



FEDERAL REGISTER

Vol. 76

Friday

No. 117

June 17, 2011

Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 485

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 485

[CMS-3202-P]

RIN 0938-AP51

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish, for the first time, conditions of participation (CoPs) that community mental health centers (CMHCs) would have to meet in order to participate in the Medicare program. These proposed CoPs would 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 would enable CMS to survey CMHCs for compliance with health and safety requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. on August 16, 2011.

ADDRESSES: In commenting, please refer to file code CMS-3202-P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address *only*:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-3202-P, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only*:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-3202-P, Mail Stop C4-26-05, 7500

Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments *only* to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

Maria Hammel, (410) 786-1775.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday

through Friday of each week from 8:30 a.m. to 4 p.m. E.S.T. To schedule an appointment to view public comments, phone 1-800-743-3951.

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I. Background

A. Introduction

In 2007, 224 certified Community Mental Health Centers (CMHCs) billed Medicare for partial hospitalization services for 25,087 Medicare beneficiaries. Currently, there are no Conditions of Participation (CoPs) in place for Medicare-certified CMHCs. As such, no regulatory basis exists to ensure basic levels of quality and safety for CMHC care. The Federal government, as the single largest payer of health care services in the United States, administers many statutory and regulatory requirements on the delivery and quality of health care furnished under its programs. Therefore, we are proposing for the first time a set of requirements that Medicare-certified CMHCs must meet in order to participate in the Medicare program. The CoPs that we are proposing would help to ensure the quality and safety of CMHC care for all clients served by the CMHC, regardless of payment source.

These requirements would focus on a short term, client-centered, outcome-oriented process that promotes quality client care. Requirements for CMHC services would 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. Overarching the proposed CMHC

requirements would be a quality assessment and performance improvement program that would build on a provider's own quality management system to improve client care performance. We would expect CMHCs to furnish health care that met the essential health and quality standards that would be established by this rule; therefore, a CMHC would use its own quality management system to monitor and improve its own performance and compliance. To achieve this objective, we are proposing new CMHC requirements.

B. Current Requirements for CMHCs

Section 1832(a)(2)(J) of the Social Security Act (the Act) established coverage of partial hospitalization services for Medicare beneficiaries. 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, 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 regimens that apply only to CMHCs that receive state funding.

A CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates two key components:

(1) The CMHC meets each of the following core requirements identified at 42 CFR 410.2:

- Provides outpatient services, including specialized outpatient services for children, elderly individuals, individuals with chronic

mental illness, and residents of the CMHC's mental health service area that have been discharged from inpatient treatment at a mental health facility.

- Provides 24 hour-a-day emergency care services.
- Provides day treatment, partial hospitalization services, or psychosocial rehabilitation services.
- Provides screening for clients being considered for admission to State mental health facilities to determine the appropriateness of such admission. (Section 1861(ff)(3)(B)(i)(II) of the Act allows CMHCs to provide these services by contract if State law precludes the entity from directly providing the screening services.)

- Provides at least 40 percent of its services to individuals who are not eligible for benefits under Medicare.

(2) The CMHC, in accordance with regulations at 42 CFR 424.24(e), provides partial hospitalization program (PHP) services that are:

- Furnished under the general supervision of a physician;
- Subject to certification or recertification by a physician that the individual would require inpatient psychiatric care if partial hospitalization services were not provided; and
- Furnished under an individualized plan of treatment that is periodically reviewed and meets the requirements of 42 CFR 424.24(e)(2).

When the partial hospitalization program benefit 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)(i) of the Act and provides the core services described in section 1913(c)(1) of the PHS Act. CMS has received complaints regarding CMHCs such as: 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 facility based on the result of a complaint investigation. Without such health and safety standards in place, CMS' oversight of CMHCs is severely limited.

C. Rationale for Proposing 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 patients and their families. Once our rules have been established, CMS will be able to survey providers, through State survey and certification agencies, to ensure that the care being furnished meets the standards. These CoPs would enable CMS to establish a survey process to promote the safety and quality of client care provided by Medicare-certified CMHCs. At this time, we are not proposing to amend our regulations at 42 CFR 488.6 to grant deeming authority for CMHCs to accrediting organizations. We are specifically soliciting public comment regarding this issue.

These proposed CoPs are part of CMS' overall effort to improve the safety and quality of all care provided to Medicare beneficiaries, regardless of the setting in which the care is provided. To that end, CMS has issued new and revised regulations for end-stage renal disease facilities, hospices, hospitals, nursing homes, transplant hospitals, organ procurement organizations, ambulatory surgery centers, and other providers. The proposed CMHC CoPs would adopt relevant provisions (for example, those related to client rights) from these other provider types to ensure that clients receive consistent protections as they move from one type of care to another.

D. Principles Applied in Developing the Proposed CMHC CoPs

We developed the proposed 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 client-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 are proposing 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 would establish staff qualifications for the CMHC.

The “Client rights” CoP would emphasize 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 would reflect 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 would incorporate a client-centered interdisciplinary team approach, in consultation with the client’s primary health care provider (if any).

The “Quality assessment and performance improvement” CoP would challenge 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 would charge 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 proposed CoPs, “Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client” and “Treatment team, active treatment plan, coordination of services,” would establish a cycle of individualized client care. The client’s care needs would be comprehensively assessed, enabling the interdisciplinary team, with the client, to establish an active treatment plan. The active treatment plan would be implemented, and the results of the care would be evaluated by updating the comprehensive assessment and active treatment plan.

These proposed CoPs present an opportunity for CMHCs, States, and CMS to join in a partnership for improvement. When implemented, CMHC programming will reflect a client-centered approach that will affect how State survey and certification agencies and CMS manage the survey process. We believe that this approach will provide opportunities for improvement in client care.

II. Provisions of the Proposed Regulations

A. Proposed Requirements

We are proposing to establish a new subpart J under the regulations at 42

CFR part 485 to incorporate the proposed CoPs for CMHCs. We are proposing that the effective date of these provisions would be 12 months after the publication of the final rule. Delaying the effective date for 12 months after the date of publication of the final rule would allow CMHCs time to educate staff, initiate their quality assessment and performance improvement (QAPI) program, and implement the new set of CoPs. The new subpart J would include the basis and scope of the subpart, definitions, and the six CoPs and standards. Below we discuss each proposed section in detail.

Basis and Scope (Proposed § 485.900)

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

Definitions (Proposed § 485.902)

In proposed § 485.902, we are proposing to include the following definitions for terms used in the CoPs for CMHCs under the proposed subpart J:

“Active treatment plan” would mean 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. This proposed definition was established by reviewing 42 CFR 424.24(e)(2) and The Joint Commission Accreditation Manual for Behavioral Health Care definition of “planning of care.”

“Community mental health center (CMHC)” would mean the entity type defined at 42 CFR 410.2.

“Comprehensive assessment” would mean 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. This proposed definition was derived from the home health and hospice assessment CoPs under 42 CFR parts 484 and 418, respectively. Clients served by home health and hospice agencies have comprehensive and complex needs, and the comprehensive assessment requirements for these providers capture the key elements we believe are also essential for assessing a CMHC client.

“Employee of a CMHC” would mean an individual—(a) Who works for the CMHC and with respect to whom the CMHC is required to issue a W–2 form;

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

“Initial evaluation” would mean an immediate care and support assessment of the client’s physical, psychosocial, and therapeutic needs (including a screen for harm to self or others), related to the client’s psychiatric illness and related conditions for which care is being furnished by the CMHC. This proposed definition is derived from the hospice CoPs at part 418, but with the addition of the term “psychiatric illness.” We added the term “psychiatric illness” to the definition to ensure that the client’s needs relate to the care and services provided by the CMHC. Similar to hospice clients, we believe that the CMHC client’s immediate care needs should be assessed and addressed as soon as possible. The initial evaluation is the vehicle that identifies a client’s immediate needs and initiates the care planning process.

“Representative” would mean 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 would include a legal guardian. This proposed definition is consistent with the definition of this term found in the CoPs for hospices at 42 CFR 418.3. We do not propose to regulate the relationship between a client and his or her authorized representative. However, we believe reference to such representatives is necessary due to the potential instability of some CMHC clients, and the need to ensure that decisions related to the client’s care and active treatment plan are made appropriately. We recognize that clients may refuse to participate in their care and active treatment or, in documented circumstances, be unable to be present. There is no implication that clients will or will not have representatives.

“Restraint” would mean—(a) 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 (b) 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" would mean the involuntary confinement of a client alone in a room or an area from which the client is physically prevented from leaving.

The proposed definitions for "restraint" and "seclusion" are used in other Medicare-certified provider CoPs such as those for hospices at § 418.3 and hospitals at 42 CFR 482.13(e)(1), and are in accordance with section 3207 of the Children's Health Act (Pub. L. 106-310).

"Volunteer" would mean an individual who—(a) Is an unpaid worker of the CMHC; or (b) 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 would have to meet the standard training requirements under 42 CFR 485.918(d).

CMHC CoP: Personnel Qualifications (Proposed § 485.904)

We are proposing to add a new CoP at § 485.904 to establish staff qualifications for CMHCs. In proposed § 485.904(a), "Standard: General qualification requirements," we are proposing 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. All personnel qualifications would have to be kept current at all times.

In proposed § 485.904(b), "Standard: Personnel qualifications for certain disciplines," we are proposing to require staff qualifications to be consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations.

"Administrator of a CMHC" would mean a CMHC employee that meets the education and experience requirements established by the CMHC governing body for that position and who is responsible for the day-to-day operation of the CMHC. This proposed definition is similar to the definition used in the hospice CoPs at part 418. We believe this proposed qualification would allow for provider flexibility to establish requirements based on the services provided by individual CMHCs.

