Supporting Statement for the Paperwork Reduction Act Submission, Medicare and Medicaid Programs: Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and supporting regulations in 42 CFR Part 485 (CMS-10282, OMB 0938-1091)

A. BACKGROUND

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the conditions of participation (CoPs) that comprehensive outpatient rehabilitation facilities (CORFS) must meet to participate in the Medicare Program. This document represents the inclusion of all current CORF CoPs currently effective and applicable eligibility and survey report forms. This package reflects the paperwork burden for a total of 274 facilities as of May 1, 2013.

The CoPs 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 CoPs to certify health care facilities wishing to participate in the Medicare and/or Medicaid programs.

To determine compliance with the CoPs, 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 currently approved information collection located at OMB Control Number 0938-0267 is being combined with this collection because the information will be more easily tracked as one package in the future. OMB 0938-0267 covers the forms CMS-359 and -360. 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 provider met the requirement.

B. JUSTIFICATION

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR 485. These regulatory requirements implement section 1861(cc) of the Social Security Act (the Act). CORFs receiving payment under Medicaid must meet the Medicare CoPs. Section 1861(cc) of the Act authorizes promulgation of regulations in the interest of the health and safety of individuals who are furnished services by a CORF. The secretary may impose additional requirements if they are necessary for the health and safety of individuals who are furnished services by CORFs.

All 274 CORFs must meet the CoPs in order to receive program payment for services provided to Medicare or Medicaid patients. Currently, 274 are in compliance. We believe many of the requirements applied to these CORFs will impose no burden since a prudent rehabilitation facility would self-impose them in the normal course of doing business. Regardless, we have attempted to estimate the associated burden for a CORF to engage in these standard industry practices.

2. Information Users

The CoPs and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a CORF qualifies to be awarded a Medicare provider agreement. CMS believes the health care industry practice demonstrates that the patient clinical records and general content of records, which is referenced in these regulations are necessary to ensure the well-being and safety of patients and professional treatment accountability and are normal part of industry practice.

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

CORFs may use various information technologies to store and manage patient clinical records as long as they are consistent with existing confidentiality in record-keeping regulations at 485.60. This regulation in no way prescribes how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

The survey report form (CMS-360) 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 of Similar Information

These requirements are specified in a way that does not require a CORF to duplicate its efforts. If a facility already maintains these general records, regardless of format they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one facility to another acceptable.

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

These requirements do affect small businesses. However, the general nature of the requirements allows the flexibility for facilities to meet the requirements in a way consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information, or require its collection, on a routine basis. Nor does the rule prescribe the manner, timing, or frequency of the records or information required to be available. CORF records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs.

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

These requirements comply with all general information collection guidelines in 5 CFR 13320.6. Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published on July 26, 2013.

9. Payment/Gift to Respondent

There are no payments or gifts associated with this collection.

10. Confidentiality

Data collected will be kept confidential to the extent provided by law. Documents related to the collection, use, or disclosure of individually identifiable or protected health information pursuant to implementing these conditions of participation are subject to the protections and standards of the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates

Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS) National Employment and Wage Data from the Occupational Employment Statistics Survey, by Occupation, May 2012, found at www.bls.gov. The salary estimates contained in this package are based on the following healthcare personnel:

"Administrator" refers to the BLS 2012 national average salary for health services manager ($47.34 per hour, $98,460 per year) (i.e., $98,460 divided by 52 weeks per year divided by 40 hours per week).

"Clerical person" refers to the BLS 2012 national average salary for medical secretaries ($14.63 per hour, $30,430 per year).

"Physical therapist" refers to the BLS 2012 national average salary for a physical therapist ($38.99 per hour, annual salary $81,110).

"Social worker" refers to the BLS 2012 national average salary for a social worker, all others ($27.29 per hour, $56,760 per year) used in this report to provide cost estimates for social or psychological services professionals.

"Accountant" refers to the BLS 2012 national average salary for an accountant and auditors ($36.44 per hour, $75,790 per year).

485.64 (a)(1), (2), (3), (4), (b)(1)and (2) - Standard: 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 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 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 firefighting equipment; and
(4) Specification of evacuation routes and procedures for leaving the facility.

