Supporting Statement for the Information Collection Requirements in Subpart A Conditions for Certification for Rural Health Clinics, 42 CFR 491.9, 491.10 and 491.11

CMS-R-38

A. BACKGROUND

We are requesting an extension of these currently approved information collection requirements under approval number 0938-0334, known as conditions of participation for rural health clinics (RHCs). The RHC conditions of participation are based on criteria prescribed in law and they are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients.

CMS uses these conditions of participation to certify RHCs wishing to participate in the Medicare program.

These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere.

B. JUSTIFICATION

1. Need and Legal Basis

These regulatory requirements implement section 1861(aa) (Attachment 1) of the Social Security Act and are intended to protect patient health, safety and assure the quality of care provided to Medicare and Medicaid beneficiaries. The current regulations containing these information collection requirements, for which an extension is being requested, are located at 42 CFR Part 491, Subpart A (Attachment 2).

Health care industry organizations establish standards that health care professionals use to measure their performance and the health care provided in rural health clinics. The information requirements contained within these regulations are comparable to such industry standards and are necessary safeguards against potential overpayments and poor health care procedures, which may occur when standards are insufficient.

We are not including burden associated with certain patient related activities such as health care plans, patient records, clinical records, etc., because prudent institutions already self-impose these activities in the course of doing business. Further, state laws require providers to maintain patient records. (For example, the annotated Code of Maryland (¶ 10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law requires record information that should include: documentation of personal interviews; diagnosis and treatment recommendations; records of professional visits and consultations; consultant notes which shall be appropriately initialed or signed; appropriate and indicated medical and laboratory data; and other data as may be required by

applicable federal and state regulations. These activities will take place even in the absence of the Medicare program. Therefore, we have included only the burden created by §491.9(b)(3) - patient care policies.

Sections of the regulations that are subject to review under the Paperwork Reduction Act are as follows:
491.9(b)(3) – Provision of services, Patient care policies.

The clinic must have in place a description of the services it furnishes directly and those furnished under contract; guidelines for management of health problems; and rules for managing drugs and biologicals. Most of' the required information constitutes standard clinical practice and need not be developed specifically for an individual facility.

491.10 - Patient health records.

Clinics are required to have a records system; procedures in place to protect record information; and must maintain records for the retention period stated. Since patient records serve as protection to the patient, as well as, the industry, the establishment and maintenance of patient records is a fundamental aspect of providing medical care that would exist even without Medicare.
.

The requirement for medical records has been an industry initiative that dates back, at least, to 1928 when the American College of Surgeons established the Association of Record Librarians of North America (ARLNA) to "elevate the standards of clinical records in hospitals and other medical institutions." In 1970, the Association (currently known as The American Health Information Management Association) expanded its involvement to community health centers and other health service facilities outside the hospital setting.

A patient's medical record plays many important roles:

1. It provides a record of the patient's health status, history and prognosis. It is the legal document describing the health care services provided to the patient.
2. It documents adherence to facility standards and procedures.
3. It provides a method for clinical communication and care planning among the individual practitioners serving the patient.
4. It provides supporting documentation for the reimbursement of services provided.
5. It is a source of data for clinical services and outcomes research.

Although the definition and requirement of a legal medical record will vary by practice and by State, it is safe to conclude that the health care industry and state requirements for creating and maintaining patient medical records predates the Rural Health Clinic Program.

Therefore, as with other providers, we are assessing no burden to this information requirement because the industry and State licensure laws require the maintenance of patient medical records.

2. Information Users

The information users are the facilities themselves. CMS and the health care industry believe that the availability and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. CMS does not collect this information.

3. Improved Information Technology

These requirements in no way prescribe how the facility should prepare or maintain these records. Each facility is free to take advantage of any technological advances that they find appropriate for their needs.

4. Duplication of Similar Information

These are requirements that are specified in a way so as not to duplicate existing facility practice. If a facility already maintains these general records, regardless of the format, they are in compliance with this requirement.

5. Small Businesses

These requirements do affect small businesses. However, the general nature of the requirements allows the flexibility for facilities to meet the requirement in a way consistent with their existing operations. Therefore, this does not have a significant economic impact on small businesses.

6. Less Frequent Collection

In order to comply with the Act, CMS requires that certain information is collected annually. If the information were collected less frequently, the facility would be out of compliance with the Act.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for the current submission of this information collection published on June 23, 2006.

The conditions of participation were established with industry participation and in line with industry standards.

9. Payment/Gift to Respondent

There is no payment/gift to respondent.

10. Confidentiality

Normal medical confidentiality practices are observed.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Total Hours and Wages)

491.9(b)(3) - Patient Care Policies:

We estimate that the initial one-time effort to develop policies and procedures will take a physician/administrator and a mid-level practitioner approximately 10 total hours. An annual review of these policies and procedures may take approximately 2 hours.

There are 3,674 existing facilities. Over the last three years, there were 634 new RHCs to the Medicare program and 329 RHCs terminated their participation in the program. Based on data from the last three years, we estimate that annually there are approximately 211 new RHCs and approximately 110 RHCs that close. Therefore, we have allowed 2 hours for the estimated 3,353 RHCs (the total existing facilities minus the average annual increase of 211 and closures of 110 RHCs) to annually conduct a review and revision of their policies. We have allowed 10 hours for the estimated 211 new facilities to develop their policies and procedures.

Burden Hours

Burden	RHCs	Hours	Total
Initial Development for New Clinics	211	10	2,110
Review and Revision	3,353	2	6,706
Total Annual Burden Hours		12	8,816

Wages

Hours/Estimated Salary/ # of RHCs		Annual Cost Estimate
New RHCs: 1 Physician/Administrator @ $58/hr X 10 hrs X 211 RHCs		$122,380
1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @$28/hr X 10hrs X 211 hours		59,080
Existing RHCs: 1 Physician/Administrator @ $58/hr X 2 hrs X 3,354 RHCs		389,064
1 Mid-level Practitioner @$28/hr X 2 hrs X 3,354 RHCs		187,824
Total Annual Cost		$758,348

491.11 – Program Evaluation

RHC are currently required to conduct an annual program evaluation and utilization review. An evaluation of a clinic's total operation including administration, policies and procedures covering personnel, fiscal and patient care areas must be done annually. Although not currently required in regulation, some RHCs, in an effort to comply with the 1997 BBA requirement, have developed a quality assessment and performance improvement (QAPI) programs to replace their annual program evaluation activities. The burden required to maintain the data remains the same for both the program evaluation and QAPI activities.

Because most of the developmental burden for this section is covered by the paperwork requirement of §491.9(b)(3), this burden represents the administrative cost to the agency for clerical activities (e.g., filing or storing the data). To maintain the data required for the annual evaluation or QAPI, we estimate it will take each clinic one hour per year to meet this requirement. The burden for this requirement is currently approved under OMB #0938-0792.

13. Capital Costs (Maintenance of Capital Cost
There are no capital costs.

14. Cost to Federal Government
Because the Federal Government does not routinely collect this information that is submitted on a non-routine basis by members of the public, and there are no personnel dedicated to the collection of this information, there is no separately identifiable personnel cost that would not have been incurred without collection of information.

15. Program Changes
There have been no program changes since the previous PRA submission. The increase in burden hours results solely from the increase in the number of RHCs.

16. Publication and Tabulation Dates
There are no publication and tabulation dates.

17. Expiration Date
This collection of information does not lend itself to the displaying of an expiration date.

18. Certification Statement
CMS is able to supply the information requested to support this burden request and has no reason to request an exception to the certification statement.

C. Collection of Information Employing Statistical Methods

There were no statistical methods employed.