"Clinical psychologist" would mean an individual who meets the qualifications at 42 CFR 410.71(d). This proposed definition by CMS is used as a basis for payment for services.

"Clinical social worker" would mean an individual who meets the qualifications at 42 CFR 410.73(a). This proposed definition also is currently in use for CMHC services paid by Medicare.

"Mental health counselor" would mean a professional counselor who is certified and/or licensed by the State (as applicable) and has the skills and knowledge to provide mental health services to clients. The mental health counselor would provide services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation and prevention programs. Information contained in The Joint Commission Accreditation Behavioral Health Care Manual contributed to the development of these proposed qualifications. These counselors have an essential role in the care of CMHC clients, and we believe that it is necessary to define this role to ensure that CMHCs use a variety of appropriate personnel to care for CMHC clients.

"Occupational therapist" would mean an individual who meets the requirements for "occupational therapist" set forth at 42 CFR 484.4. This proposed definition was established in the November 27, 2007, "Revision to Payment Policies Under the Physician Fee Schedule, and Other part B Payment Policies for 2008" final rule (72 FR 66222) that applied the same requirements for occupational therapists to a variety of provider types; we believe that this definition is appropriate for the CMHC environment.

"Physician" would mean an individual who meets the qualifications and conditions as defined in section 1861(r) of the Act and provides the services as specified at § 410.20 of this chapter and would have experience providing mental health services to clients. This proposed definition is consistent with the definition of the term "physician" in the requirements for other providers such as hospices and hospitals, with the addition of having experience with clients receiving mental health services. While we believe experience is important, we are proposing that through the CMHC's policies and procedures, the CMHC would determine the level and range of experience appropriate to care for CMHC clients.

"Psychiatric registered nurse" would mean a registered nurse that is a graduate of an approved school of

professional nursing, who is licensed as a registered nurse by the State in which he or she is practicing, and has at least 2 years of education and/or training in psychiatric nursing. This proposed definition is similar to that used for other Medicare-certified providers. We are proposing to add the additional requirement of 2 years of education and/or training in psychiatric nursing due to the sensitive and complex needs of the CMHC client.

"Psychiatrist" would mean an individual who specializes in assessing and treating persons having psychiatric disorders, is 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. Information contained in The Joint Commission Accreditation Behavioral Health Care Manual contributed to the development of these proposed qualifications.

CMHC CoP: Client Rights (Proposed § 485.910)

We are proposing to add a new CoP at § 485.910 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. The client's representative or surrogate, who could be a family member or friend that accompanies the client, may act as a liaison between the client and the CMHC to help the client communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the client that are delivered by the CMHC staff. If a client is unable to fully communicate directly with CMHC staff, then the CMHC may give client rights information to the client's representative or surrogate. The client also has the choice of using an interpreter of his or her own or one supplied by the CMHC. A professional interpreter is not considered to be a client's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the CMHC to the client.

We also propose to require that the client be provided a written copy of client rights information. This must be provided in English, for present or future reference or translation by the client's representative or surrogate. We recommend, but do not propose requiring, that a written translation be provided in languages that non-English speaking clients can read, particularly

for languages that are most commonly used by non-English-speaking clients of the CMHC.

In proposed § 485.910(a)(1), the notice of rights and responsibilities 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). Ensuring that clients are aware of their rights and how to exercise them are vital components of improving overall CMHC quality and client satisfaction.

While we propose this standard under the authority of section 1832(a)(2)(F)(i) of the Act, we are also guided by Title VI of the Civil Rights Act of 1964. Our proposed requirement has been designed to be compatible with guidance on Title VI. The Department of Health and Human Services (HHS) guidance related to Title VI of the Civil Rights Act of 1964, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311) applies to those entities that receive Federal financial assistance from HHS, including CMHCs. This guidance may assist CMHCs in ensuring that client rights information is provided in a language and manner the client understands.

At proposed § 485.910(b), "Standard: Exercise of rights and respect for property and person," we are proposing that a client would 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, in proposed § 485.910(c), 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. If services are performed by clients for the CMHC, the wages received by the clients would have to be commensurate with prevailing wages for the nature of services performed and the clients' abilities.

In proposed § 485.910(d), "Standard: Addressing violations of client rights," we are proposing that CMHCs report all complaints of alleged violations of clients' rights to the CMHC administrator. We are also proposing that the CMHC would 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 are proposing that the CMHC report verified violations of client rights to appropriate authorities having jurisdiction within five working days of the CMHC becoming aware of the violation.

The proposed client rights CoP would 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. All CMHCs also would be required to comply with Federal rules concerning the privacy of individually identifiable health information set out at 45 CFR parts 160 and 164.

In proposed § 485.910(e), "Standard: Restraint and seclusion," we are proposing that all clients would 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 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. In response to accidental injuries and deaths, we published new 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.

We are proposing that a CMHC restraint and/or seclusion could only be imposed to ensure the immediate physical safety of the client, staff, or other individuals while awaiting transfer of the client to a hospital. A transfer to a hospital immediately is necessary because the CMHC has limited staff and resources available to safely monitor a restrained or secluded client. Additionally, the safety of the patient, other clients and the staff may be in jeopardy. The hospital would be able to safely monitor the client and assess the cause of the client's behavior. We are proposing this in order to implement the restraint and seclusion language in section 3207 of the Children's Health Act (CHA), Public

Law 106–310, codified at section 591 of the Public Health Service Act (42 U.S.C. 290ii). The CHA provisions apply to any health care facility that receives support in any form from any program supported in whole or in part with funds appropriated from any Federal agency, which clearly includes all providers that participate in Medicare or Medicaid. The CHA was enacted to protect and promote every client's right to be free from "any restraints or involuntary seclusions imposed for purposes of discipline or convenience." The CHA clearly describes the circumstances in which restraints or seclusion may be appropriate.

Based on discussions with the CMHC industry and The Joint Commission, we believe restraints or seclusion are rarely, if ever, used in a CMHC setting and that there are very few deaths (if any) that occur due to restraints or seclusion in CMHCs. However, there are no data available regarding this issue. The use of restraint or seclusion would be considered contrary to targeted client outcomes and therefore we would consider the use of restraint or seclusion an adverse client event that would be tracked as part of the QAPI program (Quality assessment and performance improvement: proposed § 485.917). During the survey process the surveyors would review all reports on adverse client events and the actions taken as part of the QAPI review. We believe that including these proposed requirements in the CMHC CoPs would promote the safe use of restraint or seclusion in the rare occurrence that clients posed an immediate physical threat to themselves or others. Providing for safe use of restraints would, we believe, prevent accidental injury or death.

In order to ensure the safety of the CMHC client during the rare event of the need for restraint or seclusion pending transport to the hospital, the CMHC would be required to continuously monitor the restrained or secluded client using trained staff that met the requirements at paragraph (f) of this section. Continuously monitoring the client would include, but would not be limited to, respiratory and circulatory status, skin integrity, vital signs, and any other elements as specified by CMHC policy.

In proposed § 485.910(e)(2) through (e)(4), we are proposing that a physician or other licensed practitioner authorized by State law would be required to order the use of restraint or seclusion. A single order for seclusion or restraint would not be permitted to exceed 1 hour in duration. In the exceptionally rare circumstance that transport to the hospital did not occur within the

original 1 hour timeframe, the CMHC would obtain another order, if clinically warranted. At the time of the restraint or seclusion order, the CMHC would be required to obtain a separate order for transfer of the client to the hospital. Finally, we would require that orders for restraint or seclusion could never be written as standing orders or on an as needed (PRN) basis.

In proposed § 485.910(f), “Standard: Restraint or seclusion: Staff training requirements,” we have focused on the proper use of restraint and seclusion, the need for appropriate CMHC personnel to receive training and education in the proper use of restraint and seclusion applications and techniques, and the need for CMHC personnel to receive training and education in alternative methods for handling emergency situations that may arise. We emphasize that restraint or seclusion may only be used to protect the client or others from immediate harm, and would trigger immediate transportation to a hospital. We believe restraints or seclusion are rarely, if ever, used in a CMHC setting; therefore, the use of restraint or seclusion is an adverse event for a CMHC and should be used as part of the CMHC’s quality assessment and performance improvement program, as outlined in 485.917(a). We also emphasize that staff training requirements on restraint and seclusion would focus on training and education on alternative methods for handling behavior, symptoms, and interventions in emergency situations. Restraint or seclusion would be used only when less restrictive interventions were determined to be ineffective.

In proposed § 485.910(g), “Standard: Death reporting requirements,” we are proposing a death reporting requirement in the unlikely circumstance that a death would occur at a CMHC due to restraint and seclusion. If a client’s death was attributed to restraint or seclusion while the client was awaiting transfer to a hospital, the CMHC would be required to report the death to CMS promptly. CMS could initiate an onsite investigation and complaint survey of the CMHC in accordance with the existing complaint investigation processes and would inform the federally-mandated Protection and Advocacy Organizations for its state or territory. We encourage the public to comment on this proposed standard.

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

We are proposing to add a new CoP at § 485.914 to establish requirements

for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client. These requirements reflect our view that a client-centered, interdisciplinary, and systematic client assessment is essential to quality client care. A client-specific, comprehensive assessment identifies the client’s physical, psychological, psychosocial, emotional and therapeutic needs. 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. The initial assessment would be completed within 24 hours of the client admission to the CMHC. The comprehensive assessment would build from the initial evaluation and be completed by the physician-led interdisciplinary team in consultation with the client’s primary health care provider, if any. The interdisciplinary team would be composed of a doctor of medicine, osteopathy or psychiatry, a psychiatric registered nurse, clinical psychologist, a clinical social worker, an occupational therapist, and other licensed mental health counselors, as necessary, pursuant to § 485.916(a)(2). Each member of the team would provide input within the scope of that individual’s practice. The comprehensive assessment would be completed within 3 working days after the admission to the CMHC. We believe the current practices of the mental health industry support a client-specific assessment. This requirement would, therefore, support standards currently in place at other facilities serving mental health clients.

