

**Supporting Statement of the Comprehensive Outpatient Rehabilitation Facility (CORF)
Eligibility and Survey Forms and Information Collection Requirements in
42 CFR 485.54 through 485.66
CMS-359 and -360, OMB 0938-0267**

Background

The information collections that are included with this request are:

- CMS-359-CORF Eligibility Form

This form is utilized as the application for facilities wishing to participate in the Medicare/Medicaid program as Comprehensive Outpatient Rehabilitation Facilities (CORFs). This form initiates the process of obtaining a decision as to whether the conditions of participation are met. It also promotes data reduction (key punching) or introduction to and retrieval from the Medicare/Medicaid Automated Certification System, ASPEN, by the CMS Regional Offices (ROs). Should any question arise regarding the structure of the organization, this information is readily available without going through the process of completing the form again.

- CMS-360-CORF Survey Report Form

The form CMS-360 is an instrument used by the State survey agency to record data collected in order to determine provider compliance with individual conditions of participation and to report it to the Federal government. This form is not mandatory. However, the SAs like this paper instrument because they don't have to carry a computer during the survey. The form includes basic information on compliance (i.e., met, not met, and explanatory statements) and does not require any descriptive information regarding the survey activity itself. CMS has the responsibility and authority for certification decisions which are based on provider compliance with the conditions of participation. The information needed to make these decisions is available to CMS only through use of information abstracted from the survey checklists. The form is primarily a worksheet designed to facilitate keypunching into the ASPEN by the State Agency after the survey is completed.

- CMS-R-55

The information collection requirements contained in 42 CFR Sections 485.54 through 485.66 that are subject to OMB review are currently covered under OMB 0938-1091. The Office of Clinical Standards and Quality determined it was not necessary to determine the burden with most patient related activities (healthcare plans, patient records and clinical records) because these activities would take place in the absence of the Medicare and Medicaid programs. The remaining requirements are covered as noted above.

CMS-R-55 has become obsolete and is no longer a part of this PRA package. Surveyors do not collect recordkeeping information. The surveyors use the Form CMS-360 to record their findings regarding whether or the conditions have been met or not—not how long it would take an organization to complete any specific requirement.

A. Justification

1. Need and Legal Basis

This activity is authorized by Section 933 of the Omnibus Budget Reconciliation Act of 1980 which allows CORFs to be recognized as Medicare providers of services, and amends sections of the Social Security Act, including Section 1861(cc)(1) and 1863. These sections recognize CORFs as Medicare providers and allow the Secretary to establish conditions of participation and to use State resources under contract in determining compliance with these requirements.

The conditions of participation are based on criteria described in the law and are standards designed to ensure that each CORF has a properly trained staff to provide the appropriate type and level of care for that environment of patients.

CMS needs the conditions of participation to certify health care facilities wishing to participate in the Medicare and/or Medicaid programs.

To determine compliance with conditions of participation, the Secretary has authorized States, through contracts, to conduct surveys of health care providers. For Medicare purposes, certification is based on the State survey agency's recording of a provider or supplier's compliance or noncompliance with the health and safety requirements published in regulations. The certification form (CMS-359) is the form used in the initial stages of the process to allow a provider to participate in the Medicare program. It establishes necessary identification data for the provider for interaction with ASPEN and screens for provider capacity to meet specifications which must be met before a provider can be considered to participate in the Medicare program as a CORF. In order for the State survey agency to report to CMS its generic findings on provider compliance with the individual standards on which CMS determines certification, the agency completes the CORF Survey Report Form (CMS-360). This form is a listing of the regulatory conditions required for participation in the Medicare program.

The surveyor reports on each condition by checking a box alongside the condition or standard indicating whether or not the State found that the provider met the requirement. Space is also provided for appropriate explanatory statements regarding negative findings.

2. Information Users

CMS and the health care industry believe that having access to facility records is a standard medical practice and is necessary to ensure the well-being and safety of patients and to promote professional treatment accountability.

The request for certification and the survey form are used by CMS in making certification decisions. When a provider initially expresses an interest in participating in the Medicare program as a CORF, contact is made with the State agency that forwards the Request for Certification (CMS-359) to the provider. The information on the completed form serves as a screen for the State agency to determine whether the provider has the basic capabilities to participate in the Medicare program and whether a provider survey is appropriate. The basic identifying information from this form and individual compliance codes from the survey form are coded into ASPEN and serve as the information base for the creation of a record for future Federal certification for monitoring activity.

