**Supporting Statement for the Paperwork Reduction Act Submission,
Medicare and Medicaid Programs: Conditions of Participation
for Community Mental Health Centers and Supporting Regulations in 42 CFR 485
(CMS-, OMB Control #:)**

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval 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 (CMS-, OMB #). On June 17, 2011, we proposed for the first time new conditions of participation for CMHCs; and these revisions are due to be published as a final rule in October of 2013, 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.

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 are establishing for the first time a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program.

B. Justification

1. Need and Legal Basis

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 State agency surveyors, CMS and CMHCs for the purpose of ensuring compliance with Medicare CoPs as well as ensuring the quality of care provided by CMHCs to patients.

3. Use of Information Technology

CMS does not require a specific format for maintaining the documentation required in this information collection. CMHCs are free to select the most efficient and effective documentation format for their needs, including the maintenance of electronic records in accordance with their unique technical capabilities.

4. Duplication

There is no duplication of information.

5. Small Business Impact

This information collection affects small businesses. However, the requirements are sufficiently flexible for facilities to meet them in a way consistent with their existing operations.

6. Less Frequent Collection

With less frequent collection, CMS would not be able to ensure timely compliance with CMHC CoPs.

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 October 29, 2013.

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 2012 there were 100 Community Mental Health Centers. Based on growth figures for the last three years, we estimate that there will be approximately 5 agencies per year entering the program. In 2012, 100 freestanding CMHCs served 13,600 Medicare beneficiaries and 9,100 non-Medicare clients for an average of 227 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 2010 by the total number of Medicare-participating CMHCs in 2010 to establish the average number of Medicare beneficiaries per CMHC. This resulted in 136

beneficiaries per CMHC. We then assumed that, in order to comply with the 40 percent requirement, those 136 beneficiaries only accounted for 60 percent of an average CMHC's total patient population. This meant that an average CMHC also treated another 91 clients who did not have Medicare as a payer source, for a total of 227 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.

- §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 it will require 8 hours on a one-time basis to develop this notice, and the CMHC administrator would be responsible for this task, at a cost of $528 per CMHC and $52,800 for all CMHCs nationwide. 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 5.58 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 947 hours to comply with this requirement (.0417 hours per client x 22,700 clients). The estimated cost associated with these requirements is $28,578, based on a psychiatric nurse performing this function (947 hours x $47 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 2007, the American Association of Behavioral Health and The Joint Commission informed us that we could anticipate 52 complaints per year per CMHC and that it will take the administrator 5 minutes per complaint at the rate of $66/hour to document the complaint and resolution activities, for an annual total of 4.33 hours per CMHC or 433 hours for all CMHCs. The estimated cost associated with this requirement is $28,578.

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 4.33 hours per CMHC or 433 hours for all CMHCs. The estimated cost associated with this requirement is $28,578.

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 75 hours. The estimated cost associated with this burden for all CMHCs is $3,525.

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 35 minutes per CMHC to comply with these requirements. The estimated total annual burden associated with these requirements is 58 hours. The estimated cost associated with this requirement is $2,726.

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.

- §485.914Condition 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. The burden associated with these requirements is the time required to record the initial evaluation and comprehensive assessment, including changes and updates. We believe that documenting a client's initial evaluation and comprehensive assessment is 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.

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

noncompliance 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 3,784 hours annually) estimated to be a total of $1,778 per CMHC or $177,848 annually. Additionally, we estimate any revisions to the active treatment plan (approximately 5 minutes) will cost 88,877 annually (1891 hours x $47/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 $66/hour to comply with these requirements for a total of 400 hours annually. The estimated cost associated with this requirement is $26,400.

- §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 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 10 new CMHC applicants per year for a total of 50 hours annually and an estimated cost of $1,230. We estimate there will be 20 CMHCs up for revalidation each year for a total of 100 hours for all CMHCs, with an estimated cost of $2,400. Therefore, the annual reporting for new CMHC applicants and CMHC revalidation is estimated at 150 hours with a total cost of $3,600.

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 cost of all information collection requirements in the first year is approximately $3 million, or approximately $30,000 per average CMHC, in the first year of implementation and approximately $2.2 million, or $22,000 per average CMHC, annually thereafter. 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 Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§485.910(a)(1)	0938-New	100	100	8	800	66	52,800	0	52,800
§485.910(a)(3)	0938-New	100	22,700	.0417	947	47	44,509	0	44,509
§485.910(d)(2)	0938-New	100	5,200	.0833	433	66	28,578	0	28,578
§485.910(d)(4)	0938-New	100	5,200	.0833	433	66	28,578	0	28,578
§485.910(e)(4)(v)	0938-New	100	100	.75	75	47	3,525	0	3,525
§485.910(f)(4)	0938-New	100	700	.0833	58	47	2,726	0	2,726
§485.916(c)	0938-New	100	22,700	.1667	3784	47	177,848		177,848
§485.916(d)	0938-New	100	22,700	.0833	1891	47	88,877	0	88,877
§485.917	0938-New	100	100	4	400	66	26,400	0	26,400
§485.918(b)	0938-New	30	30	5	150	24	3,600	0	3,600
Total		100	79,530	18.7083			457,441		457,441

13. Capital Costs

There is no capital costs associated with this information collection.

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 is likely to be an increase in CMS activities, such as on-site surveys, as a result of this final 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

N/A, this is the first burden estimate.

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.