The information generated from an interdisciplinary, comprehensive assessment is critical in determining the individual care and support needs of each client. This information is used to develop each CMHC client’s active treatment plan. As a result of updates of the comprehensive assessment, a CMHC would be able to track a client’s progress towards achieving the desired care outcomes. Where progress did not occur, the interdisciplinary treatment team would consider appropriate changes to the client’s active treatment plan.

The proposed comprehensive assessment requirements would guide CMHC staff in thoroughly assessing their clients by identifying the general areas that would be included in each assessment and by identifying timeframes for the completion of each assessment.

We believe that the broad assessment outline we are proposing would encourage CMHCs to exercise flexibility in determining how best to achieve

positive outcomes. We believe that this approach is consistent with currently accepted practices in CMHCs.

In proposed § 485.914(a), “Standard: Admission,” we are proposing that each CMHC would have to determine whether a client was appropriate for its services as specified in the definition of a CMHC at § 410.2. If the client was admitted to receive partial hospitalization services, the CMHC would also have to meet separate requirements specified at proposed § 485.918(f).

In proposed § 485.914(b), “Standard: Initial evaluation,” we are proposing that a CMHC psychiatric registered nurse or clinical psychologist would be required to complete an initial evaluation to determine the client’s immediate clinical care and support needs, including an admitting diagnosis and other diagnoses; the source of the referral; the reason for admission as stated by the client or others significantly involved; identification of the client’s immediate care needs; a list of current prescriptions and over-the-counter medications, as well as other substances that the client may be taking; and for partial hospitalization services only, an explanation as to why the client would be at risk for hospitalization if the partial hospitalization services were not provided. We would require that the initial evaluation be completed within 24 hours after admission to the CMHC.

In proposed § 485.914(c), “Standard: Comprehensive assessment,” we are proposing that the CMHC physician-led interdisciplinary treatment team, in consultation with the client’s primary care provider (if any), be required to complete the comprehensive assessment in a timely manner consistent with the client’s immediate needs, but no later than 3 working days after admission to the CMHC. In proposed § 485.914(c)(3) and (c)(4), we are proposing the requirements for the content of the comprehensive assessment that we believe are critical to quality CMHC care. These content requirements are at the core of CMHC care and are needed to evaluate the client’s physical, psychological, psychosocial, medical, emotional, therapeutic and other needs related to psychiatric illness and the reason for admission. Therefore, we are proposing that the comprehensive assessment take into consideration the following factors outlined in proposed § 485.914(c)(4)(i) through (xiii):

In proposed § 485.914(c)(4)(i), we are proposing to require the CMHC to identify the reason for the client’s admission to the CMHC. This identification would include the reason

for admission and the admitting diagnosis as stated by the referral source, the client, and the CMHC. We believe that this information is necessary to ensure that the CMHC and client are clear about the reason for the client's treatment at the CHMC.

In proposed § 485.914(c)(4)(ii) through (c)(4)(ix), we are proposing to require the comprehensive assessment to address client preferences regarding what is important to, and important for the client. The comprehensive assessment would also include a psychiatric evaluation; information concerning previous and current mental status, including but not limited to, previous therapeutic interventions and hospitalizations; information regarding the onset of symptoms of the illness and circumstances leading to the admission; a description of attitudes and behavior, such as the client's non-verbal presentation; cultural factors that may affect care planning; an assessment of intellectual functions, memory and orientation; complications and risk factors that may affect care planning; functional status, including the client's ability to understand and participate in his or her own care, and the client's strengths and goals; and factors affecting client safety or the safety of others, including behavioral and physical factors.

In proposed § 485.914(c)(4)(x), we are proposing that the client's comprehensive assessment include a review of the client's current medications, including prescription and over-the-counter medications, herbal remedies, and other alternative treatments or substances that could affect drug therapy. The review and accompanying documentation would include identification of the following items:

- Effectiveness of drug therapy.
- Drug side effects.
- Actual or potential drug interactions.
- Duplicate drug therapy.
- Drug therapy requiring laboratory monitoring.

As part of the update of the comprehensive assessment, as proposed in § 485.914(d), this review would have to be repeated as often as necessary to ensure that the client continued to receive drug therapy that was effective and appropriate for his or her needs. A review of a client's drug therapy would be included in the comprehensive assessment and in the development of the active treatment plan. This review could occur at any time, as well as at the time of the comprehensive assessment. We believe it would be most appropriate when a client was prescribed or began

to take any new drug and/or when use of a drug was discontinued.

In proposed § 485.914(c)(4)(xi), we are proposing that CMHCs would be required to assess each client's need for referrals to appropriate health professionals unrelated to the client's mental illness and beyond the scope of the CMHC, such as care related to additional medical conditions and/or co-morbidities. This would include consultation of the CMHC with the client's primary health care provider, if any.

In proposed § 485.914(c)(4)(xii), we are proposing to require the CMHC to consider discharge planning options at the time of the comprehensive assessment. We believe that it is important for continuity of care that the discharge planning process begin as the CMHC assesses the client's current health care needs, living environment, support systems, and therapy goals.

In proposed § 485.914(c)(4)(xiii), we are proposing that the CMHC be required to identify the client's current support system. We believe that a smooth transition between care settings would be more likely to occur if the discharge planning process were initiated early to determine the availability of resources to assist the client after discharge from the CMHC.

In proposed § 485.914(d), "Standard: Update of the comprehensive assessment," we are proposing that the CMHC 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 have 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.

In proposed § 485.914(e), "Standard: Discharge or transfer of the client," we are proposing to require the CMHC to 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 the discharge or transfer standard, 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 is smooth, and that the appropriate care continues without being compromised (where applicable).

We welcome public comments on our proposed timeframes and content for the initial assessment, comprehensive assessment, updated comprehensive assessment, and discharge or transfer requirements.

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

We are proposing to add a new CoP at § 485.916 to establish requirements for the treatment team, active treatment plan, and coordination of services. This proposed CoP would contain five standards that reflect an interdisciplinary team approach to CMHC care delivery.

As proposed, each client would have a written active treatment plan developed by the CMHC physician-led interdisciplinary team that would specify the CMHC care and services necessary to meet the client-specific needs identified in the initial, comprehensive, and updated assessments. All CMHC services furnished to clients would have to follow each client-specific written active treatment plan.

In proposed § 485.916(a), "Standard: Delivery of services," we are proposing that the CMHC designate a physician-led interdisciplinary team for each client, which would include either a psychiatric registered nurse, clinical psychologist, or clinical 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 interdisciplinary team would include, but would not be limited to the following:

- A doctor of medicine, osteopathy or psychiatry.
- A psychiatric registered nurse.
- A clinical social worker.
- A clinical psychologist.
- An occupational therapist.
- Other licensed mental health professionals, as necessary.

We believe that the role of the interdisciplinary treatment team is paramount in directing and monitoring client care. Each discipline brings forth a unique perspective, that together creates a well thought-out and thorough active treatment plan. We understand that there are instances where two of the interdisciplinary team member's roles could be covered by one person. For example, a nurse who also holds a qualifying degree in social work, could represent both the nurse and social worker interdisciplinary treatment team. This team of medical professionals works in unison to provide comprehensive care for the client. For example, the physician/psychiatrist (depending on his or her licenses) would, at a minimum, address medication management. The psychiatric nurse would bring forth issues related to care and implementation of the active treatment plan, and the social worker would bring forth issues related to the social aspects of the client and family care. 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 a treatment team responsible for establishing policies governing the day-to-day provision of CMHC care and services.

In proposed § 485.916(b), "Standard: Active treatment plan," we are proposing to require that all CMHC services furnished to clients follow a written active treatment plan established within 3 working days after

the client's admission to the CMHC 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. 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.

In proposed § 485.914(c), "Standard: Content of the active treatment plan," we are proposing to require that each client's active treatment plan reflect 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, including the following:

- Client diagnoses;
- Treatment goals, based on what is important to and appropriate for the client, and the client's recovery goals;
- Interventions;
- A detailed statement of the type, duration and frequency of services, including social work, counseling, psychiatric nursing and therapy services, as well as services furnished by other staff trained to work with psychiatric clients, necessary to meet the specific client needs;
- Drugs, treatments, and individual and/or group therapies;
- Family psychotherapy with the primary focus on the treatment of the client's conditions (or if no family was available for such psychotherapy, we would expect the CMHC to document this in the client's clinical record); and
- The interdisciplinary treatment team's documentation of 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.

The client and/or representative would need to understand the importance of their roles in implementing elements of the active treatment plan. We believe that the client's participation and agreement

regarding care is essential in developing an effective relationship with the CMHC. Some clients would require supports to participate effectively in the planning process. While it remains important to actively engage client representatives, representative participation could not substitute for client participation, unless there was a documented reason, such as a safety risk. We would expect a CMHC to document the client's and the representative's understanding of, and agreement with, the active treatment plan in accordance with its own policies. This could include an attestation signed by the client and representative, a note in the clinical record, and/or another form of documentation decided upon by the CMHC governing body.

In proposed § 485.916(d), "Standard: Review of the active treatment plan," we are proposing to require 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. We believe that it is essential to include this requirement because it would establish the linkage between assessment information, evaluation of treatment results, and active treatment plan modification.

