

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

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the extension of the collection of information requirements for the conditions of participation (CoPs) that community mental health centers (CMHC) must meet to participate in the Medicare program. On October 29, 2013, we published for the first time new conditions of participation for CMHCs with an effective date 12 months after publication of the final rule.

Medicare part B covers partial hospitalization 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 partial hospitalization services. Under the Medicare program, apart from limited telehealth services, CMHCs are recognized as Medicare providers only for partial hospitalization services (see 42 CFR

§410.110). These services must be furnished by, or under arrangement with a CMHC that participates 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 plan of treatment 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 other than in 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 aspects of health and safety such as in patient rights, active treatment plan, quality assessment and performance improvement and governance. Section 1832(a)(2)(J) of the Act establishes coverage of partial hospitalization services for Medicare beneficiaries in CMHCs. Section 1861(ff)(2) of the Act defines partial hospitalization services as a broad range of mental health services “that are reasonable and necessary for the diagnosis or active treatment of the individual’s condition, reasonably expected to improve or maintain the individual’s condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish....”

In particular, Sections 1102 and 1871 of the Social Security Act (the Act) give CMS the general authority to establish CoPs for Medicare providers. Therefore, we established for the first time for Medicare-certified CMHCs.

Additionally, CMS published revisions to certain CMHC Conditions of Participation related to the update of the comprehensive assessment on September 30, 2019 (84 FR 51732).

B. Justification

1. Need and Legal Basis

The Statute governing CMHC's and Partial Hospitalization at be found at 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. The information collection requirements for which we are requesting OMB approval are listed below. These requirements are among other requirements classified as (or known as) the CoPs which 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 for reviewing claims as a basis for determining whether the patient is eligible for the Partial Hospitalization Plan (PHP) benefit and whether the claim meets criteria for coverage and Medicare payment. Lastly, the information will be used by CMHC's for assuring their own compliance with all requirements to assist in guiding their patient care and quality programs.

3. Use of Information Technology

CMHC's may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record-keeping regulations at 42 CFR 485.638. This regulation in no way prescribes how a CMHC should prepare or maintain these records. CMHC's 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, in 485.918, Quality assessment and performance improvement, CMS requires the CMHC's to conduct an assessment of its organization and services. 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 would not be able to 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

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

9. Payment 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. Included in the estimates is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

In 2015 there were 52 Community Mental Health Centers. Based on growth figures for the last three years, we estimate that there will be approximately 3 agencies per year entering the program. In 2015, 52 freestanding CMHCs served 3,122 Medicare beneficiaries and 2,080 non-Medicare clients for an average of 100 clients per CMHC. In order to develop the non- Medicare estimate we divided the total number of Medicare beneficiaries who received partial hospitalization services in 2015 by the total

number of Medicare-participating CMHCs in 2015 to establish the average number of Medicare beneficiaries per CMHC. This resulted in 60 Beneficiaries per CMHC. We then assumed that, in order to comply with the 40 percent requirement, those 60 beneficiaries only accounted for 60 percent of an average CMHC's total patient population. This meant that an average CMHC also treated another 40 clients who did not have Medicare as a payer source, for a total of 100 clients (Medicare + non-Medicare) in an average CMHC.

Many of the following requirements are performed only once by each CMHC (such as the development of a standard client rights disclosure), and many 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) and therefore represent a minimal, if any, burden on CMHCs.

Salary estimates:

Number of Medicare CMHCs nationwide (Based on CY 2015 CMS data)	52
Number of CMHC clients nationwide* (Estimate based on CY 2015 data)	5,202
Number of clients per average CMHC	100
Hourly rate of psychiatric nurse	\$71
Hourly rate of clinical psychologist	\$70
Hourly rate of administrator	\$91
Hourly rate of clinical social worker	\$54
Hourly rate of mental health counselor	\$43
Hourly rate of auditing or accounting clerk	\$36

*Reflects 3,122 Medicare clients and 2,080 non-Medicare clients.

Note: All salary information is from the Bureau of Labor Statistics (BLS) website at https://www.bls.gov/oes/2015/may/oes_nat.htm and includes a fringe benefits package worth 100% of the base salary. Hourly rates are based on May 2015 BLS data for each discipline, for those providing outpatient health services. FY = Fiscal Year

