



FEDERAL REGISTER

Vol. 78

Tuesday,

No. 209

October 29, 2013

Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Part 485

Medicare Program: Conditions of Participation (CoPs) for Community
Mental Health Centers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 485**

[CMS–3202–F]

RIN 0938–AP51

Medicare Program: Conditions of Participation (CoPs) for Community Mental Health Centers**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule establishes, for the first time, conditions of participation (CoPs) that community mental health centers (CMHCs) must meet in order to participate in the Medicare program. These CoPs focus on the care provided to the client, establish requirements for staff and provider operations, and encourage clients to participate in their care plan and treatment. The new CoPs enable CMS to survey CMHCs for compliance with health and safety requirements.

DATES: These regulations are effective on October 29, 2014.

FOR FURTHER INFORMATION CONTACT: Mary Rossi-Coajou, (410) 786–6051. Maria Hammel, (410) 786–1775.

SUPPLEMENTARY INFORMATION:**I. Background***A. Introduction*

In 2012, 100 certified Community Mental Health Centers (CMHCs) billed Medicare for partial hospitalization services. Currently, there are no Conditions of Participation (CoPs) in place for Medicare-certified CMHCs. As such, an insufficient regulatory basis exists to ensure quality and safety for CMHC care. 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. These CoPs will help to ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source.

These requirements focus on a short term, person-centered, outcome-oriented process that promotes quality client care. Requirements for CMHC services encompass—(1) personnel qualifications; (2) client rights; (3) admission, initial evaluation,

comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services. Bridging these CMHC requirements are quality assessment and performance improvement program requirements that build on a provider's own quality management system to improve client care performance. We expect CMHCs to furnish health care that meets the essential health and quality standards that are established by this rule; therefore, a CMHC will be expected to use its own quality management system to monitor and improve its own performance and compliance.

B. Current Requirements for CMHCs

Section 1832(a)(2)(J) of the Act established 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. . . .”

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).

A CMHC, in accordance with section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements for CMHCs in the State in which it is located, and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act (PHS Act). However, CMS has learned that most States either do not have a certification or licensure program for these types of facilities, or have regulatory requirements that apply only to CMHCs that receive Medicaid or other direct state funding.

A CMHC may receive Medicare payment for partial hospitalization services only if it meets the core requirements at § 410.2 and provides

partial hospitalization program (PHP) services that are in accordance with regulations at § 424.24(e).

When the partial hospitalization program benefit in CMHCs was first enacted, CMHCs were certified based on self-attestation. Currently, CMHCs are Medicare-certified and Medicare-enrolled based on a CMS Regional Office determination that the provider meets the definition of a CMHC at section 1861(ff)(3)(B) of the Act and provides the core services described in section 1913(c)(1) of the PHS Act. CMS has received complaints regarding some CMHCs, such as their ceasing to provide services once the CMHC has been certified, physically mistreating clients, and providing fragmented care. As there are no CoPs in place for CMHCs, many participating CMHCs have never had an onsite survey visit by CMS after their initial certification. Furthermore, there are currently only limited circumstances in which CMS can terminate a CMHC from Medicare participation based on the result of a complaint investigation. Without such health and safety standards in place, CMS's oversight of CMHCs is severely limited.

C. Rationale for Establishing CMHC CoPs

Medicare is responsible for establishing requirements to promote the health and safety of care provided to its beneficiaries. We believe that basic health and safety standards should be established for CMHCs in order to protect clients and their families. Establishing CMHC CoPs will enable CMS to survey providers, through State survey and certification agencies, to ensure that the care being furnished meets the standards.

On August 20, 2012, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) published a report entitled *Questionable Billing by Community Mental Health Centers*, OEI–04–11–00100 <http://oig.hhs.gov/oei/reports/oei-04-11-00100.asp>. In this report it was found that in 2010 approximately half of the CMHCs met or exceeded thresholds that indicated unusually high billing for at least one out of nine questionable billing characteristics. Approximately one-third of these CMHCs had at least two of the characteristics. Additionally, approximately two-thirds of the CMHCs with questionable billing were located in eight metropolitan areas. Finally, 90 percent of the CMHCs with questionable billing were located in States that do not require CMHCs to be licensed or certified. The OIG had four specific recommendations including the finalization of the proposed conditions

of participation for CMHCs. Due to the possibility of significant gaps in State requirements to ensure the health and safety of CMHC clients, we chose to propose and are finalizing a core set of health and safety requirements that will apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements will ensure a basic level of services provided by qualified staff, and will be consistent with the recommendations of the OIG. As with CoPs applied to other provider types, these requirements will apply for all clients served by the CMHC, not just Medicare beneficiaries.

D. Principles Applied in Developing the CMHC CoPs

We developed the CMHC requirements based on the following principles:

- A focus on the continuous, integrated, mental health care process that a client experiences across all CMHC services.
- Activities that center around client assessment, the active treatment plan, and service delivery.
- Use of a person-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the client's needs.
- Promotion and protection of client rights.

Based on these principles, we proposed and are finalizing the following six CoPs: (1) Personnel qualifications; (2) client rights; (3) admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client; (4) treatment team, active treatment plan, and coordination of services; (5) quality assessment and performance improvement; and (6) organization, governance, administration of services, and partial hospitalization services.

The "Personnel qualifications" CoP establishes staff qualifications for the CMHC.

The "Client rights" CoP emphasizes a CMHC's responsibility to respect and promote the rights of each CMHC client.

The "Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client" CoP reflects the critical nature of a comprehensive assessment in determining appropriate treatments and accomplishing desired health outcomes.

The "Treatment team, active treatment plan, and coordination of services" CoP incorporates a person-centered interdisciplinary team approach, in consultation with the

client's primary health care provider (if any).

The "Quality assessment and performance improvement" CoP challenges each CMHC to build and monitor its own quality management system to monitor and improve client care performance.

The "Organization, governance, administration of services, and partial hospitalization services" CoP charges each CMHC with the responsibility for creating and implementing a governance structure that focuses on and enhances its coordination of services to better serve its clients.

Two of the CoPs, "Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client" and "Treatment team, active treatment plan, and coordination of services," establish a cycle of individualized client care. The client's care needs will be comprehensively assessed, enabling the interdisciplinary team, with the client, to establish an active treatment plan. The active treatment plan will be implemented, and the results of the care will be evaluated by updating the comprehensive assessment and active treatment plan.

These CoPs present an opportunity for CMHCs, States, and CMS to join in a partnership for improvement. CMHC programming will reflect a person-centered approach that will affect how State survey and certification agencies and CMS manage the survey process. This approach provides opportunities for improvement in client care.

II. Provisions of the Proposed Rule and Analysis and Response to Public Comments

We published a proposed rule in the **Federal Register** (76 FR 35684) on June 17, 2011. In that rule, we proposed to establish a new subpart J under the regulations at part 485 to incorporate the proposed CoPs for CMHCs.

We specified that the new subpart J would include the basis and scope of the subpart, definitions, and the six CoPs and requirements.

We provided a 60-day public comment period in which we received a total of 203 timely comments from accrediting bodies, consumer advocacy organizations, CMHCs, individuals, national health care provider organizations, State agencies, and State health care provider organizations. Overall, the majority of commenters were supportive of the proposed changes. Summaries of the major issues and our responses are set forth below.

A. Basis and Scope (§ 485.900)

At § 485.900, we proposed to cite the statutory authority for CMHCs to provide services that are payable under Medicare Part B. In addition, we proposed to describe the scope of provisions in proposed subpart J.

B. Definitions (§ 485.902)

At § 485.902, we proposed to define the following terms to be used in the CoPs for CMHCs under the proposed subpart J: "active treatment plan," "community mental health center (CMHC)," "comprehensive assessment," "employee of a CMHC," "initial evaluation," "representative," "restraint," "seclusion," and "volunteer".

Comment: Some commenters expressed concern related to the requirement that all volunteers meet the standard training requirements under § 485.918(d). The commenters believe it is unreasonable to require CMHCs to provide the specific training and competency assessments required under § 485.918(d)(1) and (d)(3) for volunteers. Other commenters believe an initial orientation tailored to the actual work a volunteer will be doing ensures that volunteers will receive the information and guidelines they need from CMHCs without imposing an unnecessary and impractical barrier to using volunteers.

Response: We appreciate the feedback related to the definition of a volunteer and associated training requirements. We agree with the commenters that orientation should be tailored to the actual work the volunteer will be doing. However, the volunteer would need additional training in areas such as CMHC care and services, as well as specific in-service training and education, depending on the role of the volunteer. For example, if a volunteer role is to work in the CMHC client waiting area, we would expect the CMHC to educate the volunteer in areas such as the CMHC privacy policy, de-escalation techniques, and other pertinent training that may affect the role of that volunteer. Therefore, we are finalizing the definition of volunteer and their training requirements as proposed.

Comment: One commenter stated that it is difficult to imagine a situation where a client's representative would be terminating medical care on the client's behalf. The commenter stated that the definition should reflect the principles of client involvement and the protection of client rights, including emphasizing the right of a client to make decisions regarding treatment. The commenter stated that one possibility would be to

change the definition to state that a representative is “an individual legally authorized to make decisions on behalf of a client who is mentally and physically incapacitated,” and eliminate any reference to terminating medical care.

Response: We appreciate the feedback and suggestions related to the definition of “representative”. We agree that it would be more common for a client to have a representative who would be authorizing care, not terminating care. However, CMS uses the term “representative” across many different provider types. Therefore, we are finalizing the definition of “representative” as proposed.

CMHC CoP: Personnel Qualifications (§ 485.904)

We proposed to add a new CoP at § 485.904 to establish staff qualifications for CMHCs. The proposed CoP was divided into two standards.

At § 485.904(a), “Standard: General qualification requirements,” we proposed to require that all professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and be required to act only within the scope of their State licenses, certifications, or registrations. We also proposed that all personnel qualifications would have to be kept current at all times.

At § 485.904(b), “Standard: Personnel qualifications for certain disciplines,” we proposed to require staff qualifications to be consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations. Specifically, we proposed personnel requirements for the following disciplines: Administrator of a CMHC, Clinical Psychologist, Clinical Social Worker, Mental Health Counselor, Occupational Therapist, Physician, Psychiatric Registered Nurse, and Psychiatrist.

Comment: Several commenters agreed with requiring that “all professionals who furnish services directly must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses.” They also stated that most states allow individuals with Master’s level degrees, such as social work and psychology, to provide services under the supervision of a licensed professional. Commenters stated that a period of supervision is required for these professionals to

receive licenses. In addition, commenters stated that many peer educators and Bachelor’s level professionals do not have a process for becoming licensed, or must work in a supervised position for a certain number of hours to obtain certification.

Response: We thank the commenters for the information regarding professionals who furnish services in a CMHC. We believe that the regulations at § 485.904 allow for professionals with a Master’s degree in psychology or social work to provide services under a licensed professional as long as it is within their scope of practice and allowed by the State. If a State decides that Baccalaureate level professionals need to be supervised for a certain number of hours to meet State licensure requirements to obtain their license, we defer to that State’s decision. Our proposed language did not impose additional restrictions or require that States establish additional licensing programs or requirements. Therefore, we are finalizing § 485.904(a) as proposed.

Comment: A few commenters agreed that it is important that personnel qualifications be defined by CMS. However, they believe that the facility should qualify their staff and make sure their staff is competent to perform their job responsibilities. Commenters stated that this could be achieved by using the education, experience, and services the individual is able to perform under the scope of his or her license and based on the laws of his or her state. Commenters also believe it is important that CMS recognize that there are many different types of mental health professionals who are qualified to perform the clinical responsibilities within the CMHC, regardless of the “title of their degree.” According to the commenters, it is imperative that CMS not limit the CMHC provider to one specific degree and or license (that is, clinical social worker vs. mental health counselor) to perform “certain” roles in the CMHC, as this would be an impossible task to adhere to and an administrative and financial burden that is unnecessary to the CMHC.

Commenters also stated that CMS is required to accept the scope of state licensure of various mental health care professionals in the context of Medicare’s partial hospitalization program benefit. Congress explicitly stated in the Social Security Act that individual and group therapy services provided within a partial hospitalization program at a CMHC can be conducted by physicians, psychologists or “other mental health professionals to the extent authorized

under State law”, as noted in Section 1861(ff)(2)(A) of the Act.

Response: We thank the commenters for the comments regarding licensure, education, and experience as they relate to the personnel requirements. Our goal in requiring specific personnel requirements is to protect the health and safety of the clients served by the CMHC. That said, we agree that practitioners should not be restricted by our rules from acting within the scope of practice authorized under State law and any applicable licensing requirements. We have amended the language in this final rule to assist in ensuring that practitioners can practice to the full extent of their State licensure.

Comment: A few commenters are concerned that, in their view, CMHCs may have inadequate boards of directors, and that the board and administrator of the CMHC are permitted to be one and the same. Commenters stated that anyone with limited investment capital and no knowledge of psychiatric care can open and operate a CMHC, and that this is one of the system’s greatest weaknesses. Commenters requested that, in cases where the administrator has a financial (that is, controlling) interest in the CMHC, minimum professional standards should apply.

Response: We thank the commenters for the information regarding the administrator and board of directors. We agree that in some cases there is potential for the administrator and the governing body to be one and the same. However, we do not believe that modifying the language under personnel requirements for the administrator is the best place to address this issue. Therefore, we are finalizing the administrator personnel requirements as proposed. We have also modified the language at § 485.918(a)(1) related to the governing body to require two or more persons to serve on the governing body, one of whom must possess knowledge and experience as a mental health clinician. The administrator will be able to serve as a member of the governing body, but we will require at least one (or more) additional person(s) to be part of the governing body. For example, if the administrator has no psychiatric health background, either one of the CMHC’s clinicians or another qualified professional should be appointed to serve as a member of the governing body.

Comment: At proposed § 485.904(b)(6), a few commenters noted that CMS used the definition of physician found in section 1861(r) of the Act. The commenters requested that CMS further limit the statutory

definition of physician by limiting it to section 1861(r)(1), which lists a doctor of medicine or osteopathy. The commenter believes that this will help ensure that clients in a CMHC receive quality care from appropriately trained doctors of medicine or osteopathy legally authorized to practice medicine and surgery by the State.

Response: We thank the commenters for the comment regarding the definition of a physician, now located at § 485.904(b)(7). We understand the commenters' concerns with the broadness of the definition, and believe that requiring the physician to have experience in providing mental health services to clients will assure that these physicians are qualified to provide CMHC services. Therefore, the requirements will remain as proposed.

Comment: Some commenters expressed concern with the psychiatric registered nurse personnel requirements. Specifically, the commenters expressed concern about the requirement of 2 years of education and training in psychiatric nursing. Some commenters believe the training requirement should be reduced to 1 year. Other commenters stated that non-profit CMHCs face competition for professional staff and cannot always offer salaries as high as those offered by other providers, such as hospitals. CMHCs in rural areas have an added hurdle to recruiting and retaining clinicians. One way CMHCs can attract staff at the salaries they are able to pay is by offering recent graduates the opportunity to gain more experience working in community behavioral health. The commenters stated that it is unclear whether the two-year education and/or training requirement would disqualify recent nursing school graduates from working at non-profit CMHCs. The commenters are requesting clarification of this requirement to include approved nursing school graduates who have "education and/or training in psychiatric nursing," without specifying a length of time.

Other commenters stated that psychiatric registered nursing is specialized nursing care and an integral component in the provision of services at CMHCs. As a result, those commenters recommended that CMS remove the word "registered" and broaden the definition of "psychiatric nurse" so that it includes all licensed nurses who possess the requisite education and experience as outlined in the CoP. Furthermore, the commenters requested that the personnel requirement for psychiatric registered nurses remain in accordance with § 410.43(a)(4)(iii), "trained psychiatric

nurses," and eliminate the word "Registered." Commenters also requested that psychiatric nurses be permitted to facilitate education groups and to perform mental health assessments in the CMHC setting, as allowed by state law.

Response: We appreciate the comments regarding personnel requirements of the psychiatric registered nurse. We understand that some CMHCs may have more difficulty than others hiring a psychiatric registered nurse, due to location, salaries and competition. However, we believe that the role of the psychiatric registered nurse is specialized and essential to the care of a CMHC client. Therefore the requirements will remain as proposed. We note that, in addition to the psychiatric registered nurse, the CMHC may hire nurses such as licensed practical nurses (LPNs) or licensed vocational nurse (LVNs), as long as they meet the personnel requirements at 485.904(a). In response to commenters' concerns about the proposed work experience requirements, we have modified the time to 1 year in this final rule, and will allow the time spent in a psychiatric nursing rotation during nursing education to count towards the 1-year training requirement. We will provide further sub-regulatory guidance regarding the work experience requirements in the State operations manual, which will include interpretive guidelines for this section.

Comment: Several commenters requested that CMS add definitions for "Advanced Practice Registered Nurse," "Nurse Practitioner," or "NP" to the personnel requirements. Commenters also requested that CMS require the Advanced Practice Registered Nurse to be educated specifically in psychiatric and mental health nursing with a minimum of a Master's degree, to have experience which includes both didactic and clinical components, advanced knowledge in nursing theory, physical and psychosocial assessment, nursing interventions, and management of health care. They also stated that the NP should be practicing under a collaborative practice agreement with a board eligible psychiatrist and may perform services to the extent established by the governing bylaws, but not beyond the scope of license, certificate or other legal credentials as defined by the State in which he/she is licensed or certified. Additionally, commenters stated that advanced practice nurses—both psychiatric mental health nurse practitioners (PMHNPs) and psychiatric mental health clinical nurse specialists (PMHCNSs) need to be included in the

mix of health care providers who are authorized as gatekeepers to mental health services.

