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

Background

Currently, approved information collection requirements are Patient care policies at 42 CFR 491.9(b) and Program evaluation at 42 CFR 491.11.

This request for revision is precipitated by CMS's November 16, 2023 (88 FR 78817) final rule (CMS-1784-F, RIN 0938-AV07), which revised the Rural Health Clinic (RHC) and Federally Qualified Health Centers (FQHCs) Conditions for Certification and Conditions for Coverage (CfCs), respectively. As explained in section 15 of this Supporting Statement, § 491.8(a)(3) and (6) adds Marriage and Family Therapist (MFT) and Mental Health Counselors (MHC) to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as may be included as staff who may be available to furnish patient care services at all times the clinic or center operates. As a result of this addition, RHC or FQHC are expected to modify their existing patient care policies, as set out in § 491.9(b)(2).

Note CfCs and associated collection of information are written in regulation based on criteria described in the law and are standards designed to ensure that each of the 5,537 RHCs and 11,852 FQHCs have properly trained staff to provide the appropriate type and level of care for their patient population. CMS uses the CfCs to certify health care facilities wishing to participate in the Medicare and/or Medicaid programs.[1]

To determine compliance with the CfCs, 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 provision adds a one-time burden of 4,348 hours at a cost of $822,250.

While keeping our active response time estimates as is, we have also adjusted our number of responses by plus 1,634 and time by plus 4,520 hours. Overall, we estimate an increase of 10,329 responses and 8,868 hours (see section 15, below).

As the collection expired in March 2023, we were unable to submit the NPRM and final rule packages via ROCIS. The collection was reinstated on July 31, 2024. We are making up for the delay by submitting the package in August 2024.

We did not receive any comments related to the NPRM's collection of information requirements/burden or the 60- and 30-day reinstatement's collection of information request.

1 Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) via Quality, Certification and Oversight Report (QCOR). Calendar Year 2023. https://qcor.cms.gov . Accessed, July 31,2024.

This collection of information request does not include any collection of information instruments.

A. Justification

1. Need and Legal Basis

The regulatory requirements that are set out below under section 12, implements section 1861(aa) of the Social Security Act are intended to protect patient health, safety and assure the quality of care provided by Medicare and/or Medicaid participating RHCs and FQHCs. Section 12's information collection requirements are located at 42 CFR part 491, subpart A.

This request for revision is to incorporate revisions that were made to the RHC and FQHC CfCs, which were made to implement section 4121(b)(1) of the Consolidated Appropriations Act (CAA) of 2023 (Pub. L. 117-328, December 29, 2022). In this legislation, Congress established Medicare payment for the services furnished by MFTs and MHCs in RHCs and FQHCs. Therefore, if an RHC or FQHC furnishes services rendered by MFTs and MHCs, they must update their patient care policies to reflect the services offered.

Health care industry organizations establish standards that health care professionals use to measure their performance and the health care provided in RHCs and FQHCs. The information requirements contained within the applicable sections of the CfCs 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.

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 with 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.

The types of information collected and analyzed by the RHCs include administrative data, staff data, and patient data.

RHCs and FQHCs apply to enroll in Medicare (Form CMS-855A, OMB No. 0938-0685). Once the Medicare Administrative Contractor (MAC) has completed its review of Form CMS-855A, the state agency or accrediting organization may conduct an initial survey for RHCs. This form collects administration data such as facility state license data and ownership information. FQHCs self-attest to their compliance with Medicare CfCs and are only surveyed by CMS in connection with complaint investigations. In the event of an FQHC complaint survey, surveyors would use the following patient, staff, and facility administration data to assess for a deficiency

with § 491.9(b).

Additionally, the completion of the CMS-29 form (OMB No: 0938-0074) is required when an RHC seeks participation in the Medicare program and also when the state agency performs a survey of the RHC. RHCs must submit Form CMS-29 Verification of Clinic Data – Rural Health Clinic Program, as part of its application for certification. Facilities must provide basic information related to their location and staffing on this document.

