

Supporting Statement Medicare and Medicaid Programs: Conditions of Participation for  
Community Mental Health Centers and Supporting Regulations (CMS-10506, OMB Control  
number :0938-1245)

**A. Background**

The purpose of this package is to request a re-instatement with change to the Office of Management and Budget (OMB) of the collection of information requirements associated with the conditions of participation (CoPs) that Community Mental Health Centers (CMHCs) must meet to participate in the Medicare program.

On October 29, 2013, we published CoPs, for CMHCs (78 FR 64630). The CoPs included the following: *Personnel qualifications* (§ 485.904); *Client Rights* (§485.910); *Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client* (§ 485.914); *Treatment Team, Active Treatment Plan, and Coordination of Services* (§ 485.916); *Quality Assessment and Performance Improvement* (§ 485.917); and *Organization, Governance, Administration of Services, and Partial Hospitalization Services* (§ 485.918).

We finalized emergency preparedness requirements for CMHCs (§ 485.920) in the “2016 Emergency Preparedness (EP) Final Rule” published on September 16, 2016 (81 FR 63921). The information collections associated the EP CoPs requirements can be found under OMB Control Number 0938-1325 (CMS-10578).

On September 30, 2019, we published final rule, “*Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care,*” which revised the CMHC CoPs at § 485.914 (84 FR 51829, 51752 through 51754).

We finalized revisions to the CMHC CoPs in the “CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule,” published on November 22, 2023 (88 FR 81540, 82076 through 82079). This final rule revised the following conditions of participation : *Personnel qualifications* (§ 485.904), *Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client* (§ 485.914); *Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services* (§ 485.916); and *Organization, Governance, Administration of Services, Partial Hospitalization Services* (§ 485.918).

Medicare Part B covers partial hospitalization (PHP) services and intensive outpatient (IOP) services furnished by or under arrangements made by the CMHC if they are provided by a CMHC as defined in 42 CFR 410.110. Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101-508) amended sections 1832(a)(2) and 1861(ff)(3) of the Act to allow CMHCs to provide PHP services. Furthermore, the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-238) established in section 4124 coverage of IOP services in CMHCs. The legislation extended Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, adding to the existing coverage and payment for PHP services in CMHCs. Section 4121 of the CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs).

The services provided by CMHCs must be furnished by, or under arrangement with a CMHC participating in the Medicare program. They must include the following:

- Prescribed by a physician and furnished under the general supervision of a physician.
- Subject to certification by a physician in accordance with 42 CFR 424.24(e)(1).
- Furnished under a treatment plan that meets the requirements of 42 CFR 424.24(e)(2).
- Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from inpatient mental health facilities.
- Provides 24-hour-a-day emergency care services.
- Provides day treatment, partial hospitalization services (PHP) or intensive outpatient services (IOP) other than an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.
- Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such services unless otherwise directed by State law.
- Meets applicable licensing or certification requirements for CMHCs in the state in which it is located.
- Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Act.

We collect information on several health and safety aspects, such as *Client rights* (§ 485.910) *active treatment plans* (§ 485.916), *Quality assessment and performance improvement* (§ 485.917), and *governance* (§485.918).

## **B. Justification**

### **1. Need and Legal Basis**

The Statue governing CMHCs and partial hospitalization in Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101-508) amended sections 1832(a)(2) and 1861(ff)(3) of the Act to allow CMHCs to provide partial hospitalization services. Section 4124 in the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-238) established coverage of intensive outpatient (IOP) services in CMHCs. The legislation extended Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, adding to the existing coverage and payment for partial hospitalization (PHP) services in CMHCs. Section 4121 of the CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs).

The information collection requirements for which we request OMB approval are listed below. These requirements are among other requirements classified as Conditions of Participation (CoPs) and are based on criteria prescribed in law and are standards designed to ensure that each facility has properly trained staff to provide the appropriate safe physical environment for patients. These particular standards reflect comparable standards developed by industry organizations such as the Joint Commission.

### **2. Information Users**

The primary users of this information will be Federal and State agency surveyors for determining through the survey process, whether a CMHC qualifies for approval or re-approval under Medicare. CMS and its contractors will use this information to review claims to determine whether the patient is eligible for the PHP or IOP benefit and whether the claim meets the criteria for coverage and Medicare payment. Lastly, the information will be used by CMHCs to ensure their own compliance with all requirements to assist in guiding their patient care and quality programs. Surveyors make in-person visits to CMHCs to perform and complete surveys.