Response: We appreciate the comments regarding the utilization of advanced practice nurses (APNs) in a CMHC. We agree that non-physician practitioners, such as the APN, are essential to the care of clients served in a CMHC. To address the comments related to the use of an APN for assessment and as a member of the treatment team, we modified language in both § 485.914, "Admission, initial assessment, comprehensive assessment and discharge or transfer of the client" and § 485.916, "Treatment team, person-centered active treatment plan and coordination of services." These changes allow for APNs to serve in these roles, as permitted by State licensure. We also added a new element at § 485.904(b)(9), "Advanced practice nurse," which covers the personnel requirements for both the nurse practitioner and the clinical nurse specialist.

Comment: A few commenters requested that CMS include language in the definition of "psychiatrist" for the purpose of CMHC oversight, as set out at § 482.62(b)(1): "A physician is qualified to take the examinations for board certification upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology." Commenters agreed that qualified physician oversight of CMHC programs is of paramount importance. However, they stated that it is important that CMS clarify the personnel requirements to include psychiatrists who are board-certified or eligible to be board-certified. This clarification mirrors the CoP definition currently applied to inpatient psychiatric hospitals.

Response: We appreciate the comments regarding the personnel requirements for a psychiatrist or psychiatrist eligible to be board-certified. We believe the comment partially misquoted the regulation text. However, we agree with the commenters that it is of utmost importance to hire a board-certified psychiatrist. We also understand that it may not always be possible for a rural CMHC to employ a board-certified psychiatrist. In the rare cases that the CMHC has demonstrated that it is unable to employ a board-certified psychiatrist, we would expect the CMHC to hire a highly qualified psychiatrist who has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which

he or she practices. Therefore, in response to comments, we have modified that language by adding "board certified or is eligible to be board certified". Additional information and guidance regarding this requirement will be available in State operations manual, which includes the interpretive guidelines.

Comment: A few commenters requested that we add "activity therapist" to the personnel definitions. The commenters stated that an activity therapist is an individual who possesses a Bachelor's-level education in behavioral science or a related field, and who is certified or licensed by the state to facilitate activity groups.

Response: We appreciate the comments related to activity therapists. An activity therapist falls under the general qualifications requirement at § 485.904. CMHCs that employ activity therapists will be expected to employ individuals who are legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and they must act within the scope of any State licenses, certifications, or registrations that apply to these employees. We also expect CMHCs to have defined personnel requirements for these individuals.

Comment: Several commenters suggested CMS avoid the use of specific licensure requirements in the definition of "Clinical Social Worker" (CSW) and instead reflect the clinician's education and experience level. The commenters recommended that CMS consider and adopt the following alternative: "CMHCs must employ a full time Director of Social Services who is a Master's degree level clinician with a minimum of 2 years experience in providing care to the mentally ill and is licensed or certified to perform psychotherapy by the laws of the State in which the services are performed. Other clinicians may be utilized to provide psychotherapy provided they are licensed or certified to perform psychotherapy in the state in which the services are performed." The commenters' suggested language eliminates the use of licensing titles which are not uniform in all states and may potentially eliminate clinicians who are licensed and certified to provide services. Another commenter stated that unlike other health care settings, CSWs in CMHCs do not operate independently, but rather operate as part of a clinical team of personnel/staff rendering treatment services. They recommended that CMS' definition require that CSWs providing care in CMHCs possess a Master's degree and have a minimum of at least 2 years'

experience in providing treatments to clients with mental disorders or severe disabilities. Commenters also stated that CSWs working in the CMHC setting should be licensed or certified to perform psychotherapy by the laws of the state in which the services are performed. According to the commenters, CMS should specify that additional types of clinicians may provide psychotherapy in the CMHC setting, provided these professionals are licensed or certified to perform psychotherapy in the state in which the services are performed.

Some commenters believe that the clinical social worker definition should be expanded to reflect the services that they perform. The definition recommended by the commenters was "Clinical social work services include the assessment, diagnosis, treatment, and prevention of mental illness, emotional, and other behavioral disturbances."

Response: We appreciate the comments regarding the personnel requirements of the clinical social worker. We agree that addressing the education and experience level of the CSW may be a more appropriate means to ensure quality treatment and to meet the needs of the different types of clients served in a CMHC. This will ensure that appropriate personnel will work with each client to meet individual needs. We agree that eliminating the use of licensing titles, which are not uniform in all states and may potentially eliminate clinicians who are licensed and certified to provide services, is appropriate in these circumstances. We believe that all CMHCs must strive to employ qualified individuals to provide social work services to clients and their families. To ensure CMHCs employ a qualified individual as a clinical social worker, we are requiring that at least one of the CMHC clinical social worker(s) must meet the qualifications at § 410.73. If the CMHC chooses to also employ a social worker that does not meet § 410.73, then, at a minimum, the social worker must meet one of the following requirements:

- Have a Bachelor's degree in social work (BSW) from an institution accredited by the Council on Social Work Education; or a Bachelor's degree in psychology or sociology, and be supervised by an MSW who meets the qualifications set out at § 410.73 of this chapter.

If a CMHC chooses to employ a social worker with a Bachelor's degree in social work, psychology or sociology, the services of the social worker must be provided under the supervision of a

clinical social worker with an MSW or a doctoral degree in social work from a school of social work accredited by the Council on Social Work Education. Such BSW must also meet the qualifications set out at § 410.73 of this chapter. We believe that requiring MSW supervision of BSW services will help ensure that client needs are met. The MSW supervisor role is that of an active advisor, consulting with the BSW on assessing the needs of clients, developing and updating the social work portion of the active treatment plan, and delivering care to clients. The supervision may occur over the telephone, through electronic communication, or any combination thereof.

Comment: A few commenters recommended that CMS add additional language to the definition of mental health counselors. Commenters also stated that CMS should allow for the mental health counselors to provide mental health assessments, as permitted by state law, in addition to the other service areas included in the proposed rule. Commenters clarified that under the Joint Commission's standards, mental health counselors are qualified to perform assessments. They stated that since providing mental health assessments for state mental health entities is a core service area required of CMHCs by Federal law, it is important that the assessments be listed among the services provided by mental health counselors as outlined in the proposed rule.

Response: We appreciate the comments related to mental health counselors. The role of the mental health counselor is located at § 485.904(b)(5) under the personnel requirements. We agree the mental health counselors can provide mental health assessments, as defined by State law. Therefore, we modified the regulation text at § 485.904(b)(5), Mental health counselor, to include "assessments." We have also modified the language at § 485.914, "Admission, initial evaluation, comprehensive assessment and discharge or transfer of the client," to allow for mental health counselors to provide the assessment of the client. Specifically, we have modified the language at § 485.904(b)(5) by broadening the requirement to allow for a licensed mental health professional (acting within his or her state scope of practice requirements) to complete the initial evaluation and the comprehensive assessment.

Comment: Some commenters stated that the personnel requirement for clinical psychologists at § 485.904(b)(2) is vague and lacks quality assurance

needed to protect Medicare beneficiaries. Commenters requested that CMS consider specifying that the clinical psychologist must have graduated from a doctoral program that is accredited by the American Psychological Association or designated by the Association of State and Provincial Psychology Boards/National Register of Health Service Providers in Psychology.

Some commenters raised concern that the standard contains no verification that the psychologists are trained in health service provisions and that only requiring a generic license to authorize the individual to engage in a variety of psychological services does not distinguish between individuals who are trained and experienced in health service provision and those who are trained in research, teaching, or industrial/organizational fields.

Response: We appreciate the comments related to the psychologist personnel requirements. We agree that properly educated and trained health service psychologists will be strong CMHC team leaders. These standards will help improve client treatment, and hold CMHCs accountable for their care.

We also agree that protecting the clients served by the CMHC is of great importance. The personnel requirements for psychologists at § 485.904(b)(2) reference the clinical psychologist qualification requirements at § 410.71(d). We understand the importance of requiring the schools to be accredited. However, we do not have any data indicating that clinical psychologists graduating from non-accredited programs reduces the level of quality care provided to clients served. Without formal evidence, modifying the psychologist personnel requirement in the CoPs would create a discrepancy between the conditions of participation and the payment policy requirements at § 410.71(d).

Comment: A few commenters recommended the inclusion of physician assistants (PAs) in the proposed community mental health center conditions of participation to enable CMHCs to utilize this group of practitioners as legally authorized in accordance with applicable federal, State and local laws. Commenters believe that the lack of specific inclusion of PAs in a standard can imply to surveyors that PAs are not authorized to deliver certain medical services. Other commenters stated that PAs in psychiatry expand access to mental health services. They often work in behavioral health facilities and psychiatric units of rural and public hospitals, where psychiatrists are in

short supply. The commenters defined a physician assistant as “an individual who meets the qualifications and conditions as defined in section 1861(s)(2)(K)(i) of the Act and provides services, in accordance with State law, at § 410.74.”

Response: We appreciate the comments regarding PAs. We agree that PAs play an important role in behavioral health. Therefore we have modified the language at § 485.904(b)(8) to set requirements for PAs, and have re-designated the remaining elements accordingly.

Comment: One commenter requested that CMS recognize psychiatric technicians. The commenter stated that in California, and elsewhere in the United States, these direct-care staff are used by providers.

Other commenters requested that CMS add requirements for mental health technicians and drivers. The commenters also expressed concern regarding the level of supervision of these employees. Furthermore, the commenters stated that many CMHCs employ drivers who also work as “Mental Health Techs”. It is unclear if these medically unlicensed individuals have direct contact with clients and if so, what level of supervision should be expected.

Response: We appreciate the comments and suggestions regarding psychiatric technicians, mental health technicians and drivers. Psychiatric technicians, mental health technicians, and CMHC drivers all play important roles in the care of clients. However, we do not believe that we need to add personnel requirements for these positions at this time. We expect the CMHCs that utilize psychiatric technicians, mental health technicians, and drivers to clearly define their roles and functions (utilizing accepted standards of practice) within the CMHC’s own policies, procedures and personnel requirements. We would also expect the CMHC to educate and train these staff members, just as they educate and train their other staff, related to the functions of the CMHC and care of the CMHC clients, confidentiality, safety, and any other areas the CMHC assesses as needed. For states that have licensing and regulatory requirements for the psychiatric technician, mental health technician, and driver we would expect the psychiatric technician, mental health technician, and driver to provide services in accordance with State law.

CMHC CoP: Client Rights (§ 485.910)

We proposed to add a new CoP at § 485.910. The proposed CoP was divided into six standards.

At § 485.910(a), “Standard: Notice of rights and responsibilities,” we proposed to set forth certain rights to which CMHC clients would be entitled, and to require that CMHCs inform each client verbally of these rights in a language and manner that the client or client’s representative (if appropriate) or surrogate understands.

We also proposed to require that the client be provided a written copy of client rights information. This information would have to be accessible to persons who have limited English proficiency (LEP).

At § 485.910(a)(1), we proposed that the notice of rights and responsibilities, including information concerning how to file a grievance, would be given to the client, the client’s representative or surrogate, as appropriate, during the initial evaluation, as described at proposed § 485.914(b).

At § 485.910(b), “Standard: Exercise of rights and respect for property and person,” we proposed that a client be able to exercise his or her rights, have his or her property and person respected, voice grievances, and not be subjected to discrimination or reprisal for exercising his or her rights.

Furthermore, at § 485.910(b)(2), we proposed procedures if the client has been adjudged incompetent under State law. At (b)(3), the proposed rule addressed the appointment of a legal representative. We also proposed at § 485.910, “Standard: Rights of the client,” that the client would have the right to—(1) participate in the active treatment planning process; (2) refuse care or treatment; (3) have his or her records kept confidential; (4) be free from mistreatment, neglect, abuse, and misappropriation of his or her personal property; (5) receive information about limitations on CMHC services; and (6) not be compelled to perform services for the CMHC.

At § 485.910(d), “Standard: Addressing violations of client rights,” we proposed that CMHC personnel be required to report all complaints of alleged violations of clients’ rights to the CMHC administrator. We also proposed that the CMHC immediately investigate all alleged violations, take intermediate actions to prevent further potential client rights violations during the investigation period, and take appropriate corrective action, where necessary. Furthermore, we proposed that the CMHC report the violations to appropriate authorities having jurisdiction within 5 working days of the CMHC becoming aware of the verified violations of client rights.

We proposed the client rights CoP to act as a safeguard of client health and

safety. Open communication between CMHC staff and the client, and client access to information are vital to enhancing the client's participation in his or her coordinated active treatment plan. We also proposed to require all CMHCs to comply with Federal rules concerning the privacy of individually identifiable health information set out at 45 CFR parts 160 and 164.

At § 485.910(e), "Standard: Restraint and seclusion," we addressed the use of restraints and seclusion in a CMHC. We proposed that all clients have the right to be free from physical or mental abuse, and corporal punishment. Since accidental injuries and deaths have been documented in medical facilities due to the use of restraint and seclusion, we want to strongly discourage the use of restraints or seclusion in a CMHC environment where the clients are receiving services on an outpatient basis. However, we are aware that under extremely rare instances their application may be warranted for brief periods of time, and only while awaiting transport of the client to a hospital for evaluation and treatment when exhibiting behavior that threatens immediate harm to the client or others. In response to accidental injuries and deaths, we published hospital restraint and seclusion requirements on December 8, 2006 (71 FR 71378) that included a new standard at § 482.13. The hospital restraint and seclusion CoP is the basis for the proposed CMHC restraint and seclusion CoP, with modifications to the regulatory requirements to accommodate this outpatient setting.

The proposed restraint and seclusion standard was divided into five elements. These elements focused on the proper use of seclusion and restraints and the need for CMHC personnel to receive training and education on the proper use of seclusion and restraint application and techniques, as well as the use of alternative methods for handling situations that arise. The standard proposed specific requirements for physician orders for seclusion or restraint, along with a corresponding order for the client's immediate transfer to a hospital when restraint or seclusion is ordered. The standard also included a requirement that there must be specific documentation in the client's clinical record regarding the use of restraints.

At § 485.910(f), "Standard: Restraint or seclusion: Staff training requirements," we address the training of the CMHC staff. The training consists of specific intervals, content and trainer requirements. § 485.910(g), "Standard: Death reporting requirements" states

that a CMHC would have to report to its CMS regional office no later than close of business the next business day, any death that occurs while a client is restrained or in seclusion while awaiting transfer to the hospital.

Comment: A few commenters stated that all CMHCs should establish written policies and procedures regarding clients' rights.

Response: We appreciate the feedback on establishing policies and procedures for clients' rights. We believe it is already current standard of practice and the responsibility of each CMHC to establish written policies and procedures regarding clients' rights and the rights of the client's representative (if appropriate) or surrogate. We have provided requirements for clients' rights that facilitate the development of these policies and procedures. We are clarifying that the client's representative or surrogate must be able to exercise the rights of the client if the client is unable to represent himself or herself.

Comment: Commenters stated that the CMHC should be required to attempt to communicate with the client, and should be required to accommodate the client's communication needs, before opting to rely on a representative or surrogate.

Additionally, commenters also stated that there should also be additional emphasis on the provision of sign language interpretation for individuals who are deaf, and alternative written formats such as Braille and large print for individuals who are visually impaired.

Response: We agree that all CMHCs should attempt to communicate with the client first, and accommodate the client's communication needs. CMHCs must take appropriate steps to ensure effective communication with their clients and provide auxiliary aids and services to accommodate the client's communication needs. There are specific civil rights statutes that address the obligation of covered entities to provide appropriate auxiliary aids and services, such as Braille and large print to individuals with disabilities.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of disability in programs or activities that receive Federal financial assistance. Therefore, as recipients of Federal financial assistance (that is, loans, grants, or Medicare or Medicaid reimbursements), CMHCs must comply with the nondiscrimination requirements. Furthermore, there are also several sections of the Americans with Disabilities Act (ADA) that require facilities, such as CMHC providers, to provide appropriate accommodations

for their clients. Since section 504 and the ADA provisions are applicable to CMHCs, we are not addressing the specifics of these requirements in the CoPs.

Comment: One commenter suggested that CMS should require a CMHC with a clientele that is more than 25 percent non-English speaking to provide written translations of clients' rights information in the relevant language(s).

Response: We appreciate the feedback that if the CMHC clientele is over 25 percent non-English speaking, the CMHC must provide written translations of clients' rights information in the relevant languages.

We recognize that this is an area of concern for CMHCs, as it may be challenging for CMHCs to communicate with clients who speak languages other than English. The HHS guidance on Title VI (August 8, 2003, 68 FR 47311) applies to those entities that receive Federal financial assistance from HHS, including CMHCs. CMHCs are already expected to comply with the HHS guidance, which requires the CMHC to take reasonable steps to provide meaningful access to its programs or activities. CMHCs should take reasonable steps to provide meaningful access to persons with LEP. This may involve securing a qualified interpreter for CMHC-client communications, including those involving the notice of clients' rights. Providing meaningful access may also involve the CMHC translating written copies of the notice of rights available in the language(s) that are commonly spoken in the CMHC service area. As explained in the HHS LEP guidance at <http://www.gpo.gov/fdsys/pkg/FR-2003-08-08/pdf/03-20179.pdf> (section VI B), use of an oral interpreter presents a set of complex issues. For example, use of family members or friends as interpreters may be actively sought by some patients but may present a danger to the patient in other cases. What is required of CMHCs in particular communities will depend on what HHS terms a "four factor analysis," taking into account availability of interpreters, how many languages are commonly or rarely encountered among CMHC clients, and other situational factors. For additional information related to LEP, the Department of Health and Human Services recently released a new document highlighting the departments commitment to LEP, which is located at the following Web site: <http://www.hhs.gov/open/execorders/13166/index.html>.

Comment: Some commenters stated that a 5-day timeframe for violation reporting is too long. Other commenters

stated that the reliance on internal procedures and self-regulation may cause CMHCs to determine that most violations do not require any type of corrective action or reporting because of the fear of repercussions from State regulatory agencies or CMS.