To determine compliance with § 491.9, during the survey process conducted by state agencies or national accrediting organizations, surveyors may request the following but not limited to administrative data: meeting minutes or documentation of the biennial policy review, a copy of the facilities description of services and medical management policies to determine if it is consistent with the services advertised, review of inventory records for drugs and biologicals. For a full list of administration data assessed see the State Operations Manual Appendix G – Guidance for Surveyors: Rural Health Clinics.[2]

Staff data includes but is not limited to staff names, personnel files, and staff state licensing data. For a full list of staff data assessed see the State Operations Manual Appendix G – Guidance for Surveyors: Rural Health Clinics.[2]

Patient data: clinical records and patient appointment data. For a full list of patient data assessed see the State Operations Manual Appendix G – Guidance for Surveyors: Rural Health Clinics.[2]

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 with 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. The ICRs specified in the regulations may be used as a basis for determining whether an RHC or FQHC is meeting the requirements to participate in the Medicare program.

FQHCs self-attest to their compliance with Medicare CfCs and are only surveyed by CMS in connection with complaint investigations. In the event of an FQHC complaint survey, surveyors would use the following patient, staff, and facility administration data to assess for a deficiency with § 491.11.

The types of information collected and analyzed by the RHCs include administrative data, staff data, and patient data.

To determine compliance with this requirement, during the survey process conducted by state agencies or national accrediting organizations, surveyors may request the following, but not limited to administration data: a copy of the facilities evaluation findings summary report, written documentation related to the program evaluation, a copy of the patient care policies. For a full list of administration data assessed see the State Operations Manual Appendix G –

2 https://www.cms.gov/files/document/appendix-g-state-operations-manual

Guidance for Surveyors: Rural Health Clinics.[2]

Staff data includes but is not limited to: staff names, personnel files, and staff state licensing data. For a full list of staff data assessed see the State Operations Manual Appendix G – Guidance for Surveyors: Rural Health Clinics.[2]

Patient data includes but is not limited to: clinical records and patient appointment data. For a full list of patient data assessed see the State Operations Manual Appendix G – Guidance for Surveyors: Rural Health Clinics.[2]

As described in the background section of this Supporting Statement, the following collection of information is written in regulation based on criteria described in the law and are standards designed to ensure that RHCs and FQHCs have properly trained staff to provide the appropriate type and level of care for their patient population. The CfCs and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether an RHC or FQHC qualifies for a provider agreement under Medicare and Medicaid. To determine compliance with the CfCs, 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.

3. Improved Information Technology

The requirements do not prescribe how the clinics or centers should prepare or maintain their 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 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, these requirements are specified in a way so as not to duplicate existing clinic or center practice. If a clinic or center already maintains the patients' records, regardless of the format, they are in compliance with the requirements.

5. Small Businesses

The requirements do affect small businesses. However, the general nature of the requirements allows providers the flexibility to meet the requirements in a way consistent with their existing operations. In addition, as stated in section 4, these requirements are similar to standards developed by industry organizations. Therefore, we do not believe these requirements 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 (§ 491.9(b)) and program evaluation (§ 491.11) from every year to every two years, or biennially.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-1784-P, RIN 0938-AV07) published in the Federal Register on August 7, 2023 (88 FR 52261). We did not receive any comments related to this collection of information request.

As the collection expired in March 2023, we were unable to submit the NPRM package via ROCIS. The collection was reinstated on July 31, 2024.

The final rule published on November 16, 2023 (88 FR 78817).

As the collection expired in March 2023, we were unable to submit the final rule package via ROCIS. The collection was reinstated on July 31, 2024. We are making up for the delay by submitting the package in August 2024.

We did not receive any comments related to the NPRM’s collection of information requirements/burden or the 60- and 30-day reinstatement’s collection of information request.

9. Payment/Gift to Respondent

There are no payments/gifts to any of the respondents.

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 sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

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 CFR 1320.3(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 § 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 § 491.9(b) - Patient care policies and § 491.11 - Program evaluation.