### 3. Use of Information Technology

CMHCs may use various information technologies to store and manage documentation and patient records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation does not prescribe how a CMHC should prepare or maintain these records. CMHCs are free to take advantage of any technological advances that they find appropriate for their needs.

### 4. Duplication

There is no duplication of information.

### 5. Small Business Impact

This information collection affects small businesses. However, we minimize the impact on small businesses by allowing flexibility in how information requirements are met so that providers can meet them in a way that is consistent with their existing operations. For example, as part of the quality assessment and performance improvement plan CMS requires the CMHC to assess its organization and services (§ 485.917). Based on the results of that assessment, the CMHC would choose which quality measures and data indicators it will collect, maintain, and analyze. CMS does not prescribe what type of quality measures and data elements the hospice should use in its internal quality assessment and performance improvement program. We leave this as flexible as possible for the CMHC to be able to choose measures and associated data elements that apply to the specific area(s) the CMHC has chosen to focus on.

### 6. Less Frequent Collection

With less frequent collection, CMS could not ensure timely compliance with CMHC CoPs. In addition, collecting less frequently could have a negative impact on the client's active treatment plan and services to treat the client's condition.

### 7. Special Circumstances Leading to Information Collection

There are no special circumstances for collecting this information.

### 8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on June 30, 2025 (90 FR 27868).

CMS received one comment from an individual. The comment was out of scope of the information collection (see Attachment A).

The 30-day Federal Register notice published on September 30, 2025 (90 FR 46895).

9. Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours and Wages)

The information collection requirements are shown below, with an estimate of the annual reporting and record-keeping burdens. The estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Many of the following requirements are performed only once by each CMHC, such as developing a standard client rights disclosure at § 485.910. We are not including the burden associated with certain patient-related activities under the Conditions of Participation for CMHCs 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). Many requirements would normally be performed by the CMHC in the normal course of responsible business practices in the absence of these requirements (such as the maintenance of in-service training records). Therefore, they impose a minimal, if any, burden on CMHCs.

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](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)
Registered Nurse	29-1141	39.16	39.16	78.32
Administrator	11-1021	54.05	54.05	108.10
Auditing or Accounting Clerk	43-3031	23.04	23.04	46.08

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 CMHCs 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 118 existing CMHCs, and approximately 8 new agencies entering the program.

We received the following Medicare statistical information from CY2021 - CY2023 Medicare claims. In 2023, 36 freestanding CMHCs served 885 Medicare beneficiaries and 590 non-Medicare clients, averaging 41 clients per CMHC. In order to develop the non-Medicare estimate, we divided the total number of Medicare beneficiaries who received PHP services in 2023 by the total number of Medicare-participating CMHCs who billed for PHP in 2023 to establish the average number of Medicare beneficiaries per CMHC. This resulted in 25 Medicare beneficiaries per CMHC. We then assumed that to comply with the 40 percent requirement, those 25 beneficiaries only accounted for 60 percent of an average CMHC’s total patient population. This meant that an average CMHC also treated another 16 clients who did not have Medicare as a payer source, for a total of 41 clients (Medicare + non-Medicare) in an average CMHC.

Table 2. Number of existing CMHCs and CMHC clients

Number of Medicare CMHCs billing for PHP	36
Number of New CMHCs per year	8
Number of CMHC clients nationwide	1,475 [885 (Medicare beneficiaries) + 590 (non-Medicare clients)]
Number of clients per average CMHC	41 [25 (Medicare beneficiaries) + 16 (non-Medicare clients)]

### § 485.910 Condition of participation: Client rights

CMHCs must ensure the protection of the rights of clients receiving care and must establish and maintain procedures to do so. Section 485.910 requires CMHCs to create a written notice of the client's rights and responsibilities that each client must understand and sign. Additionally, this CoP provides standards on the rights of the client, how to address violations of client rights, client rights regarding restraint and seclusion, staff training requirements, and death reporting requirements.