We believe the CORF administrator and physical therapist will develop and maintain the disaster plan in collaboration with local fire, safety, and other appropriate experts. We believe it will take an administrator and one physical therapist four hours each per CORF to develop a disaster plan and two hours each per CORF to maintain the plan in collaboration with local qualified fire, safety, and other appropriate experts in the community. It will take one clerical person two hours to put the plan into final written form. Thus, we estimate it will take the team of administrator, physical therapist, and clerical person a total of 10 hours to develop the plan and 6 hours to maintain the plan.

Hours/Est. Salary/ # of CORFs (274)	**Annual Burden Hours**	**Annual Cost Estimate**
a. 1 Administrator @ $47.34/hr. x 4 hr. x 1 a yr. x 274 CORFs to develop the disaster plan	1,096	$51,884
1 Physical therapist @ $38.99/hr. x 4 hr. x 1 a yr. x 274 CORFs to develop the disaster plan	1,096	$42,733
1 Clerical person @ $14.63/hr. x 2 hr. x 1 a yr. x 274 CORFs to develop and maintain the plan	548	$8,017
a. 1 Administrator @ $47.34/hr. x 2 hr. x 1 a yr. x 274 CORFs to maintain the disaster plan	548	$25,942
1 Physical therapist @ $38.99/hr. x 2 hr. x 1 a yr. x 274 CORFs to maintain the disaster plan	548	$21,366
1 Clerical person @ $14.63/hr. x 2 hr. x 1 a yr. x 274 CORFs to maintain the plan	548	$8,017
Total	**4,384**	**$157,959**

485.66 (b)(1), (2), and (3) (i), (ii) – Standard: Utilization review plan
A CORF that participates in the Medicare and Medicaid programs 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.

We believe one administrator, one physical therapist, and one social or psychological services provider will comprise the utilization review committee. It will take this committee two hours to develop the utilization review plan and two hours to review and implement the utilization review plan anually. One clerical person will take one hour to put the developed documents in final typed format.

Hours/Est. Salary/ # of CORFs (274)	**Annual Burden Hours**	**Annual Cost Estimate**
1 Administrator @ $47.34/hr. x 2 hrs. x 1 a yr. x 274 CORFs for plan development	548	$25,942
1 PT @ $38.99/hr. x 2 hrs. x 1 a yr. x 274 CORFs for plan development	548	$21,366
1 social or psychological services professional @ $27.29 x 2 hrs. x 1 a yr. x 274 CORFs for plan development	548	$14,954
1 Clerical person @ $14.63/hr. x 1 hr. x 1 a yr. x 274 CORFs for plan final document.	274	$4,008
1 Administrator @ $47.34/hr. x 2 hrs.(4 qtrs @ 30 min) x 1 a yr. x 274 CORFs for plan review and implementation	548	$25,942
1 PT @ $38.99/hr. x 2 hr.(4 qtrs @30 min) x 1 a yr. x 274 CORFs for plan review and revision	548	$21,366
1 social or psychological services professional @ $27.29 x 2 hr.(4 qtrs @30 min) x 1 a yr. x 274 CORFs for plan review and	548	$14,954

revision		
Total	**3562**	**$128,532**

Certification Form – CMS-359 – Based on past usage of this form and the general nature of the questions, we estimate it takes approximately fifteen minutes to complete this form. The burden for this is based on the 40 currently certified CORFs surveyed on an annual basis.

Certification Form – CMS-360 – The survey report form is completed by the State agency surveyor based on the results of his/her 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 of 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 three hours per survey report form. The burden for this request is based on the 40 currently certified CORFs surveyed on an annual basis.

Certification Forms Estimated Burden	**Reporting**	**Annual Cost Estimate**
CMS-359	10 hours (15 min x 40 sites x $47.34 per hour for administrator)	$473
CMS-360	120 hours (3 hrs x 40 sites x $38.99 per hour for physical therapist)	$4,678
Total	**130 hours**	**$5,151**

13. Capital Costs

There are no additional capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements for CORF facilities that are accrued at the Federal level due to the ability for surveyors to view and complete documentation and forms electronically.

15. Changes to Burden

Changes to the burden are a reflection of the decrease in number of Medicare certified CORFs at this time compared to the previous collection and the changes in current average hourly rate for medical professionals used in the calculations.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date because data collection and forms are used on a continual basis.