AMERICAN NURSES ASSOCIATION

8515 Georgia Avenue, Suite 400
Silver Spring, Maryland 20910-3492
301 628-5000 • Fax 301 628-5001
www.NursingWorld.org

Karen A. Daley, PhD, MPH, RN, FAAN
President

Marla J. Weston, PhD, RN
Chief Executive Officer

August 16, 2011

Donald M. Berwick, MD
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-1850

Attention: CMS –3202-P

Submitted electronically to http://www.regulations.gov

Re: **Medicare Program; Conditions of Participation (CoPs) for Community Mental Health Centers.**
CMS-3202-P; RIN 0938-AP51. 75 Fed.Reg. 35684 (June 17, 2011).

Dear Dr. Berwick,

The American Nurses Association (ANA) welcomes the opportunity to offer comments on this proposed rule. The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses (RNs), the single largest group of health care professionals in the United States. We represent RNs in all roles and practice settings, through our state and constituent member nurses associations and organizational affiliates, including the American Psychiatric Nurses Association. Our members include Advanced Practice Registered Nurses (APRNs) such as Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse-Midwives (CNMs), and Certified Registered Nurse Anesthetists (CRNAs).

ANA appreciates this effort by CMS (the Centers for Medicare & Medicaid Services) to establish oversight and minimal standards to ensure safety and quality at community mental health centers (CMHCs), along with the emphasis on quality improvement and outcomes which would build upon existing quality improvement programs. Twelve months should be a sufficient time period to permit CMHCs to make necessary changes to educate staff, implement quality assessment and performance improvement (QAPI) programs, and to otherwise comply with the proposed conditions of participation (CoPs).

ANA supports the principle of a client-centered, interdisciplinary approach upon which the proposed CoPs are based. We are concerned, however, that some of the proposed standards may create barriers to building effective teams. We are also concerned that CMHCs will incur increased (and potentially unreimbursed) additional costs and increased documentation demands, with potential negative impact on staff time, operational dollars, and patient care. Below are suggestions for the final rule, to help

achieve positive outcomes through integrated, compassionate care for Medicare beneficiaries.

§ 485.904(b)(7) Conditions of Participation: Personnel qualifications for certain disciplines; *Psychiatric registered nurse.*

As set forth in section 485.904(b) of the proposed rule, *"Standard*: *Personnel qualifications for certain disciplines*, subsection (7) currently defines a "Psychiatric registered nurse" as follows:

> (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. This proposed definition is similar to that used for other Medicare-certified providers."

CMS notes that "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."

We suggest the following modifications to this definition to more accurately reflect the prevailing characteristics and training of Psychiatric Mental Health (PMH) RNs and to reflect the different scope of practice, advanced degrees, and additional training and licensure of APRNs, as follows:

> "(7)(a) *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 experience providing mental health services to clients.
>
> "(b) *Advanced Practice Psychiatric Nurse*. An individual who specializes in assessing and treating persons having psychiatric disorders; is certified by a national certifying body as a Psychiatric Clinical Nurse Specialist (CNS) or Nurse Practitioner (NP) and licensed in the State as an advanced practice registered nurse or has documented equivalent education, training or experience, and is fully licensed to practice advanced psychiatric nursing in the State in which he or she practices."[1]

These definitions have been endorsed by our colleagues at the American Psychiatric Nurses Association. CMS has noted that the proposal to require 2 years of education and/or training in psychiatric nursing, for RNs, is "due to the sensitive and complex

[1] For additional information about Advanced Practice Nurses, see the "Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education" (http://nursingworld.org/consensusmodeltoolkit).

needs of the CMHC client." However, we believe that each CMHC should have discretion to evaluate the experience of each PMH RN, in light of his or her unique background and the characteristics and needs of the center's patient population. For example, 2 years of working with adolescent psychiatric patients may not be appropriate experience for working with patients with dementia.

In addition, we share the concerns of the National Association of Social Workers, with the NPRM's (notice of proposed rulemaking) reference, at p. 35691, to a "nurse who also holds a qualifying degree in social work" who "could represent both the nurse and social worker [on the] interdisciplinary treatment plan." We agree with NASW that the appropriate, qualifying clinical licensure in social work would be required (in addition to an educational degree) before assuming such responsibilities.