In proposed § 485.916(e), "Standard: Coordination of services," we are proposing 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. This proposed standard would also make it easier for the CMHC to ensure that the care and services were provided in accordance with the active treatment plan, and that all care and services provided were based on the comprehensive and updated assessments of the client's needs. An effective communication system would also enable the CMHC to ensure the ongoing sharing of information among all disciplines providing care and services, whether the care and services were being provided by employees or by individuals under contract with the CMHC.

We believe that this proposed standard is appropriate because a CMHC client typically encounters many services delivered at different times by a variety of individuals with different

skills. Communication and integration of services and observations among members of the interdisciplinary treatment team and others providing care is essential to meet and respond to the client's needs in a timely manner. Additionally, this would ensure that the CMHC actively coordinated the care that they were providing with the care being furnished by other providers, including a client's primary health care provider (if any).

We recognize the value of an interdisciplinary approach to the delivery of CMHC services. This approach reflects actual industry practice, and as a result, we believe the proposed requirement is in step with accepted standards of practice.

We are specifically soliciting public comment on the proposed requirements for delivery of services, content of the active treatment plan, the time frames for review of the active treatment plan, and the coordination of services standard.

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

We are proposing to add a new CoP at § 485.917 to specify the requirements for a quality assessment and performance improvement program. During the last decade, the health care industry has begun to address quality issues preemptively. In this proposed rule, we have outlined the scope of the proposed quality assessment and performance improvement (QAPI) requirement, the guidelines for identifying performance improvement activities, and the individuals responsible for ensuring that a CMHC has a QAPI program. In this rule, we are proposing that each CMHC develop, implement, and maintain an effective, 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.

The desired overall outcome of the proposed QAPI CoP is that the CMHC would drive its own quality improvement activities and improve its provision of services. With an effective QAPI program in place and operating properly, the CMHC could better identify the activities that led to poor client outcomes, and take actions to improve performance.

This proposed condition would require the CMHC to develop, implement and maintain an effective data-driven QAPI program. The program would establish a planned approach to quality improvement and would take

into account the complexity of the CMHC's organization and services, including those provided directly or under contract. The CMHC would have to take all actions necessary to implement improvements in its performance as identified by its QAPI program. The CMHC would also be responsible for ensuring that the professional services it offered were carried out within current clinical practice guidelines as well as professional practice standards applicable to CMHC care.

In proposed § 485.917(a), "Standard: Program scope," we are proposing that the CMHC's QAPI program 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. The use of restraint and seclusion is contrary to targeted client outcomes; therefore, we would consider the use of restraint and seclusion to be an adverse client event that would be tracked and analyzed as part of the QAPI program.

In proposed § 485.917(b), "Standard: Program data," we are proposing to require the CMHC QAPI program 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 are not proposing to require that CMHCs use any particular process, tools or quality measures. However, a CMHC that used available quality measures could expect an enhanced degree of insight into the quality of its services and client satisfaction than if it began the quality measure development process anew.

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 met 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.

The proposed program data standard would require the CMHC to monitor the effectiveness of its 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.

In proposed § 485.917(c), "Standard: Program activities," we are proposing to require a 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 are also proposing 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.

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

As part of its QAPI program, a CMHC could use an IT performance improvement project that allowed the CMHC to invest in information technology; that is, we would allow CMHCs to undertake a program of

investment and development of an IT system that was geared to improvements in patient safety and quality, as a QAPI project. In recognition of the time required to develop and implement this type of system, we would not require that such activities have a demonstrable benefit in their initial stages, but we would expect that quality improvement goals and their achievement would be incorporated in the plan for the program. Initial stages of development would include activities such as installation of hardware and software, testing of an installed system, training of staff, piloting the system, and CMHC-wide implementation of the system. Upon implementation of the system, monitoring would begin and data would be collected over time as part of the process to evaluate the impact of the new system on patient safety and quality. We believe that recognizing an investment in IT as part of QAPI demonstrates this Administration's deep commitment to patients, high quality care, and flexibility. This approach would allow CMHCs the flexibility to invest appropriate efforts in their quality program and the freedom to make decisions about the best way to improve the quality of care. We believe that giving CMHCs the flexibility to review their own organizations and QAPI programs would improve the effectiveness and efficiency of their services, the outcomes of care they provided, and client satisfaction with their services.

In proposed § 485.917(e), "Standard: Executive responsibilities," we are proposing to require that the CMHC's governing body be responsible and accountable for ensuring that the ongoing quality improvement program is defined, implemented and maintained, and evaluated annually. The governing body would be required to appoint one or more individuals responsible for operating the QAPI program, and would have to ensure that the program addressed priorities for improved quality of client-centered 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, the most appropriate level of care. Therefore, it would be incumbent on the governing body to lend its full support to agency quality improvement and performance improvement efforts.

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

We are proposing to add a new CoP at § 485.918 that would require the CMHC to set out the CMHC's administrative and governance structure and would clarify performance expectations for the governing body. The overall goal of this CoP would be to ensure that the management structure was organized and accountable.

In this proposed organization and administration of services CoP, we would list the services that the statute (section 1861(ff)(3) of the Act) requires CMHCs to furnish. We are also proposing 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 were 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.

In proposed § 485.918(a), "Standard: Governing body and administrator," we are proposing 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.

In proposed § 485.918(b), "Standard: Provision of services," we are proposing to specify a comprehensive list of services that a CMHC would be required to provide. At § 485.918(b)(1)(v), we are proposing 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 42 CFR § 410.2 set out in the November 24, 2010 Outpatient Prospective Payment System final rule (OPPS) (75 FR 71800, 72259). Both this CMHC proposed rule and the OPPS 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).

Enactment of section 1301(a) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (HCERA 2010) 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 begins at least 12 months after the date of enactment (that is, April 1, 2011). As of that date, a CMHC must provide at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act (Medicare).

We are proposing to measure whether a CMHC is providing "at least 40 percent of its services" by the amount of reimbursement for all services furnished. This is only one of several possible approaches to implementing this measurement, and we are seeking public comment on this approach. Alternatives we considered included calculating whether at least 40 percent of the CMHC's units of service were furnished to non-Medicare patients, the number of non-Medicare patients served by the CMHC, or the dollar amount of services billed overall by the CMHC. We believe that the percentage of total revenues received by the CMHC that are payments from Medicare versus other payers is an approach that can be measured efficiently.

Accordingly, the CMHC would be required to demonstrate to the Medicare program that it is receiving no less than 40 percent of its reimbursement from payers other than Medicare, including but not limited to commercial entities, Medicaid and CHIP. Additionally, we propose to measure the 40 percent of its services on an annual basis. We are seeking public comment on whether we should determine if a CMHC meets the 40 percent requirement annually or at some other interval. We are seeking comment 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 is total reimbursement from Medicare, we are interested in

comments on how we should define reimbursement.

We are interested in comments addressing whether such a calculation should include uncompensated care or any other aspect of reimbursement. For example, the denominator would include total reimbursement received, including co-payments/co-insurance paid by Medicare beneficiaries and private patients and reimbursement received by Medicare for bad-debt. The numerator would include reimbursement by non-Medicare payers, which would include co-pays/co-insurance from privately insured individuals, reimbursement from Medicaid, other reimbursement from States, private pay and charity/uncompensated care. If instead we choose to measure based on service increment, we are interested in receiving comments on the specific definition for the services to be included in the calculation and how they would be counted. We are also interested in receiving comments regarding data sources for the metrics that comprise the components of a measure of the 40 percent threshold. In addition, we are interested in seeking comment 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 are interested in receiving comments on any other definitions of what constitutes a measure of the 40 percent threshold. For example, if there is a way to use a combined metric relying in part on reimbursement and in part on beneficiary/patient counts, and in part on service use. Finally, we are interested in seeking comments on how this measurement would be accomplished; for example, we would be interested in hearing commenters' ideas on how each of these measures would be included in the metric calculation and the best data sources for the calculation. We stress that we are concerned that the implementation of this provision not negatively impact access to care, and are seeking additional comment on strategies that would correctly balance the implementation of this new requirement with access concerns.

We will carefully consider all public comments received on this provision, and would respond to public comments in the final rule. We intend to issue sub-regulatory guidance implementing this requirement after the publication of the final rule.

We want to clarify that although we have proposed an approach to

calculating the 40 percent threshold, we are broadly seeking comments on the proposed approach as well as any other approaches that commenters think might be appropriate as a basis for determining whether a CMHC meets the requirement of providing at least 40 percent of its services to non-Medicare patients. We are also seeking comment on any aspect of how this requirement would be implemented at the provider level, what operational changes might be needed and whether there is a need for any additional financial/management document(s) to enable assessment of whether a CMHC meets the 40 percent threshold. For example, we would be interested in hearing commenters' views about whether or not a CMHC should use an independent auditing agency to review its financial statements and certify whether the CMHC meets the 40 percent threshold. We expect to draw on the comments received and make a final decision about the definition of what constitutes 40 percent in the final regulation.

Medicare-certified CMHCs are already required to provide most of the services set out in this proposed provision 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.

In proposed § 485.918(c), "Standard: Professional management responsibility," we are proposing 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.

In proposed § 485.918(d), "Standard: Staff training," which would apply to all employees, staff under contract, and volunteers, we are proposing 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 assess competence levels, determine training content, determine the duration and frequency of training for all employees, and track the training on a yearly basis.

In proposed § 485.918(e)(1), "Environmental conditions," and (e)(2), "Building," would require the CMHC to provide services in an environment that was 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. These proposed requirements would help to ensure that CMHC services were provided in a physical location that was both safe and conducive to meeting the needs of CMHC clients.