Section 485.910(a) requires that during the initial evaluation of each client, the CMHC must provide the client, the client’s representative, or surrogate with verbal and written notice of the client’s rights and responsibilities. Additionally, the CMHC must inform and distribute written information on the policies for filing a grievance. Lastly, the CMHC must obtain the client, or the client’s representative’s signature confirming they received a copy of the notice of rights and responsibilities.

*Initial policy development for a new CMHC:* We estimate that § 485.910(a)(1), the initial one-time effort to develop the written policies and procedures for a newly Medicare-certified CMHC

requires approximately 8 hours for the Administrator. This would result in a one-time burden of 64 hours (8 hr x 8 responses) at a cost of \$6,918 (64 hr x \$108.10).

**Obtaining and retaining client signature:** We estimate that § 485.910(a)(3) will take a Registered Nurse 2.5 minutes per client to obtain the client's and client representative's (if appropriate) signature confirming that he or she has received a copy of the notice of rights and responsibilities. This would result in an annual burden of 62 hours (.0417 hr x 1,475 responses) at a cost of \$4,856 (62 hr x \$78.32).

Table 3. Annual Burden for § 485.910(a), Client rights

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Initial policy development for a new CMHC	8	8	8	64	108.10 (Administrator)	6,918
Obtaining and retaining client signature	44 (36 existing CMHCs + 8 new CMHCs)	1,475	.0417 (2.5 minutes)	62	78.32 (Registered Nurse)	4,856
TOTAL	52	1,483	8.04	126	Varies	11,774

**Documentation of complaint:** Section 485.910(d)(2) requires a CMHC to document a client's or client representative's complaint of an alleged violation and the steps taken by the CMHC to resolve it. The burden of this requirement is the time it will take to document the necessary aspects of the issues. We reviewed the CMS survey data for CY 2021-CY 2023, and there were 21 complaints or an average of 7 complaints per year. We estimate it will take the administrator .0833 hours, or 5 minutes per complaint, at the rate of \$108.10/hour, to document the complaint and resolution activities. This will result in an annual total of .58 hr, or 35 minutes (.0833 hours x 7 complaints per year) for all CMHCs that receive a complaint. The estimated cost associated with this requirement is \$63 (.58 hr x \$108.10).

**Reporting complaint:** Section 485.910(d)(4) requires the CMHC to report, within 5 working days of becoming aware of the violation, all confirmed violations to the state and local bodies having jurisdiction. We anticipate that it will take the administrator 5 minutes (.0833 hours) per complaint to report, for an annual total of 0.58 hr, or 35 minutes (.0833 hours x 7 complaints per year) for all CMHCs. The estimated cost associated with this requirement is \$63 (.58 hr x \$108.10).

Table 4. Annual Burden for § 485.910(d), Documenting and Reporting a Complaint

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Documentation of complaint	7	7	.0833 (5 minutes)	.58	108.10 (Administrator)	63
Reporting complaint	7	7	.0833 (5 minutes)	.58	108.10 (Administrator)	63
TOTAL	14	14	.17	1	216.20	126

*Documenting restraint or seclusion:* Section 485.910(e)(2) requires written orders for physical restraint or seclusion, and §485.910(e)(4)(v) requires physical restraint or seclusion be supported by documentation in the client’s clinical record of the client’s response or outcome. The burden associated with this requirement is the time and effort necessary to document the use of physical restraint or seclusion in the client’s clinical record. We estimate that a nurse will take .75 hr., or 45 minutes per event, to document this information. Similarly, we estimate that there will be 1 occurrence of the use of physical restraint or seclusion per CMHC annually. The estimated annual burden associated with this requirement for all CMHCs is 27 hours (.75 hours x 36 CMHCs). The estimated cost associated with this burden for all CMHCs is \$2,115 (27 hours x \$78.32 nurse).