Response: We understand that the 5 working days timeframe may seem too long. However, the CMHC may require a shorter timeframe through its policies and procedures. The CMHC is required to immediately report an incident to the administrator, who must immediately investigate all alleged violations. The CMHC must take action to prevent further potential violations while the alleged violation is being verified. This process begins as soon as the alleged violation is discovered and will likely be resolved sooner than 5 days. Additionally, because CMHCs are not residential facilities, it is unlikely that the involved client will be in the facility during the entire 5-day period.

We also understand the commenters' concern with the CMHC internal investigation procedures. We believe requiring CMHCs to investigate potential violations of client rights by CMHC staff (including contracted or arranged services) may represent a conflict of interest, or insufficient to protect clients and their families.

For this reason, we are amending the requirement at § 485.910(d)(4) to require that all violations be reported to State survey and certification agencies, and verified by the appropriate investigator, violations also be reported to State and local entities having jurisdiction. While we understand the commenters' concern with the CMHC internal investigation procedures, we believe requiring CMHCs to investigate potential violations of client rights by CMHC staff (including contracted or arranged services) will protect clients and their families. Reporting violations, when verified in accordance with CMHC policies and procedures and any applicable State and local laws and regulations related to client health and safety, is an integral part of improving the quality of CMHC care provided to Medicare beneficiaries. Ultimately the CMHC must follow Federal and State laws related to client health and safety, as well as follow its own internal policies and procedures. We expect significant violations, such as illegal actions by CMHC staff, to be reported to State and local authorities. We believe that the framework in this regulation, coupled with a CMHC's own policies and procedures and State and local requirements related to client health and safety, will allow CMHCs to adapt the requirements to the particular needs

and concerns of their client populations now and in the future.

If State requirements for reporting violations are stricter than our Federal requirements, the stricter State requirements would take precedence. Stricter State requirements may be those that require violations to be reported regardless of whether they are verified, or requirements that verified violations be reported in less than five days. However, if State requirements are less stringent than Federal requirements, then the Federal requirements will take precedence.

Comment: One commenter stated that there should be a limit to the number of clients attending a group session. Specifically, the commenter requested that CMS add an additional requirement at § 485.910(c), "Standard: Rights of the client," limiting a PHP group maximum size to 12–15 clients. The commenter stated that this would help to ensure all clients receive full benefit from PHP sessions.

Response: We appreciate the commenter's concern regarding the number of clients attending a group session. We believe that the CMHC would need to determine, through its policies, procedures, and guidelines related to group therapy sessions, what is appropriate for each client. There are many different acuity levels and needs for CMHC clients which may require larger or smaller group sizes. All the participants within a given group should have the same acuity level and group session treatment goal. A group's size should be based on the needs and abilities of its participants. A group should not be too small to prevent the benefit of learning and sharing from other participants that occurs in a "group," nor too large as to prevent all members from the benefit of actively participating. We expect the CMHC and the client's therapist or team will exhibit sound clinical judgment and clinical practice when assigning a client to a particular group or group psychotherapy and when developing the actual group. Therefore, we will leave it up to the clinical expertise and sound professional judgment of the CMHC trained staff to determine what works best for each client. For each client there is a periodic reassessment and review of the client's progress. This review will allow adjustments for such treatments, including the size of the group to which the client belongs or the need for individualized therapy.

Comment: Several commenters stated that restraint and seclusion are not used in CMHCs. Therefore, they believe training of staff should focus on de-escalation techniques. Commenters

stated that following established procedures for involuntary hospitalization should minimize or completely eliminate the need to use restraint and/or seclusion. Likewise, other commenters stated that State law prohibits CMHCs from using seclusion and restraint in any program. As a result, CMHCs no longer train staff on these prohibited practices. Instead, CMHCs train staff in de-escalation techniques and crisis management. Furthermore, some commenters stated that there is no evidence that CMHCs' use of seclusion or restraint is a concern, and the training and reporting requirements would create administrative and financial burdens.

Response: We appreciate the feedback from the commenters on restraint and seclusion. We agree that if State law is more stringent than Federal law, State law takes precedence. That is, if the use of seclusion and restraint is prohibited by the State, then the CMHC is not allowed to use seclusion and restraint techniques in the process of providing services to CMHC clients. The requirements at § 485.910(f)(1) and (f)(2) state that training of CMHC staff focuses on techniques to identify staff and client behaviors, events and environmental factors that may trigger circumstances that require the use of restraint or seclusion, as well as the use of nonphysical intervention skills. We believe that training CMHC staff to identify potential triggers and to use positive behavioral intervention supports and nonphysical intervention skills, also known as de-escalation techniques, is compatible with State law even in states that expressly prohibit the use of seclusion and restraint techniques. While the concepts are related, identifying triggers and using nonphysical interventions are not the same as using seclusion and restraint techniques. Therefore, all CMHCs, even those located in states that prohibit the use of seclusion and restraint techniques, are required to train their staff in the use of nonphysical interventions in order to assure the safety of all clients and staff. Training on nonphysical interventions could be incorporated into the CMHC staff in-service training requirements at § 485.918(d)(3). This type of training meets the requirements of the regulation.

We emphasize that in states where the use of seclusion and restraint techniques are permitted, they may only be used to protect the client or others from immediate harm, and their use would trigger immediate transportation to a hospital. In the rare occurrence that a restraint and seclusion order is

needed, the duration of the order is for 1 hour. If there is a delay in the arrival of client transport extending past the 1 hour order duration, a second order would need to be obtained. We believe that if this delay occurs, it is in the best interest of the health and safety of the client that a re-assessment of the client's condition be made to determine if restraints remain necessary, before the second order is obtained.

Comment: A few commenters stated that restraint and seclusion death reporting should be expanded to include the reporting of deaths that occur as the result of abuse or neglect. Other commenters requested an additional requirement, such as reporting the incident to the relevant protection and advocacy agency. One commenter recommended that CMS be very specific in defining what it means by "attributed to." Commenters recommended that reporting should be required only when restraint and seclusion was determined to be a direct cause of death. Additionally, commenters stated that CMS should investigate the death as part of the complaint survey investigation process.

Response: We agree with the commenters on reporting deaths that occur as a result of abuse or neglect. We expect that a health care provider or agency that believes a CMHC client is the subject of abuse or neglect will report the concern to the proper State authorities. This requirement falls under § 485.910(d)(1), to ensure that all alleged violations involving abuse or neglect are reported immediately to the CMHC administrator. An investigation should immediately occur and procedures should be put in place to prevent further potential violations while the alleged violation is investigated. The CMHC is then required to take appropriate corrective action in accordance with State law (which may include contacting appropriate advocacy agencies), if the alleged violation is verified by the CMHC administration or verified by an outside entity having jurisdiction.

Should a seclusion or restraint-related death occur, our intent is to ensure that the CMHC immediately notify CMS and begin to fully investigate the death. Waiting to determine if the death was directly caused by the use of restraint or seclusion could potentially have negative impact on other clients being served by the CMHC. We acknowledge that seclusion and restraint are rarely, if ever, used and that the likelihood of death ever having to be reported is extremely low. However, it is imperative that the CMHC report any instance where a death of a client is

associated with the use of seclusion or restraint. Should a seclusion or restraint-related death occur, we would initiate an onsite complaint survey of the CMHC in accordance with the existing complaint investigation process.

CMHC CoP: Admission, Initial Evaluation, Comprehensive Assessment and Discharge or Transfer of the Client (§ 485.914)

We proposed to add a new CoP at § 485.914 to establish requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client. The proposed CoP at § 485.914 identified general areas that would be included in a client assessment and the timeframes for completing the assessments to help the CMHC ensure it was identifying the needs in all areas in a timely fashion. The proposed CoP was divided into five standards.

At § 485.914(a), "Standard: Admission," we proposed to require the CMHC to determine whether a client is appropriate for the services the CMHC provides. At § 485.914(b), "Standard: Initial evaluation," we proposed to require the CMHC psychiatric registered nurse or clinical psychologist to complete the initial evaluation. We stated that the care needs identified in the initial evaluation would include, but would not be limited to, those necessary for treatment and management of the psychiatric illness. We also specified that the initial assessment would be completed within 24 hours of the client admission to the CMHC.

At § 485.914(c), "Standard: Comprehensive assessment," we proposed that a physician-led interdisciplinary team, in consultation with the client's primary health care provider (if any), complete the comprehensive assessment. We stated that the comprehensive assessment would build from the initial evaluation and identify the client's physical, psychological, psychosocial, emotional and therapeutic needs. The interdisciplinary team would be composed of a doctor of medicine, osteopathy or psychiatry; a psychiatric registered nurse, a clinical psychologist, a clinical social worker, an occupational therapist, and other licensed mental health counselors, as necessary. Each member of the team would provide input within the scope of that individual's practice. As proposed, the comprehensive assessment would include information about the client's psychiatric illness and history, complications and risk factors, drug profile review, and the need for referrals

and further evaluations by appropriate health care professionals. The comprehensive assessment would be completed within 3 working days after the admission to the CMHC.

At § 485.914(d), "Standard: Update of the comprehensive assessment," we proposed that the CMHC would update the comprehensive assessment via the physician-led interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), no less frequently than every 30 days, and when changes in the client's status, response to treatment, or goals occurred. The update would have to include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. We believe that these frequent reviews are necessary since clients with ongoing mental illness may be subject to frequent and/or rapid changes in status, needs, acuity, and circumstances, and the client's treatment goals may change, thereby affecting the type and frequency of services that should be furnished. The physician-led interdisciplinary treatment team would use assessment information to guide necessary reviews and/or changes to the client's active treatment plan.

At § 485.914(e), "Standard: Discharge or transfer of the client," we proposed that the CMHC complete a discharge summary and forward it to the receiving facility/provider, if any, within 48 hours of discharge or transfer from the CMHC. If the client is being discharged due to non-compliance with the treatment plan, the CMHC would forward the discharge summary and, if requested, other pertinent clinical record information to the client's primary health care provider (if any). The discharge summary would be required to include—(1) a summary of the services provided while a client of the CMHC, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies; (2) the client's current active treatment plan at the time of discharge; (3) the client's most recent physician orders; and (4) any other documentation that would assist in post-discharge continuity of care. Furthermore, under this standard we proposed that the CMHC would have to adhere to all Federal and State-related requirements pertaining to medical privacy and the release of client information. We believe this standard would help ensure that the information flow between the CMHC and the receiving entity was smooth, and that the appropriate care continued without being compromised (where applicable).

Comment: Several commenters stated that under Medicaid and State law, CMHCs are allowed a wide range of staff to provide initial evaluations, from unlicensed, Master's level practitioners (under supervision of a licensed professional) to licensed Master's level clinicians, including social workers and counselors. Commenters also stated that State laws allow for licensed clinical social workers (LCSWs) or other mental health counselors to conduct initial evaluations. Other commenters stated that use of a psychiatric RN or clinical psychologist to conduct the initial evaluation should only apply to PHP programs.

Response: We appreciate the comments regarding the appropriate staff to conduct an initial evaluation. We understand currently that there may be several different staff the CMHC uses to conduct an initial evaluation, and that the types of staff used may vary from State to State. While it may be appropriate for a psychiatric RN or psychologist to conduct an initial evaluation on a client, we understand that this may not be appropriate for all clients and is not necessarily a standard of practice in the CMHC setting. We would expect the CMHC to assign the most appropriate mental health professionals to conduct the initial evaluation. Therefore, the CMHC may add additional requirements under their policy and procedures to require the initial evaluation on all PHP clients to be conducted by a psychiatric RN, acting within his or her State's scope of practice, or by a clinical psychologist, who meets the qualifications in § 410.71(d), acting within his or her State's scope of practice. We have removed the requirement that a psychiatric RN or clinical psychologist conduct the initial evaluation.

We also understand that there may be unlicensed staff (completing their education or licensure requirements) conducting initial evaluations under the supervision of a licensed professional. We believe that the initial evaluation is paramount in meeting the immediate needs of the client and beginning the active treatment plan. Therefore, we have amended the language at § 485.914(b)(1) to allow a licensed mental health professional acting within his or her State scope of practice to conduct the initial evaluation. We will allow staff working towards completing their education or licensure requirements to complete the initial evaluation under the direct supervision of a licensed mental health professional (as required by all State law and regulations related to the supervision of

unlicensed professionals and students) employed by the CMHC.

Comment: One commenter stated the CMHC should be required to notify a client's primary care provider, if any, in lieu of a formal consultation. The commenter stated that such notification would be contingent upon a client's understanding and consent.

Response: This comment was somewhat unclear. We believe it is referring to communication between the CMHC and the client's primary care provider during the comprehensive assessment. We agree with the commenter that the CMHC should obtain consent from the client when sharing information between the CMHC and the PCP. Therefore, we have amended the language at § 485.914(c)(4)(ii) regarding the CMHC receiving the client's consent before client information is obtained or shared with the client's primary care provider.

Comment: Commenters asked to add additional assessment criteria such as environmental factors. Commenters stated that strengths and barriers related to a client's home, work, or social environments can play a critical role in the success or failure of key interventions.

Response: We agree that it is important to assess environmental factors related to the home and work environments in the overall development and coordination of the active treatment plan. Furthermore, we believe the assessment and coordination of information related to environmental factors such as housing and employment services, as well as the client's preferences and personal goals, are essential in developing a recovery focused active treatment plan and to meeting the client's recovery goals. Therefore we amended the assessment language at § 485.14(b)(4)(v) to include environmental factors and at § 485.16(e)(5) to include coordination of services with other healthcare and non-medical providers.

We would like to stress the importance of client privacy and confidentiality and remind CMHCs that HIPAA applies to release of protected health information by CMHCs; it is generally prohibited to release client information to non-health care entities without the express consent of the client. If CMHCs do release such information to state or local agencies, they must generally obtain consent from the client before such release.

Comment: Some commenters believe that the medication review should be limited to requiring that the partial hospitalization program maintain only a current list of the individual's

medications, prescriptions and over-the-counter medications, as well as contact information for the treating practitioner of the individual served.

Response: We appreciate the comments on medication review. We believe that listing the current medications (both prescription and over-the-counter) is extremely important for all clients during the initial evaluation. The information documented will be reviewed during the comprehensive assessment and may impact the development of the active treatment plan. Therefore, we believe that the documentation of current medications is essential to the start of care for the CMHC clients.

Comment: Commenters stated that a psychiatrist should be required to address medication management.

Response: We appreciate the comments regarding a psychiatrist addressing medication management. The initial evaluation requires documentation of both prescription and over-the-counter medications. The comprehensive assessment requires a drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy. We expect the drug profile section of the comprehensive assessment to be completed by a CMHC licensed mental health professional (such as the psychiatrist, MD or nurse practitioner) with the appropriate knowledge, skills, and certification or licensure, and acting within his or her State's scope of practice, to assess drug therapy.

Comment: Commenters stated that a CMHC should be assessing the social service needs of pediatric clients. They also stated that, when appropriate, a referral should be made to social services, child welfare, and/or the juvenile justice system for pediatric clients.

Response: We agree that assessing for the social service needs of pediatric clients is very important. We expect that the assessment of a pediatric client would include social service and child welfare questions. We also expect that a referral be made to social services and/or child welfare services, if appropriate. Therefore, we have added language at § 485.914(c)(4)(xiv) to address the pediatric assessment.

Comment: Some commenters stated that additional assessment criteria should be added to the comprehensive assessment. Commenters stated that CMHCs should assess for client strengths and goals, as well as a history of trauma.

Response: We agree that it is important to assess the client for strengths, goals and a history of trauma. We believe that a history of trauma is already incorporated into the regulation language at § 485.914(c)(4)(ii) and (iii). These sections outline the assessment expectation of the psychiatric evaluation, which would review medical history and severity of symptoms, as well as assessment information concerning previous and current medical status, including but not limited to, previous therapeutic interventions and hospitalizations. Section § 485.915(c)(4)(viii) addresses clients' goals and requires the client to be assessed for functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

Comment: Some commenters stated that CMS should change the comprehensive assessment timeframe from 3 working days to 7 program days. Other commenters stated the assessment time-frames should be extended from 3 working days to 5 working days.

Response: We appreciate the comments related to the assessment timeframe. However, we are unclear on what the commenters meant by "program days". The commenters did not clarify or give examples regarding the term "program days". We use the term "working days", which allows the CMHC to not count the days that the CMHC is closed. Other commenters asked that we extend the time-frame for completion of the assessment. We understand that the clients a CMHC may see vary greatly in their treatment needs and that assessing a complex client may take longer than 3 working days. However, we believe that all clients should be assessed in a timely manner regardless of their diagnosis. Therefore, we have amended the timeframe for the assessment at § 485.914(c)(2) from 3 working days to 4 working days, with day 1 starting the day after admission. For example, if a client is admitted on a Friday, the CMHC would need to have the comprehensive assessment completed within 4 working days, which would be by Thursday.

Comment: A few commenters requested that we extend the permissible timeframe for a CMHC to prepare and forward a discharge summary to a receiving facility or provider, if any, to 30 days from the date of discharge. The commenters stated that the proposed 48-hour requirement is inconsistent with the existing requirement for inpatient psychiatric providers and unnecessarily

places an administrative burden upon CMHCs.

Response: We appreciate the comments related to forwarding the discharge summary. We acknowledge that there is a 30-day discharge paperwork requirement for discharge from an inpatient psychiatric facility. However, the inpatient discharge expectation is that the client summary information is sent at the time of discharge to the receiving entity. Best practices would suggest that at discharge there would be no break in service and that the receiving entity receive the appropriate information to continue to meet the needs of the client. However, we understand that a CMHC is open during regular business hours and requiring a 48-hour timeframe may be unreasonable. Therefore, we modified the language at § 485.914(e)(1) to require the CMHC to forward the discharge summary to the receiving entity or practitioner within 2 working days after the discharge. For example, if a client discharges from the CMHC on Friday the discharge summary should be sent to the receiving provider by close of business on Tuesday.