In proposed § 485.918(e)(3), "Infection control," we are proposing 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 aggressive actions be taken to protect all the clients and staff.

This proposed CoP would allow the CMHC to have flexibility in meeting its infection control, prevention and education objectives. For example, the extent of training in infection control that would be necessary for the CMHC's personnel would depend on the client mix and experience of the staff. One

example of “current best practices” is the standard precautionary use of gloves when handling blood or blood products. While we would expect that established best practices be followed, we are not proposing any specific approaches to meeting this requirement. We would expect to see clear evidence that the CMHC sought to minimize the spread of disease and infection through the use of effective techniques by its staff and through its efforts to help clients understand what can and should be done for infection control purposes.

In proposed § 485.918(e)(4), “Therapy sessions,” we are proposing 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.

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

In proposed § 485.918(g), “Standard: Compliance with Federal, State, and local laws and regulations related to the health and safety of clients,” we are proposing that the CMHC and its staff would 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.

B. Health Disparities

In 1985, the Secretary of the Department of Health and Human Services (HHS) issued a landmark report which revealed large and persistent gaps in health status among Americans of different racial and ethnic groups and served as an impetus for addressing health inequalities for racial and ethnic minorities in the U.S. This report led to the establishment of the Office of Minority Health (OMH) within HHS, with a mission to address these disparities within the Nation. National concerns for these differences, termed health disparities, and the associated excess mortality and morbidity have been expressed as a high priority in national health status reviews, including Healthy People 2000 and 2010.

Since that time, research has extensively documented the pervasiveness of racial and ethnic disparities in health care and has led to

the acknowledgement of racial and ethnic disparities as a national problem. As a result, more populations have been identified as vulnerable, which necessitated the development of programs and strategies to reduce disparities for vulnerable populations, and the emergence of new leadership to address such disparities. Currently, vulnerable populations can be defined by race/ethnicity, socio-economic status, geography, gender, age, disability status, risk status related to sex and gender, and other populations identified to be at-risk for health disparities. Other populations at risk may include persons with visual or hearing problems, cognitive perceptual problems, language barriers, pregnant women, infants, and persons with disabilities or special health care needs.

Although there has been much attention at the national level to ideas for reducing health disparities in vulnerable populations, we remain vigilant in our efforts to improve health care quality for all persons by improving health care access and by eliminating real and perceived barriers to care that may contribute to less than optimal health outcomes for vulnerable populations. For example, we are aware that immunization rates remain low among some minorities. Despite the long-term implementation of some strategies like the use of language translators in hospitals, health literacy and its impact on health care outcomes continues to be in the forefront.

We are always seeking better ways to address the needs of vulnerable populations; therefore, we are specifically requesting comments in regard to how our proposed requirements could be used to address disparities.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 are soliciting public comment on each of the issues for the information collection requirements (ICRs) discussed below.

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

Proposed § 485.910(a) would require that the CMHC develop a notice of rights statement to be provided to each client. We estimate that it would 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 \$424 per CMHC and \$94,976 for all CMHCs nationwide. In addition, this standard would require that the CMHC provide each client and client’s representative or surrogate with a verbal and written notice of the client’s rights and responsibilities during the initial evaluation visit, in advance of furnishing care. The CMHC would also be required to obtain the client’s and client representative’s (if appropriate) signature confirming that he or she has received a copy of the notice of rights and responsibilities. The CMHC would 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 the burden for the time associated with disclosing the information would be 2.5 minutes per client or approximately 4.67 hours per CMHC. Similarly, we estimate that the burden for the CMHC to document the information would take 2.5 minutes per client or approximately 4.67 hours per CMHC. At an average of 5 minutes (.0833 hours) per client to complete both tasks, we estimate that all CMHCs would use 2,090 hours to comply with this proposed requirement (.0833 hours per client × 25,087 clients). The estimated cost associated with these requirements would be \$75,240, based on a psychiatric nurse performing this function (2,090 hours × \$36 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 fully encompassed in that regulation and guidance, we have estimated no paperwork burden.

Proposed § 485.910(d)(2) would require a CMHC to document a client's or client representative's complaint of the alleged violation and the steps taken by the CMHC to resolve it. The burden associated with this proposed requirement is the time it would 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 would take the administrator 30 minutes per complaint at the rate of \$53/hr to document the complaint and resolution activities, for an annual total of 26 hours per CMHC or 5,824 hours for all CMHCs. The estimated cost associated with this requirement is \$308,672.

Proposed § 485.910(d)(4) would require the CMHC to report all confirmed violations to the State and local bodies having jurisdiction within 5 working days of becoming aware of the violation. We anticipate that it would take the administrator 5 minutes per complaint to report, for an annual total of 4.3 hours per CMHC or 971 hours for all CMHCs. The estimated cost associated with this requirement is \$51,463.

Proposed § 485.910(e)(2)(v) would require written orders for a physical restraint or seclusion, and proposed § 485.910(e)(5)(v) would require physical restraint or seclusion be supported by a documentation of the client's response or outcome in the client's clinical record. The burden associated with this requirement would be the time and effort necessary to document the use of physical restraint or seclusion in the client's clinical record. We estimate that it would take 45 minutes per event to document this information. Similarly, we estimate that there will be 1 occurrence of the use of physical restraint or seclusion per CMHC. The estimated annual burden associated with this requirement for all CMHCs would be 168 hours. The estimated cost associated with this burden for all CMHCs is \$6,048.

Proposed § 485.910(f) would specify restraint or seclusion staff training requirements. Specifically, § 485.910(f)(1) would require that all client care staff working in the CMHC 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 on the use of alternative methods to restraint and seclusion. Proposed § 485.910(f)(4) would require that a CMHC document in the personnel records that each employee successfully completed the restraint and seclusion training and demonstrated competency. We estimate that it would take 35 minutes per CMHC to comply with these requirements. The estimated total annual burden associated with these requirements would be 131 hours. The estimated cost associated with this requirement would be \$4,704.

Proposed § 485.910(g) would require 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 (*e.g.*, 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 and seclusion in a CMHC. For purposes of the PRA, we estimate the annual number of deaths to be zero. However, there are no data available regarding this issue. We are soliciting public comment, thus allowing the CMHC provider community the opportunity to provide feedback on this issue. With the number of deaths estimated at zero, under 5 CFR 1320.3(c)(4), this proposed 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)

Proposed § 485.914(b) through (d) would require 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 proposed requirements would be 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.

Proposed § 485.914(e) would require that, if the client were transferred to another facility, the CMHC would be 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 would be required to provide a copy of the client's discharge summary and clinical record, if requested, to the client's attending physician. The burden associated with this proposed requirement would be the time it takes to forward the discharge summary and clinical record, if requested. This proposed requirement is considered to be a usual and customary business practice under § 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)

Proposed § 485.916(b) would require all CMHC care and services furnished to clients and their families to follow a written active treatment plan established by the CMHC physician-led interdisciplinary treatment team. The CMHC would be required to ensure that each client and representative receives education provided by the CMHC as appropriate to the care and services identified in the active treatment plan.

The proposed provisions at § 485.916(c) specify the minimum elements that the active treatment plan would include. In addition, in proposed § 485.916(d), the physician-led interdisciplinary team would be 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 would include information from the client's updated comprehensive assessment, and would document the client's progress toward the outcomes specified in the active treatment plan. The burden associated with these proposed requirements would be the time it would take to document the active treatment plan (approximately 45 minutes) estimated to be a total \$3,024 per CMHC or \$677,376 nationally. Additionally, we estimate any revisions to the active treatment plan (approximately 15 minutes) would cost \$1008 per CMHC or \$225,792 nationally.

Proposed § 485.916(e) would require 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 proposed requirement would be the time and effort required to develop and maintain the system of communication in accordance with the CMHC's policies and procedures. While this proposed requirement is subject to the PRA, the associated burden would be considered to be usual and customary business practice as stated in 5 CFR 1320.3(b)(2).

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

Proposed § 485.917 would require a CMHC to develop, implement, and maintain an effective ongoing CMHC-wide data-driven quality assessment and performance improvement (QAPI) program. The CMHC's governing body would have to ensure that the program reflected the complexity of its organization and services; involved all CMHC services, including those services furnished under contract or arrangement; focused on indicators related to improved behavioral health outcomes and support services provided; and demonstrated improvement in the CMHC's performance. The CMHC would be 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 would be 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 would be required to document what quality improvement projects were being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

The burden associated with these requirements would be the time it would take to document the development of the quality assessment and performance improvement and associated activities. We estimate that it would take each CMHC administrator an average of 24 hours per year at the rate of \$53/hr to comply with these requirements for a total of 5,376 hours annually. The estimated cost associated with this requirement is \$284,928.

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

Proposed § 485.918(c) would list 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 would be 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 proposed requirement is the time and effort necessary to develop, draft, execute, and maintain the written agreements. We believe these proposed 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.

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

Proposed § 485.918(e)(3) would require 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 proposed requirement would be the time it would take to develop and maintain policies and procedures and document the monitoring of the infection control program. We believe this proposed 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 1 below summarizes the estimated annual reporting and recordkeeping burdens for this proposed rule.

