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 Conditions for Medicare Certification (CfCs) for Rural Health Clinics (RHCs) are based on criteria prescribed in law and designed to ensure that each RHC has 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 5,349 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.

Federally Qualified Health Centers (FQHCs) are also subject to Conditions for Certification to participate in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of Medicare and Medicaid beneficiaries. The information collection requirements described herein affect approximately 11,252 FQHCs.

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

This is a reinstatement information collection. There are no collection instruments.

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.

The current regulations incorporate the changes to the Conditions of Participation for FQHCs and RHCs outlined in the Final Rule, “Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23),” proposed on September 20, 2018 (83 FR 47686), and finalized on September 30, 2019 (84 FR 51732). The

information collection record for the changes made by this Final Rule can be found at ICR 202002-0938-011.

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 the burden associated with certain patient-related activities under the Conditions of Participation for RHCs and FQHCs because the activities are considered usual and customary business practices and are exempt from the PRA in accordance with 5 CFR1320.3(b)(2). For example, staff at RHCs and FQHCs are required to maintain the records and ensure they are completely and accurately documented, readily accessible, and systematically organized per 42 CFR §449.10. Yet this activity would take place even in the absence of the Medicare and Medicaid programs. Therefore, we have included only the burden created by 42 CFR §491.9(b) - patient care policies and 42 CFR §491.11 - program evaluation.

This ICR also does not include the burden on FQHCs and RHCs associated with the "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" which is addressed at OMB control number 0938-1325 .

2. Information Users

For 491.9(b) - Provision of services, Patient care policies, the information users are the RHCs or FQHCs themselves, patients and state agencies or national accreditation organizations. Patients may request policies or services offered directly from the RHC or FQHC. In addition, the state agency or accrediting organization may utilize these requirements as evidence of compliance for Medicare or Medicaid certification requirements. CMS does not collect the clinic's or center's written policies under this section; instead, a clinic or center maintains the information to document compliance with CMS requirements.

For 491.11 - Program Evaluation, the information users are the RHCs or FQHCs themselves and state agencies or national accreditation organizations. The clinic or center uses the evaluation findings to measure its performance and make corrections based on the findings. In addition, the state agency or accrediting organization may utilize these requirements as evidence of compliance for Medicare OR Medicaid certification requirements. CMS does not collect the clinic's or center's evaluation program or findings, but they are maintained by the clinics or centers to document compliance with CMS requirements.

3. Improved Information Technology

These requirements in no way prescribe how the clinics or centers should prepare or maintain these records. Each clinic or center 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 clinic or center practice. If a clinic or center already maintains these patients 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

The regulations were changed in 2019 to reduce the frequency of collection as part of the review of the policies (42 CFR § 491.9(b)) and program evaluation (42 CFR § 491.11) from every year to every two years, or biennially. The burden estimates in this ICR account for this change.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register published on March 28, 2024 (89 FR 21523). There were no public comments received.

The 30-day Federal Register published on June 11, 2024 (89 FR 49178).

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.

New RHCs per year	335
New FQHCs per year	727
Existing RHCs	5,349
Existing FQHCs	11,252
Physician/Administrator wage	$210/hour
Administrator wage	$124/hour
Mid-level Practitioner wage	$118/hour

We obtained the number of new and existing RHCs and FQHCs from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) for the calendar year of 2022 via the data reports available at Quality, Certification and Oversight Report (QCOR) at https://qcor.cms.gov. Based on this data source, there are an estimated 5,349 RHCs and 11,252 FQHCs operating every year and approximately 335 new RHCs and 727 new FQHCs added to the Medicare program each year.

We obtained the salary data for non-metropolitan settings for the following healthcare personnel from the May 2022 National Occupational Employment and Wage Estimates United States at the United States Bureau of Labor Statistics (BLS) website at https://www.bls.gov/oes/tables.htm. We added 100% to the base compensation to account for overhead and fringe benefits for each position. We also rounded all amounts to the nearest dollar.

Physicians who manage RHCs or FQHCs earn an average hourly wage of $105. We added $105 dollars to that amount to allow for fringe benefits and overhead for an average hourly wage of $210.