Comment: A few commenters asked who should be responsible for ensuring the discharge plan is complete.

Response: The discharge process is part of the client's active treatment plan and should be discussed and incorporated in the plan from the initial evaluation. The interdisciplinary team is responsible for the care and services for each client. Moreover, § 485.916(a)(2) requires the CMHC to determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed, and to ensure that the active treatment plan is implemented as indicated. Best practices would suggest that this coordinator would also manage the discharge process of the client. However, the CMHC has the flexibility to have any licensed professional who serves on the client's interdisciplinary treatment team coordinate the discharge plan.

Comment: One commenter asked that we eliminate the requirements regarding discharge for non-compliance.

Response: While we understand the commenter's concern regarding discharge for non-compliance, and believe that this rarely happens, we believe the CMHC wants to serve its clients to the best of its ability. Unfortunately, when a client is non-compliant with his or her active treatment plan, it may be in the best

interest for both the client and the CMHC to discharge the client to a care level that meets the client's needs. If non-compliance became an issue for a client, the client's interdisciplinary team would need to document that it addressed the issue and tried repeatedly to work with the client and family, and that discharge was the last option. The CMHC must ensure that the client's discharge information is forwarded to the appropriate practitioner as required in § 485.914(e).

CMHC CoP: Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We proposed to add a new CoP at § 485.916 to establish requirements for an active treatment plan and coordination of services.

At § 485.916(a), "Standard: Delivery of services," we proposed that the CMHC designate a physician-led interdisciplinary team for each client. We proposed that the interdisciplinary team include a psychiatric registered nurse, clinical psychologist, or a Master's level prepared or Doctoral level prepared social worker, who would be a coordinator responsible, with the client, for directing, coordinating and managing the care and services provided to the client. The team would be composed of individuals who would work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

The CMHC would designate a psychiatric registered nurse, clinical psychologist or clinical social worker who was a member of the interdisciplinary treatment team to coordinate care, ensure the continuous assessment of each client's needs, and ensure the implementation and revision of the active treatment plan. Depending on the number and/or type of clients served by the CMHC, the CMHC may have more than one interdisciplinary team. If so, the CMHC is required to designate one treatment team responsible for establishing policies and procedures governing the day-to-day operations of the CMHC, and the care and services provided to clients.

At § 485.916(b), "Standard: Active treatment plan," we proposed to require that all CMHC services furnished to clients follow a written active treatment plan established by the CMHC physician-led interdisciplinary treatment team and the client (and representative, if any), in accordance with the client's psychiatric needs and goals within 3 working days after the client's admission to the CMHC. The CMHC would have to ensure that each client and, if relevant, primary

caregiver(s), received education and training that was consistent with the client's and caregiver's responsibilities, as identified in the client-specific active treatment plan. Education is necessary to ensure that the client and caregiver understand the services and treatments contained in the active treatment plan, and their roles in actively participating in, and following the plan.

At § 485.916(c), "Standard: Content of the active treatment plan," we proposed to require that each client's active treatment plan reflects client goals and interventions for problems identified in the comprehensive and updated assessments. This proposed requirement would ensure that care and services were appropriate to the level of each client's specific needs. The active treatment plan would include all of the services necessary for the care and management of the psychiatric illness. We would also require a detailed statement of the type, duration and frequency of services, including social work, counseling, psychiatric nursing and therapy services. Services furnished by other staff trained to work with psychiatric clients necessary to meet the specific client's needs should also be documented. The interdisciplinary treatment team should document the client's and representative's (if any) understanding, involvement, and agreement with the active treatment plan, in accordance with the CMHC's own policies. This would include information about the client's need for services and supports, and treatment goals and preferences.

At § 485.916(d), "Standard: Review of the active treatment plan," we proposed that a revised active treatment plan be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan would have to be reviewed at intervals specified in the plan, but no less frequently than every 30 calendar days.

At § 485.916(e) "Standard: Coordination of services," we proposed to require that the CMHC maintain a system of communication and integration to enable the interdisciplinary treatment team to ensure the overall provision of care and the efficient implementation of day-to-day policies and procedures. This proposed standard would also make it easier for the CMHC to ensure that the care and services are provided in accordance with the active treatment plan, and that all care and services provided are based on the

comprehensive and updated assessments of the client's needs. An effective communication system also enables the CMHC to ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are being provided by employees or by individuals under contract with the CMHC.

Comment: Several commenters stated that the family and/or significant other should be included in the active treatment planning process.

Response: We appreciate the suggestion to add family and/or significant other involvement in the active treatment plan. We agree with the commenters, but prefer to use the term "primary caregiver" instead of family and/or significant other. The term "primary caregiver" is a broader term that encompasses family and significant others but also represents caregivers such as friends or significant others. Therefore, we have amended the language at § 485.916(b), "Standard: Active treatment plan" to add "primary caregiver."

Comment: Many commenters believe that the proposed CoPs were over-reaching in requiring an interdisciplinary team (IDT) which "would include" many disciplines. Commenters stated that CMS should replace "would include" with "may include" in order to allow for the individualization of the treatment planning for each client. Other commenters disagreed with CMS regarding the staff requirements for the IDT being standard medical practice.

Response: We agree with the comments related to the members of the IDT. We understand that CMHC clients vary from clients receiving PHP to clients receiving short term counseling or medication management. We believe there may be clients who, based on their diagnosis and assessment, may only need a one-person IDT to meet their care needs. For example, a client who is being treated for medication management may be required to be seen by a practitioner a couple of times a year. Therefore, the proposed "one size fits all" approach to the IDT membership may not serve the client's interests and potentially takes away from the CMHC's flexibility to serve the client's needs, and the needs of other clients. Therefore, we have amended the language at § 985.916(a)(2) to allow the CMHC to determine (based on the findings of the client's comprehensive assessment), the appropriate licensed mental health professionals and other CMHC staff to serve on the client's interdisciplinary team. The amended

language now states that the interdisciplinary team may include: A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC), a psychiatric registered nurse, a clinical social worker, a clinical psychologist, an occupational therapist, other licensed mental health professionals, and other CMHC staff, as necessary. We note that the interdisciplinary team membership must be based on the client's assessed needs. CMHCs will be expected to demonstrate a correlation between the client's comprehensive assessment, assessed needs, members serving on the interdisciplinary team, and the active treatment plan. Therefore a PHP client's interdisciplinary team members are likely to be different than the client who is being treated by the CMHC for short-term counseling or medication management.

Comment: A few commenters stated that CMHCs often do not have the resources to engage a physician in leading team care, treatment, and services planning. According to commenters, there is no recognized data to demonstrate improved outcomes in PHPs by having a physician leading the care team. Other commenters stated that the concept of a collaborative healthcare team should not be restricted to a "physician-led interdisciplinary team" as it may be more achievable if viewed as an interdisciplinary team that includes a physician. The commenters also believe that a physician-led interdisciplinary team limits the capacity of advanced practice registered nurses, nurse practitioners and clinical psychologists, who are qualified and licensed to lead interdisciplinary teams.

Response: We appreciate the comments regarding the physician leading the interdisciplinary team. We proposed this standard to ensure physician involvement in the interdisciplinary team process. However, we agree that there is no documented research that demonstrates improved outcomes in PHPs by having a physician leading the team, and such a requirement may limit collaboration and the role of the other qualified practitioners. Therefore, based on the client's needs, in addition to a physician, we have amended the language at § 485.916(a)(1), to now allow for a nurse practitioner, a clinical nurse specialist, a clinical psychologist, a physician assistant, or clinical social worker to serve as the leader of the team, if permitted by State law and within his or her scope of practice. This allows the CMHC greater flexibility to meet the client's needs. We stress that while this change allows additional

advanced practice practitioners to lead the team, it in no way minimizes the physician's involvement in managing the medical component of the client's care and/or serving on the interdisciplinary group.

In the instance of partial hospitalization, clients need acute services and must be under the care of a physician. According to the statutory requirements, which are implemented in CMS regulations at 42 CFR 424.24(e), PHP services must be prescribed by a physician and under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program). Furthermore, upon admission, a physician must certify that in absence of PHP services, the person would otherwise require inpatient psychiatric treatment. If continued PHP treatment is necessary, a physician must recertify as of the 18th day of treatment and no less than every 30 days after that documenting the need for this level of service. Therefore, a physician is inextricably involved in a PHP client's treatment team.

Comment: Several commenters stated that advanced practice nurses, including both psychiatric mental health nurse practitioners (PMHNPs) and psychiatric mental health clinical nurse specialists (PMHCNSs), need to be included in the list of professionals who can lead multidisciplinary teams. Other commenters stated that occupational therapists, social workers and other licensed mental health counselors should be added to the list of professionals who can serve as coordinators.

Response: We appreciate the comments regarding leading the interdisciplinary team. There are two different requirements in the proposed CoPs where we discuss leadership of the interdisciplinary team. In § 485.916(a)(1), we proposed that the interdisciplinary team be led by a physician. We proposed this standard to ensure physician involvement in the interdisciplinary team process. However, we agree that allowing a nurse practitioner, a clinical nurse specialist, a physician assistant, or a psychologist would allow the CMHC greater flexibility to meet the client's needs. While we allow for additional advanced practice practitioners to lead the team, that in no way minimizes the physician involvement in managing the medical component of the client's care.

At § 485.916(a)(2), we proposed a psychiatric registered nurse, a clinical

psychologist, or a clinical social worker, who is a member of the interdisciplinary team to coordinate care and treatment decisions with each client, to ensure that each client's needs were assessed and to ensure the active treatment plan was implemented as indicated. We understand that there may be other licensed mental health professionals serving on the interdisciplinary team that could be appropriate to coordinate the client's care. Therefore, we have amended the language at § 485.916(a)(2) to allow the CMHC to determine (based on the findings of the client's comprehensive assessment) which appropriate licensed mental health professional(s) on the client's interdisciplinary team should coordinate care and treatment decisions with each client. This coordinator role would work to ensure that each client's needs are assessed and to ensure that the active treatment plan is implemented as indicated.

Comment: A few commenters stated that social workers and occupational therapists are not needed for every client, but should be available.

Response: Services offered to a client should be based on the client's assessed needs. If a client is assessed to need the services of a social worker and/or an occupational therapist, we would expect those disciplines to be part of the interdisciplinary team. We note that the needs of CMHC clients vary from clients receiving PHP to clients receiving short term counseling. Therefore, the proposed approach to the interdisciplinary team membership may not serve the client's interests and potentially takes away from the CMHC's flexibility to serve the client's needs. Therefore, we have amended the language at § 485.916(a)(2) to allow for the CMHC to determine (based on the findings of the client's comprehensive assessment) the appropriate licensed mental health professional(s) and other CMHC staff that will serve on the client's interdisciplinary team.

Comment: One commenter stated that a Licensed Professional Counselor (LPC) can fulfill the clinical, psychological, and social work needs of clients.

Response: We appreciate the comment regarding LPCs fulfilling multiple client needs. We agree there are times when an LPC may be able to meet several different assessed needs of the client, as long as the State licensure permits them to do so. We would expect to see documentation by the LPC of the progress toward the client's goals. The expectation is that if goals are not being met and additional needs are assessed, the interdisciplinary team will bring in

additional team members to address the client's needs.

Comment: One commenter stated that a peer specialist or family peer advocate should be added to the IDT. Another commenter stated that CMS should require support of the recovery model by allowing for peers (persons with lived experience of mental illness, or peer specialists) to be part of the treatment team.

Response: We appreciate the comments regarding peer specialists and family peer advocates. We agree that, depending on the CMHC's client needs and programs, peer specialists or family peer advocates may be appropriate to meet individual client needs. Therefore, we have amended the language at § 485.916(a)(2)(vii) to permit other CMHC staff or volunteers to serve on the interdisciplinary team, as necessary.

Comment: A few commenters stated that the timeframe for developing the active treatment plan should be extended from 3 working days to 5 working days.

Response: We appreciate the commenters' request for extension of the active treatment plan timeframe. We believe that completing the assessment in a timely manner is very important. In this final rule, we have amended the timeframe of the comprehensive assessment to be completed within 4 working days. Therefore, we also amended the language at § 485.916(b) to extend the timeframe for completion of the active treatment plan to 7 working days.

In the instances of partial hospitalization, due to the acuity level of the clients served, we expect the partial hospitalization program to meet the requirement at § 424.24.

Comment: A few commenters recommended amending the treatment plan language to allow organizations to document the understanding of either the individual served or, if the individual served is unable to acknowledge his or her understanding and/or agreement, the representative's understanding of, and agreement with, the treatment plan.

Response: We appreciate the commenters' suggestion. We agree that having the CMHC document the client's and/or the client representative's understanding of the active treatment plan is necessary. We would expect the CMHC to document the client's understanding and involvement in his or her active treatment plan. If the client is unable to understand the active treatment plan, the CMHC would document the client's representative's understanding and involvement in the active treatment plan. Therefore, we

have amended the language in § 485.916(c)(7).

Comment: A few commenters stated that we should include the individual's preferences and personal goals in the active treatment plan. Another commenter recommended that we revise the standards to reflect current recovery-focused care planning to better align with the recommendations previously set forth by the Substance Abuse and Mental Health Services Administration.

Response: We appreciate both commenters' suggestions to include the client's preferences and personal goals in the active treatment plan and to have a recovery focused active treatment plan. We agree with both of the commenters, and have amended § 485.916(b) accordingly. We expect that the interdisciplinary team will work together to establish the client's individual active treatment plan in accordance with the client's recovery goals and preferences.

Comment: One commenter recommended that we require the development of a crisis plan for each client.

Response: We agree with the commenter that crisis planning is important for the health and safety of clients. However, the individual client's risk factors are assessed during the comprehensive assessment and the information gathered in the assessment and active treatment plan would be used to guide the care of the client if an emergency should occur. Therefore, we do not believe it is necessary to add an additional regulatory requirement addressing crisis planning.

CoP: Quality Assessment and Performance Improvement (Proposed § 485.917)

We proposed to add a new CoP at § 485.917 to specify the requirements for a quality assessment and performance improvement program (QAPI). The proposed QAPI CoP was divided into five standards.

At § 485.917(a), "Standard: Program scope," we proposed that a CMHC QAPI would include, but not be limited to, an ongoing program that is able to show measureable improvement in indicators linked to improving client care outcomes and behavioral health support services. We expect that a CMHC would use standards of care and the findings made available in current literature to select indicators to monitor its program. The CMHC would have to measure, analyze, and track quality indicators, including areas such as adverse client events and other aspects of performance that assess processes of care, CMHC services and operations. The term

"adverse client events," as used in the field, refers to occurrences that are harmful or contrary to the targeted client outcomes, including sentinel events such as an unexpected occurrence involving death or serious injury. The use of restraint or seclusion is contrary to targeted client outcomes; therefore, we would consider the use of restraint or seclusion to be an adverse client event that would be tracked and analyzed as part of the QAPI program.

At § 485.917(b), "Standard: Program data," we proposed to require the CMHC to incorporate quality indicator data, including client care data and other relevant data, into its QAPI program. A fundamental barrier in identifying quality care is lack of measurement tools. Measurement tools can identify opportunities for improving medical care and examining the impact of interventions.

We did not propose to require CMHCs to use any particular process, tools or quality measures. However, a CMHC that uses available quality measures could expect an enhanced degree of insight into the quality of its services and client satisfaction.

The CMHC could also develop its own data elements and measurement process as part of its program. A CMHC would be free to develop a program that meets its needs. We recognize the diversity of provider needs and concerns with respect to QAPI programs. As such, a provider's QAPI program would not be judged against a specific model. We expect the CMHC to develop and implement a continuous QAPI program that stimulates the CMHC to constantly monitor and improve its own performance, and to be responsive to the needs and satisfaction levels of the clients it serves.

At § 485.917(b), we proposed to require that data collected by the CMHC, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the CMHC's governing body. Once collected, the CMHC would use the data to monitor the effectiveness and safety of services, and target areas for improvement. The main goal of the proposed standard would be to identify and correct ineffective and/or unsafe care. We expect CMHCs to assess their potential client load and identify circumstances that could lead to significant client care issues, and concentrate their energies in these areas.

At § 485.917(c), "Standard: Program activities," we proposed to require the CMHC to set priorities for its performance improvement activities that focus on high risk, high volume or

problem-prone areas; consider the prevalence and severity of identified problems; and give priority to improvement activities that affect client safety, and quality of client outcomes. We expect that a CMHC would take immediate action to correct any identified problems that would directly or potentially threaten the care and safety of clients. Prioritizing areas of improvement is essential for the CMHC to gain a strategic view of its operating environment and to ensure consistent quality of care over time.

We also proposed to require the CMHC to track adverse client events, analyze their causes, and implement preventive actions that include feedback and learning throughout the CMHC. In implementing its QAPI program, a CMHC is expected to treat staff and clients/representatives as full partners in quality improvement. Staff members and clients/representatives are in a unique position to provide the CMHC with structured feedback on, and suggestions for, improving the CMHC's performance. We expect the CMHC to demonstrate how the staff and clients have contributed to its quality improvement program.

At § 485.917(d), "Standard: Performance improvement projects," we proposed to require that the number and scope of improvement projects conducted annually would reflect the scope, complexity and past performance of the CMHC's services and operations. The CMHC would document what improvement projects were being conducted, the reasons for conducting them and the measurable progress achieved by them.

At § 485.917(e), "Standard: Executive responsibilities," we proposed to require that the CMHC's governing body would be responsible and accountable for ensuring that the ongoing quality improvement program is defined, implemented, maintained, and evaluated annually. The governing body would ensure that the program addressed priorities for improved quality of care and client safety. The governing body would also have to specify the frequency and level of detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. The governing body's most important role would be to ensure that staff was furnishing, and clients were receiving, safe, effective, quality care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality improvement and performance improvement efforts.