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

Labor and Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2023/may/oes_nat.htm). In this regard, the following table (Table 1) presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Table 1. Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Physicians	29-1210	126.85	126.85	253.70

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Practitioner: Mid-level (physician assistants and nurse practitioners)	29-1071 (physician assistants) 29-1171 (nurse practitioners)	62.26 avg [62.74 (physician assistants) + 61.78 (nurse practitioners)]	62.26	124.52

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Requirements and Associated Burden Estimates

We obtained the number of new and existing RHCs and FQHCs from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) for calendar year 2023 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 5,537 RHCs and 11,852 FQHCs operating every year, and approximately 323 new RHCs and 768 new FQHCs are added to the Medicare program each year.

Table 2. New and Existing RHCs and FQHCs

New RHCs per year	323
New FQHCs per year	768
Existing RHCs	5,537
Existing FQHCs	11,852

§ 491.9(b) - Patient care policies

RHCs and FQHCs 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 § 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 practitioners (hereinafter, "mid-level practitioner") 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 § 491.9(b)(4).

Initial policy development for a new clinic or center: 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 and a mid-level practitioner, or a total of 10 hours per new clinic or center for the initial year.

Table 3. Annual Burden for Initial Policy Development

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Initial policy development for a new clinic or center (§ 491.9(b)(2)	1,091 (323 New RHCs + 768 New FQHCs)	1,091	5	5,455	253.70 (Physician)	1,383,934
		1,091	5	5,455	124.52 (Mid-level Practitioner)	679,257
TOTAL	1,091	1,091	10	10,910	varies	2,063,190

Biennial review of existing policies for every Medicare-certified clinic or center: We estimate that a review of patient policies by every certified RHC and FQHC requires approximately 2 hours each for a physician 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/2 years).

Table 4. Annual Burden for Periodic Reviews

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Biennial review of existing policies for every Medicare-certified clinic/center (§ 491.9(b)(2)	17,389 (5,537 Existing RHCs + 11,852 Existing FQHCs)	17,389	1	17,389	253.70 (Physician)	4,411,589
		17,389	1	17,389	124.52 (Mid-level Practitioner)	2,165,279
TOTAL	17,389	17,389	2	34,778	Varies	6,576,868

This request for revision *permits MFT and MHCs to furnish services in RHC and FQHC.* Section 491.8(a)(3) and (6) adds MFT and MHCs to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an RHC or FQHC provides services furnished by an MFT or MHC, they will be required to update their patient care policy, as set out in § 491.9(b)(2) of the CfCs.

We estimate that it takes existing RHCs and FQHCs 4 hours every 2 years (2 hours every 1 year) for clinical staff to review and make changes to all patient care policies. Based on this, we estimate that adding MFT and MHC services (as necessary) to the patient care policies would take an additional quarter of the burden already allotted for biannual reviews. This would result in a one-time burden of 4,348 hours (0.50 hr x 8,695 RHC and FQHCs) at a cost of $782,640 [(2,174 hr x $253.70/hr) + (2,174 hr x $124.52/hr)].

Table 5. New One-time Requirement/Burden (CMS-1784-F)

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Permitting MFT and MHCs to Furnish Services in RHC/FQHCs (§ 491.9(b)	8,695 (2,769 RHCs) + 5,926 FQHCs)	4,347	.5	2,174	253.70 (Physician)	551,544
		4,348	.5	2,174	124.52 (Mid-level Practitioner)	270,706
TOTAL	8,695	8,695	1.0	4,348	Varies	822,250

§ 491.11 - Program Evaluation

Every RHC and FQHC must conduct or arrange for a biennial evaluation of its program to determine if the utilization of services was appropriate, if established policies were followed, or if any changes are needed. Specifically, the evaluation includes a 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 § 491.11(b). Every clinic or center must conduct a program evaluation every two years (biennially) per § 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 and a mid-level practitioner approximately 5 hours each, for a total of 10 hours per new clinic or center for the initial year.

