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Honorable Marilyn B. Tavenner, MHA, RN
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3244-P / RIN 0938-AQ89
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: **Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation.** 76 Fed. Reg. 65891 (October 24, 2011)

Dear Ms. Tavenner:

The American Nurses Association (ANA) offers the following comments regarding the proposed revisions by the Centers for Medicare and Medicaid Services (CMS) to the Medicare and Medicaid conditions of participation (CoPs), 42 CFR Parts 482 and 485. As detailed requirements for participation in Medicare and Medicaid programs by hospitals and critical access hospitals, the CoPs have a profound impact upon patient care and nursing practice for both registered nurses (RNs) and advanced practice registered nurses (APRNs) within hospital settings, and beyond. Designed to protect patient health and safety, the CoPs serve as compliance guidelines for State surveyors, as well as minimum standards for the Joint Commission and other private hospital accreditors.

Registered nurses are the largest group of health care professionals, and have more direct, ongoing interaction with hospital patients and their families than any other single category of health care professionals. Sixty percent of RNs are employed by hospitals, as staff nurses, administrators, case managers, and in other roles.[1] Nurses care for patients on the front lines, 24 hours a day, 7 days a week, providing ongoing nursing care and interventions – including but not limited to the: assessment of a patient's physical and mental status; analysis of information used to diagnose and plan patient care; evaluation of nursing care; documentation; administration of medications and nutritional supplements; assisting with surgical and other procedures; pain management; wound care; restorative care including the promotion of ambulation, physical activities and activities of daily living; patient and family education; coordination of treatments, care and diagnostic testing; emotional support for patients and their family and friends; discharge and transitional planning; and support of a dignified death. Nurses work as members of an interprofessional team to promote patient centered care.

Advanced practice registered nurses serve in a variety of roles in the care of hospitalized patients, providing key components of inpatient and outpatient care. Many hold or have applied for hospital privileges. Nurse practitioners (NP) who practice as primary care providers need hospital privileges to

[1] In 2010, 57.3% of RNs worked in general medical and surgical hospitals. Another 3.1% worked in specialty hospitals. U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes291111.htm.

provide key components of inpatient care, particularly coordination of care, which has been shown to reduce readmission rates. NPs also provide hospital-based care in a variety of inpatient settings, including intensive care units and specialty units, and in specialty areas such as pediatrics and cardiology. Clinical nurse specialists (CNSs) serve as educators, researchers and consultants in many specialties and also coordinate transitional care.[2] Certified registered nurse anesthetists (CRNAs) work primarily in the operating room, administering anesthesia and providing related care before and after surgery. They also have an increasingly critical role in providing pain management services. With the vast majority of births in the United States taking place in hospitals, admitting and discharge privileges are particularly vital for certified nurse-midwives (CNMs). In addition to their direct patient care roles, many APRNs specialize in organizational roles such as quality assessment and improvement planning, as well as care coordination, which has been shown to reduce readmission rates.[3]

President Obama recently issued Executive Order 13563 to reduce the burden imposed by unnecessary regulation, and in doing so recognized the potential for a more effective and efficient regulatory framework that could "promote economic growth, innovation, job-creation, and competitiveness." As the largest single group of health care professionals, the nation's 3.1 million registered nurses are innovators and must play an active role in redesigning the U.S. health care system. ANA is proud to represent RNs and APRNs in all roles and practice settings, through our constituent and state nurses associations and affiliated nursing specialty organizations.

PART 482—CONDITIONS OF PARTICIPATON FOR HOSPITALS

Proposed Section 482.13: Condition of participation: Patient's Rights

ANA urges CMS to reconsider the proposed change in the reporting requirement for patient deaths after soft wrist restraints have been used. We strongly believe all restraint and seclusion related deaths should be reported in the same manner, regardless of the form of restraint or seclusion. We do, however, support the proposed amendment allowing such reporting to occur by electronic means, as well as by telephone or facsimile.

Under proposed section 482.13(g)(1), hospitals would have until the close of the following business day to report the death of any patient: (i) while in restraint or seclusion; (ii) within 24 hours of removal from restraint or seclusion; or (iii) within a week after restraint or seclusion "where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death."[4] The proposed revision of section 482.13(g)(2) provides a much longer, less stringent reporting procedure that would apply to deaths involving a patient "When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials . . ." [5] For the latter, hospitals would simply have to record the death into a log, within seven days, making that log available for CMS inspection at any time. ANA does not support this distinction based on use of soft wrist restraints, as compared to other restraints.