Comment: One commenter suggested that as an alternative to the requirement

that CMHCs develop their own QAPI programs, CMS could point CMHCs to specific, existing programs, such as NCQA's Managed Behavioral Health Organization (MBHO) Certification program, to ensure consistency among facilities in delivering high quality care.

Response: We acknowledge that there are existing programs that may be used by CMHCs in their efforts to meet the QAPI standards. We would caution, however, that participation in such programs does not guarantee that the CMHCs are in compliance with this requirement. As required in § 485.917(b)(2)(ii), CMHCs must use the quality indicator data that they have gathered to identify and prioritize opportunities for improvement. In addition, § 485.917(a)(1) requires the CMHC QAPI program to show measurable improvement in the areas related to improved behavioral health outcomes and CMHC services specific to the individual facility. Furthermore, § 485.917(d)(1) requires that the scope and number of a CMHC's performance improvement projects are to be based on the unique needs of the CMHC and its client population. These requirements require the CMHC to develop, implement, and assess performance improvement projects that reflect the areas of weakness, as identified through the data they have collected, and the needs of their organization. If a CMHC participates in a certification program that does not address one more of the areas of weakness, or if that performance improvement project will not enable the CMHC to demonstrate measurable improvement in areas identified as needing to be addressed, then participation in a certification program alone would not meet the QAPI requirements in this rule.

CMHCs utilizing resources from a quality improvement organization will still be expected to provide separate documentation evidencing their QAPI program.

Comment: Several commenters stated their strong support for the proposed rule regarding QAPI. According to the commenters, the existence of a QAPI program ensures the provision of quality services, identifies weaknesses in the care process, and encourages the provider to make changes in order to improve their current practices. A few commenters stated that they were committed to supporting CMHCs in developing better data systems and using that data to improve service quality and efficiency.

Response: We appreciate the overall support for the data collection and QAPI requirements, as this support will help ensure that CMHCs develop a data-

driven program for continuous quality improvement that reflects the needs of the clients and CMHCs alike.

Comment: Several commenters supported CMS' decision to work with the NCQA and Mathematica to develop measures for use in inpatient psychiatric facilities, and requested that CMS facilitate the development and adoption of robust, harmonized, tested, and validated measures around schizophrenia that could also be used in other settings, such as CMHCs. In addition, the commenters encouraged further development of functional measures, such as the ability to return to work, that could be used as important indicators of successful treatment, especially for those clients with negative symptoms such as delusional behavior. The commenters stated that such measures would provide CMHCs with an important tool for use in evaluating their own quality programs.

Response: We appreciate the support for CMS' work with the NCQA. At this time there are no plans for CMS to develop measures specific to CMHCs. However as CMS works with NCQA and the Substance Abuse and Mental Health Services Administration (SAMHSA), we will continue to pursue measures appropriate for the CMHC setting. CMHCs can use the search term "mental health" on the National Quality Forum Web site at <http://www.qualityforum.org/Qps/QpsTool.aspx> to find additional measures-related resources.

Comment: Several commenters strongly agree that CMHCs should track "adverse client events" and immediately "correct any identified problems that would directly or potentially threaten the care and safety of clients." Commenters stated that all existing CMHCs should not have any issues complying with this requirement.

Response: We appreciate the support for tracking adverse events. We believe it is essential to the CMHC QAPI program to begin tracking and analyzing adverse events at the same time it begins collecting client level outcomes measures data elements and CMHC-wide measures that are available. Adverse events generally result in harm to a client; they serve as important indicators for areas of potential improvement. If CMHCs do not collect adverse event information, they may be missing important data from which to assess their performance.

CMHC CoP: Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

We proposed to add a new CoP at § 485.918, to set out the CMHC's

administrative and governance structure and to clarify performance expectations for the governing body. As explained in the proposed rule, the overall goal of this CoP is to ensure that the management structure is organized and accountable. The proposed CoP was divided into seven standards.

In the proposed organization and administration of services CoP, we proposed to list the services that the statute (section 1861(ff)(3) of the Act) requires CMHCs to furnish. We also proposed a standard that would require a CMHC to provide in-service training to all employees and staff, including those under contract or under arrangements, who have client contact. This requirement would assist in ensuring that all staff serving CMHC clients was up to date on current standards of practice. The CMHC would be required to have written policies and procedures describing its methods for assessing staff skills and competency, and to maintain a written description of in-service training offered during the previous 12 months.

At § 485.918(a), "Standard: Governing body and administrator," we proposed to emphasize the responsibility of the CMHC governing body (or designated persons so functioning) for managing all CMHC facilities and services, including fiscal operations, quality improvement, and the appointment of the administrator. The administrator would be responsible for the day-to-day operation of the CMHC and would report to the governing body. The administrator would have to be a CMHC employee, and meet the education and experience requirements established by the CMHC's governing body. The specifics of the administration of the CMHC would be left to the discretion of the governing body, thereby affording the CMHC's management with organizational flexibility. The proposed governing body standard reflects our goal of promoting the effective management and administration of the CMHC as an organizational entity without dictating prescriptive requirements for how a CMHC must meet that goal.

At § 485.918(b), "Provision of services," we proposed to specify a comprehensive list of services that a CMHC would be required to provide. At § 485.918(b)(1)(v), we proposed to require the CMHC to provide at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Act (Medicare). This proposed requirement would track the changes to § 410.2 set out in the November 24, 2010 Outpatient Prospective Payment System (OPPS)

final rule (75 FR 71800, 72259). Both the CMHC proposed rule and the OPSS final rule changes implement the statutory changes made by section 1301(a) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (HCERA).

Enactment of section 1301(a) of HCERA revised the definition of a CMHC set forth at section 1861(ff)(3)(B) of the Act by adding a provision to the existing requirements for CMHCs, effective on the first day of the first calendar quarter that began at least 12 months after the date of enactment (that is, April 1, 2011). As of that date, a Medicare-participating CMHC must provide at least 40 percent of its services to individuals who are not eligible for benefits under Medicare.

We proposed to measure whether a CMHC is providing at least 40 percent of its services to individuals who are not eligible for Medicare benefits by the amount of reimbursement for all services furnished. Additionally, we proposed to measure the 40 percent of its services on an annual basis. We solicited public comments on whether we should determine if a CMHC meets the 40 percent requirement annually or at some other interval. We also solicited comments on both the definition of terms used in any approach to measuring the 40 percent threshold and the data sources for that measurement. Specifically, since the measure proposed to determine the 40 percent threshold was total reimbursement from all payers, for all services provided, we were interested in comments on how we should define reimbursement.

We also requested feedback on whether the proposed calculation should include uncompensated care or any other aspect of reimbursement, and on whether CMS should require the CMHCs to attest to whether they meet the 40 percent requirement, or whether we should subject them to verification auditing.

Furthermore, we stated our interest in receiving comments on any other approaches that could constitute a measure of the 40 percent threshold. We stressed that we were concerned that the implementation of this provision not negatively impact access to care.

Medicare-certified CMHCs are already required to provide most of the services set out in the proposed provision of services standard through the existing CMS payment rules (42 CFR 410.2, § 410.110, and § 424.24(e)). It is essential for CMHCs to have sufficient numbers of appropriately educated and trained staff to meet these service expectations. For example, CMHCs that provide partial hospitalization services

could provide the services of “other staff trained to work with psychiatric clients” (42 CFR 410.43(a)(3)(iii)). Non-specified staff might be responsible for supervising clients and ensuring a safe environment. CMHCs would be expected to have a sufficient number of appropriately-trained staff to meet these responsibilities at all times.

At § 485.918(c), “Standard: Professional management responsibility,” we proposed to require that where services are furnished by other than CMHC staff, a CMHC would have to have a written agreement with another agency, individual, or organization that furnishes the services. Under this agreement, the CMHC would retain administrative and financial management and oversight of staff and services for all arranged services. The CMHC would have to have a written agreement that specified that all services would have to be authorized by the CMHC, be furnished in a safe and effective manner, and be delivered in accordance with established professional standards, the policies of the CMHC and the client’s active treatment plan. As part of retaining financial management responsibility, the CMHC would retain all payment responsibility for services furnished under arrangement on its behalf.

At § 485.918(d), “Standard: Staff training,” which would apply to all employees, staff under contract, and volunteers, we proposed to require a CMHC to take steps to develop appropriate in-service programs, including initial orientation for each new employee or volunteer furnishing services. The new employee orientation would address specific job duties. The CMHC could also provide staff training under arrangement.

We would not require a specific staff in-service training program; rather, we would expect each CMHC to determine the scope of its own program, including the manner in which it chose to deliver the training, assess competence levels, determine training content, determine the duration and frequency of training for all employees, and track the training on a yearly basis.

At § 485.918(e)(1), “Standard: Environmental conditions,” and (e)(2), “Building,” we proposed to require the CMHC to provide services in an environment that is safe, functional, sanitary, comfortable, and in compliance with all Federal, State, and local health and safety standards, as well as State health care occupancy regulations. We indicated that these proposed requirements would help to ensure that CMHC services are provided in a physical location that is both safe

and conducive to meeting the needs of CMHC clients.

At § 485.918(e)(3), “Infection control,” we proposed to address the seriousness and potential hazards of infectious and communicable diseases. We would require a CMHC to develop policies, procedures, and monitoring, as well as take specific actions to address the prevention and control of infections and disease.

We believe that a CMHC should follow nationally accepted infection control standards of practice and ensure that all staff know and use current best preventive practices. Periodic training is one way to assure staff understanding, and we would expect the CMHC to establish a method to ensure that all staff receives appropriate training. Where infection and/or communicable diseases are identified, we would expect actions be taken to protect all the clients and staff.

At § 485.918(e)(4), “Therapy sessions,” we proposed that the CMHCs ensure that all individual and group therapy sessions be conducted in a manner that maintains client privacy and dignity. We believe that a safe, private environment would enhance the effectiveness of the therapy sessions.

At § 485.918(f), “Standard: Partial hospitalization services,” we proposed that all partial hospitalization services would be required to meet all applicable requirements of 42 CFR parts 410 and 424.

At § 485.918(g), “Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients,” we proposed that the CMHC and its staff be required to operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations related to the health and safety of clients. If State or local law provided for licensing of CMHCs, the CMHC would have to be licensed. In addition, the CMHC staff would have to follow the CMHC’s policies and procedures.

Comment: Many commenters strongly agree with the overall goal of the administrative standard at § 485.918(a). They believe it would ensure that the management structure is organized and accountable.

Response: We appreciate the overall support for the administrative standard. This support would help ensure efficient operation of the CMHC and that the CMHC meets the needs of the clients and CMHCs alike.

Comment: Some commenters strongly support the option of allowing the CMHCs to receive oversight from the Joint Commission, or other accrediting

bodies. Other commenters encouraged CMS to defer to the states regarding deemed status, by recognizing deeming authority for CMHCs in those states that allow deeming. However, some commenters stated that CMS should not adopt deeming authority for CMHCs.

Response: We appreciate the wide array of comments related to deeming. As stated in the proposed rule, we are not proposing to amend our regulations at § 488.6 to grant deeming authority for CMHCs to accrediting organizations. CMS's regulation at § 488.6 does not permit deeming for CMHCs. To allow for deeming authority to occur for CMHCs, there would need to be a regulatory change. We will take this under advisement for future rulemaking.

Comment: Many commenters stated that CMS should use the language in Section 1301 of HCERA to calculate the 40 percent threshold. Specifically, they noted that the Congress used the phrase "40 percent of its services to individuals" without making any reference at all to reimbursement or payment in the statute. Commenters also stated that to be consistent with the major themes of the Affordable Care Act (which incorporates HCERA), the legislative language in Section 1301 of HCERA indicates the need for a patient-centric approach rather than a reimbursement-based approach. Additionally, many commenters stated that using an independent auditing agency to review CMHC financial statements to certify compliance with the 40 percent threshold would be overly burdensome and confusing for the CMHC.

Response: We agree with the commenters on the 40 percent calculation. We proposed several different potential ideas for calculating the 40 percent. After carefully considering all the comments received, we are adopting a patient-centric approach and will require that the calculation of 40 percent be based on CMHC services to individuals.

Comment: Commenters offered very detailed recommendations on how to calculate the 40 percent threshold, the implementation process, the timeframes, and the consequences if the CMHC does not meet the 40 percent threshold. Also, commenters stated that the calculation to determine the 40 percent threshold should be based on a patient-centric methodology, including the following elements:

- Numerator: The numerator would include an unduplicated census of individuals who rely solely on health

care coverage provided through private sector insurance or public health programs other than Medicare, indigent individuals and any other uninsured or inadequately insured individuals who receive behavioral health services from the CMHC.

- Denominator: The denominator would include an unduplicated census for all clients who receive services from the CMHC.

- Validation: For each reporting period, the CMHC could attest to the accuracy of the numbers reported to CMS for the patient-centric numerator and denominator identified above. Medicare providers are required to prepare attestations in other contexts involving eligibility to receive Medicare reimbursement, including, but not limited to, the attestations used in the calculation of bad debt.

- Annual Reporting Period: Adopt an annual reporting period based on a facility's cost reporting year.

- Failure to Meet Performance Level: Providers that fail to meet the 40 percent threshold by more than five percent during a particular year should be placed on probation for 12 months and required to develop and implement a corrective action plan to bring the facility into compliance with the 40 percent requirement. If a facility fails to meet the threshold for a second consecutive year, that CMHC should be rendered ineligible for Medicare reimbursement during the subsequent year.

Response: We agree with the commenters' recommendations for calculating the 40 percent threshold. Therefore, we amended the proposed § 485.918 (b)(1)(v) to read "provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act." We have removed the subsequent phrase, which read "as measured by the total revenues received by the CMHC that are payments from Medicare versus payers other than Medicare." We agree that the numerator should include an unduplicated census of individuals who receive services not paid for in whole or in part by Medicare. This may include individuals who rely solely on health care coverage provided through private sector insurance or public health programs other than Medicare, or whose insurance doesn't cover the behavioral health services they receive from the CMHC. The denominator would consist of an unduplicated census of all clients who receive services from the CMHC, including Medicare beneficiaries. The

calculation will determine the total percentage of individuals who are not eligible for benefits under title XVIII of the Act. The CMHC needs to assure continued compliance with the 40 percent threshold on an annual basis—that is, 40 percent of the clients served by the CMHC during each intervening 12 month period must be individuals for whom services are not paid for by Medicare.

We will not be using the proposed language on reimbursement or cost report information to calculate the 40 percent. Rather, we will require all CMHCs to verify their compliance with the 40 percent requirement by sending documentation to the appropriate Part A/Part B Medicare Administrative Contractor (A/B MAC) from an independent entity such as an accounting technician, which will certify that it has reviewed the client care data for the CMHC. The documentation must be sent upon initial application for Medicare provider status, and upon revalidation, including off cycle revalidation, thereafter to the relevant A/B MAC (see revalidation requirements at § 424.515). The documentation must state whether the CMHC met or did not meet the 40 percent requirement for the prior 3 months (in the case of the initial application) or for each of the intervening 12 month periods between initial enrollment and revalidation. If the CMHC did not meet the 40 percent threshold, the A/B MAC will notify the CMHC that they have 30 days to correct the issue or their Medicare enrollment and billing privileges will be denied for non-compliance (see § 424.530(a)(1)) or revoked for non-compliance (see § 424.535(a)(1)).

If an A/B MAC denies or revokes a CMHC's Medicare billing privileges, the CMHC is afforded provider enrollment appeal rights, and may reapply or seek reinstatement into the Medicare program subject to the provisions found in § 424.535.

We appreciate the commenters' suggestions related to failure to meet the 40 percent threshold. However, we disagree with the proposed probationary period and the suggestion of a 5 percent margin. The law does not allow for a probationary period or margins. This final rule becomes effective one year after publication of this rule in the **Federal Register**. This means all CMHCs will have one year to implement the provisions of this rule before the independent entity audit or a survey would occur.

Comment: Several commenters stated that volunteers should not be included in the staff education component described by § 485.918(d)(1) and recommended that any reference to volunteers in this section be removed.

Response: We appreciate the commenters' opinions. However, we believe that educating volunteers about CMHC care and services and person-centered planning is just as important for the volunteer as it is for the staff member. Volunteers are asked to interact with clients in many different situations, such as the waiting room and reception area. For the safety of the client and the volunteer, volunteers should have a basic understanding of the types of clients served and the workings within the CMHC.

Comment: A few commenters stated that § 485.918(d)(3) requires that CMHCs "assess the skills and competence of all individuals furnishing care...." They stated that it is not clear what such a skills and competency assessment would contain, and how much time it would take to develop and administer such assessments for each position within every CMHC. Commenters suggested that this requirement would be met by QAPI. Other commenters suggested that the requirement for CMHC staff to receive consistent and ongoing continuing education is best enforced through the personnel requirements. Commenters stated that licensure and credentialing laws typically include requirements for ongoing continuing education. Other commenters stated that while in-service training may be appropriate in some circumstances, CMS should recognize and support existing continuing education practices required for practitioner licensure and certification.

Response: To clarify, we are requiring the CMHC to create policies and procedures by which to evaluate their employees relevant to the duties assigned to each employee, which can be tied to the CMHC policies related to personnel requirements. The specifics of these policies and procedures would be up to each individual CMHC. The

commenters are correct that this could also be part of the QAPI program. If an area of concern is recognized by staff administering the QAPI program, or the CMHC administration, then it is expected that the CMHC would conduct in-service training related to the area of concern. We understand that there may be specific individual provider licensure requirements based on State laws and regulations; however, this would be specific to the provider type, such as nurse or therapist to maintain his or her license or certification. Section 485.918(d)(3) is specifically related to overall training of the CMHC staff, whether it is specific to issues brought up through the QAPI program or new or edited policies and/or procedures within the CMHC. In-service training can also be used to meet other State and/or Federal requirements, such as infection control.

