMB approval expires on 05/31/2023.

The form CMS-2567 Statement of Deficiencies and Plan of Correction is the means by which State and CMS surveyors document findings of compliance or noncompliance (deficiencies) resulting from inspection of Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) laboratories. 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, 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.

In December, 2020, Congress passed the Consolidated Appropriations Act, 2021 (CAA, 2021). Section 407 of CAA, 2021, amended Part A of Title XVIII of the Social Security Act (the Act) at section 1822 establishing hospice program survey and enforcement requirements. This amendment, in part, now requires the Accrediting Organizations (AOs) that accredit hospice programs to include the form CMS-2567 to document the findings of their hospice program surveys beginning on October 1, 2021. As of June 2021, there are 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.

To enable AOs to use the form CMS-2567, we must revise it by adding fields for the AO name. Also, the instructions must be updated to include AOs as another group which utilizes the form CMS-2567. We have also included the burden calculations from CMS-1747-P (*Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements*), related to the one-time update needed to each of AO’s proprietary electronic systems in order to use the form CMS-2567 as directed by the CAA, 2021.

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B. Justification

1. Need and Legal Basis

Section 1864(a) of the Social Security 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 is the means by which the survey findings are documented. This section of the law further requires that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The CMS-2567 is the vehicle for this disclosure. The regulations at 42 CFR 488.18 require that State survey agencies document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS-2567. 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, now 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. Information Users

The information from the form CMS-2567 is used by the SAs, 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 and facility compliance.

3. Use of Information Technology

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, the information collection is necessary for the businesses to participate 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

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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 30 day Federal Notice was published on July 13, 2021 (86 FR 36751). There has been no outside consultation since the last approval.

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 this paperwork package.

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). In this regard, 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.

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
Computer and Information Analysts	15-1210	\$48.40	\$48.40	\$96.80
Medical or Health Services Manager	11-9111	\$55.37	\$55.37	\$110.74
Medical Secretaries and Administrative Assistants	43-6013	\$18.31	\$18.31	\$36.62
Registered Nurse (RN)	29-1141	\$38.47	\$38.47	\$76.94

a. Time & Cost Burden Related to Hospice Surveys Performed by the AOs

The form CMS-2567 is used by SAs to document their survey findings across all programs. The SAs performed approximately 64,500 surveys in 2019. Beginning on October 1, 2021, AOs that accredit hospice programs will also be required to use the

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form CMS-2567 to document their hospice program survey findings. At this time, only AOs with hospice programs are required to use the form CMS-2567.

The chart below shows the estimated number of hospice program surveys performed by three applicable AOs in 2019.

Accrediting Organization	Number of Surveys Hospice Performed in 2019
CHAP	585 surveys
ACHC	291 surveys
TJC	572 surveys
Total	1,448 surveys

As the above table shows, there are three AOs that perform hospice program surveys. We estimate that these three AOs will perform approximately 1,448 hospice program surveys per year.

We estimate that **each** hospice program survey takes approximately two days (**16 hours**).

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 = 23,168 hours

Surveyors are typically Registered Nurses (RN). 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 for **each AO hospice program survey** would be **\$1,231**

- 16 hours x \$76.94 = \$1,231

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

- 23,168 hours surveys x \$76.94 = \$1,782,546

b. Time & Cost Burden Related to All Surveys Performed by the SAs

The SAs perform approximately 65,948 surveys per year of all types and programs. We estimate that **each** SA survey takes approximately 2 days (**16 hours**).

