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

A. Background

The 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 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 2567. This form facilitates analysis of deficiencies and plans of correction, and disclosure of information concerning deficiencies.

B. <u>Justification</u>

1. Need and Legal Basis

Section 1864(a) of the Social Security Act requires that the Secretary use State survey agencies 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.

2. Information Users

The information from the CMS-2567 is used by the States and CMS regional offices 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, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance.

3. <u>Improved 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.

4. <u>Duplication and Similar Information</u>

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

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 published on August 19, 2019 (84 FR 42921). There were no public comments.

The 30-day Federal Register notice published on December 6, 2019 (84 FR 66913). 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 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

Reporting burden is based on approximately 64,500 surveys annually that will identify deficiencies that require a health care facility complete a Plan of Correction on the CMS-2567 form.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm).

We estimate that it will take approximately 110 minutes for each form to be completed. For the approximately 64,500 surveys annually, the national time burden to complete the form will be 118,250 hours (1.83 hours X 64,500 surveys). We estimate that it will take approximately 10 minutes for record keeping for each form. For the 64,500 surveys annually, the national record keeping time burden will be 10,750 hours (.16 hours X 64,500 surveys).

National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$/hr)	Adjusted hourly wage (\$/hr)
Healthcare Support Occupations	31-9090	16.63	16.63	33.26
Management Occupations	11- 0000	50.11	50.11	100.22
Medical Secretaries	43-6013	17.83	17.83	35.66

The cost for completion of this form has been calculated at the average national salary of \$100.22 per hour (Hourly wage + fringe benefits). Based on a timeframe of 110 minutes (1.83 hours) to complete the form, the cost per facility will be \$183.40 (100.22 x 1.83). For the approximately 64,500 surveys annually, the national cost to complete the form will be \$11,829,300 (183.40 cost per facility x 64,500 surveys) .

We estimate that it will take approximately 10 minutes for record keeping for each form and this would likely be done by a Medical Secretary. The cost for this has been calculated at the average national salary of \$36.55 per hour (Hourly wage + fringe benefits). Based on a timeframe of 10 minutes (0.16 hours) for this task, the cost per facility will be \$5.85 per form. For the approximately 64,500 surveys annually, the national cost for this task will be \$377,196.

We estimate that it will take approximately 10 minutes for third party disclosure for each form. The cost for this has been calculated at the average national salary of a Healthcare Support Occupation at \$33.26 per hour. Based on a timeframe of 10 minutes for this task, the cost per facility will be \$5.32 per form (33.26 x .16 hours). For the approximately 64,500 surveys annually, the national cost for this task will be \$343,243.

The total burden cost for the CMS-2567 is estimated to be \$12,549,739.20.

Note: While facilities were 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 2567 and Plan of Correction.

13. Annualized Cost of Burden

There are no annualized costs associated with this collection.

14. Cost to Federal Government

There is no cost to the government.

15. Program Changes / Burden Changes

The program has not increased in survey frequency since 2015 and remains at 64,500 CMS-2567 forms. The increase is based on inflation of the average national salary since 2015. The annual burden hours increased slightly due to correction of an arithmetic error.

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. <u>Certification Statement</u>

There are no exceptions to the certification statement.

C. <u>Collections of Information Employing Statistical Methods</u>

There are no statistical methods employed in this information collection.