Comment: A few commenters stated that assessing for self-harm is not enough. Commenters stated that CMHCs need to educate and train staff on suicide prevention. Commenters believe that these regulations could help address a well-established training deficit among service providers and their organizations and could reduce consumer suicide-related morbidity and mortality. Commenters also stated that if staff are untrained and cannot demonstrate competency in the clinical assessment of suicide risk, clients may be at risk.

Response: We agree with the commenter that the importance of suicide prevention education is critical to all staff within the CMHC. Therefore, we have modified the language at § 485.914(b)(4)(ix) to read: "Factors affecting client safety or the safety of others, including behavioral and physical factors as well as suicide risk factors." This is an example of where the use of in-service training in § 485.918(c)(3) would benefit the entire CMHC staff and meet the in-service training requirements. It is very important that CMHCs follow current standards of practice and continually monitor and educate their staff as it

relates to current standards of practice such as suicide prevention.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We published a proposed rule in the **Federal Register** (76 FR 35684) on June 17, 2011. The comment period closed on August 16, 2011. We did not receive any comments related to the PRA section of this rule.

We have made several assumptions and estimates in order to assess the time that it will take for a CMHC to comply with the provisions and the associated costs of compliance. CMHC client data from outside sources are limited; therefore, our estimates are based on available Medicare data. We have detailed these assumptions and estimates in Table 1 below. We have also detailed many of the standards within each CoP, and have noted whether or not there is an impact for each in the section below. However, the requirements contained in many of the CoPs are already standard medical or business practices and, as a result, do not pose an additional burden on CMHCs.

TABLE 1—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE COLLECTION OF INFORMATION AND IMPACT ANALYSIS SECTIONS

Number of Medicare CMHCs nationwide (Based on CY 2012 CMS data)	100
Number of CMHC clients nationwide* (Estimate based on CY 2010 data)	22,700
Number of clients per average CMHC	227
Hourly rate of psychiatric nurse	\$47
Hourly rate of clinical psychologist	\$54
Hourly rate of administrator	\$66
Hourly rate of clinical social worker	\$35
Hourly rate of mental health counselor	\$31
Hourly rate of auditing or accounting clerk	\$24

* Reflects 13,600 Medicare clients and 9,100 non-Medicare clients.

Note: All salary estimates include benefits and overhead package worth 48 percent of the base salary. Salary estimates were obtained from <http://www.bls.gov/>.

A. ICRs Related to Condition of Participation: Client Rights (§ 485.910)

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 9.47 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 × 22,700 clients). The estimated cost associated with these requirements is \$44,509, based on a psychiatric nurse performing this function (947 hours × \$47 per hour).

We note that we do not impose any new language translation or interpretation requirements. Under Title VI of the Civil Rights Act of 1964, recipients of federal financial assistance, such as CMHCs, have long been prohibited from discriminating on the basis of race, color, or national origin. Language interpretation is required under some circumstances under that statute and the HHS regulations at 45 CFR part 80 (see previous discussion of Office for Civil Rights guidance issued in 2003). Because we impose no new requirements not already fully encompassed in that regulation and

guidance, we have estimated no paperwork burden.

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/hr 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 while a CMHC client was in restraint or seclusion in the CMHC while 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 commenters 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.

B. ICRs Related to Condition of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

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.

C. ICRs Related to Condition of Participation: Treatment Team, Active Treatment Plan, and Coordination of Services (§ 485.916)

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 (.1667 hours per client or approximately 3,784 hours nationally) estimated to be a total of \$1,778 per CMHC or \$177,848 nationally. Additionally, we estimate any revisions to the active treatment plan (approximately 5 minutes) will cost \$525 per CMHC or \$88,877 nationally (1891 hours × \$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.

D. ICRs Related to Condition of Participation: Quality Assessment and Performance Improvement (§ 485.917)

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/hr to comply with these requirements for a total of 400 hours annually. The estimated cost associated with this requirement is \$26,400.

E. ICRs Related to Condition of Participation: Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

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 \$1,200. 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).

Table 2 below summarizes the estimated reporting and recordkeeping burden for this final rule.

TABLE 2—ESTIMATED REPORTING AND RECORDKEEPING BURDENS

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

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-3202-F]; Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

IV. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The overall economic impact for all new CoPs in this final rule is estimated to be \$3 million in the first year of implementation and \$2.2 million annually thereafter. Therefore, this is not an economically significant or major final rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, most CMHCs are considered to be small entities, either by virtue of their nonprofit or government status or by having revenues of less than \$10 million in any one year (for details, see the Small Business Administration's Web site at http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf). We estimate there are approximately 100

CMHCs with average admissions of approximately 227 clients per CMHC.¹

We estimate that implementation of this rule will cost CMHCs approximately \$3 million, or approximately \$30,000 per average CMHC, in the first year of implementation and \$2.2 million, or approximately \$22,000 per average CMHC, after the first year of implementation and annually thereafter. Therefore, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities, because the cost impact of this rule is less than 1 percent of total CMHC Medicare revenue (approximately \$218 million per year, as shown by CY 2010 claims data).

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number

¹ In order to develop this 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.

of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals since there are few CMHC programs in those facilities. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that

threshold is approximately \$141 million. This final rule will not have an impact on the expenditures of State, local, or tribal governments in the aggregate, or on the private sector of \$141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule has no Federalism implications.

B. Anticipated Effects on CMHCs

We are establishing a new subpart J under the regulations at 42 CFR part 485 to incorporate the CoPs for CMHCs (which will be effective 12 months after the publication of this final rule). The new subpart J includes the basis and scope of the subpart, definitions, and six conditions.

Section III of this rule, Collection of Information Requirements, provides a detailed analysis of the burden hours and associated costs for all burdens related to the collection of information by CMHCs that are required by this rule. That section, in tandem with this regulatory impact analysis section, presents a full account of the burdens that are imposed by this rule. As shown above in table 2 the total cost of all information collection requirements in the first year is estimated to be \$457,441. In addition, table 3 below presents the total first year cost of \$2,596,809 for all other requirements. Therefore, the total cost for implementing all CoP requirements, including information collection and other costs that CMHCs must meet in order to participate in the Medicare program, is estimated to be \$3 million in the first year of implementation and 2.2 million annually thereafter.

TABLE 3—TOTAL ESTIMATES FOR ALL REQUIREMENTS DESCRIBED IN THIS SECTION

	Total time (hours) per average CMHC	Total industry time (hours)	Total cost per average CMHC	Total industry cost
Client rights	1st year: 167.47 Annual: 67.47	1st year: 16,747 Annual: 6,747	1st year: \$10,968 Annual: \$3,449	1st year: \$1,096,809 Annual: \$344,909
Treatment team. Active Treatment Plan, and Coordination of Services	265	26,500	\$11,568	\$1,156,800
Quality Assessment and Performance Improvement	20	2,000	\$1,320	\$132,000
Organization, Governance, Administration of Services	1st year: 32 Annual: 24	1st year: 3,200 Annual: 2,400	1st year: \$2,112 Annual: \$1,584	1st year: \$211,200 Annual: \$158,400
Totals	1st year: 484.47 Annual: 376.47	1st year: 48,447 Annual: 37,647	1st year: \$25,968 Annual: \$17,921	1st year: \$2,596,809 Annual: \$1,792,109

Note: Costs presented in this table do not include those accounted for in Section III. Collection of Information Requirements.

We have detailed, below, many of the standards within each CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many of the provisions are already standard medical or business practices. These requirements will, therefore, not pose additional burden to CMHCs because they are already standards of practice. *Client Rights* (§ 485.910)

Section 485.910(a), “Standard: Notice of rights and responsibilities,” requires that during the initial evaluation, the CMHC must provide the client and the client’s representative or surrogate (if appropriate) with verbal and written notice of the client’s rights and responsibilities in a language and manner that the individual understands. Communicating with clients, and their representatives or surrogates, in a

manner that meets their communication needs is a standard practice in the health care industry. Because we are implementing a requirement that is fully compatible with existing civil rights requirements and guidance, we believe that the requirement to communicate with clients in a manner that meets their communication needs will impose no additional costs.

In addition, this standard requires a CMHC to provide each CMHC client and representative verbal and written notification of the CMHC client’s rights. We estimate the burden for the time associated with providing the verbal notice will be 2.5 minutes (0.0417 hours) per client or approximately 9.47 hours per CMHC. We note that the burden associated with providing the written notice is discussed in the Collection of Information section of this

rule. We estimate that all CMHCs will use 947 hours to comply with this requirement (0.0417 hours per client × 22,700 clients). The estimated cost associated with these requirements is \$44,509, based on a psychiatric registered nurse performing this function (947 hours × \$47 per hour).

With respect to the CoP for client rights, the standard addressing violations of client rights requires a CMHC to investigate alleged client rights violations, and take corrective actions when necessary and appropriate. We estimate that the CMHC administrator will spend, on average, 25 minutes investigating each alleged client rights violation. For purposes of our analysis, we assume that an average CMHC will investigate 1 alleged violation per week, for a total of 22 hours annually, at a cost of \$1,452

annually per CMHC. All CMHCs nationwide require 2,200 hours, with an average labor cost of \$66 per hour for the administrator, the estimated nationwide cost of \$145,200.

In addition, we are implementing three standards under the CoP for client rights pertaining to restraint and seclusion, staff training requirements for restraints and seclusion, and death reporting requirements. These standards include requirements that guide the appropriate use of seclusion and restraint interventions in CMHCs, when necessary, to ensure the physical safety of the client and others while awaiting the client's transport to a hospital. They are adapted from the clients' rights CoP for hospitals published as a final rule in the **Federal Register** on December 8, 2006 (71 FR 71378), and codified at § 482.13.

We anticipate that CMHCs will be minimally impacted by these standards. Several public commenters stated that restraints and seclusion are never used in CMHCs and therefore are not needed in CMHCs. However, we are still estimating the burden to facilities for restraint and seclusion use. We do not have access to several key pieces of information to estimate the burden. For example, we do not have data on the volume of staff in CMHCs, or the varying levels and qualifications of CMHC staff that may use restraint and seclusion. Factors such as size of facility, services rendered, staffing, and client populations vary as well. We are hesitant to make impact estimates in this rule that may not account for these and other unforeseen variations. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

The restraint and seclusion standards set forth the client's rights in the event that he or she is restrained or secluded, and sets limits on when and by whom restraint or seclusion can be implemented. We recognize that there will be some impact associated with performing client assessment and monitoring to ensure that seclusion or restraint is only used in a safe and effective manner, when necessary, to protect the client and others from immediate harm, pending transport to the hospital. However, client assessment and monitoring are standard components of client care, and this requirement does not pose a burden to a CMHC.

The standards on staff training for restraint or seclusion that we are codifying at § 485.910(f) set out the staff training requirements for all appropriate client care involving the use of seclusion and restraint in the CMHC.

Training is important for the provision of safe and effective restraint or seclusion use. We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded client, or provide care for a restrained or secluded client, the staff be trained and able to demonstrate competency in the performance of these actions. The staff training requirements will address the following broad areas: Training intervals, training content, trainer requirements, and training documentation.

To reduce regulatory burden and create a reasonable requirement while assuring client safety, we are mandating that only those staff who would be involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for, restrained or secluded clients would be required to have this training.

In this final rule, we are finalizing broad topics to be covered in training, and are not requiring that staff be trained by an outside organization. We believe that in-house training could be more economical than sending staff off site for instruction. However, CMHCs will have the option of sending either selected or all staff to outside training if they believe this is warranted.

Therefore, we have based our burden estimate on a CMHC nurse being trained by an outside organization (for example, the Crisis Prevention Institute) to provide such training. We believe that most CMHCs then will have this nurse function as a program developer and as a trainer of the appropriate CMHC staff. In addition, we believe in most instances this professional will be a psychiatric registered nurse.

Train-the-trainer programs are the way many CMHCs provide staff instruction. For example, the 4-day instructor certification program given by the Crisis Prevention Institute (CPI, Inc.) costs \$1,999 for tuition plus travel, lodging, and participant salary. More detailed information regarding the train-the-trainer programs can be found on CPI, Inc.'s Web site at <http://www.crisisprevention.com>.

We estimate, on average, that the cost to train one nurse will include the following expenses: (1) Round trip travel at approximately \$400 to cover the need for either local or distant travel; (2) lodging for 3 nights (at \$120 per night) for approximately \$360; and (3) meals and incidental expenses for 4 days (at \$50 per day) for approximately \$200, depending upon the location within the particular State. Therefore,

we anticipate the cost to train one nurse is approximately \$2,959 plus the nurse's total salary of \$1,504 for 4 days (at \$376 per day). The total estimated training cost for all CMHCs is approximately \$446,300.

We believe that CMHCs will add seclusion and restraint training onto their in-service training programs. The train-the-trainer program described above provides CMHCs with the necessary personnel and materials to implement a staff-wide seclusion and restraint training program. We estimate that developing this staff-wide training program requires 40 hours of the trainer's time on a one-time basis for all affected CMHCs, at a cost of \$1,880 per CMHC.

We are requiring that each individual who could potentially be involved in restraint and seclusion of a client have training in the proper techniques. According to the National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Due to a lack of data on the average number of employees in a CMHC, for purposes of this analysis only, we assume that an average CMHC will need to train seven employees in seclusion and restraint techniques. Based on one psychiatric registered nurse trainer conducting an 8-hour training course for seven CMHC staff members, we estimate that this requirement will cost \$2,728 as calculated below.

- 8 trainer hours at \$47/hr = \$376
- 56 trainee hours at \$42/hr = \$2352
- \$376 trainer cost + \$2,352 trainee costs = \$2,728

We are also requiring that each individual receive documented, updated training. Again, according to National Association of Psychiatric Health Systems (NAPHS), annual updates involve about four hours of staff and instructor time per employee who has direct client contact. We assume an average size CMHC has seven employees with direct client contact who must be trained in de-escalation techniques. Therefore, we estimate that it will cost \$1,364 annually to update each person's training as shown below.

- 4 trainer hours at \$47/hr = \$188
- 28 trainee hours at \$42/hr = \$1,176
- \$188 trainer costs + \$1,176 trainee costs = \$1,364

We require that each CMHC revise its training program annually as needed. We estimate this task, which must be completed by the trainer, to take approximately 4 hours annually per CMHC and have calculated below the

estimated total annual cost for all CMHCs.
 • 4 hours × \$47/hr = \$188 per CMHC

• \$188 per CMHC × 100 CMHCs = \$18,800 nationwide
 Table 4 below shows the initial year (one-time) and annual estimated CMHC

burden, respectively, associated with the standards for the client rights CoP.

TABLE 4—CLIENT RIGHTS BURDEN ASSESSMENT

Standard	Time per average CMHC	Total time (in hours)	Cost per average CMHC	Total cost
Client rights notification	9.47 hours	947	\$445	\$44,509
Addressing violations	22 hours	2,200	1,452	145,200
4 day trainer training*	32 hours	3,200	4,463	446,300
Staff training program development*	40 hours	4,000	1,880	188,000
Staff training*	64 hours	6,400	2,728	272,800
Staff training update	32 hours	3,200	1,364	136,400
Staff training program update	4 hours	400	188	18,800
Totals 1st year	167.47	16,747	10,968	1,096,809
Totals Annually	67.47	6,747	3,449	344,909

* Initial year (one-time) burden items.

Admission, Initial Evaluation, Comprehensive Assessment and Discharge or Transfer of the Client (§ 485.914)

With respect to the CoP for admission, initial evaluation, comprehensive assessment and discharge or transfer of the client, we believe that several of the standards associated with the CoP are unlikely to impose a burden on CMHCs. Specifically, the requirements for admitting a client, initially evaluating a client, and completing a comprehensive assessment of each client's needs are standard medical practice; therefore, they do not impose a burden upon a CMHC.

Moreover, the requirement to update the comprehensive assessment does not impose a burden upon CMHCs. Currently, all CMHCs are required by CMS payment rules (§ 424.24(e)(3)) to recertify a Medicare client's eligibility for partial hospitalization services. Therefore, the 13,600 Medicare beneficiaries who received partial hospitalization services have already received an updated assessment in order for the CMHC to recertify their eligibility. In addition, updating client assessments is part of standard medical practice to ensure that care is furnished to meet current client needs and treatment goals. Therefore, we believe that this requirement does not impose a burden upon a CMHC. Further, as part of the CMHC care model, it is assumed that clients will eventually be discharged or transferred from the CMHC's care. As such, CMHCs routinely plan for and implement client discharges and transfers. Therefore, we believe that the standard for the discharge or transfer of the client is part of a CMHC's standard practice and does not pose additional burden to CMHCs.

Treatment Team, Active Treatment Plan, and Coordination of Services (§ 485.916)

Under the CoP for treatment team, active treatment plan, and coordination of services, we assessed the potential impact of the following standards on CMHCs: Delivery of services, active treatment plan, content of the active treatment plan, review of the active treatment plan, and coordination of services. First, the standard for delivery of services sets forth the required members of each CMHC's client's active treatment team and requires these members to work together to meet the needs of each CMHC client. We believe it is standard practice within the CMHC industry to include these identified members in an active treatment team and, therefore, this requirement does not pose a burden.

Furthermore, this standard requires the CMHC to determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to be designated for each client as a care coordinator. The designated individual will be responsible for coordinating an individual client's care, including ensuring that the client's needs are fully assessed and reassessed in a timely manner, and that the client's active treatment plan is fully implemented. CMHCs may choose to assign a single individual to perform this function for all clients of the CMHC, or it may divide this duty between several individuals, assigning specific clients to specific individuals. While we believe that CMHCs already actively work to coordinate client assessment, care planning, and care implementation, we also believe that designating specific individuals to perform this function

may be new to CMHCs. We estimate that, on average, designated CMHC staff will spend 20 to 30 minutes per client per week (76 to 114 hours annually) overall to fulfill this requirement. The annual cost per CMHC associated with this requirement is \$3,572 to \$5,358 for a psychiatric registered nurse, \$2,356 to \$3,534 for a mental health counselor, or \$2,660 to \$3,990 for a clinical social worker. The aggregate annual cost for all CMHCs is \$357,200 to \$535,800 if a psychiatric registered nurse is used; \$235,600 to \$353,400 if a mental health counselor is used, or \$266,000 to \$399,000, if a clinical social worker is used. This estimated burden is shown in Table 5 below.