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We also estimate that the total annual time burden **across all SA surveys** would be **1,055,168 hours.**

- 65,948 surveys x 16 hours = 1,055,168 hours

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

- 16 hours x \$76.94 = \$1,231

We also estimate that the total annual cost burden **across all SA surveys** would be **\$81,184,626.**

- 1,055,168 hours x \$76.94 = \$81,184,626

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 form CMS-2567 to be completed. Between the AOs and the SA, we estimate that there would be 65,948 ((64,500 + 1,448) forms CMS-2567 completed 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 form CMS-2567 is completed by a person who holds a management position at the facility. 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 \$55.37. This wage, adjusted for the employer's fringe benefits and overhead, would be **\$110.74.**

We estimate the cost burden for the completion ***of each*** CMS-2567 form to be **\$203.04.**

Step 1:

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

Step 2:

- 1 hour x \$110.74 = \$110.74 (for 1 hour)

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Step 3:

- \$110.74 divided by 60 minutes = \$1.846 per minute
- \$1.846 per minute x 50 minutes = \$92.30 (for 50 min.)

Step 4:

- \$110.74 + \$92.30 = \$203.04

We further estimate that the cost burden for the completion for ***all*** 65,948 form CMS-2567 per year would be **\$13,389,020.**

- 120,905 hours x \$110.74 per hour = \$13,389,020

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

We estimate that it will take approximately **10 minutes** to perform the record keeping tasks related to **each** form CMS-2567. 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 form CMS-2567 to the facility.

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

- 10 minutes per each form CMS-2567 x 65,948 form CMS-2567s per year = 659,480 minutes
- 659,480 minutes divided by 60 min. per hour = 10,991 hours per ***all*** forms CMS-2567/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 \$18.31. This wage, adjusted for the employer's fringe benefits and overhead, would be **\$36.62.**

We estimate that the total cost burden for the record keeping for **each** form CMS-2567 would be **\$6.10.**

- \$36.62 per hour divided by 60 min per hour = \$0.610 per minute
- \$0.610 per minute x 10 minutes = \$6.10

We further estimate that the total cost burden for the record keeping for ***all*** 65,948 forms CMS-2567 completed annually would be **\$402,490.**

- 10,991 hours x \$36.62 = \$402,490

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e. Additional One-time Burden Related to Hospice Program AOs Incorporation of the Form CMS-2567 into Proprietary Electronic Documentation Systems

AOs would need to make a one-time update to their existing proprietary electronic documentation systems to include the Form CMS-2567. We estimate that this task would be performed by a computer and information analyst.

According to the U.S Bureau of Labor statistics, the mean hourly wages for a computer and information analyst is \$48.40. This wage adjusted for the employer's fringe benefits and overhead would be **\$96.80**.

We estimate that it would take at least two persons working on a full-time basis for three days for the AO staff to revise their system to add the required form CMS-2567.

Therefore, we estimate that the total time required for the two team members to perform this task would be **48 hours**. As of March 2021, there are three AOs that accredit Medicare certified hospice programs. The total time burden across these three AOs is **144 hours** (48 hours x 3 AOs). We estimate that the cost burden related to the work performed by two computer and information analysts would be **\$4,646.50** (24 hours X \$193.60 (\$96.80 X 2)).

The **total cost** across the three AOs is **\$13,939** (3 AOs X \$4,646.50).

f. 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 to perform SA survey	16 hours
• Time to perform AO hospice program survey	16 hours
• Time to complete the form CMS-2567	1.833 hours
• Time for record keeping	0.166 hours
• <u>One-time for electronic incorporation</u>	<u>48 hours</u>
• TOTAL TIME	82 hours

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

• Time to complete all SA surveys	1,055,168 hours
• Time to complete all AO hospice program surveys	23,168 hours
• Time to complete all forms CMS-2567	120,905 hours
• Time for record keeping	10,991 hours
• <u>One-time for electronic incorporation</u>	<u>144 hours</u>
• TOTAL TIME	1,210,376 hours

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

• Cost to complete each SA or AO hospice program survey	\$1,231.00
• Cost to complete each form CMS-2567	\$ 203.04
• Cost for record keeping for each form CMS-2567	\$ 6.10
• <u>One-time cost for electronic incorporation</u>	<u>\$ 4,646.50</u>
• TOTAL Time Burden	\$6,086.64