Table 6. Annual Burden for Initial Development of Program Evaluation

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Initial development of program evaluation (§ 491.11)	1,091 (323 New RHCs + 768 New FQHCs)	1,091	5	5,455	253.70 (Physician)	1,383,934
		1,091	5	5,455	124.52 (Mid-level Practitioner)	679,257
TOTAL	1,091	1,091	10	10,910	varies	2,063,190

Biennial review of program evaluation for every Medicare-certified clinic or center: We estimate that conducting a program evaluation requires 3 hours each for a physician 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/2 years).

Table 7. Annual Burden for Program Evaluation

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Conduct biennial program evaluation(§ 491.11)	17,389 (5,537 Existing RHCs + 11,852 Existing FQHCs)	17,389	1.5	26,083.50	253.70 (Physician)	6,617,384
		17,389	1.5	26,083.50	124.52 (Mid-level Practitioner)	3,247,917
TOTAL		17,389	3	52,167	Varies	9,865,301

Summary of Annual Burden Estimates

Table 8. Burden Summary

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Initial policy development for a new clinic or center (§ 491.9(b)	1,091	1,091	10	10,910	varies	2,063,190
Biennial review of existing policies for every Medicare-certified clinic/center (§ 491.9(b)	17,389	17,389	2	34,778	varies	6,576,868
Permitting MFT and MHCs to Furnish Services in RHC/FQHCs (§ 491.9(b)	8,695	8,695	1.0	4,348	varies	822,250
Initial development of program evaluation (§ 491.11)	1,091	1,091	10	10,910	varies	2,063,190
Conduct biennial program evaluation (§ 491.11)	17,389	17,389	3	52,167	varies	9,865,301
TOTAL	**45,655**	**45,655**	**Varies**	**113,113**	**Varies**	**21,390,799**

Collection of Information Instruments and Instruction/Guidance Materials

None. All instructions are codified in the CFR.

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 §§ 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 of $10,180 ($101,800 annual salary x 0.10) per year.[3]

15.Changes to Burden

This request for revision was precipitated by the November 16, 2023 (88 FR 78817) final rule (CMS-1784-F, RIN 0938-AV07). This final rule implements section 4121 of the CAA by making conforming changes at §491.8(a)(3) and (6), which added MFT and MHCs to the list of staff who may be the owner or an employee of the clinic or center or may furnish services under contract to the clinic or center as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an RHC or FQHC provides services furnished by an MFT or MHC, they will be required to update their patient care policy, as set out in § 491.9(b)(2) of the CfCs.

At the time of the final rule's publication, the existing requirement required that policies be developed with the advice of a group of professional personnel that includes one or more physicians and one or more mid-level practitioners, with at least one member who is not a member of the clinic or center staff. The patient care policies must describe the services the clinic or center furnishes directly, through agreement or arrangement, guidelines for medical management of health problems, and rules for the storage, handling, and administration of drugs and biologicals.

However, the final rule's inclusion of MFTs and MHCs as professionals who can provide services in an RHC and FQHC adds an additional burden associated with the existing requirement at § 491.9(b)(3)(i). This requirement states that policies include "A description of the services they provide directly or through agreement or arrangement." Therefore, if an RHC or FQHC provides services furnished by an MFT or MHC they must update their policies to include a description of the services provided.

We note that the time and effort required to conduct this activity will vary depending on whether a clinic or center chooses to provide services furnished by an MFT or MHC. We also believe that some RHCs and FQHCs may already provide services furnished by an MFT or MHC. State Medicaid programs can cover ambulatory care services (including mental health and substance use disorder services) under a number of different mandatory Medicaid benefits such as outpatient hospital services, physician services, RHC and FQHC services, as well as optional benefits such as rehabilitative services, and services of other licensed practitioners.

The National Association of Community Health Center's 2017 policy assessment suggests that 21 State Medicaid programs cover services provided by MFTs, and 25 State Medicaid programs cover services provided by licensed professional counselors. Due to approximately half of the State's Medicaid programs already covering services furnished by an MFT or MHC and the assumption that some centers and clinics will not provide these services, we believe only 50

3 Annual salary equal to the average General Schedule (GS) 13, 2024.

percent of RHCs and 50 percent of FQHCs will incur this burden. The total RHCs and FQHCs who will have to meet this one-time burden is 2,769 clinics and 5,926 centers, or 8,695 combined.