§ 485.910(e) Conditions of Participation: Client Rights. *Standard: Restraint and seclusion*

Longstanding ANA policy views restraint or seclusion of clients/patients as contrary to the fundamental goals and ethical traditions of the nursing profession, which upholds the autonomy and inherent dignity of each individual. In keeping with the goals of the proposed rule's restraint and seclusion standards, ANA believes that restraint is rarely appropriate, and only when no other viable option is available. [2]

ANA appreciates that CMS seeks consistency among the provisions regarding the use of restraint and seclusion within the context of hospitals, hospice, nursing homes, and other providers. The intention to provide consistent protections for patients as they move from one kind of care to another is a needed piece to the coordination of care requirements. Consistency among the various settings also benefits providers who will be able to have similar expectations regarding their own responsibilities across the spectrum of care.

§ 485.910(f) Conditions of Participation: Client Rights. *Standard: Restraint or seclusion; Staff training requirements*.

ANA has concerns regarding the proposed staffing requirements in this section. We are in complete agreement that "All 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 the use of alternative methods to restraint and seclusion…" However, we take exception with the expectation that physicians would be excluded from this requirement. We base this on our reading of the definition of "employee" (proposed § 485.902), and CMS's "expectation" (76 Fed. Reg. 35700) that physicians would be

[2] ANA Position Statement: Reduction of Patient Restraint and Seclusion in Health Care Settings - 10/17/01
http://www.nursingworld.org/MainMenuCategories/EthicsStandards/Ethics-Position-Statements/prtetrestrnt14452.aspx

excluded from the care team's training. This directly harms the effectiveness of the interdisciplinary care that the proposed rule seeks to encourage.

The proposed rule's requirement is that only CMHC staff who have "direct contact with clients" must be trained in restraint and seclusion use. This seems inconsistent with the fact that a physician (or other licensed practitioners authorized by the State) is the individual responsible for the order (renewable on an hourly basis) for restraint or seclusion, which other staff implement. It also undermines the effectiveness of the "physician-led interdisciplinary treatment team" that determines the client's comprehensive assessment (regularly reviewed and renewable at a minimum of thirty days). If physicians involved are not part of the uniform training required of all other pertinent staff, it would once again silo the physician's role from all other healthcare professionals. It would set the stage for miscommunication, conflicting expectations, lack of coordination, and potential friction among the interdisciplinary team responsible for the care of an especially vulnerable client population. This completely defeats CMS's stated goal to improve quality management systems and client care performance. The ANA strongly urges CMS to revise the training provision to include *all* healthcare professionals and support staff involved in the client's care, including physicians.

§ 485.914(c)(4) Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client. *Standard: Comprehensive assessment.*

The expectation of three working days after a patient's admission to the CMHC for staff to complete a comprehensive assessment may be difficult. In particular, evaluations performed by professionals that require physician co-signatures could cause significant delays in treatment. The advanced practice psychiatric nurse (PMH APRN) is educated and qualified to perform psychiatric evaluations without "supervision" and/or oversight, as recognized in many States.

We suggest the following wording below to indicate the inclusion of PMH APRNs and the psychological evaluation as a component of the psychiatric assessment.

> "(4) The comprehensive assessment, at a minimum, must include the following:
> (ii) A psychiatric evaluation, completed by a psychiatrist, psychologist or advanced practice psychiatric nurse, that includes the medical history and severity of symptoms.

§ 485.916(a) Condition of participation: Treatment team, client-centered active treatment plan, and coordination of services. *Standard: Delivery of services*

The current list of the interdisciplinary team includes "a psychiatric RN." We understand that the list is not all-inclusive, but since the definition of "psychiatric RN" does not reflect the training or current scope of practice of PMH APRNs, who play a critical role in

the provision of mental health services, ANA recommends specific inclusion of PMH APRN within the personnel qualifications.

We suggest that the wording of § 485.916(a)(2) be changed to the following, with new language in red:

"The interdisciplinary team would 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) An advanced practice psychiatric nurse (NP or CNS).
(iii) A psychiatric registered nurse.
(iv) A clinical social worker.
(v) A clinical psychologist.
(vi) An occupational therapist.
(vii) Other licensed mental health professionals, as necessary."

Interdisciplinary Team Approach

ANA supports the principle 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." Indeed, CMS has stated in the NPRM, "We believe that the role of the interdisciplinary team is paramount in directing and monitoring client care," (76 Fed. Reg. 35691) and often refers to a "client-centered interdisciplinary team." However, CMS has also made multiple references throughout the NPRM to a "physician-led" team – and to the need for "general supervision of a physician." We do not find repeated references to a "physician-led" team consistent with that principle.