TABLE 1—ESTIMATED ANNUAL 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	224	224	8	1,792	53	94,976	0	94,976
§ 485.910(a)(3)	0938–New	224	25,087	.0833	2,090	36	75,240	0	75,240
§ 485.910(d)(2)	0938–New	224	11,648	.5	5,824	53	308,672	0	308,672
§ 485.910(d)(4)	0938–New	224	11,648	.0833	971	53	51,463	0	51,463
§ 485.910(e)(4)(v)	0938–New	224	224	.75	168	36	6,048	0	6,048
§ 485.910(f)(4)	0938–New	224	224	.583	131	36	4,704	0	4,704
§ 485.916(c)	0938–New	224	25,087	.75	18,815	36	677,340	677,340
§ 485.916(d)	0938–New	224	25,087	.25	6,272	36	225,792	0	225,792
§ 485.917	0938–New	224	224	24	5,376	53	284,928	0	284,928
Total	224	99,453	41,439	1,729,163

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the

ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–3202–P.

Fax: (202) 395–6974; or

E-mail:
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 proposed new Conditions of Participation in this rule is estimated to be \$4.1 million in the first year of implementation and \$2.6 million after the first year of implementation and annually thereafter. Therefore, this is not an economically significant or major 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://ecfr.gpoaccess.gov/cgi/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13>). We estimate there are approximately 224 CMHCs with average admissions of approximately 112 clients per CMHC (based on the number of Medicare clients in 2007 divided by the number of CMHCs in 2007). However, we cannot estimate the full impact of this rule because we do not know the total number of non-Medicare patients served by CMHCs. Therefore, we are requesting information on the total number of non-Medicare clients served. We are also soliciting data on the potential effect of this rule on patients’ access to services, as well as comments regarding whether specific data exists measuring availability of necessary services to this patient population.

We estimate that implementation of this proposed rule would cost CMHCs approximately \$4.1 million, or \$18,475 per average CMHC, in the first year of implementation and \$2.6 million, or \$11,566 per average CMHC, after the first year of implementation and annually thereafter. Therefore, the Secretary has determined that this rule would 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.

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 of small rural hospitals. This analysis must conform to the provisions of section 603 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 rule would 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 proposed 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 2011, that threshold is approximately \$136 million. This rule would not have an impact on the expenditures of State, local, or tribal governments in the aggregate, or on the private sector of \$136 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 rule has no Federalism implications.

B. Anticipated Effects on CMHCs

We are proposing to establish a new subpart J under the regulations at 42 CFR part 485 to incorporate the proposed CoPs for CMHCs (which would be effective 12 months after the publication of the final rule). The new subpart J would include sections on the basis and scope of the subpart, definitions, and six conditions. For purposes of this section of this proposed rule, we have assessed the impact of all proposed CoPs that may present a burden to a CMHC.

We have made several assumptions and estimates in order to assess the time that it would take for a CMHC to comply with the proposed 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 2 below. We have also detailed many, but not all, of the proposed standards within each proposed 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 proposed CoPs are already standard medical or business practices and as a result do not pose an additional burden on CMHCs.

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION ON CMHCs

Number of Medicare CMHCs nationwide	224
Number of Medicare CMHC clients nationwide	25,087
Number of Medicare clients per average CMHC	112
Hourly rate of psychiatric nurse	\$36
Hourly rate of clinical psychologist	\$48
Hourly rate of administrator	\$53

TABLE 2—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE IMPACT ANALYSIS SECTION ON CMHCs—Continued

Hourly rate of clinical social worker	\$28
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Note: All salary estimates include benefits package worth 30 percent of the fringe base salary. Salary estimates were obtained from <http://www.bls.gov/>.

As stated earlier, we estimate that implementation of the six CoPs that we are proposing would not significantly impact CMHCs. We estimate that implementation of this proposal would cost CMHCs approximately \$4.1 million, or \$18,475 per average CMHC, in the first year of implementation and \$2.6 million, or \$11,566 per average CMHC, annually thereafter. We have detailed below many, but not all, of the proposed standards within each proposed CoP, and have noted whether or not there is an impact for each. However, the requirements contained in many of the proposed provisions are already standard medical or business practices. These proposed requirements would, therefore, not pose additional burden to CMHCs because they are already standards of practice. The CoP that we are proposing for client rights would set forth the rights of CMHC clients, ensure that client and client’s representative or surrogate are educated about their rights, establish a process for the investigation and reporting of client rights violations, and establish requirements governing the use of restraint and seclusion methods in CMHCs.

In proposed § 485.910(a), “Standard: Notice of rights and responsibilities,” we are proposing that during the initial evaluation, the CMHC would have to provide the client and the client’s representative (if appropriate) or surrogate with verbal and written notice of the client’s rights and responsibilities in a language and manner that the individual understands. Communicating with the clients, and their representative or surrogate, including the provision of a written notice of rights, in a manner that meets their communication needs is a standard practice in the health care industry. Similar requirements already exist for many other health care provider types, including hospice providers, long term care facilities, ambulatory care surgery centers, and end-stage renal disease facilities. Because we are proposing a requirement that is fully compatible with existing civil rights requirements and guidance, we believe that this proposed standard will impose no additional costs.

This standard would require a CMHC to develop a notice of rights statement to be provided to each CMHC client. We estimate that it would require 8 hours on a one-time basis to develop this

notice, and that the CMHC administrator would be responsible for this task, at a cost of \$424 per CMHC and \$94,976 for all CMHCs nationwide. In addition, this standard would require a CMHC to provide each CMHC client and representative verbal and written notification of the CMHC client’s rights, and obtain a signature certifying that they received such notification at the time of the initial evaluation. We estimate the burden for the time associated with disclosing the information would be 2.5 minutes per client or approximately 4.67 hours per CMHC. Similarly, we estimate that the burden for the CMHC to document the information would take 2.5 minutes per client or approximately 4.67 hours per CMHC. At an average of 5 minutes (.0833 hours) per client to complete both tasks, we estimate that all CMHCs would use 2090 hours to comply with this proposed requirement (.0833 hours per client × 25,087 clients). The estimated cost associated with these requirements would be \$75,240, based on a psychiatric nurse performing this function (2090 hours × \$36 per hour).

With respect to the proposed CoP for client rights, the proposed standard addressing violations of client rights would require a CMHC to investigate alleged client rights violations, take corrective actions when necessary and appropriate, and report verified violations to State and local bodies having jurisdiction. We estimate that the CMHC administrator would spend, on average, 30 minutes investigating each alleged client rights violation. For purposes of our analysis, we assume that an average CMHC would investigate 1 alleged violation per week, for a total of 26 hours annually, at a cost of \$1,378 annually per CMHC. All CMHCs nationwide would require 5,824 hours at an estimated cost of \$308,672.

In addition, we are proposing 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 proposed standards would 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 transport to a hospital. They are adapted to reflect 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.

While we anticipate that CMHCs would be impacted by these proposed standards, we do not have access to several key pieces of information to estimate the burden. For example, we do not have reliable data on the prevalence of restraint and seclusion use, the volume of staff in CMHCs, or the varying levels and qualifications of CMHC staff who may use restraint seclusion. Factors such as size, services rendered, staffing, and client populations vary as well. We are hesitant to make impact estimates in this proposed rule that may not account for these and other unforeseen variations. Therefore, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

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

We are proposing to specify elements at § 485.910(e)(4)(v) regarding the documentation that must be included in the client’s clinical record when the client is restrained or secluded. We estimate on average that it would 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 restraint and seclusion per CMHC per year. Based on the nurses hourly rate the total cost for documenting restraint and seclusion would be \$27 per CMHC.

The proposed standard on staff training for restraint or seclusion that we are proposing to codify in § 485.910(f) would set out the training requirements for all appropriate client care staff involved in the use of

seclusion and restraint in the CMHC. Training is important for the provision of safe and effective restraint or seclusion use. We would 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 proposed staff training requirements would address the following broad areas: training intervals; training contents; trainer requirements; and training documentation.

To reduce regulatory burden and create a reasonable requirement while assuring client safety, we would mandate 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. While we would expect physicians to be trained in the proper use of restraint or seclusion, we do not expect that they would be trained with the other CMHC staff. Therefore, we have not included physicians in the burden associated with these requirements. Instead, we would require that the appropriate CMHC staff who have direct contact with clients must be trained in restraint or seclusion use.

In this proposed rule, we are proposing broad topics to be covered in training, and would not require 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 would 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, we refer readers to <http://www.crisisprevention.com>, below) to provide such training. We believe that most CMHCs then would 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 would be a psychiatric 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 \$1,529 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 would 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 would be approximately \$2,489 plus the nurse's total salary of \$1,152 for 4 days (at \$288 per day). The total estimated training cost for all CMHCs would be approximately \$815,584.

We believe that CMHCs would add seclusion and restraint training onto their existing in-service training programs. The train-the-trainer program described above would provide 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 would require 40 hours of the trainer's time on a one-time basis for all affected CMHCs, at a cost of \$1,440 per CMHC.

We would require 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 would need to train 7 employees in seclusion and restraint techniques. Based on 1 nurse trainer conducting an 8-hour training course for 7 CMHC staff members, we estimate that this requirement would cost \$2,248 as calculated below.

- 8 trainer hours at \$36/hr = \$288
- 56 trainee hours at \$35/hr = \$1,960
- \$288 trainer cost + \$1,960 trainee costs = \$2,248

We are also proposing to require that each individual receive documented, updated training. Again, according to National Association of Psychiatric Health Systems (NAPHS), annual updates involve about 4 hours of staff and instructor time per employee who has direct client contact. We assume an average size CMHC has 7 employees with direct client contact who must be

trained in de-escalation techniques. Therefore, we estimate that it would cost \$1,124 annually to update each person's training as shown below.

- 4 trainer hours at \$36/hr = \$144
- 28 trainee hours at \$35/hr = \$980
- \$144 trainer costs + \$980 trainee costs = \$1,124

Additionally, we are proposing to require recordkeeping for documenting in each trained individual's personnel record that he or she successfully completed training. We estimate that it would take the trainer 5 minutes per trainee to document each participant's completion of the training. As described above, we estimate that 7 CMHC staff members would require such documentation and have calculated below the estimated total annual cost for this proposed requirement for all CMHCs.