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[2] Naylor, M.D., Brooten, D.A., Campbell, R.L., Maislin, G., McCauley, K.M., Schwartz, J.S. 2004. Transitional care of older adults hospitalized with heart failure: A randomized controlled trial. *Journal of the American Geriatric Society, 52(5),* 675-684.
[3] Id.
[4] Proposed 42 CFR 482.13(g)(1)(iii), 76 Fed. Reg. 65906 (Oct. 24, 2011).
[5] Although the proposed rule's discussion of the provision refers to two-point wrist restraint, the proposed regulatory language itself would apply to one- or two-point wrist restraint. 42 CFR 482.13(g)(2).

The goal of reducing the administrative burden on nurses and hospitals is a laudable one, and one that ANA often seeks in an effort to give RNs more time for direct patient care. We balance that, however, with the goal served by recording and reporting patient data. In the instance of hospitalized patients' deaths associated with the use of restraints, the balance weighs in favor of assuring that patients' safety and rights are protected. ANA does not believe this balance shifts simply because of the form or fabric of restraint. **Consequently, we recommend adoption of proposed section 482.13(g)(1), and rejection of proposed section 482.13(g)(2).**

Hospitals are responsible for providing the level of monitoring and frequency of reassessment that will ensure each patient's safety, using the CoPs as a minimum standard. Reporting requirements for deaths that *could* be related to the use of restraints or seclusion exist for a reason. Patients have the right to "be free from physical or mental abuse, and corporal punishment. All patients 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." [6] And hospitals are accountable for the questionable imposition of restraints or seclusion, where patient safety is compromised so much that death results. The purpose in reporting deaths is not simply the reporting in and of itself; it is the reporting that creates the end goal of accountability.

No matter what they are made of, wrist restraints are designed to accomplish the same basic purpose. Per the proposed reporting distinction, the only difference is in the softer material with which the restraint is made, an evolution of the technology to make the restraint more comfortable for the patient and more secure for the safety of others. This is particularly true for some elderly, the disabled, or children. CMS does not discuss death report data related to other types of restraints or seclusion, yet concludes that deaths related to soft wrist restraints do not suggest a "cause-and-effect relationship." How is it that a death that could be related, even indirectly, to a soft wrist restraint calls for less accountability? So much so that it not only goes unreported immediately, but it need not even be logged for up to a week following the death.

ANA is unaware of any changes in the rules regarding restraints and seclusion, including staff training and death reporting provisions, since 2006. Hospitals accordingly have established protocols to comply with these rules. Distinguishing between wrist restraints "composed solely of soft, non-rigid cloth-like material" and all other wrist restraints, and requiring two separate reporting mechanisms, would be confusing and likely upset existing, well-established uniform reporting protocols. CMS previously noted in its 2006 version of the final rule "that a uniform definition of restraint across care settings is a good approach, adds clarity, and avoids confusion . . . This definition renders unnecessary the otherwise impossible task of naming each device." [7] The same rationale applies today. Creating different rules for a particular form of wrist restraint would undercut CMS's commitment to achieving the goal of the President's Executive Order, which seeks to simplify and harmonize overlapping and related regulations.

While CMS's calculations approximate a cost of $11.25 per report of a death associated with soft wrist restraints, the proposed rule does not estimate the administrative cost and burden of creating and maintaining a separate log of such events, "available for CMS review at any time." We believe, on balance, that the goal of assuring patient safety and hospital accountability far outweighs the revised subsection's questionable reduction in administrative burden.

As a separate matter, ANA is troubled by the estimates used in the anticipated regulatory impact analysis of the revised section 482.13. CMS estimates that the "full reporting of all such instances"

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[6] 42 CFR 482.13(e).
[7] 71 Fed. Reg. 71388.

where a patient has died while in, or within 24 hours of removal of, soft, non-rigid wrist restraints "would result in 882,000 occurrences." [8]

This number raises questions, as do the downstream calculations based on this number. In 2007, there were a total of 765,651 hospital inpatient deaths from all causes. Of these, an estimated 512,391 hospital inpatient deaths were Medicare beneficiaries; Medicaid patients accounted for 61,765 hospital deaths.[9] This totals 574,156 deaths in 2007 for beneficiaries in both programs. Even if the 882,000 estimated occurrences include all form of restraint or seclusion (not just soft wrist restraints), CMS's estimate translates to an average of 180 deaths per year per facility or, roughly, a patient dying every other day in such restraints (or within 24 hours of removal) in each of the approximately 4900 hospitals. This is indeed "much greater" (as CMS notes) than the 2006 estimate of 20 deaths per year per facility… by a factor of nine.