**Medicare statistical information (where noted) is from CY2015 claims.

- §485.910 Condition of participation: Client rights

Section 485.910(a) requires that the CMHC develop a notice of rights statement to be provided to each client. We estimate that 3 new CMHC's will become new Medicare providers per year. We estimate that it will require these new providers 8 hours on a one-time basis to develop this notice, and the CMHC administrator at the rate of \$91/hour would be responsible for this task, at a cost of \$728 (8 hours X \$91) per CMHC and \$2,184 (\$728 X 3 CMHCs) for all new CMHCs. In addition, this standard requires that the CMHC 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. The CMHC will have to retain the signed documentation showing that it complied with the requirements, and that the client and the

client's representative demonstrated an understanding of these rights. We estimate that the time it will take for the CMHC to document the information will be 2.5 minutes per client or approximately 4.17 hours per CMHC. At an average of 2.5 minutes (.0417 hours) per client to complete both tasks, we estimate that all CMHCs will use 217 hours to comply with this requirement (.0417 hours per client x 5,202 clients). The estimated cost associated with these requirements is \$15,407, based on a psychiatric nurse performing this function (217 hours x \$71 per hour).

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 associated with this requirement is the time it will take to document the necessary aspects of the issues. In late 2016, we took a look at the CMS survey data and we anticipate 24 complaints per year per CMHC and that it will take the administrator 5 minutes per complaint at the rate of \$91/hour to document the complaint and resolution activities, for an annual total of 2 hours per CMHC or 104 hours (.0833 hours X 1,248 responses) for all CMHCs. The estimated cost associated with this requirement is \$9,464 (104 hours X \$91).

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 per complaint to report, for an annual total of 2 hours per CMHC or 104 hours (.0833 hours X 1,248 responses) for all CMHCs. The estimated cost associated with this requirement is \$9,464 (104 hours X \$91).

Section 485.910(e)(2) requires written orders for a physical restraint or seclusion, and §485.910(e)(4)(v) requires physical restraint or seclusion be supported by a 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 it will take 45 minutes per event for a nurse 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 39 hours (.75 hours X 52 CMHCs). The estimated cost associated with this burden for all CMHCs is \$2,769 (39 hours X \$71 nurse).

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 35 minutes per CMHC to comply with these requirements. The estimated total annual burden associated with these requirements is 30.33 hours (35 x 52= 1820/60). The estimated cost associated with this requirement is \$2,153 (30.33 x \$71).

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, if ever, used in CMHCs, and that there are very few deaths (if any) that 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. Specifically, §485.914(b) requires 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. 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 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 and over-the-counter medications, as well as other substances that the client may be taking. For partial hospitalization services only, the initial evaluation must include an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided. §485.914(c)(1) requires the CMHC to conduct a comprehensive assessment on each client, to be completed by licensed mental health professionals who are members of the interdisciplinary treatment team. We estimate each CMHC averages 100 clients per CMHC. We believe that the burdens associated with these requirements is the time required to record the initial and comprehensive assessment and that this documentation is usual and customary business practice under 5CFR 1320.3(b)(2) and as such, the burden associated with these requirements is exempt from PRA.

Section §485.914(d)(1) requires that the CMHC update each client's comprehensive assessment via the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred, and in accordance with current standards of practice. Additionally at §485.914(d)(3), we require the minimum 30 day assessment update time frame for those clients who receive PHP services. The burden associated with these requirements is the time required to record an updated assessment. We estimate that, in accordance with the need-based assessment update requirements, each non-PHP client would receive 2 assessment updates in a year. Therefore, under §485.914(d)(1) we estimate that each CMHC averages 40 non PHP clients per CMHC and that the time it will take for the CMHC to document the update of the comprehensive assessment will be 10 minutes per client, or approximately 7 hours per CMHC. Additionally, we estimate each client will have 2 updates of the comprehensive assessment, and that each CMHC will spend approximately 14 hours total (7 hours x 2) on assessment updates per year. Since an updated assessment averages of 10 minutes (.1667 hours) per client/assessment to complete the task and each client will have 2 updated assessments, we estimate that all CMHCs will use 693 hours to comply with this requirement (.1667 hours per client x 2,080 clients x 2 updates). The estimated cost associated with this requirement is \$49,203 based on a psychiatric nurse performing this function (693 hours x \$71 per hour).

Additionally, under §485.914(d)(3), each client admitted for PHP services will also receive assessment updates every 30 days. However, under §424.24(e) the CMHC is required to update PHP 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 burden because the CMHC would already perform an assessment update every 30 days in order to meet the plan of care update requirements that are necessary as a condition for Medicare payment. In short, the 30 day assessment update would be performed in the absence of the regulation at §485.914(d)(3) and, as such, the burden associated with it is exempt from the PRA.

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 is required to 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 care and services furnished to clients and their families to follow a written active treatment plan established by the interdisciplinary treatment team. The CMHC is required to 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.