An Administrator is an individual at a RHC or FQHC who plans, directs, or coordinates medical and health services. We used the average hourly wage for ***medical and health services managers*** who work in specialty hospitals (excluding psychiatric and substance abuse) of $62 and added 100% of wages for fringe benefits for an average hourly wage of $124.

Mid-level Practitioner refers to a physician's assistant or nurse practitioner at a RHC or FQHC who is responsible for patient care. We used the average hourly wage of both ***physician assistants and nurse practitioners*** who worked in specialty hospitals (excluding psychiatric and substance abuse) of $59 and added 100% of wages for fringe benefits and

overhead for an average hourly wage of $118.

491.9(b) - Patient Care Policies

FQHCs and RHCs must create written policies that include information about: a) the services provided either directly or by agreement; b) rules for the storage, handling, and administration of drugs and biologicals; and c) guidelines for medical management, such as "conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center."

Per Section 491.9(b)(2), the policies must be developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioner***s*** and at least one member in the group is not a clinic or center staff member. These patient care policies must be reviewed by similar staff positions at each clinic or center every two years (biennially) per Section 491.9(b)(4).

<u>Initial policy development for a new clinic or center</u>

We estimate that the initial one-time effort to develop the written policies and procedures for a newly Medicare certified RHC and FQHC requires approximately ***5 hours each*** for a physician/administrator and a mid-level practitioner, or a total of 10 hours per new clinic or center for the initial year.

<u>Biennial review of existing policies for every Medicare certified clinic/center</u>

We estimate that a review of patient policies by every certified RHC and FQHC requires approximately ***2 hours each*** for a physician/administrator and a mid-level practitioner, or a total of 4 hours for every policy review. Because this review is only required every two years, the annualized number of hours every clinic or center must spend on policy review is 2 hours per year (4 hours every 2 years).

491.9(b) - Patient Care Policies

Table 2. Annual Burden Hours and Costs for 42 CFR § 491.9(b)

Requirement	Position	Hourly Wage	Burden Hours Per Event	Cost Estimate Per Event
Develop policies and procedures at each new clinic or center				
One-time burden on new clinics/centers	1 Physician/Administrator	$210	5	$1,050
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner)	$118	5	$590
	Subtotal per event per year		10	$1,640
	Annualized Total per event		**10**	**$1,640**
	# of Events/year			
	New RHCs	335	3,350	$5,494,000
	New FQHCs	727	7,270	$11,922,800
	One-time burden for new clinics/centers		**10,620**	**$17,416,800**
Review policies and procedures at every clinic or center every 2 years (biennially)				
Existing clinics/centers every 2 years	1 Physician/Administrator	$210	2	$420
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner)	$118	2	$236
	Sub-Total per event ***every 2 years***		4	$656
	Annualized Total per event		**2**	**$328**
	# of Events/year			
	Existing RHCs	5,349	10,698	$3,508,944
	Existing FQHCs	11,252	22,504	$7,381,312
	Annual Burden for all clinics/centers		**33,202**	**$10,890,256**

491.9(b) Total		**43,822**	**$28,307,056**

Table 2a. Annual Burden Hours and Costs for 42 CFR § 491.9(b) by Provider

By Provider Type		# of Providers	Annual Burden Hours	Annual Cost Estimate
RHCs	New	335	3,350	$5,494,000
	Existing	5,349	10,698	$3,508,944
FQHCs	New	727	7,270	$11,922,800
	Existing	11,252	22,504	$7,381,312
			43,822	**$28,307,056**

491.11 - Program Evaluation

Every RHC and FQHC must conduct or arrange for a biennial evaluation of its program to determine if utilization of services were appropriate, established policies were followed, or if any changes are needed. Specifically, the evaluation includes review of: (1) utilization of clinic or center services, including at least the number of patients served and the volume of services; (2) a representative sample of both active and closed clinical records; and (3) the clinic's or center's health care policies per Section 491.11(b). Every clinic or center must conduct a program evaluation every two years (biennially) per Section 491.11(a).

Initial development of program evaluation

We estimate that the initial one-time effort to develop the program evaluation will take a physician/administrator and a mid-level practitioner approximately ***5 hours each***, for a total of 10 hours per new clinic or center for the initial year.