Table 5. Annual Burden for § 485.910(e)(4), Documenting a restraint or seclusion

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Documenting restraint or seclusion	36	36	.75 (45 minutes)	27	78.32 (Registered Nurse)	2,115
TOTAL	36	36	.75	27	78.32	2,115

*Documenting staff training:* Section 485.910(f) specifies restraint or seclusion staff training requirements. Specifically, §485.910(f)(1) requires that all client care staff working in the CMHC be trained and able to demonstrate competency in the application of restraints and implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion, and on the use of alternative methods to restraint and seclusion. Section 485.910(f)(4) requires that a CMHC document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency in the skill. We estimate that it will take a nurse .5833 hr., or 35 minutes per CMHC, to comply with these requirements. These requirements estimated total annual burden is 21 hours (.5833 hours x 36 CMHCs). The estimated cost associated with this requirement is \$1,645 (21 x \$78.32).

Table 6. Annual Burden for § 485.910(f)(4), Staff training

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Documenting staff training	36	36	.5833	21	78.32 (Registered Nurse)	1,645
TOTAL	36	36	.5833	21	78.32	1,645

*Death Reporting Requirements:* Section 485.910(g) requires the CMHC to report any death that occurred in a CMHC while the client was in restraint or seclusion awaiting transfer to a hospital. We have a parallel requirement in all other CMS rules dealing with programs and providers where restraint or seclusion may be used (for example, in our hospital conditions of participation). Based on informal discussions with the CMHC industry and The Joint Commission, we believe restraints and seclusion are rarely used in CMHCs, and very few deaths (if any) occur due to restraint or seclusion in a CMHC. Several comments received related to the proposed CMHC rule (76 FR 35684) published on June 17, 2011, stated that the majority of CMHCs have a restraint or seclusion-free policy. Therefore, restraint or seclusion is not permitted in these agencies. Hence, we believe the number of deaths associated with this

requirement is estimated at zero. Under 5 CFR 1320.3(c)(4), this requirement is not subject to the PRA as it would affect fewer than 10 entities in a 12-month period.

#### § 485.914 Condition of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client

Section 485.914(b) through (e) requires each CMHC to conduct and document in writing an initial evaluation and a comprehensive client-specific assessment; maintain documentation of the assessment and any updates; and coordinate the discharge or transfer of the client.

Per § 485.914(b), a licensed mental health professional employed by the CMHC and acting within his or her state scope of practice requirements must complete the initial evaluation within 24 hours of the client's admission to the CMHC. Additionally, § 485.914(c)(1) requires CMHCs to conduct a comprehensive assessment for each of their clients and that these assessments be completed by licensed mental health professionals who are interdisciplinary treatment team members. At § 485.914(d)(1) CMHCs must also update each client's comprehensive assessment when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. Additionally, under § 485.914(d)(2), each client admitted for PHP or IOP services will also receive assessment updates every 30 days. Last, § 485.914(e) requires that, if the client were transferred to another facility, the CMHC is required to forward a copy of the client's CMHC discharge summary and clinical record, if requested, to that facility.

*Initial evaluation:* The initial evaluation, at a minimum, must include the admitting diagnosis as well as other diagnoses, the source of referral, the reason for admission as stated by the client or other individuals who are significantly involved, and the identification of the client's immediate clinical care needs related to the psychiatric diagnosis. The initial evaluation must also include a list of current prescriptions, over-the-counter medications, and other substances the client may be taking. For PHP services only, the initial evaluation must explain why the client would be at risk for hospitalization if the PHP services were not provided. We believe that the burdens associated with § 485.914(b) the time required to record the initial evaluation and comprehensive assessment and that this documentation is usual and customary business practice under 5 CFR 1320.3(b)(2) and as such, the burden associated with these requirements is exempt from PRA.

*Comprehensive assessment:* We estimate that the burdens associated with § 485.914(c) the time required to record the initial evaluation and comprehensive assessment and that this documentation is usual and customary business practice under 5 CFR 1320.3(b)(2) and as such, the burden associated with these requirements is exempt from PRA.

*Updating the comprehensive assessment for non-Medicare clients:* The burden of these requirements is the time required to record an updated assessment. Therefore, under § 485.914(d)(1), we estimate that 36 CMHCs bill Medicare for PHP and IOP services, and averages 590 non-Medicare clients, and that the time it will take for a Registered Nurse to document the update of the comprehensive assessment will be .1667 hours, or 10 minutes per non-Medicare client. We estimate that, in accordance with the need-based assessment update requirements, each non-Medicare client would receive 2 assessment updates in a year.