Finally, paragraph (a)(4) of this standard requires a CMHC that has more than one interdisciplinary treatment team to designate a single team that is responsible for establishing policies and procedures governing the day-to-day provision of CMHC care and services. We believe that using multiple disciplines to establish client care policies and procedures is standard practice and does not pose a burden.

The active treatment plan standard and its content sets forth the requirements for each client's active treatment plan. The written active treatment plan will be established by the client and interdisciplinary treatment team. It will address the client's needs as they were identified in the initial evaluation and subsequent comprehensive assessment. We estimate that establishing the first comprehensive active treatment plan requires 35 minutes of the interdisciplinary treatment team's time. We estimate that compliance with the requirements at § 485.916(c) requires a licensed professional member of the

interdisciplinary team (for this burden estimate, we used the nurse) a total of 35 minutes per client, for a total of 132 hours per CMHC. Based on the nurses' hourly rate, the total cost will be \$6,204 per CMHC.

The standard for review of the active treatment plan requires the interdisciplinary treatment team to review and revise the active treatment plan as necessary, but no less frequently than every 30 calendar days. We estimate that updating the content of the active treatment plan requires 10

minutes of the interdisciplinary treatment team's time. Therefore, we estimate that compliance with the requirements at § 485.916(d) requires a licensed professional member of the interdisciplinary team (for this burden estimate we used the nurse) a total of 10 minutes per client, for a total of 38 hours per CMHC. Based on the nurse's hourly rate, the total cost will be \$1,786 per CMHC.

In addition, the coordination of services standard requires a CMHC to have and maintain a system of

communication, in accordance with its own policies and procedures, to ensure the integration of its services and systems. We believe that active communication within health care providers, including CMHCs, is standard practice; therefore, this requirement does not impose a burden.

Table 5 below shows the annual estimated CMHC burden associated with the standards for the treatment team, active treatment plan, and coordination of services CoP.

TABLE 5—TREATMENT TEAM, ACTIVE TREATMENT PLAN, AND COORDINATION OF SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Psychiatric Registered Nurse ..	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	\$3,572 to \$5,358 Average: \$4,465	\$357,200 to \$535,800 Average: \$446,500
Mental Health Counselor	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	\$2,356 to \$3,534 Average: \$2,945	\$235,600 to \$353,400 Average: \$294,500
Clinical Social Worker	76 to 114 Average: 95	7,600 to 11,400 Average: 9,500	\$2,660 to \$3,990 Average: \$3,325	\$266,000 to \$399,000 Average: \$332,500
**Total Average (for all disciplines)	76 to 114 Total Average: 95	Total Average Range: 7,600–11,400 Total Average: 9,500	Total Average Range: \$2,862–\$4,294 Total Average: \$3,578	Total Average Range: \$286,200–\$429,400 Total Average: \$357,800
Development of the Active Treatment Plan	132	13,200	\$6,204	\$620,400
Review and Update of the Active Treatment Plan	38	3,800	\$1,786	\$178,600
Total	265	26,500	\$11,568	\$1,156,800

* Note: CMHC will choose one of the providers in table 5 to coordinate each client care.

** Note: The Total columns represent an average of all 3 provider type.

Quality Assessment and Performance Improvement (§ 485.917)

The proposed rule provided guidance to the CMHC on how to establish a quality assessment and performance improvement program. It is estimated that a CMHC will spend approximately 20 hours a year to implement a quality assessment and performance improvement program. Many providers are already using comprehensive quality assessment and performance improvement programs for accreditation

or independent improvement purposes. For those providers who choose to develop their own quality assessment and performance improvement program, we estimate that it will take 9 hours to create a program. We also estimate that CMHCs 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. Both the program development and

implementation will most likely be managed by that CMHC's administration. Based on an administrator's hourly rate, the total cost of the quality assessment and performance improvement condition of participation is \$1,320 per CMHC. \$66 per hour × 20 hours = \$1,320

Table 6 below shows the annual estimated CMHC burden associated with the standards for the quality assessment and performance improvement CoP.

TABLE 6—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN ASSESSMENT

Standard	Time per CMHC (hours)	Total time (hours)	Cost per CMHC	Total cost
QAPI development	9	900	\$594	\$59,400
QAPI implementation	11	1,100	726	72,600
Total annually	20	2,000	1,320	132,000

Organization, Governance, Administration of Services, and Partial Hospitalization Services (§ 485.918)

Under the CoP for organization, governance, administration of services,

and partial hospitalization services, we assessed the potential impact of the following standards on CMHCs: Governing body and administration, provision of services, professional

management responsibility, staff training, and physical environment. The governing body and administration standard requires a CMHC to have a designated governing body that assumes

full legal responsibility for management of the CMHC. This standard will also require the CMHC governing body to appoint an administrator, in accordance with its own education and experience requirements, who is responsible for the day-to-day operations of the CMHC. Having a governing body and a designated administrator are standard business practices; therefore, this requirement does not impose a burden.

The provision of services standard sets forth a comprehensive list of services that CMHCs are currently required by statute and regulation to furnish, requires the CMHC and all individuals furnishing services on its behalf to meet applicable State licensing and certification requirements, and 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.

In addition, the professional management responsibility standard requires that, if a CMHC chooses to provide certain services under agreement, it must ensure that the agreement is written. This standard will also require the CMHC to retain full professional management responsibility for the services provided under arrangement on its behalf. Full professional management responsibility will include paying for the arranged services and ensuring that the services are furnished in a safe and effective manner. Having a written agreement

and retaining professional management of all care and services provided is standard practice in the health care industry. Therefore, this requirement does not impose a burden.

Further, the staff training standard requires a CMHC to educate all staff who have contact with clients and families about CMHC care and services. It also requires a CMHC to provide an initial orientation for each staff member that addresses his or her specific job duties. Educating staff about the nature of CMHC care and their particular job duties are standard practices that would not impose a burden upon CMHCs.

This standard also requires a CMHC to assess the skills and competency of all individuals furnishing client and family care in accordance with its own written policies and procedures.

Finally, this standard requires a CMHC to provide and document its in-service training program. This standard does not prescribe the content or format of the CMHC's assessment and in-service training programs. Rather, it allows CMHCs to establish their own policies and procedures to meet their individual needs and goals. For example, this can be done by in-servicing on a need recognized through the QAPI program. We believe these requirements reflect standard practice in the industry and present no additional burden.

The physical environment standard requires CMHCs to furnish services in a safe, comfortable, and private

environment that meets all Federal, State, and local health and safety requirements and occupancy rules. We believe that this requirement does not impose a burden on CMHCs as it is considered standard practice to provide services in a physical location that is both safe and conducive to meeting the needs of CMHC clients.

This standard also requires a CMHC to have an infection control program. While basic precautions such as thorough hand washing and proper disposal of medical waste are standard practice, developing a comprehensive infection control program may impose a burden on CMHCs. We estimate that an administrator will spend 8 hours on a one-time basis developing infection control policies and procedures and 2 hours per month conducting follow up efforts. The estimated cost associated with this provision is \$528 to develop the infection control program and \$1,584 annually to follow-up on infection control issues in the CMHC. We believe that staff education regarding infection control will be incorporated into the CMHC's in-service training program, described above and therefore doesn't impose additional burden.

Table 7 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the standards for the organization, governance, administration of services, and partial hospitalization services CoP.

TABLE 7—ORGANIZATION, GOVERNANCE, ADMINISTRATION OF SERVICES, AND PARTIAL HOSPITALIZATION SERVICES BURDEN ASSESSMENT

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Infection control policies and procedures *	8	800	\$528	\$52,800
Infection control follow-up	24	2,400	1,584	158,400
Total 1st Year	32	3,200	2,112	211,200
Total Annually	24	2,400	1,584	158,400

* Initial year (one-time) burden items.

We believe that the burden associated with this rule is reasonable and necessary to ensure the health and safety of all CMHC clients.

1. Estimated Effects of CoPs for CMHCs on Other Providers

We do not expect the CoPs for CMHCs included in this rule to affect any other providers.

2. Estimated Effects of CoPs for CMHCs on the Medicare and Medicaid Programs

The budget impacts to the Medicare and Medicaid programs resulting from implementation of the CoPs for CMHCs included in this 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.

C. Alternatives Considered

CMHC providers have been operating without federally-issued health and safety requirements since the 1990 inception of Medicare coverage of partial hospitalization services in CMHCs. In place of Federal standards, we have relied upon State certification and licensure requirements to ensure the health and safety of CMHC clients.

However, CMS has learned that most States either do not have certification or licensure requirements for CMHCs or that States do not apply such certification or licensure requirements to CMHCs that are for-profit, privately owned, and/or not receiving State funds. Due to the possibility of significant gaps in State requirements, to ensure the health and safety of CMHC clients, we chose to propose and are finalizing a core set of health and safety requirements that will apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements ensure a basic level of services provided by qualified staff.

We also considered proposing a more comprehensive set of CoPs for CMHCs. Such a comprehensive set of CoPs would go beyond the requirements in this rule to address other areas of CMHC services and operations, such as a clinical records requirement that would outline the specific contents of a clinical record. While we believe that these areas are important and may warrant additional consideration in future rulemaking, we do not believe that it is appropriate to begin with an expansive set of CoPs at this time. Furthermore, a comprehensive set of CoPs may be difficult for CMHCs to manage, considering that many CMHCs are not currently required to meet any health and safety standards. As a result, we chose to focus on a core set of requirements and allow for the option of additional CoPs in the future.

Additionally, we considered proposing fewer CoPs. However, all of the CoPs included in this regulation are intended to act as a cohesive system. For example eliminating the assessment requirement would most likely cause issues with the formation of the interdisciplinary team and the client's active treatment plan. We believe that the CoPs build on each other, and that eliminating one or more would introduce vulnerabilities in patient safety.

D. Conclusion

We estimate that this final rule will cost CMHCs approximately \$3 million in the first year of implementation and approximately \$2.2 million 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.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

- 1. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 (hh)).

- 2. Add and reserve subpart I, and add a new subpart J to part 485 to read as follows:

Subpart I—[Reserved]

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

Sec.

- 485.900 Basis and scope.
- 485.902 Definitions.
- 485.904 Condition of participation: Personnel qualifications.
- 485.910 Condition of participation: Client rights.
- 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.
- 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.
- 485.917 Condition of participation: Quality assessment and performance improvement.
- 485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

Subpart J—Conditions of Participation: Community Mental Health Centers (CMHCs)

§ 485.900 Basis and scope.

(a) *Basis.* This subpart is based on the following sections of the Social Security Act:

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as “partial hospitalization services” and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to

provide partial hospitalization services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services.

(b) *Scope.* The provisions of this subpart serve as the basis of survey activities for the purpose of determining whether a CMHC meets the specified requirements that are considered necessary to ensure the health and safety of clients; and for the purpose of determining whether a CMHC qualifies for a provider agreement under Medicare.

§ 485.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Active treatment plan means an individualized client plan that focuses on the provision of care and treatment services that address the client's physical, psychological, psychosocial, emotional, and therapeutic needs and goals as identified in the comprehensive assessment.

Community mental health center (CMHC) means an entity as defined in § 410.2 of this chapter.

Comprehensive assessment means a thorough evaluation of the client's physical, psychological, psychosocial, emotional, and therapeutic needs related to the diagnosis under which care is being furnished by the CMHC.

Employee of a CMHC means an individual—

(1) Who works for the CMHC and for whom the CMHC is required to issue a W-2 form on his or her behalf; or

(2) For whom an agency or organization issues a W-2 form, and who is assigned to such CMHC if the CMHC is a subdivision of an agency or organization.

Initial evaluation means an immediate care and support assessment of the client's physical, psychosocial (including a screen for harm to self or others), and therapeutic needs related to the psychiatric illness and related conditions for which care is being furnished by the CMHC.

Representative means an individual who has the authority under State law to authorize or terminate medical care on behalf of a client who is mentally or physically incapacitated. This includes a legal guardian.

Restraint means—

(1) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces

the ability of a client to move his or her arms, legs, body, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a client for the purpose of conducting routine physical examinations or tests, or to protect the client from falling out of bed, or to permit the client to participate in activities without the risk of physical harm (this does not include a client being physically escorted); or

(2) A drug or medication when it is used as a restriction to manage the client's behavior or restrict the client's freedom of movement, and which is not a standard treatment or dosage for the client's condition.

Seclusion means the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

Volunteer means an individual who is an unpaid worker of the CMHC; or if the CMHC is a subdivision of an agency or organization, is an unpaid worker of the agency or organization and is assigned to the CMHC. All volunteers must meet the standard training requirements under § 485.918(d).

§ 485.904 Condition of participation: Personnel qualifications.

(a) *Standard: General qualification requirements.* All professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC, must be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of their State licenses, certifications, or registrations. All personnel qualifications must be kept current at all times.

(b) *Standard: Personnel qualifications for certain disciplines.* The following qualifications must be met:

(1) *Administrator of a CMHC.* A CMHC employee who meets the education and experience requirements established by the CMHC's governing body for that position and who is responsible for the day-to-day operation of the CMHC.

(2) *Clinical psychologist.* An individual who meets the qualifications at § 410.71(d) of this chapter.

(3) *Clinical social worker.* An individual who meets the qualifications at § 410.73 of this chapter.

(4) *Social worker.* An individual who—

(i) Has a baccalaureate degree in social work from an institution accredited by the Council on Social

Work Education, or a baccalaureate degree in psychology or sociology, and is supervised by a clinical social worker, as described in paragraph (b)(3) of this section; and

(ii) Has 1 year of social work experience in a psychiatric healthcare setting.

(5) *Mental health counselor.* A professional counselor who is certified and/or licensed by the State in which he or she practices, and has the skills and knowledge to provide a range of behavioral health services to clients. The mental health counselor conducts assessments and provides services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation, and prevention programs.

(6) *Occupational therapist.* A person who meets the requirements for the definition of "occupational therapist" at § 484.4 of this chapter.

(7) *Physician.* An individual who meets the qualifications and conditions as defined in section 1861(r) of the Act, and provides the services at § 410.20 of this chapter, and has experience providing mental health services to clients.

(8) *Physician assistant.* An individual who meets the qualifications and conditions as defined in section 1861(s)(2)(K)(i) of the Act and provides the services, in accordance with State law, at § 410.74 of this chapter.

(9) *Advanced practice nurse.* An individual who meets the following qualifications:

(i) Is a nurse practitioner who meets the qualifications at § 410.75 of this chapter; or

(ii) Is a clinical nurse specialist who meets the qualifications at § 410.76 of this chapter.

(10) *Psychiatric registered nurse.* A registered nurse, who is a graduate of an approved school of professional nursing, is licensed as a registered nurse by the State in which he or she is practicing, and has at least 1 year of education and/or training in psychiatric nursing.

(11) *Psychiatrist.* An individual who specializes in assessing and treating persons having psychiatric disorders; is board certified, or is eligible to be board certified by the American Board of Psychiatry and Neurology, or has documented equivalent education, training or experience, and is fully licensed to practice medicine in the State in which he or she practices.

§ 485.910 Condition of participation: Client rights.

The client has the right to be informed of his or her rights. The CMHC must

protect and promote the exercise of these client rights.

(a) *Standard: Notice of rights and responsibilities.* (1) During the initial evaluation, the CMHC must provide the client, the client's representative (if appropriate) or surrogate with verbal and written notice of the client's rights and responsibilities. The verbal notice must be in a language and manner that the client or client's representative or surrogate understands. Written notice must be understandable to persons who have limited English proficiency.

(2) During the initial evaluation, the CMHC must inform and distribute written information to the client concerning its policies on filing a grievance.

(3) The CMHC must obtain the client's and/or the client representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The client has the right to—

(i) Exercise his or her rights as a client of the CMHC.

(ii) Have his or her property and person treated with respect.

(iii) Voice grievances and understand the CMHC grievance process; including but not limited to grievances regarding mistreatment and treatment or care that is (or fails to be) furnished.

(iv) Not be subjected to discrimination or reprisal for exercising his or her rights.

(2) If a client has been adjudged incompetent under State law by a court of proper jurisdiction, the rights of the client are exercised by the person appointed in accordance with State law to act on the client's behalf.

(3) If a State court has not adjudged a client incompetent, any legal representative designated by the client in accordance with State law may exercise the client's rights to the extent allowed under State law.

(c) *Standard: Rights of the client.* The client has a right to—

(1) Be involved in developing his or her active treatment plan.

(2) Refuse care or treatment.

(3) Have a confidential clinical record. Access to or release of client information and the clinical record client information is permitted only in accordance with 45 CFR parts 160 and 164.

(4) Be free from mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property.

(5) Receive information about specific limitations on services that he or she will be furnished.

(6) Not be compelled to perform services for the CMHC, and to be compensated by the CMHC for any work performed for the CMHC at prevailing wages and commensurate with the client's abilities.

(d) *Standard: Addressing violations of client rights.* The CMHC must adhere to the following requirements:

(1) Ensure that all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of client property by anyone, including those furnishing services on behalf of the CMHC, are reported immediately to the CMHC's administrator by CMHC employees, volunteers and contracted staff.

(2) Immediately investigate all alleged violations involving anyone furnishing services on behalf of the CMHC and immediately take action to prevent further potential violations while the alleged violation is being verified. Investigations and documentation of all alleged violations must be conducted in accordance with procedures established by the CMHC.