- 5 minutes per trainee × 7 trainees = 35 minutes annually
- 35 minutes × \$36/hr = \$21 annually
- 35 minutes per CMHC × 224 CMHCs = 130.6 hours nationwide
- 130.6 hours industry wide × \$36/hr = \$4,701.60 nationwide

We would require that each CMHC revise its training program annually as needed. We estimate this task, which would 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 × \$36/hr = \$144 per CMHC
- \$144 per CMHC × 224 CMHCs = \$32,256 nationwide

Finally, the proposed standard for reporting client deaths applies to all deaths associated with the use of restraint or seclusion throughout the CMHC. A CMHC would be required to report to CMS each death that occurs while a client is in restraint or seclusion at the CMHC.

Each death would require reporting to CMS by telephone no later than the close of business the next business day following the facility's learning of the client's death. We have no data on which to base an estimate of the number of deaths in CMHCs that may be related to the use of seclusion and restraint. However, based on a lack of complaints to State agencies and CMS, we believe such deaths to be rare occurrences. Although our goals are to ensure the safe and appropriate use of seclusion and restraint and to reduce associated deaths, we are aware that the actual number of reported deaths from seclusion and restraint may increase due to these reporting requirements. Therefore, we anticipate there would be a burden associated with this proposed requirement due to the increased

number of deaths that would be reported by CMHCs. Given the lack of historical data, we assume the number of reports certainly should average less than one per CMHC per year. We

believe the impact associated with this proposed provision (that is, making a telephone call and filling in a written report) to be negligible.

Tables 3 and 4 below show the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the proposed standards for the client rights CoP.

TABLE 3—CLIENT RIGHTS BURDEN ASSESSMENT (FIRST YEAR)

Standard	Time per average CMHC (hours)	Total time (in hours)	Cost per average CMHC	Total cost
Client rights form development	8	1,792	\$424	\$94,976
Client rights notification, signature, and documentation	9.3	2,090	336	75,240
Addressing violations	26	5,824	1,378	308,672
Reporting violations	4.3	971	228	51,463
Documenting Restraint and Seclusion	0.75	168	27	6,048
4 day trainer training	32	7,168	3,641	815,584
Staff training program development	40	8,960	1,440	322,560
Staff training	64	14,336	2,248	503,552
Staff training records	0.58	130.6	21	4,702
Totals 1st year	184.93	41,439.6	9,743	2,182,797

TABLE 4—CLIENT RIGHTS BURDEN ASSESSMENT (ANNUAL)

Standard	Time per average CMHC	Total time (in hours)	Cost per average CMHC	Total cost
Client rights notification, signature, and documentation	9.3 hours	1090	\$336	\$75,240
Addressing violations	26 hours	5,824	1,378	308,672
Reporting violations	4.3 hours	971	228	51,463
Documenting Restraint and Seclusion	0.75 hours	168	27	6,048
Staff training update	32 hours	7,168	1,124	251,776
Staff training records	35 minutes	130.6	21	4,704
Staff training program update	4 hours	896	144	32,256
Totals Annually	76.85 hours	17,247.6	3,258	730,159

With respect to the proposed CoP for admission, initial evaluation, comprehensive assessment and discharge or transfer of the client, we believe that several of the proposed standards associated with the CoP are unlikely to impose a burden on CMHCs. Specifically, the proposed requirement for admitting a client is standard medical practice; therefore, this requirement would not impose a burden upon a CMHC.

Similarly, the proposed requirement to initially evaluate a client to collect basic information (for example, the admitting diagnosis and referral source) and to determine his or her immediate care and support needs is standard medical practice. Therefore, this requirement would not impose an additional burden upon a CMHC. We believe that this evaluation, conducted by a psychiatric nurse or clinical psychologist, would take 30 to 45 minutes per client.

While we are also proposing to require a comprehensive assessment of each client's needs, this is standard medical practice; therefore, this

requirement would not impose a burden upon a CMHC. We believe that each discipline involved in the CMHC interdisciplinary treatment team (physician, psychiatric nurse, clinical social worker, clinical psychologist, occupational therapist, and any other licensed mental health counselors), in coordination with the client's primary care provider (if any), would complete their respective portions of the comprehensive assessment. We estimate that each discipline would spend 20 to 30 minutes completing its portion of the comprehensive assessment, for a total of 2 to 3 hours per client.

Moreover, we do not believe that the proposed requirement to update the comprehensive assessment would 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 25,087 Medicare beneficiaries who received partial hospitalization services in 2007 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 would not impose a burden upon a CMHC. We estimate that updating the comprehensive assessment would require 30 minutes per client.

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 proposed standard for the discharge or transfer of the client is part of a CMHC's standard practice and would not pose additional burden to CMHCs.

Under the CoP for treatment team, active treatment plan, and coordination of services, we assessed the potential impact of the following proposed 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 would set forth the required members of each CMHC’s active treatment team and would require 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 would not pose a burden.

Furthermore, this standard would require a psychiatric nurse, clinical psychologist, or clinical social worker who is a member of the interdisciplinary treatment team to be designated for each client as a care coordinator. The designated individual would 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 would spend 20 to 30 minutes per week (37 to 56 hours annually) overall to fulfill this requirement. The annual cost per CMHC associated with this requirement would be \$1,332 to \$2,016 for a psychiatric registered nurse, \$1,776 to \$2,688 for a clinical psychologist, or \$1,036 to \$1,568 for a clinical social worker. The aggregate annual cost for all CMHCs would be \$298,368 to \$451,584 if a psychiatric registered nurse is used; \$397,824 to \$602,112 if a clinical

psychologist is used, or \$232,064 to \$351,232, if a clinical social worker is used. This estimated burden is shown in Table 5 below.

Finally, subsection (a)(3) of this standard would require 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 proposed active treatment plan standard and its content would set forth the requirements for each client’s active treatment plan. The written active treatment plan would be established by the client and interdisciplinary treatment team. It would address the client’s needs as they were identified in the initial evaluation and subsequent comprehensive assessment. The treatment plan would include several required elements (for example, an identification of a client’s treatment goals and his or her prescribed drugs), all of which are considered to be standard practice in the mental health care industry. We estimate that establishing the first comprehensive active treatment plan would require 45 minutes of the interdisciplinary treatment team’s time. The burden associated with this proposed requirements would be the time it would take to document the active treatment plan in the clinical record. We estimate that compliance with the requirements at § 485.916(c) would require a nurse a total of 45 minutes per client, for a total of 84 hours per CMHC. Based on the nurses’ hourly rate, the total cost would be \$3,024 per CMHC.

The proposed standard for review of the active treatment plan would require the interdisciplinary treatment team to review and revise the active treatment

plan as necessary, but no less frequently than every 30 calendar days. The revised treatment plan would include several required elements, such as the client’s progress toward the treatment goals identified in the previous treatment plan. We estimate that updating the active treatment plan would require 15 minutes of the interdisciplinary treatment team’s time. The burden associated with this proposed requirement would be the time it would take to update the active treatment plan as a client’s care progresses (estimated to be 15 minutes). Therefore, we estimate that compliance with the requirements at § 485.916(d) would require a nurse a total of 15 minutes per client, for a total of 28 hours per CMHC. Based on the nurses’ hourly rate, the total cost would be \$1,008 per CMHC.

In addition, the proposed coordination of services standard would require 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. This communication would be required to, among other things, ensure that information is shared among all disciplines providing care and services for each client and ensure that information is shared with other health care providers, including the client’s primary care provider (if any) that care for CMHC clients as necessary and appropriate. We believe that active communication within health care providers, including CMHCs, is standard practice; therefore, this requirement would not impose a burden.

Table 5 below shows the annual estimated CMHC burden associated with the proposed 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 Coordinator.	37 to 56 Average: 47	8,288 to 12,544 Average: 10,416	\$1,332 to \$2,016 Average: \$1,674	\$298,368 to \$451,584 Average: \$374,976
Clinical Psychologist	37 to 56 Average: 47	8,288 to 12,544 Average: 10,416	\$1,776 to \$2,688 Average: \$2,232	\$397,824 to \$602,112 Average: \$499,968
Clinical Social Worker	37 to 56 Average: 47	8,288 to 12,544 Average: 10,416	\$1,036 to \$1,568 Average: \$1,302	\$232,064 to \$351,232 Average: \$291,648
** Total Average (for all disciplines).	Total Average: 47	Total Average Range: 8,288–10,416. Total Average: 9,352	Total Average Range: \$1,381–\$2,613. Total Average: \$1,736	Total Average Range: \$309,418–\$468,309 Total Average: \$388,864
Development of the Active Treatment Plan.	84 hours	18,816 hours	\$3,024	\$677,376
Review and Update of the Active treatment Plan.	28 hours	6,272 hours	\$1008	\$225,792

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

	Time per average CMHC (in hours)	Total time (in hours)	Cost per average CMHC	Total cost
Total	159 hours	34,440 hours	\$5,768	\$1,292,032

* **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 would provide guidance to the CMHC on how to establish a quality assessment and performance improvement program. Based on an annual census of 112 Medicare beneficiaries per CMHC, it is estimated that a CMHC would spend approximately 24 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 would take 12 hours to create a program. We also estimate that CMHCs would spend 4 hours a year collecting and analyzing data. In addition, we estimate that CMHC would spend 3 hours a year training their staff and 5 hours a year implementing performance improvement activities. Both the program development and

implementation would 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 would be \$1,272 per CMHC.