Table 7. Annual Burden for § 485.914(d)(1), Updating non-Medicare Client's Comprehensive Assessment



Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Updating the comprehensive assessment for non-Medicare clients	36	1,180 (590 non-Medicare clients x 2 assessments)	.1667 (10 minutes)	197	78.32 (Registered Nurse)	15,429
TOTAL	36	1,180	.1667	197	78.32	15,429

Updating the comprehensive assessment for PHP and IOP clients: Additionally, under § 485.914(d)(2), each client admitted for PHP or IOP services will also receive assessment updates every 30 days. However, under § 424.24(e), the CMHC is required to update the PHP or IOP client's recertification and plan of treatment every 30 days. To update the recertification and plan of treatment, the CMHC would need to update the client's assessment. Therefore, the assessment update requirements at § 485.914(d)(3) would not impose a burden because the CMHC would already perform an assessment update every 30 days to meet the plan of care update requirements necessary for Medicare payment. In short, the 30-day assessment update would be performed in the absence of the regulation at § 485.914(d)(2), and, as such, the burden associated with it is exempt from the PRA.

Discharge or transfer of the client: Section 485.914(e) requires that, if the client were transferred to another facility, the CMHC is required to forward a copy of the client's CMHC discharge summary and clinical record, if requested, to that facility. If a client is discharged from the CMHC because of non-compliance with the treatment plan or refusal of services from the CMHC, the CMHC must provide a copy of the client's discharge summary and clinical record, if requested, to the client's primary health care provider. The burden associated with this requirement is the time it takes to forward the discharge summary and clinical record if requested. This requirement is considered to be a usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

#### § 485.916 Condition of Participation: Treatment Team, Active Treatment Plan, and Coordination of Services

Section 485.916(b) requires all CMHC services furnished to clients and their families to follow a written active treatment plan established by the interdisciplinary treatment team. The CMHC must ensure that each client and representative receives education provided by the CMHC, as appropriate, for the care and services identified in the active treatment plan.

Developing the active treatment plan: The requirements at § 485.916(c) specify the minimum elements that the active treatment plan must include. We estimate that developing an active treatment plan will take a Registered Nurse approximately .1667 hours, or 10 minutes per client, for a total annual burden of 246 hours (.1667 hr x 1,475 clients). The estimated cost associated with this requirement is \$19,266.72 (246 hr x 78.32).

Updating the active treatment plan: In addition, at § 485.916(d), the interdisciplinary team must review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's updated comprehensive assessment and must document the client's progress toward the outcomes specified in the active treatment plan. We estimate that it will take a Registered Nurse .0833 hours, or 5 minutes to update the active treatment plan with an estimated 2 updates per client, or a total of 10 minutes per client. The total annual burden for

a Registered Nurse to update the active treatment plan is 246 hours  $((.0833 \text{ hr} \times 1,475) \times 2)$ . The estimated cost associated with this requirement is \$19,267  $(246 \text{ hr} \times 78.32)$ .

Table 8. Annual Burden for § 485.916, Development and Updates to a Client's Active Treatment Plan

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Developing the active treatment plan	1,475 (855 Medicare beneficiaries + 590 Medicare beneficiaries)	1,475	.1667	246	78.32 (Registered Nurse)	19,267
Updating the active treatment plan	1,475 (855 Medicare beneficiaries + 590 Medicare beneficiaries)	2,950 (2 updates/client)	.0833	246	78.32 (Registered Nurse)	19,267
TOTAL	1,475	4,425	.25	492	78.32	38,534

Coordination of Services: Section 485.916(e) requires a CMHC to develop and maintain a system of communication and integration to ensure compliance with the requirements at § 485.916(e)(1) through (e)(5). The burden associated with this requirement will be the time and effort required to develop and maintain the communication system in accordance with the CMHC's policies and procedures. We believe that the requirement is usual and customary business practice under 5 CFR 1320.3(b)(2) and, as such, the burden associated with it is exempt from the PRA.