If correct, this suggests that hospital restraint policies need serious review. The number documents deaths; it does not include the use of restraints where no death occurs, which one might conclude is significantly more frequent. In light of the regulatory imperative to use the least restrictive form of restraint only if no alternatives exist, this implication is of concern. This is particularly so because vulnerable populations such as the elderly, psychiatric and disoriented patients are among those most likely to be subject to physical or chemical restraints or seclusion.

ANA policy states that "only when there is no other viable option should restraints be employed." [10] CMS has a comparable policy wherein less restrictive alternatives should be determined to be ineffective in preventing harm to the patient or others before restraints or seclusion are used. When restraints or seclusion are used, the type or technique must be the least restrictive intervention to prevent harm. CMS's numbers, if correct, suggest this requirement is widely flouted.

Second, it is difficult to imagine – though one would like to believe – that among 882,000 estimated deaths, not a single one would be related directly or indirectly to the use of soft, two-point wrist restraints. Since the reporting requirement has been in place for several years, it would seem reasonable to expect that CMS has the data that definitively supports its conclusion.

The Department of Health and Human Services Office of Inspector General's 2006 report, "Hospital Reporting of Deaths Related to Restraint and Seclusion" noted communications lapses among CMS, the Food and Drug Administration (FDA) – which monitors deaths associated with a medical device, Protection and Advocacy Agencies (P&As), and state survey agencies working on behalf of CMS.[11] These communications problems prevent development of a central repository for accurate accounting of all deaths related to restraint and seclusion. **We urge CMS to establish a mechanism allowing communication and information sharing between these entities, if it has not already done so.**

The OIG report documented significant underreporting to CMS by hospitals of restraint or seclusion related deaths, as well as delays. Less than one third of deaths were reported to CMS by the close of

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[8] 76 Fed. Reg. 65902.
[9] Statistical Brief #81. Healthcare Cost and Utilization Project (HCUP). April 2010. Agency for Healthcare Research and Quality, Rockville, MD. www.hcup-us.ahrq.gov/reports/statbriefs/sb81.jsp.
[10] ANA Position Statement: Reduction of Patient Restraint and Seclusion in Health Care Settings. 2001. http://gm6.nursingworld.org/MainMenuCategories/EthicsStandards/Ethics-Position-Statements/prtetrestrnt14452.html.
[11] Department of Health and Human Services Office of Inspector General. 2006. "Hospital Reporting of Deaths Related to Restraint and Seclusion." http://oig.hhs.gov/oei/reports/oei-09-04-00350.pdf

the following business day, as required. The median delay was a week. Has this improved in the intervening six years?

Timely notification enables a timely response by CMS to patient safety issues. "Because hospitals rarely undergo routine reviews to address restraint and seclusion death reporting, timely complaint investigations are an important opportunity for [State] surveyors to ensure that hospitals' policies and procedures are appropriate." [12] ANA believes the rationale for timely reporting has not changed since the OIG report was published, regardless of the form of restraint.

Proposed Section 482.22: Condition of participation: Medical staff

ANA recommends that CMS revise section 482.22(a) *Standard: Composition of the medical staff* to require hospitals to include practitioners other than physicians on their medical staffs. Currently, subsection (a) states: "The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, **may** also be composed of other practitioners appointed by the governing body" (emphasis added). While we commend CMS for moving in the right direction to recognize the value of non-physicians in the proposed regulation, we urge CMS to change the word "may" in this provision to "shall." This change is necessary to ensure that hospitals keep an open door to APRNs and other non-physician practitioners, so that patients can have access to the providers of their choice within the hospital setting.

The modification ANA proposes is consistent with the landmark Institute of Medicine report, *The Future of Nursing: Leading Change, Advancing Health,* which recommends that CMS:

> Amend or clarify the requirements for hospital participation in the Medicare program to **ensure** that advanced practice registered nurses are eligible for clinical privileges, admitting privileges, and membership on medical staff [emphasis added].[13]

Consumers and health care advocates increasingly recognize a fact well-known among APRNs: that access, quality and continuity of care are enhanced when APRNs have appropriate clinical privileges, including the ability to admit and discharge patients. As the AARP has noted, "Federal and state laws and regulations, as well as individual hospital bylaws and policies, can block hospitalized patients' access to the provider of their choice, if that provider is an APRN." [14]

ANA's recommended change to the proposed language also strengthens the goal of furthering patient-centered, interdisciplinary healthcare teams. Just as consumers need access to APRNs, they need unfettered access to physical, occupational and respiratory therapists; psychologists; podiatrists; chiropractors; and other practitioners. Furthermore, allowing all health care professionals to practice to the full extent of their education and licensure allows for greater efficiency of care.