The U.S. healthcare system, seeking proven solutions to our crisis in cost, quality and access, is undergoing a significant shift from an outmoded hierarchical "physician-led" structure toward team-based structures. There is a growing realization that no one provider can deliver all the care that patients need, nor should one provider be responsible for the provision of that care. Rather, we are shifting emphasis toward patient-centered care coordination from a team of qualified health professionals. The Joint Commission's new Standards and Elements of Performance for the Primary Care Medical Home are the most recent example of a shift from language that mandated a "physician directed medical practice" toward provider-neutral language that speaks to how the "primary care clinician and the interdisciplinary team work in partnership with the patient."

Depending on the clinical setting and the needs of an individual patient, a physician may well be the appropriate person to lead the interdisciplinary team. However, the growing evidence regarding both the intransigence of the American healthcare system in failing to adopt practices that avoid and prevent medical errors, as well as challenges in

providing high quality, efficient care and the best possible outcomes for patients, raise serious questions about the efficacy and wisdom of automatic reliance upon the traditional leadership model of physicians always serving as "captain of the ship." Mental health care, in particular, involves a wide array of highly qualified providers, including psychologists, licensed clinical social workers, and psychiatric mental health APRNs – as well as psychiatrists and other physicians – any one of whom may be the best person to take leadership of a patient's care. And CMS has noted the need to improve the safety and quality of care in CMHCs, given complaints of withdrawn services, physical mistreatment, and fragmented care.

ANA recognizes that CMS rules and regulations must be consistent with existing statutory language and requirements, which can prevent the agency from truly implementing a 21st century healthcare system. For example, Medicare Part B regulations for partial hospitalization, at 42 CFR § 424.24(e), require that physicians diagnose and establish treatment plans for patients under their care.

However, we believe it is in the best interest of patients for CMS to endeavor, throughout its policies and regulations, to be ever mindful of the value of the inter-disciplinary team approach, and to strive to develop and employ language that is inclusive, cognizant and respectful of the important contributions of all types of providers.

Regulatory Impact Analysis – Anticipated Effects on CMHCs

ANA is concerned that the time estimates for participating in interdisciplinary team assessments, for (at least) 30 day review, and for care coordination seem quite low. For example, at page 35702, column 1, staff designated by the CMHC *specifically* for care coordination "would spend 20 to 30 minutes per week *overall"* to fulfill this requirement. Also, on same page, the nurse participates in the interdisciplinary team meeting *and* is expected to document any decisions/modifications/updates *for each client* with a total time estimate of 15 minutes to perform both of these functions. We are concerned that these time estimates are unrealistic.

ANA has a long history of working to ensure safe staffing in all healthcare settings, but in this environment we are particularly concerned, as ANA policy links the problem of insufficient nurse staffing to the potential for inappropriate use of restraint or seclusion. ANA is concerned that a lack of personnel to provide adequate monitoring of patients and less restrictive approaches to behavior management may place patients at greater risk of violation of their rights and of harm caused by being placed in seclusion and/or restraints.

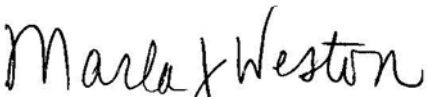
In the NPRM, CMS notes that there is little reliable evidence to document the prevalence of restraint and seclusion use (76 Fed. Reg. 35699). The agency further notes that, "[b]ased on discussions with the CMHC industry and The Joint Commission, we believe restraint or seclusion are rarely, if ever, used in a CMHC setting and that there are very few deaths (if any) that occur due to restraint or seclusion in CMHCs."

We question whether this conclusion regarding the extent of use of restraint is accurate, especially in light of the paucity of supporting data.

There is, however, significant data documenting the prevalence and severity of workplace violence experienced by RNs and other healthcare personnel. For example, in 2009 there were 2,050 assaults and violent acts reported by RNs requiring an average of 4 days away from work (BLS, Private Industry, State and Local Government, 2011) The challenge is to ensure that the use of restraint and seclusion remains rare and appropriate, while recognizing the need to ensure safety of healthcare personnel.

The ANA appreciates the opportunity to comment on this important rule. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Lisa Summers, CNM, DrPH; lisa.summers@ana.org; 301-628-5058.

Sincerely,



Marla J. Weston, PhD, RN
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American Nurses Association

Cc: Karen A. Daley, PhD, MPH, RN, FAAN
President
American Nurses Association