

Supporting Statement
Medicare and Medicaid Programs: Conditions for Certification for Rural Health Clinics and Conditions for Coverage for FQHCs 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 4,160 RHCs.

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.

In addition, Federally Qualified Health Centers (FQHC) are subject to Conditions for Coverage that must be met in order to begin and continue participating in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. The information collection requirements described herein affect approximately 7,874 FQHCs.

The current information collection requirements at 42 CFR 491.9(b) and 491.11 are applicable to both RHCs and FQHCs.

CMS published revisions to certain RHC Conditions for Certification and FQHC Conditions for Coverage in Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23) on September 30, 2019 (84 FR 51732).

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) - patient care policies and 491.11 - program evaluation.

2. Information Users

For 491.9(b) - 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 current regulations, CMS requires that certain information is collected annually. If the information were collected less frequently, the facility would be out of compliance with the regulations. In accordance with this package, we are taking regulatory action to reduce those collection burdens to occur biennially.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

This information collection request is associated with Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23) which was proposed on September 20, 2018 (83 FR 47686), and finalized on September 30, 2019 (84 FR 51732).

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)

Table 1: Estimates used throughout

RHC sites	4,160
FQHC sites	7,874
Physician wage	\$200/hour

Administrator wage	\$108/hour
Mid-level Practitioner wage	\$100/hour

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 May 2017 National Occupational Employment and Wage Estimates from the U.S. Bureau of Labor Statistics at www.bls.gov/oes/current/oes_nat.htm.

“Physician” salary is based on a general practitioner with an annual salary of \$208,560 and a mean hourly wage of \$100. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$200.

“Administrator” salary is based on an annual salary of \$111,680 with a mean hourly wage of \$54. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$108.

“Mid-level Practitioner (Physician Assistant, Nurse Practitioner)” refers to a physician assistant or nurse practitioner with an annual salary of \$104,760 and a mean hourly wage of \$50. We have factored in a benefits and overhead package equal to 100% of the annual salary, bringing the hourly wage to \$100.

491.9(b) - Patient Care Policies:

The clinic or center 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. Over the last three years, we estimate there were approximately 30 new RHCs sites and 425 new FQHC sites added to the Medicare program each year. Therefore, we estimate it would take approximately 10 hours for the new facilities to develop their policies and procedures. These policies and procedures must be reviewed biennially, so we estimate it would take 4 hours for 4,160 RHCs and 7,874 FQHCs to biennially (annualized to 2 hours/year) conduct a review and revision of their policies.

Table of Annual Burden Hours and Annual Cost Estimates

	Hours/Estimated Salary/Number of sites	Hourly Wage	Annual Burden Hours	Annual Cost Estimate
New RHCs	1 Physician/Administrator @ \$200/hour x 5 hours x 30 new RHCs to develop policies and procedures	\$200	150	\$30,000
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @	\$100	150	\$15,000

	Hours/Estimated Salary/Number of sites	Hourly Wage	Annual Burden Hours	Annual Cost Estimate
	\$100/hour x 5 hours x 30 RHCs			
New FQHCs	1 Physician/Administrator @ \$200/hour x 5 hours x 425 new FQHCs to develop policies and procedures	\$200	2,125	\$425,000
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @ \$100/hour x 5 hours x 425 FQHCs	\$100	2,125	\$212,500
Existing RHCs	1 Physician/Administrator @\$200/hour x 1 hours (2 hours biennially) x 4,160 RHCs	\$200	4,160	\$832,000
	1 Mid-level Practitioner @ \$100/hour x 1 hours (2 hours biennially) x 4,160 RHCs	\$100	4,160	\$416,000
Existing FQHCs	1 Physician/Administrator @\$200/hour x 1 hour (2 hours biennially) x 7,874 FQHCs	\$200	7,874	\$1,574,800
	1 Mid-level Practitioner @ \$100/hour x 1 hour (2 hours biennially) x 7,874 FQHCs	\$100	7,874	\$787,400
Sub-Total		-	0	0

491.11 - Program Evaluation.

Clinics or centers are currently required to conduct program evaluation and utilization reviews. An evaluation of a clinic's total operation including administration, policies and procedures covering personnel, fiscal and patient care areas must be done biennially. 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.