#### § 485.917 Condition of Participation: Quality assessment and performance improvement

Section 485.917 requires a CMHC to develop, implement, and maintain an effective ongoing CMHC-wide data-driven quality assessment and performance improvement (QAPI) program. The CMHC is required to maintain and demonstrate evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS. The CMHC must take actions aimed at performance improvement and, after implementing those actions, must measure its success and track its performance to ensure that improvements were sustained. The CMHC is required to document what quality improvement projects were conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

Initial development of the QAPI Program: We estimate that the initial one-time effort for the administrator to create a QAPI program for a newly Medicare-certified CMHC requires approximately 9 hours. This requirement has an estimated total annual burden of 72 hours  $(9 \text{ hr} \times 8 \text{ new CMHCs})$ . The estimated cost associated with this requirement is \$7,783  $(72 \text{ hr} \times \$108.10)$ .

Implementation of the QAPI Program: We also estimate that the administrator will spend 4 hours a year collecting and analyzing data. In addition, we estimate that a CMHC will spend 3 hours a year training their staff and 4 hours a year implementing performance improvement activities. Because the CMHC must implement a QAPI program annually, the number of hours every CMHC must spend on their QAPI program is 11 hours per year. This requirement has an

estimated total annual burden of 484 hours (11 hr x 44 total CMHCs). The estimated cost associated with this requirement is \$52,320 (484 hr x \$108.10).

Table 9. Annual Burden for § 485.917, Initial Development and Implementation of the QAPI Program

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Initial Development of the QAPI program	8	8	9	72	108.10 (Administrator )	7,783
Implementing the QAPI Program	44 (36 existing CMHCs + 8 new CMHCs)	44	11	484	108.10 (Administrator )	52,320
TOTAL	52	52	20	556	108.10	60,103

§ 485.918 Condition of Participation: Organization, governance, administration of services, partial hospitalization services, and intensive outpatient services

Section 485.918(b) lists the care and services a Medicare CMHC must primarily engage in regardless of payer type. Specifically, § 485.918(b)(1)(v) requires each CMHC to provide at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act as measured by the total number of CMHC clients treated by the CMHC and not paid for by Medicare, divided by the total number of clients treated by the CMHC. The burden associated with this requirement is the time it takes for an independent entity, auditing or accounting clerk, contracted by the CMHC to calculate compliance with the 40 percent requirement and create a letter for the CMHC to submit to CMS. CMHCs are required to revalidate their compliance with this requirement every 5 years.

*Initial Compliance and Certification Statement:* To enroll in Medicare, a certification statement is required upon initial application. We estimate the initial one-time effort for an auditing or accounting clerk to calculate compliance with the 40 percent requirement and create the certification statement requires 1 hour. This requirement has an estimated total annual burden of 8 hours (1 hr x 8 new CMHCs). The estimated cost associated with this requirement is \$369 (8 hr x \$46.08).

*Revalidation of Compliance and Certification Statement:* We estimate that calculating compliance with the 40 percent requirement and create a certification letter to submit to CMS requires approximately 5 hours for each CMHC that is due for its 5-year revalidation, or 1 hour annually. Based on the average number of CMHCs due for revalidation during CY 2021 – CY 2023 provided to us by the Center for Program Integrity (CPI), we estimate there will be 6 CMHC applicants per year who must revalidate their compliance with the 40 percent requirement as well as submit a certification statement to CMS. This requirement has an estimated total annual burden of 6 hours (1 hr x 6 CMHCs due for revalidation). The estimated cost associated with this requirement is \$277 (6 hr x \$46.08).

Table 10. Annual burden for § 485.918, Initial and Revalidation of the Compliance and Certification Statement

Requirement	Respondents	Responses	Time per	Total time	Labor Cost	Total Cost
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			Response (hr)	(hr)	(\$/hr)	(\$)
Initial Compliance and Certification Statement for new CMHCs	8	8	1	8	46.08 (Auditing or Accounting Clerk)	369
Revalidation of Compliance and Certification Statement for existing CMHCs	6	6	1	6	46.08 (Auditing or Accounting Clerk)	277
TOTAL	14	14	2	14	46.08	646

**Professional management responsibility:** Section 485.918(c) lists the CMHC’s professional management responsibilities. A CMHC could enter into a written agreement with another agency, individual, or organization to furnish any services under the arrangement. The CMHC is required to retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care. The burden associated with this requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreements. We believe these written agreements are part of the usual and customary business practices of CMHCs under 5 CFR 1320.3(b)(2) and, as such, the burden associated with them is exempt from the PRA.