Conduct biennial program evaluation

We estimate that conducting a program evaluation requires ***2 hours each*** for an Administrator, a physician/administrator and a mid-level practitioner, or a total of 6 hours per evaluation. The annualized number of hours that every clinic or center must spend on conducting the required program evaluation is 3 hours per year (6 hours every 2 years).

491.11 - Program Evaluation

Table 3. Annual Burden Hours and Costs for 42 CFR § 491.11

Requirement	Position	Hourly Wage	Burden Hours Per Event	Cost Estimate Per Event
Develop and implement an evaluation process at each new clinic or center				
One-time burden on new clinics/center	1 Physician/Administrator	$210	5	$1,050
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner)	$118	5	$590
	Subtotal per event per year		10	$1,640
	Annualized Total per event		**10**	**$1,640**
	# of Events/year			
	New RHCs	335	3,350	$5,494,000
	New FQHCs	727	7,270	$11,922,800
	One-time burden for new clinics		**10,620**	**$17,416,800**
Conduct a program evaluation at every clinic or center every 2 years (biennially)				
Existing clinics/centers every 2 years	1 Physician/Administrator	$210	2	$420
	1 Mid-level Practitioner (Physician Assistant, Nurse Practitioner)	$118	2	$236
	1 Administrator	$124	2	$248
	Sub-Total per event ***every 2 years***		6	$904
	Annualized Total per event		**3**	**$452**
	# of Events/year			
	Existing RHCs	5,349	16,047	$7,253,244
	Existing FQHCs	11,252	33,756	$15,257,712
	Annual Burden for all clinics/centers		**49,803**	**$22,510,956**

491.11 Total	**60,423**	**$39,927,756**

Table 3a. Annual Burden Hours and Costs for 42 CFR § 491.11 by Provider

By Provider Type		# of Providers	Annual Burden Hours	Annual Cost Estimate
RHCs	New	335	3,350	$5,494,000
	Existing	5,349	16,047	$7,253,244
FQHCs	New	727	7,270	$11,922,800
	Existing	11,252	33,756	$15,257,712
			60,423	**$39,927,756**

Table 4. Total Annual Burden Hours and Costs for 42 CFR §§ 491.9(b) & 491.11

	Section	Total Burden Hours	Total Cost Estimates
RHCs	§491.9(b)	14,048	$9,002,944
	§491.11	19,397	$12,747,244
FQHCs	§491.9(b)	29,774	$19,304,112
	§491.11	41,026	$27,180,512
Total		**104,245**	**$68,234,812**

Table 4a. Total Annual Burden Hours and Costs by Provider

By Provider Type		# of Providers	Annual Burden Hours	Annual Cost Estimate
RHCs	New	335	6,700	$10,988,000
	Existing	5,349	26,745	$10,762,188

FQHCs	New	727	14,540	$23,845,600
	Existing	11,252	56,260	$22,639,024
			104,245	**$68,234,812**

13. Capital Costs (Maintenance of Capital Cost)

There are no capital costs.

14. Cost to Federal Government

The Federal Government does not routinely collect and review the materials that are required by RHCs and FQHCs under Sections §§ 491.9(b) and 491.11. However, federal personnel costs are incurred for the federal staff who monitor changes to the CfCs for RHCs and FQHCs and who periodically update the annual burden hours and costs based on changes in the requirements, wages and the number of facilities impacted through re-approval of this information collection review.

We estimate the annual cost to the federal government for this ICR to be 10% of 2 FTEs at CMS, or an average 9,723 ($97,227 annual salary x 0.10) per year[1].

15.Changes to Burden

Per the table below, the estimated burden has increased from the previously approved burden of 69,270 to 104,245.

		Annual Hours in this ICR	Previously Approved Hours (3/2020)
RHC	491.9(b)	14,048	8,620
	491.11	19,397	12,780
FQHC	491.9(b)	29,774	19,998
	491.11	41,026	27,872
Total		**104,245**	0

The increase of 34,975 burden hours reflects necessary adjustments to the previously approved burden due to:

- Increase in hourly wages due to COLA/inflation.
- Increased number of total RHCs (from 4,160 to 5,349) and FQHCs (7,874 to 11,252)
- Significant increase in number of newly certified RHCs (from 30 to 335) and

1 Annual salary equal to the average General Schedule (GS) 13, 2023.

FQHCs (from 425 to 727)

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.

18. Certification

There is no exception to the certification.