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. A biennial updated program evaluation and utilization review may take approximately 6 hours.

There are 4,160 existing facilities. Over the last three years, we estimate there were approximately 30 new RHCs and 425 new FQHC sites added to the Medicare program each year. Therefore, we estimate it would take 10 hours for the new facilities to develop their new program evaluation process and utilization review. We have allowed 6 hours for the estimated 4,160 RHC and 7,874 FQHC locations to biennially conduct a review and update their program evaluation and utilization review reports.

	Hours/Estimated Salary/Number of sites	Hourly Wage	Annual Burden Hours	Annual Cost Estimate
New RHCs	1 Physician/Administrator @ \$200/hour x 5 hours x 30 new RHCs to develop program eval process and utilization review	\$200	150	\$30,000
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @ \$100/hour x 5 hours x 30 RHCs	\$100	150	\$15,000
New FQHCs	1 Physician/Administrator @ \$200/hour x 5 hours x 425 new FQHCs to develop program eval process and utilization review	\$200	2,125	\$425,000
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner) @ \$100/hour x 5 hours x 425 FQHCs	\$100	2,125	\$212,500
Existing RHCs	1 Administrator @ \$108/hour x 1 hour (2 hours biennially) x	\$108	4,160	\$449,280

	Hours/Estimated Salary/Number of sites	Hourly Wage	Annual Burden Hours	Annual Cost Estimate
	4,160 RHCs			
	1 Physician @ \$200/hour x 1 hour (2 hours biennially) x 4,160 RHCs	\$200	4,160	\$832,000
	1 Mid-level Practitioner @ \$100/hour x 1 hour (2 hours biennially) x 4,160 RHCs	\$100	4,160	\$416,000
Existing FQHCs	1 Administrator @ \$108/hour x 1 hour (2 hours biennially) x 7,874 FQHCs	\$108	7,874	\$850,392
	1 Physician @ \$200/hour x 1 hour (2 hours biennially) x 7,874 FQHCs	\$200	7,874	\$1,574,800
	1 Mid-level Practitioner @ \$100/hour x 1 hour (2 hours biennially) x 7,874 FQHCs	\$100	7,874	\$787,400
Sub-Total		-	0	0
Total (491.9 & 491.11)		-	69,270	\$9,885,072

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

These ICRs have been updated in accordance with the finalized regulations at 84 FR 51732. These burden estimates are unchanged from what was estimated for the proposed rule,

which was an annual burden of 69,270 hours.

As explained in the pertinent final rule (84 FR 51732), the most recently approved information collection request neglected to account for the burden to FQHCs from these provisions, and the annual burden was calculated to be 37,216 hours as a result. The table below reflects necessary adjustments to that prior ICR, as well as the program changes finalized in 84 FR 51732.

		Annual Hours Before Final Rule*	Annual Hours After Final Rule
RHC	491.9(b)	16,940	8,620
	491.11	25,260	12,780
FQHC	491.9(b)	35,746	19,998
	491.11	51,494	27,872
Total		0	0

*This column reflects what the burden was most recently estimated to be, including adjustments to the number of affected facilities (both RHCs and FQHCs), and the associated hourly burden estimates.

We note one anomaly between the above estimates, and the estimates presented in the final rule. Because these formerly annual requirements were changed to occur on a biennial basis, the analysis in the rule counted reductions in burden hours of 48,136 hours and 72,204 hours over that two year period, eventually followed by the statement “or annualized savings of half these amounts.” The numbers above reflect the annualized change of 60,170 hours ((48,136 hours + 72,204 hours) / 2 years).

We also note that the final rule estimate of a 60,170 hour burden reduction is only the estimate for existing facilities to switch from annual to biennial requirements in 42 CFR 491.9(b) and 491.11. That estimate does not include, and the changes do not affect, the estimated 9,100 hours in start-up burden for 30 new RHCs and 425 new FQHCs added to the Medicare program each year. Accordingly, the total annual burden of these requirements is estimated to be 69,270 hours (60,170 hours + 9,100 hours).

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.