

**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**

A. 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 (MMACS) 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. The form is primarily a coding worksheet designed to facilitate keypunching and retrieval into the MMACS at the CMS ROs. 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.

CMS-R-55

The information collection requirements contained in 42 CFR Sections 485.54 through 485.66 that are subject to OMB review.

B. 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 MMACS 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.

Section 485.56 Condition of Participation: Governing body and administration

(d) Standard: Institutional budget plan. The facility must have an institutional budget plan that...

(2) Provides for

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of \$100,000 are

anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and
(iii) Annual review and updating by the governing body.

(e) Standard: Patient care policies. The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

- (1) A description of the services the facility furnishes through employees and those furnished under arrangements.
- (2) Rules for and personnel responsibilities in handling medical emergencies.
- (3) Rules for the storage, handling, and administration of drugs and biologicals.
- (4) Criteria for patient admission, continuing care, and discharge.
- (5) Procedures for preparing and maintaining clinical records on all patients.
- (6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.
- (7) A procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged.
- (8) A requirement that patients accepted by the facility must be under the care of a physician.
- (9) A requirement that there be a plan treatment established by a physician for each plan of treatment established by a physician for each patient.
- (10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

Section 485.58 Condition of participation: Comprehensive rehabilitation program

(b) Standard: Plan treatment. For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

- (1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.
- (2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.
- (3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.
- (4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before continued or discontinued.
- (5) It must be revised if the comprehensive reassessment of the patient's

treatment is

status or the results of the patient case review conference indicate the need for revision.

Section 485.60 Condition of participation: Clinical records

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) Standard: Content. Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to ensure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain:

- (1) The initial assessment and subsequent reassessments of the patient's needs;
- (2) Current plan of treatment;
- (3) Identification data and consent or authorization forms;
- (4) Pertinent medical history, past and present;
- (5) A report of pertinent physical examinations if any;
- (6) Progress notes or other documentation that reflect patient reaction to treatment, and tests or injury, or the need to change the established plan of treatment;
- (7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

Section 485.64 Condition of participation: Disaster procedures

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All these personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) Standard: Disaster plan. The facility's written disaster plan must be developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. The plan must include-

- (1) Procedures for prompt transfer of casualties and records;
- (2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

- (3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and
- (4) Specification of evacuation routes and procedures for leaving the facility.

Section 485.66 Condition of Participation: Utilization review plan

The facility must have in effect a written utilization review plan that is implemented at least each quarter to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(b) Standard: Utilization review plan. The utilization review plan must contain written procedures for evaluating-

- (1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;
- (2) The applicability of the plan of treatment to established goals; and
- (3) The adequacy of clinical records with regard to-
 - (i) Assessing the quality of services provided; and
 - (ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of

services.

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 MMACS 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 MMACS. 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

A 60-day Federal Register notice was published on March 13, 2009, attached.

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

Recordkeeping

Calculations will be significantly different from the last PRA package submitted due to the large decrease in the number of CORF providers (from 630 to 429). Also, CMS appears to average no more than two new CORFs per year. Therefore, any “initial development” would apply to two facilities only, not to the number of facilities that are surveyed each year.

485.56(d)(2)(ii)

Any facility planning a capital expenditure of over \$100,000 would have available the information required by this regulation, such as land survey, building design and budget. It would take one administrator about 3 hours to compile the information. Only facilities with a capital expenditure of \$100,000 or more, however, would have to compile this information. Development of a capital expenditure item would take about 3 hours. These ICRs apply to the two new facilities per year.

485.56(d)(2)(ii)

Initial development	3 hours
x new facilities	<u>2</u>
	6 hours

485.56(d)(2)(iii)

The administrator or other appropriate person would need to contact the governing body to see if any changes in the capital expenditure plan have been made during the year and to do the necessary paperwork to revise the existing plan. This would take about 30 minutes. The revisions would need to be presented to and approved by a committee composed of representatives of the governing body, the administrative staff and the medical staff. This would take about 30 minutes. Total annual review and update times is estimated at 1 hour. This would apply to all facilities not just the facilities that are surveyed each year (the last PRA package looked only at annual surveyed facilities).