(3) Take appropriate corrective action in accordance with State law if the alleged violation is investigated by the CMHC's administration or verified by an outside entity having jurisdiction, such as the State survey and certification agency or the local law enforcement agency; and

(4) Ensure that, within 5 working days of becoming aware of the violation, all violations are reported to the State survey and certification agency, and verified violations are reported to State and local entities having jurisdiction.

(e) *Standard: Restraint and seclusion.*

(1) All clients have the right to be free from physical or mental abuse, and corporal punishment. All clients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion, defined in § 485.902, may only be imposed to ensure the immediate physical safety of the client, staff, or other individuals.

(2) The use of restraint or seclusion must be in accordance with the written order of a physician or other licensed independent practitioner who is authorized to order restraint or seclusion in accordance with State law and must not exceed one 1-hour duration per order.

(3) The CMHC must obtain a corresponding order for the client's immediate transfer to a hospital when restraint or seclusion is ordered.

(4) Orders for the use of restraint or seclusion must never be written as a standing order or on an as-needed basis.

(5) When a client becomes an immediate threat to the physical safety of himself or herself, staff or other individuals, the CMHC must adhere to the following requirements:

(i) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the client or other individuals from harm.

(ii) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the client or other individuals from harm.

(iii) The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by State law.

(iv) The condition of the client who is restrained or secluded must be continuously monitored by a physician or by trained staff who have completed the training criteria specified in paragraph (f) of this section.

(v) When restraint or seclusion is used, there must be documentation in the client's clinical record of the following:

(A) A description of the client's behavior and the intervention used.

(B) Alternatives or other less restrictive interventions attempted (as applicable).

(C) The client's condition or symptom(s) that warranted the use of the restraint or seclusion.

(D) The client's response to the intervention(s) used, including the rationale for continued use of the intervention.

(E) The name of the hospital to which the client was transferred.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The client has the right to safe implementation of restraint or seclusion by trained staff. Application of restraint or seclusion in a CMHC must only be imposed when a client becomes an immediate physical threat to himself or herself, staff or other individuals and only in facilities where restraint and seclusion are permitted.

(1) *Training intervals.* In facilities where restraint and seclusion are permitted, all appropriate client care staff working in the CMHC must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a client in restraint or seclusion and use of alternative methods to restraint and seclusion. In facilities where restraint and seclusion are not

permitted, appropriate client care staff working in CMHC must be trained in the use of alternative methods to restraint and seclusion. Training will occur as follows:

(i) Before performing any of the actions specified in this paragraph (f).

(ii) As part of orientation.

(iii) Subsequently on a periodic basis, consistent with the CMHC's policy.

(2) *Training content.* The CMHC must require all appropriate staff caring for clients to have appropriate education, training, and demonstrated knowledge based on the specific needs of the client population in at least the following:

(i) Techniques to identify staff and client behaviors, events, and environmental factors that may trigger circumstances that could require the use of restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) In facilities where restraint and seclusion are permitted, choosing the least restrictive intervention based on an individualized assessment of the client's medical and behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion that are permitted in the CMHC, including training in how to recognize and respond to signs of physical and psychological distress.

(v) In facilities where restraint and seclusion are permitted, clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) In facilities where restraint and seclusion are permitted, monitoring the physical and psychological well-being of the client who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by the CMHC's policy.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address clients' behaviors.

(4) *Training documentation.* The CMHC must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements.* The CMHC must report deaths associated with the use of seclusion or restraint.

(1) The CMHC must report to CMS each death that occurs while a client is in restraint or seclusion awaiting transfer to a hospital.

(2) Each death referenced in paragraph (g)(1) of this section must be

reported to the CMS Regional Office by telephone no later than the close of business the next business day following knowledge of the client's death.

(3) Staff must document in the client's clinical record the date and time the death was reported to CMS.

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

The CMHC must ensure that all clients admitted into its program are appropriate for the services the CMHC furnishes in its facility.

(a) *Standard: Admission.* (1) The CMHC must determine that each client is appropriate for the services it provides as specified in § 410.2 of this chapter.

(2) For clients assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements as specified in § 485.918(f).

(b) *Standard: Initial evaluation.* (1) 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.

(2) The initial evaluation, at a minimum, must include the following:

(i) The admitting diagnosis as well as other diagnoses.

(ii) The source of referral.

(iii) The reason for admission as stated by the client or other individuals who are significantly involved.

(iv) Identification of the client's immediate clinical care needs related to the psychiatric diagnosis.

(v) A list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking.

(vi) For partial hospitalization services only, include an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided.

(3) Based on the findings of the initial evaluation, the CMHC must determine the appropriate members of each client's interdisciplinary treatment team.

(c) *Standard: Comprehensive assessment.* (1) The comprehensive assessment must be completed by licensed mental health professionals who are members of the interdisciplinary treatment team, performing within their State's scope of practice.

(2) The comprehensive assessment must be completed in a timely manner,

consistent with the client's immediate needs, but no later than 4 working days after admission to the CMHC.

(3) The comprehensive assessment must identify the physical, psychological, psychosocial, emotional, therapeutic, and other needs related to the client's psychiatric illness. The CMHC's interdisciplinary treatment team must ensure that the active treatment plan is consistent with the findings of the comprehensive assessment.

(4) The comprehensive assessment, at a minimum, must include the following:

(i) The reasons for the admission.

(ii) A psychiatric evaluation, completed by a psychiatrist, non-physician practitioner or psychologist practicing within the scope of State licensure that includes the medical history and severity of symptoms. Information may be gathered from the client's primary health care provider (if any), contingent upon the client's consent.

(iii) Information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations.

(iv) Information regarding the onset of symptoms of the illness and circumstances leading to the admission.

(v) A description of attitudes and behaviors, including cultural and environmental factors that may affect the client's treatment plan.

(vi) An assessment of intellectual functioning, memory functioning, and orientation.

(vii) Complications and risk factors that may affect the care planning.

(viii) Functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals.

(ix) Factors affecting client safety or the safety of others, including behavioral and physical factors, as well as suicide risk factors.

(x) A drug profile that includes a review of all of the client's prescription and over-the-counter medications; herbal remedies; and other alternative treatments or substances that could affect drug therapy.

(xi) The need for referrals and further evaluation by appropriate health care professionals, including the client's primary health care provider (if any), when warranted.

(xii) Factors to be considered in discharge planning.

(xiii) Identification of the client's current social and health care support systems.

(xiv) For pediatric clients, the CMHC must assess the social service needs of the client, and make referrals to social

services and child welfare agencies as appropriate.

(d) *Standard: Update of the comprehensive assessment.* (1) The CMHC must update the 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.

(2) The assessment must be updated no less frequently than every 30 days.

(3) The update must include information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals.

(e) *Standard: Discharge or transfer of the client.* (1) If the client is transferred to another entity, the CMHC must, within 2 working days, forward to the entity, a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(2) If a client refuses the services of a CMHC, or is discharged from a CMHC due to noncompliance with the treatment plan, the CMHC must forward to the primary health care provider (if any) a copy of—

(i) The CMHC discharge summary.

(ii) The client's clinical record, if requested.

(3) The CMHC discharge summary must include—

(i) A summary of the services provided, including the client's symptoms, treatment and recovery goals and preferences, treatments, and therapies.

(ii) The client's current active treatment plan at time of discharge.

(iii) The client's most recent physician orders.

(iv) Any other documentation that will assist in post-discharge continuity of care.

(4) The CMHC must adhere to all Federal and State-related requirements pertaining to the medical privacy and the release of client information.

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

The CMHC must designate an interdisciplinary treatment team that is responsible, with the client, for directing, coordinating, and managing the care and services furnished for each client. The interdisciplinary treatment team is composed of individuals who work together to meet the physical, medical, psychosocial, emotional, and therapeutic needs of CMHC clients.

(a) *Standard: Delivery of services.* (1) An interdisciplinary treatment team, led by a physician, NP, PA, CNS, clinical psychologist, or clinical social worker, must provide the care and services offered by the CMHC.

(2) Based on the findings of the comprehensive assessment, the CMHC must determine the appropriate licensed mental health professional, who is a member of the client's interdisciplinary treatment team, to coordinate care and treatment decisions with each client, to ensure that each client's needs are assessed, and to ensure that the active treatment plan is implemented as indicated.

(3) The interdisciplinary treatment team may include:

- (i) A doctor of medicine, osteopathy or psychiatry (who is an employee of or under contract with the CMHC).
- (ii) A psychiatric registered nurse.
- (iii) A clinical social worker.
- (iv) A clinical psychologist.
- (v) An occupational therapist.
- (vi) Other licensed mental health professionals, as necessary.
- (vii) Other CMHC staff or volunteers, as necessary.

(4) If the CMHC has more than one interdisciplinary team, it must designate the treatment team responsible for establishing policies and procedures governing the coordination of services and the day-to-day provision of CMHC care and services.

(b) *Standard: Person-centered active treatment plan.* All CMHC care and services furnished to clients must be consistent with an individualized, written, active treatment plan that is established by the CMHC interdisciplinary treatment team, the client, and the client's primary caregiver(s), in accordance with the client's recovery goals and preferences, within 7 working days of admission to the CMHC. The CMHC must ensure that each client and the client's primary caregiver(s), as applicable, receive education and training provided by the CMHC that are consistent with the client's and caregiver's responsibilities as identified in the active treatment plan.

(c) *Standard: Content of the person-centered active treatment plan.* The CMHC must develop a person-centered individualized active treatment plan for each client. The active treatment plan must take into consideration client recovery goals and the issues identified in the comprehensive assessment. The active treatment plan must include all services necessary to assist the client in meeting his or her recovery goals, including the following:

- (1) Client diagnoses.

(2) Treatment goals.

(3) Interventions.

(4) A detailed statement of the type, duration, and frequency of services, including social work, psychiatric nursing, counseling, and therapy services, necessary to meet the client's specific needs.

(5) Drugs, treatments, and individual and/or group therapies.

(6) Family psychotherapy with the primary focus on treatment of the client's conditions.

(7) The interdisciplinary treatment team's documentation of the client's or representative's and primary caregiver's (if any) understanding, involvement, and agreement with the plan of care, in accordance with the CMHC's policies.

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized 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 initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter if such services are included in the active treatment plan.

(e) *Standard: Coordination of services.* The CMHC must develop and maintain a system of communication that assures the integration of services in accordance with its policies and procedures and, at a minimum, would do the following:

(1) Ensure that the interdisciplinary treatment team maintains responsibility for directing, coordinating, and supervising the care and services provided.

(2) Ensure that care and services are provided in accordance with the active treatment plan.

(3) Ensure that the care and services provided are based on all assessments of the client.

(4) Provide for and ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services are provided by employees or those under contract with the CMHC.

(5) Provide for ongoing sharing of information with other health care and non-medical providers, including the primary health care provider, furnishing services to a client for conditions unrelated to the psychiatric condition for which the client has been admitted,

and non-medical supports addressing environmental factors such as housing and employment.

§ 485.917 Condition of participation: Quality assessment and performance improvement.

The CMHC must develop, implement, and maintain an effective, ongoing, CMHC-wide data-driven quality assessment and performance improvement program (QAPI). The CMHC's governing body must ensure that the program reflects the complexity of its organization and services, involves all CMHC services (including those services furnished under contract or arrangement), focuses on indicators related to improved behavioral health or other healthcare outcomes, and takes actions to demonstrate improvement in CMHC performance. The CMHC must maintain documentary evidence of its quality assessment and performance improvement program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The CMHC program must be able to demonstrate measurable improvement in indicators related to improving behavioral health outcomes and CMHC services.

(2) The CMHC must measure, analyze, and track quality indicators; adverse client events, including the use of restraint and seclusion; and other aspects of performance that enable the CMHC to assess processes of care, CMHC services, and operations.

(b) *Standard: Program data.* (1) The program must use quality indicator data, including client care, and other relevant data, in the design of its program.

(2) The CMHC must use the data collected to do the following:

(i) Monitor the effectiveness and safety of services and quality of care.

(ii) Identify opportunities and priorities for improvement.

(3) The frequency and detail of the data collection must be approved by the CMHC's governing body.

(c) *Standard: Program activities.* (1) The CMHC's performance improvement activities must:

(i) Focus on high risk, high volume, or problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems.

(iii) Give priority to improvements that affect behavioral outcomes, client safety, and person-centered quality of care.

(2) Performance improvement activities must track adverse client events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the CMHC.

(3) The CMHC must take actions aimed at performance improvement and, after implementing those actions, the CMHC must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* CMHCs must develop, implement and evaluate performance improvement projects.

(1) The number and scope of distinct performance improvement projects conducted annually, based on the needs of the CMHC's population and internal organizational needs, must reflect the scope, complexity, and past performance of the CMHC's services and operations.

(2) The CMHC must document what performance improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The CMHC's governing body is responsible for ensuring the following:

(1) That an ongoing QAPI program for quality improvement and client safety is defined, implemented, maintained, and evaluated annually.

(2) That the CMHC-wide quality assessment and performance improvement efforts address priorities for improved quality of care and client safety, and that all improvement actions are evaluated for effectiveness.

(3) That one or more individual(s) who are responsible for operating the QAPI program are designated.

§ 485.918 Condition of participation: Organization, governance, administration of services, and partial hospitalization services.

The CMHC must organize, manage, and administer its resources to provide CMHC services, including specialized services for children, elderly individuals, individuals with serious mental illness, and residents of its mental health service area who have been discharged from an inpatient mental health facility.

(a) *Standard: Governing body and administrator.* (1) A CMHC must have a designated governing body made up of two or more designated persons, one of which may be the administrator, that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement. One member of the governing body must possess knowledge and experience as a mental health clinician.

(2) The CMHC's governing body must appoint an administrator who reports to

the governing body and is responsible for the day-to-day operation of the CMHC. The administrator must be a CMHC employee and meet the education and experience requirements established by the CMHC's governing body.

(b) *Standard: Provision of services.* (1) A CMHC must be primarily engaged in providing the following care and services to all clients served by the CMHC regardless of payer type, and must do so in a manner that is consistent with the following accepted standards of practice:

(i) 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.

(ii) Provides 24-hour-a-day emergency care services.

(iii) Provides day treatment, partial hospitalization services other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

(iv) 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.

(v) Provides 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 for whom services are not paid for by Medicare, divided by the total number of clients treated by the CMHC for each 12-month period of enrollment.

(A) A CMHC is required to submit to CMS a certification statement provided by an independent entity that certifies that the CMHC's client population meets the 40 percent requirement specified at this paragraph (b)(1)(v).

(B) The certification statement described in paragraph (b)(1)(v)(A) of this section is required upon initial application to enroll in Medicare, and as a part of revalidation, including any off cycle revalidation, thereafter carried out pursuant to § 424.530 of this chapter. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. Medicare enrollment will also be denied or revoked if the 40 percent requirement as specified in this paragraph (b)(1)(v) is not met.

(vi) Provides individual and group psychotherapy utilizing a psychiatrist, psychologist, or other licensed mental

health counselor, to the extent authorized under State law.

(vii) Provides physician services.

(viii) Provides psychiatric nursing services.

(ix) Provides clinical social work services.

(x) Provides family counseling services, with the primary purpose of treating the individual's condition.

(xi) Provides occupational therapy services.

(xii) Provides services of other staff trained to work with psychiatric clients.

(xiii) Provides drugs and biologicals furnished for therapeutic purposes that cannot be self-administered.

(xiv) Provides client training and education as related to the individual's care and active treatment.

(xv) Provides individualized therapeutic activity services that are not primarily recreational or diversionary.

(xvi) Provides diagnostic services.

(2) The CMHC and individuals furnishing services on its behalf must meet applicable State licensing and certification requirements.

(c) *Standard: Professional management responsibility.* A CMHC that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management and oversight of staff and services for all arranged services. As part of retaining financial management responsibility, the CMHC must retain all payment responsibility for services furnished under arrangement on its behalf. Arranged services must be supported by a written agreement which requires that all services be as follows:

(1) Authorized by the CMHC.

(2) Furnished in a safe and effective manner.

(3) Delivered in accordance with established professional standards, the policies of the CMHC, and the client's active treatment plan.

(d) *Standard: Staff training.* (1) A CMHC must provide education about CMHC care and services, and person-centered care to all employees, volunteers, and staff under contract who have contact with clients and their families.

(2) A CMHC must provide an initial orientation for each individual furnishing services that addresses the specific duties of his or her job.

(3) A CMHC must assess the skills and competence of all individuals furnishing care and, as necessary, provide in-service training and education programs where indicated. The CMHC must have written policies and procedures describing its method(s)

of assessing competency and must maintain a written description of the in-service training provided during the previous 12 months.

(e) *Standard: Physical environment.*

(1) *Environmental conditions.* The CMHC must provide a safe, functional, sanitary, and comfortable environment for clients and staff that is conducive to the provision of services that are identified in paragraph (b) of this section.

(2) *Building.* The CMHC services must be provided in a location that meets Federal, State, and local health and safety standards and State health care occupancy regulations.

(3) *Infection control.* There must be policies, procedures, and monitoring for the prevention, control, and investigation of infection and communicable diseases with the goal of avoiding sources and transmission of infection.

(4) *Therapy sessions.* The CMHC must ensure that individual or group therapy sessions are conducted in a manner that maintains client privacy and ensures client dignity.

(f) *Standard: Partial hospitalization services.* A CMHC providing partial hospitalization services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.43 of this chapter.

(3) Meet the requirements for coverage as described in § 410.110 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(e) of this chapter.

(g) *Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients.* The CMHC and its staff must operate and furnish services in compliance with all applicable Federal,

State, and local laws and regulations related to the health and safety of clients. If State or local law provides for licensing of CMHCs, the CMHC must be licensed. The CMHC staff must follow the CMHC's policies and procedures.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 19, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 24, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–24056 Filed 10–28–13; 8:45 am]

BILLING CODE 4120-01-P