3. Improved Information Technology

The requirements in the regulation in no way prescribe how facilities prepare or maintain these records. Facilities are free to take advantage of any technological advancement that they find appropriate for their needs.

The survey form serves primarily as a coding worksheet for inputting minimal compliance information into the ASPEN. The standardized format and simple check box method provide for consistent reporting by State survey agencies and easy automation of basic findings. Recording this information would be no easier for State surveyors using direct access equipment. State reporting in this format avoids the need for multiple systems and adaptation of numerous data files to CMS specifications.

4. Duplication and Similar Information

The requirements are unique and are specified in a way so they do not duplicate existing facility practice. If a facility already maintains these general records, regardless of format, they are in compliance with this requirement.

The survey and certification forms do not duplicate any information collection. The form addresses specifically the unique regulatory conditions of participation directed to CORFs for participating in the Medicare program. State survey agencies conduct these reviews with Federal funds under contract with CMS. This form is a basic deliverable under the contracts and is the only one of its kind collected by CMS for CORFs.

5. Small Business

The requirements do not have a significant impact on small businesses.

6. Less frequent Collection

State submission of provider survey forms depends on the frequency of provider surveys. These submissions, in turn, depend on the frequency of surveys specified in regulations and the availability of survey funds. It is a basic contract requirement that State surveyors transmit their compliance findings for each survey they conduct.

7. Special Circumstances for Information Collection

These requirements comply with all general information collection guidelines in 5 CFR 1320.6.

8. Federal Register and Outside Consultants

The 60-day Federal Register notice published on June 27, 2012 (77 FR 38297). No comments were received.

CMS also published CORF conditions of participation (CoP) in 1982. We solicited public comments and have used the Paperwork Reduction Act to continue to provide the public an opportunity to review these CoPs.

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

We do not pledge confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Estimate of Burden (Reporting)

- Certification Form - CMS-359

Based on past usage of this form and the general nature of the questions, we estimate that it takes approximately 15 minutes to complete this form.

- Survey Form - CMS-360

The survey report form is completed by the State agency surveyor based on the results of

his investigation of provider compliance with each individual condition of participation. The surveyor compiles all information pertaining to the provider's compliance with health and safety requirements and summarizes this on the survey form. The surveyor ascertains and documents, as objectively as possible, whether the provider meets each requirement. In relation to each standard on the form, the surveyor checks "met" or "not met." The mere checking of these blocks does not, in all cases, provide sufficient information to support a conclusion. In these instances, brief statements will be needed to support a finding of compliance or noncompliance with the conditions.

Since this form is completed by checking boxes either met or not met with a few explanatory statements, we estimate that for experienced State agency surveyors to prepare and complete the form as necessary, it would take approximately 3 hours per survey report form.

The burden for this request is based on 42 currently certified CORFs surveyed on an annual basis.

- Total estimated yearly burden:

Reporting	
CMS-359	10.5 hours (15 min x 42)
CMS-360	<u>126</u> hours (3 hrs x 42)
TOTAL	136.5 hours

We estimate the cost to be \$ 2,047.50 (136.5 hrs x \$15 per hr)

13. Capital Costs

There is no capital costs associated with this collection.

14. Federal Cost Estimates

All costs associated with this request are incurred by the Federal government. The requirements are comparable to independent industry standards, and we believe there's no supplemental cost to the public. The cost to the Federal government is based on the time it takes a surveyor to complete the forms. There are currently 42 CORFs surveyed annually. We estimated 3.25 hours of completion time equaling \$2,047.5 for contracting costs to complete forms.

Printing and Distribution	
CMS-359	2,987 copies
CMS-360	<u>3,180 copies</u>
Total	6,167

Contracting Cost-	\$1,200
Printing	<u>\$2,000</u>
Total	\$3,700

15. Changes in Burden/Program Changes

Burden decrease is due to the number of respondents who have opted to terminate their participation in the Medicare program (e.g., 476 in 2009 v. 295 in 2012). Also, the information collection requirements contained in 42 CFR 485.54 through 485.66 that are subject to OMB review are currently covered under OMB 0938-1091. The Office of Clinical Standards and Quality determined it was not necessary to determine the burden with most patient related activities (healthcare plans, patient records and clinical records) because these activities would take place in the absence of the Medicare and Medicaid programs.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

CMS does not object to displaying the OMB expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods.

There are no statistical methods associated with this information collection.