485.56(d)(2)(iii)

Annual update & review	1 hour
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x all facilities

429
429 hours

485.56(e)

These policies govern the services the facility provides and are a specific statutory requirement. While many of these procedures are routinely followed as professionally accepted standard operating procedures, the facility may need to establish some of them in writing and consolidate them into one location. These should be developed by the group of professionals (or reviewed by them) and would be periodically amended as needed. Some facilities have existing policies that may need to be rewritten and/or reorganized.

Time: In our best estimate it would take the facility approximately 5 hours to comply with these regulations including developing information that is not now present. These information collection requirements (ICR) are a one-time burden which have already been captured. In addition, we estimate it would take a facility one hour to organize existing policies to be consistent with published regulations. Therefore, the burden associated with these ICR's is the time required for some facilities to write and others to rewrite these policies. The last PRA package based its "Revision" figures on the number of CORFs that are surveyed each year as opposed to all CORFs who review and possibly revise their policies.

485.56(e)

Initial development	5 hours
x 2 new facilities	x 2
	10 hours
Revisions to policies	1 hour
x 427 facilities	x <u>427</u>
	427 hours
TOTAL	437 hours

485.58(b)

The plan of treatment is statutorily mandated and is established by the physician before the services can be provided. It is especially important in this type of service where several health professionals are involved in patient care. A plan of treatment is routinely established for patients, as part of good medical practice, and while certain information must be included in this plan of treatment for the facility to be certified, for the most part, it conforms to practices already established and performed in the field.

Time: Since we do not feel that this requirement poses much of a burden as it is already

followed to a great extent, we estimate that the additional burden to a facility is approximately 312 hours.

The 1 hour per day was derived through the following calculation:
Facility/operations 52 weeks/yr. x 6 days/week x 1 hr./day=312 hours average
30 patients/day x 2 additional min./day=60 min. or 1 hr./day.

485.58(b)

All facilities	312 hours
	x <u>427</u>
	133,224 hours

485.60

Clinical records are maintained in accordance with accepted professional standards and practice. The information we require with respect to the clinical record is consistent with good medical practice and is already being followed by the majority of the facilities.

Time: Many variables affect the maintenance of clinical records (i.e., the type and frequency of treatment the patient receives, number of patients, etc.) and it is difficult to estimate the time needed to comply with this requirement. However, since many facilities are already collecting this information to some extent, we estimate that it will take a facility approximately 156* additional hours to comply with this requirement.

*This figure was arrived at through the following calculation: 52 wks/yr x 6 days x .5hr/day= 156 hours ave. (30 patients/day x 1 additional min. = 30 min. or .5 hours to include this information on the clinical record.)

485.60

Maintenance	156 hours
All facilities	x <u>427</u>
	66,612hours

485.64

The facility needs to have a written plan defining the handling of patients, personnel, records and the public during disasters. To be certified the facility is required to have a plan containing the basic procedures to be performed and identifying responsible individuals. Many facilities develop plans as a matter of good business and/or medical practice. In addition, many State and local governments require such plans.

Time: In our best estimate, it would take the facility approximately 3 hours to comply with this requirement by including information not normally required. These ICRs apply to the two new facilities per year.

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 two new CORFs and 54 currently certified CORFs surveyed on an annual basis.

Total estimated yearly burden:

Recordkeeping	
485.56(d)(2)(ii)	6 hours
485.56(d)(2)(iii)	429 hours
485.56(e)	437 hours
485.58(b)	133,224 hours
485.60	66,612 hours
485.64	6 hours
485.66	6 hours

SUB-TOTAL 200,720 hours

Reporting	
CMS-359	13.5 hours (15 min x 54)
CMS-360	<u>162</u> hours (3 hrs x 54)

SUB-TOTAL 175.5 hours

TOTAL 200,895.5 hours

We estimate the cost to be \$ 3,013,432.5 (200,895.5 hrs x \$15 per hr)

13. Annualized Cost of Burden

There are no annualized 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 54 CORFs surveyed annually. We estimated 3.25 hours of completion time equaling \$2,925 for contracting

costs to complete forms.

Printing and Distribution

CMS-359	\$465	1,855 copies
CMS-360	<u>\$320</u>	1,725 copies
Total	\$785	

Contracting Cost-	\$2,925	
Printing	<u>785</u>	
	\$3,700	

15. Changes in Burden/Program Changes

There are no program changes. Burden decrease is due to a decrease in the number of respondents and in the method of calculations as previously noted in number 12 of this document.

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.

C. Collections of Information Employing Statistical Methods.

There are no statistical methods associated with this information collection.