ANA also recommends that language be added to ensure that all practitioners are granted clinical privileges and accorded all categories of medical staff privileges, including voting rights and full due process. Many hospitals have created alternative categories within the medical staff to create distinctions between physicians (as full members of the medical staff) and other health care professionals. These are often called "associate," "special," or "limited" privileges. In its background information, CMS references this possibility, noting "such a structure is neither required nor suggested,"

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[12] Id. at 15.
[13] Institute of Medicine (IOM). 2011. *The Future of Nursing: Leading Change, Advancing (Recommendation 1).* Washington, DC: The National Academies Press.
[14] http://www.aarp.org/health/doctors-hospitals/info-10-2011/Removing-Barriers-to-Advanced-Practice-Registered-Nurse-Care-Hospital-Privileges.html#.To368q6FiEc.email

but provided as "an example of one possible way for a hospital to align all of its practitioners under the 'Medical Staff' rules."

Such an option may serve the needs of a limited number of APRNs; however in most hospitals the full potential of APRNs will only be realized when they can access the rights and responsibilities of full medical staff privileges. In most hospitals, admitting and discharge privileges are limited to members of the medical staff. The ability to serve on some hospital committees may also be restricted to members of the medical staff, which undercuts the increasing importance of team-based, interdisciplinary care. And most problematic, rights to due process are sometimes extended only to members of the medical staff. ANA urges CMS to add language that would ensure that all practitioners who are accorded clinical privileges and appointed to all categories of medical staff privileges are accorded voting rights and full due process.

ANA endorses the recommended change to Section 482.22(a)(5). In addition, this section should be further strengthened by:

- Adding assurances that hospital policies and procedures are uniform, transparent, objective and timely and that decisions are made in a 60-day time period. Any rejection of an application should include a written explanation and include the option for an appeal and fair hearing.
- Require that if privileging occurs through a process that does not involve the medical staff, such as through a human resources department, the health care professional has the right to serve on hospital committees, to cast a vote on policies that affect their privileges and to a fair and impartial hearing if privileges are denied.

The modifications CMS proposed do not address some of the barriers faced by APRNs seeking hospital privileges. ANA urges CMS to consider adding language that would ensure that the process is transparent, objective and timely. For example, APRNs often face considerable delay in action on a completed application for hospital privileges. CMS should require that such applications be acted upon expeditiously; decisions should be made and the candidate should be notified within 60 days of application. We also urge CMS to require that any denial be accompanied by a written explanation containing reasons for the action, as well as an option for an appeal and fair hearing.

While it is reasonable and appropriate for all providers to follow the medical staff rules, it is important that providers have certain rights as well as responsibilities. Currently, providers privileged through a process that does not include the medical staff, such as by a human resources department, are often denied the right to serve on hospital committees or cast a vote on policies that affect their privileges, and can face a challenge to their hospital privileges without a fair and impartial hearing.

In proposing federal options for maximizing the value of advanced practice nurses, scope of practice expert Barbara J. Safriet, JD, LLM has noted that one of the current impediments to removal of practice restrictions is "organized medicine's continued opposition to expanding the authority of other providers to practice," [15] and she calls upon the federal government to articulate national priorities and use the regulatory process to facilitate the full scope of practice of APRNs. More extensive reform of hospital practice privileges is an opportunity for the federal government to significantly increase access to care.

[15] Safriet, B. J. 2010. "Federal options for maximizing the value of advanced practice nurses in providing quality, cost-effective health care." Commissioned by the Committee on the Robert Woods Johnson Foundation Initiative on the Future of Nursing, at the Institute of Medicine (*Future of Nursing* Appendix H on CD-ROM). Barbara Safriet was formerly associate dean of Yale Law School.

ANA proposes the following modifications to section 482.22(b)(3), to allow hospitals the flexibility to follow a truly interdisciplinary model of care in their medical staff composition. As the conditions of participation are likely to be in effect for several years, it is crucial that CMS take into account the need for hospitals to adapt to the evolving nature of patient care, particularly in light of the growing prevalence and importance of non-physician practitioners, and the looming shortage of physicians in several specialty and geographical areas. Consequently, we urge CMS to consider eliminating the list of the specific types of providers who are permitted responsibility for the medical staff, and instead allow such roles to be available to those who are most qualified and appropriate. We offer the following language as a new section 482.22(b)(3):

> Proposed § 482.22(b)(3) The responsibility for organization and conduct of the medical staff should be assigned to a member of the medical staff with appropriate skills to perform the necessary oversight activities.