The provisions at §485.916(c) specify the minimum elements that the active treatment plan must include. In addition, in §485.916(d), the interdisciplinary team is required to 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. The burden associated with these requirements is the time it takes to document the active treatment plan, approximately 10 minutes per client or approximately 867 hours ($10 \times 5202 = 52,020/60$) annually, estimated to be a total of \$1,183.78 ($10 \times 100 = 1000/60 = 17 \times \71) per CMHC or \$61,557 ($867 \times \71) annually. Additionally, we estimate a revisions to the active treatment plan (approximately a total of 10 minutes (5 min per update with an estimated 2 updates per client) will cost \$61,557 annually ($867 \text{ hours} \times \$71/\text{hour}$)).

- Section 485.916(e) requires a CMHC to develop and maintain a system of communication and integration to ensure compliance with the requirements contained in

§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 system of communication 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 is required to 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.

The burden associated with these requirements is the time it takes to document the development of the quality assessment and performance improvement and associated activities. We estimate that it will take each CMHC administrator an average of 4 hours per year at the rate of \$91/hour to comply with these requirements for a total of 208 hours annually (4 x 52). The estimated cost associated with this requirement is \$18,928 (208 x \$91).

- §485.918 Condition of Participation: Organization, Governance, Administration of Services, and Partial Hospitalization Services

Section 485.918(b) lists care and services a Medicare CMHC must be primarily engaged in regardless of payer type. Specifically, §485.918(b)(1)(v) requires the 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 contracted by the CMHC to calculate compliance with the 40 percent requirement and create a letter for the CMHC to submit to CMS. We estimate it will take the independent entity an average of 5 hours at \$36 per hour per new CMHC applicant and 5 hours for each CMHC that is due for its every 5 year revalidation to calculate compliance with the 40 percent requirement and create a letter to CMS. We estimate there will be 3 new CMHC applicants per year for a total of 15 hours annually and an estimated cost of \$540 (15x \$36). We estimate there will be 10 CMHCs up for revalidation each year for a total of hours for all CMHCs, with an estimated cost of \$1,800 (50 x \$36). Therefore, the annual reporting for new CMHC applicants and CMHC revalidation is estimated at 65 hours with a total cost of \$2,340 (65 x \$36).

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 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.

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 is required to 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 are exempt from the PRA.

Section 485.918(e)(3) requires the CMHC to maintain policies, procedures, and monitoring of an infection control program for the prevention, control and investigation of 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).

Total Burden Estimate

The total burden hours are 3,218. The total cost of all information collection requirements is approximately \$235,026. We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

Table 1: Burden and Cost Estimates Associated with Information Collection Requirements

Regulation Sections	OMB	Respondents	Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor Cost of Reporting	Total Labor Costs of Reporting
§485.910 (a)(1)	0938-1245	3	3	8	24	91	2,184
§485.910 (a)(3)	0938-1245	52	5,202	.0417	217	71	15,407
§485.910 (d)(2)	0938-1245	52	1,248	.0833	104	91	9,464
§485.910 (d)(4)	0938-1245	52	1,248	.0833	104	91	9,464
§485.910 (e)(4)(v)	0938-1245	52	52	.75	39	71	2,769
§485.910 (f)(4)	0938-1245	52	364	.0833	30	71	2,153
§485.914 (d)	0938-1245	52	4,160	.1677	693	71	49,203
§485.916 (c)	0938-1245	52	5,202	.1667	867	71	61,557
§485.916 (d)	0938-1245	52	5,202	.1667	867	71	61,557
§485.917	0938-1245	52	52	4	208	91	18,928
§485.918 (b)	0938-1245	13	13	5	65	36	2,340
Total			22,746		3,218		\$235,026

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The budget impacts to the Medicare and Medicaid programs resulting from implementation of this non-economically significant rule are negligible. Even though there continues to be CMS activities, such as on-site surveys, as a result of this rule, CMS will likely be compelled by budgetary constraints to accommodate these activities into its existing budget. We note, however, that the rule-induced activities

have an opportunity cost equal to the value of activities that would have been done in the rule's absence.

15. Changes to Burden

These ICRs have been updated in accordance with the finalized regulations at § 485.914(d) in 84 FR 51732. These burden estimates are unchanged from what was estimated for the proposed rule, which resulted in an annual burden of 3,218 hours. There is, however, one discrepancy between these estimates and the estimates in the aforementioned final rule. In the final rule, the estimates were inadvertently changed to indicate that the requirements would impact all 161 CMHCs rather than just the approximately 52 Medicare-participating CMHCs. As a result, the number of CMHCs and burden hours may slightly differ from what was calculated in the final rule.

We also note that the Emergency Preparedness Requirements for CMHCs that were finalized in 84 FR 51732 can be found under OMB Control Number 0938-1325.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS will display the 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.