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

• Cost to complete all SA surveys	\$78,588,913
• Cost to complete all AO hospice surveys	\$ 1,725,553
• Cost to complete all forms CMS-2567	\$13,389,020
• Cost for record keeping	\$ 402,490
• <u>One-time cost for electronic incorporation</u>	<u>\$ 13,939.50</u>
• TOTAL Cost Burden	\$94,119,916

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 completion 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	+1,448	64,500 responses
b. Time burden to complete each survey	16 hours	16 hours	0 hours
c. Time burden for record keeping per each CMS-2567 form	0.166 hours	0.166 hours	0.166 hours

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d. Time burden for completion of <u>each</u> CMS-2567 form	1.833 hours	0 hours	1.83 hours
e. Time burden across all <u>SAs</u> to complete <u>all surveys</u>	1,055,168 hours	+1,055,168 hours	0 hours
f. Time burden across all <u>AOs</u> to perform hospice surveys	23,168 hours	+ 23,168 hours	0 hours
g. Time burden for completion of <u>ALL</u> CMS-2567 form	120,905 hours	+2,655 hours	118,250 hours
h. Time burden for record keeping across all <u>SAs & AOs</u>	10,991 hours	+241 hours	10,750 hours
i. One-time “time” burden for incorporation of the form CMS-2567 into each AO’s electronic documentation systems	48 hours	+48 hours	0 hours
j. Cost burden for completion of <u>each survey</u>	\$1231.00	+\$1,231.00	\$0
k. Cost burden for completion of <u>EACH</u> CMS-2567 form	\$203.04	+\$19.64	\$183.40
l. Cost burden for record keeping – per <u>EACH</u> form CMS-2567	\$6.10	+\$0.16	\$5.94
m. One-time “cost” burden for incorporation of the form CMS-2567 into each AO’s electronic documentation systems	\$4,646.50	+\$4,646.50	\$0
n. Cost burden across <u>ALL SAs</u> to complete <u>all surveys</u>	\$81,184,626	+\$81,184,626	\$0
o. Cost burden across <u>ALL AOs</u> to perform hospice surveys	\$1,782,546	+\$1,782,546	\$0
p. Cost burden for completion of <u>ALL forms</u> CMS-2567	\$13,389,020	+\$1,559,720	\$11,829,300
q. Cost burden for record keeping across <u>ALL forms</u> CMS-2567	\$402,490	+\$19,360	\$383,130
r. Cost burden for one-time incorporation of the form CMS-2567 into <u>ALL three AOs</u> electronic systems	\$13,939	+13,939	\$0
Total Responses	65,948 responses	+1,448	64,500 responses
Total Hour Burden	1,210,376 hours	+ 1,070,626 hours	139,750 hours
Total Cost Burden	\$94,119,916	+\$81,550,156	\$12,569,760

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As, the above table shows, the total number of responses has increased by 1,448. The total annual time burden has increased by 1,070,626 hours and the total annual cost burden has increased by \$81,550,156. These increases are due to the reasons discussed below.

First, in the previous PRA package for form CMS-2567, grossly underestimated the time and cost burden because it did not consider the burdens required to perform surveys. According to the definition of burden at 5 CFR 1320.2(b)(1), this burden should have been included in the burden calculations.

Second, due to the statutory changes brought on by the CAA, 2021 - AOs with hospice programs must begin use of the form CMS-2567 not later than October 1, 2021. Therefore, we have included additional users and a one-time systems update time/cost burden. It is important to note that the time and cost burden associated with hospice program AOs incorporation of the form CMS-2567 into their electronic documentation systems is a one-time burden and not annually.

Finally, we have updated the wage rates used in the burden calculations to the most current wage rates produced by the U.S. Bureau of Labor Statistics. For example, the hourly wage for a Medical or Health Services Manager went from \$100.22 to \$110.74. This is an increase of \$10.52 per hour and contributed to the increased cost burden.

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 form.

18. Certification Statement

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.