Each clinic or center is required by the existing requirement at § 491.9(b)(2) to have at least one physician at $253.70/hr and one mid-level practitioner at $124.52/hr reviewing and updating the policies.

We estimate that it takes existing RHCs and FQHCs 4 hours every 2 years for clinical staff to review and make changes to all patient care policies. Based on this, we estimate that adding MFT and MHC services (as necessary) to the patient care policies would take an additional quarter of the burden already allotted for biannual reviews. This would result in a one-time burden of 4,348 hours (0.50 hr x 8,695 RHCs and FQHCs) at a cost of $822,250 [(2,174 hr x $253.70/hr) + (2,174 hr x $124.52/hr)].

Table 9. One-time Requirement/Burden

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Permitting MFT and MHCs to Furnish Services in RHC/FQHCs	8,695 (2,769 RHCs + 5,926 FQHCs)	4,347	0.5	2,174	253.70 (Physician)	551,544
		4,348	0.5	2,174	124.52 (Mid-level Practitioner)	270,706
TOTAL	8,695	8,695	1.0	4,348	varies	822,250

While keeping our active response time estimates as is, we have also adjusted our number of responses by plus 1,634 (10,329 -8,695) and time by plus 4,520 hours (8,868 hr – 4,348 hr). Overall, we estimate an increase of 10,329 respondents, 10,329 responses, and 8,868 hours (see Table 10).

Table 10. All Adjustments and Program Changes

Requirement	Responses			Time per Response (hr)			Total Time (hr)		
	Current	Revised	Difference	Current	Revised	Difference	Current	Revised	Difference
Initial policy development for a new clinic or center (§ 491.9(b))	1,062	1,091	29	10	10	0	10,620	10,910	290
Biennial review of existing policies for every Medicare-certified clinic/center (§ 491.9(b))	16,601	17,389	788	2	2	0	33,202	34,778	1,576
Permitting MFT and MHCs to Furnish Services in RHC/FQHCs (§ 491.9(b))	-	8,695	8,695	-	1.0	1.0	-	4,348	4,348
Initial development of program evaluation (§ 491.11)	1,062	1,091	29	10	10	0	10,620	10,910	290
Conduct biennial program evaluation (§ 491.11)	16,601	17,389	788	3	3	0	49,803	52,167	2,364
TOTAL	35,326	45,655	10,329	25	26	1	104,245	113,113	8,868

We have also reformatted our burden tables in section 12 of this Supporting Statement with the aim of making them more reader friendly. To sync, we made the same change to our active ROCIS IC table. For example, our active Table 2 (below) has been reformatted to look like Tables 3 and 4 (also, below).

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

clinics/centers every 2 years				
	# 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**

PROPOSED Table 3 (see Section 12, above). Annual Burden for Initial Policy Development

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Initial policy development for a new clinic or center (§ 491.9(b)(2)	1,091 (323 New RHCs + 768 New FQHCs)	1,091	5	5,455	253.70 (Physician)	1,383,934
		1,091	5	5,455	124.52 (Mid-level Practitioner)	679,257
TOTAL	1,091	1,091	10	10,910	varies	2,063,190

PROPOSED Table 4 (see Section 12, above). Annual Burden for Periodic Reviews

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Biennial review of existing policies for every Medicare-certified clinic/center (§ 491.9(b)(2)	17,389 (5,537 Existing RHCs + 11,852 Existing FQHCs)	17,389	1	17,389	253.70 (Physician)	4,411,589
		17,389	1	17,389	124.52 (Mid-level Practitioner)	2,165,279
TOTAL	17,389	17,389	2	34,778	Varies	6,576,868

Also, what was eight ICs is now five from our reformatting effort.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

The expiration date is displayed.

18. Certification

There is no exception to the certification.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.