# Supporting Statement
# Medicare and Medicaid Programs: Conditions for Certification for Rural Health Clinics in 42 CFR 491 (CMS-R-38; OMB#0938-0334)

A. Background

The Rural Health Clinic (RHC) conditions for certification (CfCs) 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. The information collection requirements described herein are needed to implement the Medicare and Medicaid CfCs for a total of 4,247 RHCs.

The current information collection requirements for CMS-R-38 are 42 CFR491.9 (b)(3), and 491.11.

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) 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 are located at 42 CFR Part 491, Subpart A .

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, and clinical records 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 would take place even in the absence of the Medicare and Medicaid programs. Therefore, we have included only the burden created by §491.9(b)(3) - patient care policies and 491.11 - program evaluation.

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.

*491.11 - Program Evaluation.*

RHCs 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.

2. Information Users

For 491.9(b)(3) - Provision of services, Patient care policies, the information users are the facilities themselves, patients and state agencies or national accreditation organizations. Patients may request policies or services offered directly from the facility. In addition, the state agency or accrediting organization may utilize these requirements as evidence of compliance for Medicare certification requirements. CMS does not collect the facility evaluation and utilization review information, but it is maintained in order to comply with CMS requirements.

For 491.11 - Program Evaluation, the information users are the facilities themselves and state agencies or national accreditation organizations. The facility may use the data or information collected for analysis of facility performance on their own accord to improve customer service. In addition, the state agency or accrediting organization may utilize these requirements as evidence of compliance for Medicare certification requirements.

CMS does not collect the facility evaluation and utilization review information, but it is maintained in order to comply with CMS requirements.

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 published November 4, 2016 (81 FR 76945). There were no public comments received. The 30-day Federal Register notice published January 17, 2017. There were no public comments received.

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)

The salary estimates in this information collection package take into account non-metropolitan settings for the following healthcare personnel. The estimates are based on data obtained from the most recent data of the U.S. Bureau of Labor Statistics at http://www.bls.gov.

"Physician" salary is based on a general practitioner with an annual salary of $182,650 and a median hourly salary of $88. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the median hourly salary wage to $176.
"Administrator" salary is based on an annual salary of $106,070 with a median hourly salary of $51. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the median hourly salary wage to $102.00.
"Mid-level Practitioner (Physician Assistant, Nurse Practitioner)" refers to a physician assistant or nurse practitioner with an annual salary of $90,360 and a median hourly salary of $44. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the median hourly salary wage to $88.00.

*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 4,247 existing facilities. Over the last three years, there were 81 new RHCs added to the Medicare program. Therefore, we have allowed 2 hours for the estimated 4,247 RHCs to annually conduct a review and revision of their policies. We have allowed 10 hours for the estimated 81 new facilities to develop their policies and procedures.

Table of Annual Burden Hours and Annual Cost Estimates

| Hours/Estimated Salary/Number of RHCs | | Annual Burden Hours | Annual Cost Estimate |
|---|---|---|---|
| New RHCs:<br>1 Physician/Administrator @ $176/hour x 10 hours x 81 new RHCs to develop policies and procedures | | 810 | $142,560 |
| 1 Mid-level Practitioner | | 810 | $71,280 |

| Hours/Estimated Salary/Number of RHCs | | Annual Burden Hours | Annual Cost Estimate |
|---|---|---|---|
| (Physician Assistant, Nurse Practitioner) @ $88/hour x 10 hours x 81 RHCs | | | |
| Existing RHCs:<br>1 Physician/Administrator @$176/hour x 2 hours x 4,247 RHCs | | 8,494 | $1,494,944 |
| 1 Mid-level Practitioner @ $88/hour x 2 hours x 4,247 RHCs | | 8,494 | $747,472 |
| Sub-Total | | 18,608 | $2,456,256.00 |

*491.11 - Program Evaluation.*

RHCs 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.

We estimate that the initial one-time effort to develop the program evaluation process and utilization review will take a physician/administrator and a mid-level practitioner approximately 10 total hours. An annual updated program evaluation and utilization review may take approximately 2 hours.

There are 4,247 existing facilities. Over the last three years, there were 81 new RHCs added to the Medicare program. Therefore, we have allowed 2 hours for the estimated 4,247 RHCs to annually conduct a review and update their program evaluation and utilization review reports. We have allowed 10 hours for the estimated 81 new facilities to develop their new program evaluation process and utilization review.

| Hours/Estimated Salary/Number of RHCs | Hourly Salary | Annual Burden Hours | Annual Cost Estimate |
|---|---|---|---|
| New RHCs:<br>1 Physician/Administrator @ $176/hour x 10 hours x 81 new RHCs to develop program eval process and utilization review | $176.00 | 810 | $142,560 |
| 1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @ | | 810 | $71,280 |

| Hours/Estimated Salary/Number of RHCs | Hourly Salary | Annual Burden Hours | Annual Cost Estimate |
|---|---|---|---|
| $88/hour x 10 hours x 81 RHCs | $88.00 | | |
| Existing RHCs:<br>1 Physician/Administrator @$176/hour x 2 hours x 4,247 RHCs | $176.00 | 8,494 | $1,494,944 |
| 1 Mid-level Practitioner @ $88/hour x 2 hours x 4,247 RHCs | $88.00 | 8,494 | $747,472 |
| Sub-Total | - | 18,608 | $2,456,256.00 |
| Total (491.9 & 491.11) | - | 37,216 | $4,912,512 |

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 costs results solely from the increase in benefits and overhead package costs that were calculated at 100% of the annual salary for the applicable occupations.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number or by visiting the CMS website at https://www.cms.gov/center/provider-type/rural-health-clinics-center.html.