\$53 per hour × 24 hours = \$1,272
 We believe that these estimates may not be a complete reflection of the impact that this CoP may have on CMHCs, because we do not know the total number of clients served by CMHCs. Therefore, we are requesting public comment regarding the total number of all clients served by CMHCs annually and the length of time on service.

(a) **Standard: Program scope.** This standard would require that the CMHC assess its organization and develop a formal quality assessment and performance improvement program that is capable of showing measurable improvement through the use of quality indicator data.

(b) **Standard: Program data.** The proposed rule would require the use of

quality indicator data in a quality assessment and performance improvement program, but would not require any specific data collection or utilization, nor would it require CMHCs to report the collected data. CMHCs would, therefore, be provided flexibility with minimal burden. The CMHC must use the data to monitor the effectiveness and safety of services and quality of care. As part of the monitoring process, the data must be used to assist in the prioritization of the aforementioned opportunities for improvement.

(c) **Standard: Program activities.** This standard would identify certain areas that would be required to be covered in a CMHC’s customized quality assessment and performance improvement program. The categories would be sufficiently broad to allow for a vast range of acceptable compliance methods. This would minimize burden.

Table 6 below shows the annual estimated CMHC burden associated with the proposed 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	12	2688	\$636	\$142,464
QAPI implementation	12	2688	636	142,464
Total annually	24	5376	1272	284,928

Under the proposed CoP for organization, governance, administration of services, and partial hospitalization services, we assessed the potential impact of the following proposed standards on CMHCs: governing body and administration, provision of services, professional management responsibility, staff training, and physical environment. The proposed governing body and administration standard would require a CMHC to have a designated governing body that assumes full legal responsibility for management of the CMHC. This standard would 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 would not impose a burden.

The proposed provision of services standard would set forth a comprehensive list of services that CMHCs are currently required by statute and regulation to furnish. This standard would also require the CMHC and all

individuals furnishing services on its behalf to meet applicable State licensing and certification requirements. As this standard is a compilation of requirements that CMHCs must already meet, it would not impose a burden.

In addition, the proposed professional management responsibility standard would require that, if a CMHC chooses to provide certain services under agreement, it must ensure that the agreement is written. This standard would also require the CMHC to retain full professional management responsibility for the services provided under arrangement on its behalf. Full

professional management responsibility would 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 would not impose a burden.

Further, the proposed staff training standard would require a CMHC to educate all staff who have contact with clients and families about CMHC care and services. It would also require 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 would require 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 would require a CMHC to

provide and document its in-service training program. This proposed standard does not prescribe the content or format of the CMHC's skills assessment and in-service training programs. Rather, it would allow CMHCs to establish their own policies and procedures to meet their individual needs and goals. Due to this inherent flexibility, we cannot estimate the impact of this proposed provision at this time; therefore, we specifically invite comments on this issue.

The proposed physical environment standard would require 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 proposed requirement would 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 proposed standard would also require 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 would 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 proposed provision would be \$424 to develop the infection control program and \$1,272 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.

Table 7 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with the proposed 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	1,792	\$424	\$94,976
Infection control follow-up	24	5,376	1,272	284,928
Total 1st year	32	7,168	1,696	379,904
Total annually	24	5,376	1,272	284,928

Table 8 below shows the initial year (one-time) and annual estimated CMHC burden, respectively, associated with all requirements in this proposed CMHC rule.

TABLE 8—TOTAL BURDEN ASSESSMENT FOR ALL REQUIREMENTS IN THE FIRST YEAR COP

	Total time (hours) per average CMHC	Total industry time	Total cost per average CMHC	Total industry cost
Client rights	1st year: 184.93 Annual: 76.85	1st year: 41,439.6 Annual: 17,247.6	1st year: \$9,743 Annual: \$3,258	1st year: \$2,182,797 Annual: \$730,159
Treatment team. Active Treatment Plan, and Coordination of Services.	Range: 37–56 Average: 47 Total: 159	Range: 8,288–12,544 Average: 10,416 Total: 34,440	Range: \$1,381– \$2,613. Average: \$1,736 \$5,768	Range: \$309,418– \$468,309 Average: \$388,864 Total: 1,292,032 \$284,928
Quality Assessment and Performance Improvement.	24	5,376	\$1,272	\$284,928
Organization, Governance, Administration of Services.	1st year: 32 Annual: 24	1st year: 7,168 Annual: 5,376	1st year: \$1,696 Annual: \$1,272	1st year: \$379,904 Annual: \$284,928
Totals	1st year: 399.93 Annual: 283.93	1st year: 88,423.6 Annual: 62,439.6	1st year: \$18,479 Annual: \$11,570	1st year: \$4,139,661 An- nual: \$2,592,047

All first year costs include the annual burden for Treatment team, Active Treatment Plan, and Coordination of Services and Quality Assessment and Performance Improvement CoPs.

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 Proposed CoPs for CMHCs on Other Providers

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

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

The costs to the Medicare and Medicaid programs resulting from implementation of the proposed CoPs for CMHCs included in this proposed rule would be negligible.

C. Alternatives Considered

We considered not proposing CoPs for CMHCs. These providers have been operating without federally-issued health and safety requirements since the 1990 inception of Medicare coverage of partial hospitalizations 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 significant gaps in State requirements to ensure the health and safety of CMHC clients, we chose to propose a core set of health and safety requirements that would apply to all CMHCs receiving Medicare funds, regardless of the State in which the CMHC is located. These requirements would ensure a basic level of services provided by qualified staff.

We also considered proposing a comprehensive set of CoPs for CMHCs. Such a comprehensive set of CoPs would go beyond the requirements in this proposed rule to address other areas of CMHC services and operations, such as the specific contents of a CMHC's quality assessment and performance improvement program, and its specific clinical record content and procedures. 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. 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. Rather than potentially overwhelming CMHCs with

a substantial number of new requirements at one time, we chose to focus on a set of requirements and allow for the option of additional CoPs in the future.

D. Conclusion

As stated earlier, we estimate that the changes that we are proposing in this proposed rule to implement CoPs for CMHCs will not have a significant economic effect on Medicare payments to CMHCs. We estimate that this proposal would cost CMHCs approximately \$4.1 million, or \$18,475 per average CMHC, in the first year of implementation and approximately \$2.6 million, or \$11,566 per average CMHC, annually. We believe that the burden that would be 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.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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 proposes to amend 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 a new subpart J to part 485 to read as follows:

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, client-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 those partial hospitalization services furnished by a community mental health center (CMHC) that are defined in section 1861(ff)(2)(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(a) of this chapter.

(4) *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 provides services in areas such as psychotherapy, substance abuse, crisis management, psychoeducation, and prevention programs.

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

(6) *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.

(7) *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 2 years of education and/or training in psychiatric nursing.

(8) *Psychiatrist.* An individual who specializes in assessing and treating persons having psychiatric disorders; is 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 provided, at a minimum, in English.

(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 by CMHC employees and contracted staff to the CMHC's administrator.

(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 verified 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, verified violations are reported to State and local entities having jurisdiction (including the State survey and certification agency).

(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 a duration of 1 hour per order.

(3) The CMHC must obtain a corresponding order for the client's immediate transfer to the 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 themselves, 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 a 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 themselves, staff or other individuals.

(1) *Training intervals.* 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 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 require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) 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 used in the CMHC, including training in how to recognize and respond to signs of physical and psychological distress.

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) 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 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) The CMHC's psychiatric registered nurse or clinical psychologist 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 that 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.

(c) *Standard: Comprehensive assessment.*

(1) The comprehensive assessment must be completed by a CMHC physician-led interdisciplinary treatment team, in consultation with the client's primary health care provider (if any).

(2) The comprehensive assessment must be completed in a timely manner, consistent with the client's immediate needs, but no later than 3 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 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 or psychologist with physician counter signature, that includes the medical history and severity of symptoms.

(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 behavior, including cultural 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.

(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. The profile must provide documentation that includes, but is not limited to, the effectiveness of drug therapy; drug side effects; actual or potential drug interactions; duplicate drug therapy; and drug therapy requiring laboratory monitoring.

(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.

(d) *Standard: Update of the comprehensive assessment.*

(1) The CMHC must update the comprehensive assessment via the CMHC physician-led 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 goals 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 facility, the CMHC must, within 48 hours, forward to the facility, 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, client-centered active treatment plan, and coordination of services.

The CMHC must designate a physician-led 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) A physician-led interdisciplinary treatment team must provide the care and services offered by the CMHC.

(2) The CMHC must designate a psychiatric registered nurse, clinical psychologist, or 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 are assessed and to ensure that the active treatment plan is implemented as indicated. The interdisciplinary

treatment team must include, but is not limited to, individuals who are licensed, and in compliance with State law, to practice in the following professional roles:

- (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.

(3) 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: 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 physician-led interdisciplinary treatment team and the client, in accordance with the client's psychiatric needs and goals, within 3 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 active treatment plan.* The CMHC must develop an individualized active treatment plan for each client. The active treatment plan must take into consideration client 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 and representative's (if any) understanding, involvement, and agreement with the plan of care, in accordance with the CMHC's policies.

(d) *Standard: Review of the 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.

(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 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.

§ 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 client-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 services 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 (or designated person(s)) that assumes full legal authority and responsibility for the management of the CMHC, the services it furnishes, its fiscal operations, and continuous quality improvement.

(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 chronic mental illness, and residents of its mental health services 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 revenues received by the CMHC that are payments from Medicare versus payers other than Medicare.

(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 client-centered planning 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: May 26, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: June 3, 2011.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

[FR Doc. 2011-14673 Filed 6-16-11; 8:45 am]

BILLING CODE 4120-01-P