**Staff Training:** Section 485.918(d) describes the standard for training. In particular, § 485.918(d)(2) requires a CMHC to provide an initial orientation for each employee, contracted staff member, and volunteer that addresses the employee’s or volunteer’s specific job duties. Section 485.918(d)(3) requires a CMHC to have written policies and procedures describing its method(s) of assessing competency. In addition, the CMHC must maintain a written description of the in-service training provided during the previous 12 months. These requirements are considered to be usual and customary business practices under 5 CFR 1320.3(b)(2) and, as such, the burden associated with them is exempt from the PRA.

**Physical Environment:** Section 485.918(e)(3) requires the CMHC to maintain policies, procedures, and monitoring of an infection control program to prevent, control, and investigate infection and communicable diseases. The burden associated with this requirement is the time it takes to develop and maintain policies and procedures and document the monitoring of the infection control program. We believe this documentation is part of the usual and customary medical and business practices of CMHCs and, as such, is exempt from the PRA under 5 CFR 1320.3(b)(2).

#### Summary of Annual Burden Estimates

The total burden hours are 1,434. The total cost of all information collection requirements is approximately \$122,885. We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

Table 11. Burden and Cost Estimates Associated with Information Collection Requirements

Regulation Sections	OMB	Respondents	Responses	Burden per Response	Total Annual Burden (hr)	Hourly Labor Cost of Reporting (\$)	Total Labor Costs of Reporting (\$)
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				(hr)			
§485.910 (a)(1)	0938- 1245	8	8	8	64	108.10	6,918
§485.910 (a)(3)	0938- 1245	44	1,475	.0417	62	78.32	4,856
§485.910 (d)(2)	0938- 1245	7	7	.0833	1	108.10	63
§485.910 (d)(4)	0938- 1245	7	7	.0833	1	108.10	63
§485.910 (e)(4)(v)	0938- 1245	36	36	.75	27	78.32	2,115
§485.910 (f)(4)	0938- 1245	36	36	.5833	21	78.32	1,645
§485.914 (d)(1)	0938- 1245	36	1,180	.1667	197	78.32	15,429
§ 485.916(c)	0938- 1245	1,475	1,475	.1667	246	78.32	19,267
§ 485.916(d)	0938- 1245	1,475	2,950	.0833	246	78.32	19,534
§ 485.917	0938- 1245	52	52	20	556	108.10	60,103
§ 485.918 (b)	0938- 1245	14	14	2	14	46.08	646
TOTAL			7,240		1,435		\$130,639

### 13. Capital Costs

There are no capital costs.

### 14. Cost to Federal Government

Under the *1864 Agreement*,<sup>1</sup> State Survey Agencies review CMHCs for compliance with the CoPs. While state surveyors conduct this review, CMS funds the states through contracts to support these activities. The cost to the federal government is the cost for the state to assess CMHCs for compliance with the CoPs is **388** total annual burden hours with an annual cost of **\$22,892**.

The burden for completing this responsibility was calculated using a loaded hourly median wage of \$59 per hour for a State Survey Agency reviewer (BLS Occupation Code 19-3022) which includes benefits and overhead. For initial compliance review, we estimate the cost to the Federal government to ensure each facility's compliance to be 4 hours, with a net cost of \$236 per facility (4 hours x \$59). For ongoing compliance, we estimate the cost to the Federal government to ensure each facility's compliance to be 1 hour, with a net cost of \$59 per facility (1 hour x \$59). The burden to the Federal government for each applicable information collection (IC) is calculated below with only those facilities that are impacted by each IC.

