

Supporting Statement for
Statement of Deficiencies and Plan of Correction (CMS-2567)
and Supporting Regulations contained in
42 CFR 488.18, 488.26, and 488.28

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 each deficiency discovered as part of an inspection. It also provides a uniform format for providers, suppliers and CLIA laboratories to describe plans to correct each deficiency. This form facilitates analysis of deficiencies and disclosure of information concerning deficiencies.

B. Justification

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, Medicaid, 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. 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. Improved Information Technology

This form is frequently produced in an automated fashion by the CMS, ASPEN survey

software. This reduces printing costs and automates the capture of survey data.

4. Duplication and Similar Information

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 business' 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 most facility types. 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

A 60-day Federal Register notice was published on May 1, 2009, attached.

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. Any identifiable data subject to the Privacy Act is deleted prior to disclosure.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this paperwork package.

12. Estimation of Burden

Approximately 60,000 surveys annually will require that a health care facility complete a Plan of Correction on the CMS-2567 form. The CMS-2567 Plan of Correction form will take approximately two hours to complete. 2 hours/facility x 60,000 = 120,000 hrs.

The cost to each facility for completion of the CMS-2567 has been calculated at the standard rate of \$41.66 per hour.

120,000 hours x \$41.66 = \$4,999,200

13. Annualized Cost of Burden

There are no annualized costs associated with this collection.

14. Cost to Federal Government

The estimated annual cost is less than \$1,600.

15. Program Changes / Burden Changes

This is a reinstatement without change of a previously approved collection.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

CMS does not want to display the OMB expiration date, as it would involve the destruction of too many forms every three years; these forms are used on a continuing basis.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.