For this reinstatement,

<sup>1</sup> Center for Medicaid and Medicare (CMS). (2022). "State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement". <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfo/policy-and-memos-states-and/state-obligations-survey-entirety-medicare-and-medicaid-health-and-safety-requirements-under-1864>

Table 12. Total Burden and Costs for Federal Government

Regulation Sections	# of Facilities	Hourly Wage	Hours/Task	Total Burden Hours	Total Burden Costs
§485.910 (a)(1)	8	\$59	4	32	\$1,888
§485.910 (a)(3)	44	\$59	1	44	\$2,596
§485.910 (d)(2)	7	\$59	1	7	\$413
§485.910 (d)(4)	7	\$59	1	7	\$413
§485.910 (e)(4)(v)	36	\$59	1	36	\$2,124
§485.910 (f)(4)	36	\$59	1	36	\$2,124
§485.914 (d)(1)	36	\$59	1	36	\$2,124
§ 485.916(c)	36	\$59	1	36	\$2,124
§ 485.916(d)	36	\$59	1	36	\$2,124
§ 485.917 – Initial Development QAPI Program	8	\$59	4	32	\$1,888
§ 485.917 – Implementing QAPI Program	44	\$59	1	44	\$2,596
§ 485.918 (b) - Initial Compliance and Certification Statement	8	\$59	4	36	\$2,124
§ 485.918 (b) - Revalidation of Compliance and Certification Statement	6	\$59	1	6	\$354
TOTAL				388	\$22,892

### 15. Changes to Burden

The overall change in burden from the previously approved package is a decrease of 1,883 total annual burden hours, from 3,218 hours to 1,435 hours. This is because there has been a reduction in the number of CMHCs billing Medicare (from 52 CMHCs in 2015 to 36 CMHCs in 2021), as well as a decrease of clients receiving services at a CMHC (from 5,202 clients in 2015 to 1,475 clients in 2021).

In addition to estimating burden hours, we have estimated costs for these burden hours based on average hourly wages for nurses, administrators, and auditing or accounting clerks. We obtained

these average hourly wages from the United States Bureau of Labor Statistics’ May 2023 National Occupational Employment and Wage Estimates United States ([https://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](https://www.bls.gov/oes/current/oes_nat.htm#00-0000)) accessed on August 15, 2024. In accordance with current policy and to ensure we more accurately account for overhead and fringe benefits, we have increased the amount we add to the average hourly rate for each position to an amount equal to 100 percent of the hourly rate.

For the preceding package, we estimated that the average number of CMHCs billing Medicare was 52, with approximately 3 CMHCs entering the Medicare program per year. We also estimated the total burden was \$235,026, which averages to \$4,518 per agency (\$235,026/52).

For the current package, we estimate the average number of CMHCs billing Medicare is 36, with approximately 8 CMHCs entering the Medicare program per year. We estimate that the total burden is \$122,885, which averages to \$3,413 per agency (\$122,885/36).

This iteration of the Supporting Statement also includes a change to § 485.917 *Condition of Participation: Quality assessment and performance improvement* to include a burden for CMHCs entering the Medicare program. CMHCs are required to develop, implement, and maintain an effective ongoing CMHC-wide data-driven quality assessment and performance improvement (QAPI) program (78 FR 64617). Newly Medicare-certified CMHCs must develop a QAPI program aimed at performance improvement. Once implemented, to ensure that CMHCs sustain their improvements, they must track their success and performance. We estimate that the initial one-time effort for the administrator to create a QAPI program for a newly Medicare-certified CMHC requires approximately 9 hours. This requirement has an estimated total annual burden of 72 hours (9 hr x 8 new CMHCs). The estimated cost associated with this requirement is \$7,783 (72 hr x \$108.10).

Table 13. Initial Development of the QAPI Program

Requirement	Respondents	Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
Initial Development of the QAPI Program	8	8	9	72	108.10 (Administrator )	7,783
TOTAL	8	8	9	72	108.10	7,783

Table 14. Total Hours

IC	Prior ICR Hours	Current ICR Hours
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42 CFR 485.910(a)(1)	24	64
42 CFR 485.910(a)(3)	217	62
42 CFR 485.910(d)(2)	104	1
42 CFR 485.910(d)(4)	104	1
42 CFR 485.910(e)(4)(v)	39	27
42 CFR 485.910(f)(4)	30	21
42 CFR 485.914(d)	693	197
42 CFR 485.916(c)	867	246
42 CFR 485.916(d)	867	246
42 CFR 485.917	208	556
42 CFR 485.918(b)	65	14
Total hours	3,218	1,435

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

**C. Collections of Information Employing Statistical Methods**

These information collection requirements do not employ statistical methods.