Barring acceptance of this approach, ANA recommends adding a new subsection (b)(3)(iv), to make explicit that APRNs may serve in this capacity:

> Proposed § 482.22(b)(3)(iv) An advanced practice registered nurse, when permitted by State law of the State in which the hospital is located.

Currently, the hospital may assign responsibility for organization and conduct of the medical staff to a doctor of medicine or osteopathy and, when permitted by State law, a doctor of dental surgery or dental medicine. CMS proposes to add doctors of podiatric medicine to this list. If CMS decides to retain the list approach (as opposed to permitting any qualified member to lead), ANA urges CMS to add APRNs to the list as well. APRNs receive educational preparation in organizational leadership and ethics in their undergraduate nursing and graduate APRN programs. The *Essentials of Baccalaureate Education for Professional Nursing Practice* include basic organizational and systems leadership for quality care and patient safety. Both *The Essentials of Master's Education in Nursing* and *The Essentials of Doctoral Education for Advanced Nursing Practice*, used by educational programs that prepare APRNs, include organizational and systems leadership. Moreover, both currently and in the past, nurses have taken key leadership roles within health care systems and organizations, from Clara Barton's creation of the American Red Cross, to Mary Wakefield heading the Health Resources and Services Administration. Several nurses have served as CEOs of hospitals or hospital systems, and many nurses are also at the helm of quality improvement programs.

ANA also endorses the position of the Association of periOperative Registered Nurses (AORN), supporting the ability of registered nurse first assistants (RNFAs) to be privileged to perform as first assistant for surgical procedures in Medicare-participating hospitals.

ANA supports CMS's decision to not amend the existing rule regarding the history and physical examination of patients at the time of admission or registration. CMS seeks comment on the fact that it has chosen **not** to amend section 482.24(c)(2), which requires a history and physical (H & P) to be completed and documented for each patient no more than 30 days before, or 24 hours, after admission. A hospital may adopt a policy allowing submission of an H & P done prior to admission by a practitioner who is not a member of the medical staff (i.e. an NP or other health care professional). A growing number of hospitals depend upon APRNs to perform these, and grant clinical privileges that include the performance of an H & P.

When an H & P is completed prior to admission, the regulation also requires documentation in the medical record of an examination for any changes that might be significant for the planned course of

treatment. CMS is concerned that in some instances, a second, complete H & P is being conducted, when a more limited examination would be sufficient. CMS has not specified the extent of the examination that must be conducted, state that the practitioner may indicate that the H & P was reviewed, the patient examined and that "no change" has occurred. ANA believes the current requirement is adequate and no change is necessary. It is appropriate to defer to the clinical judgment of the hospital staff to determine the extent of the necessary examination.

Proposed Section 482.23: Condition of participation: Nursing services

ANA commends CMS for recognizing the contributions of nursing services within hospitals in its revisions to the CoPs. We offer the following points and suggestions regarding these issues of crucial importance to the nursing profession, which directly impact the quality of care which patients receive.

Proposed Section 482.23(b): Staffing and delivery of care

ANA strongly urges CMS to consider adding additional provisions to section 482.23(b) to support and ensure safe and adequate nurse staffing in Medicare and Medicaid hospitals. There is resounding evidence that nurse staffing impacts patient outcomes, and that optimal nurse staffing results in better patient outcomes and improved quality.[16] Nevertheless, the lack of appropriate nurse staffing remains one of the more common problems in health care. The negative effects upon quality of patient care are wide-ranging. The results can be catastrophic. Gaps and errors in care take a real toll upon patients' health, incurring unnecessary additional costs. This is particularly true in hospitals where economic restrictions are creating pressure to cut nurse staffing in order to balance budgets.

CMS has a decisive opportunity to help ensure that nurse staffing is appropriate, so that Medicare and Medicaid beneficiaries have access to quality health care and ultimately improved health.
CMS has attempted to reflect the importance of nurse staffing in the proposed CoP changes. The proposed language, however, is not sufficient to ensure that accrediting bodies (e.g., The Joint Commission) set standards to fulfill the intent of the CoPs, which is to improve the level of care that patients receive while allocating resources efficiently. ANA suggests that CMS develop a system to ensure compliance with all the registered nurse staffing standards that are in the CoPs. It may be appropriate for CMS to consult, and work in concert with, accrediting bodies that have deemed status under CMS, to develop such a system. Ultimately, these bodies should also be required to ensure compliance with such standards.

To that end, ANA recommends that CMS add requirements to help assure that hospitals provide adequate numbers of registered nurses and other staff to provide the best quality care to patients. ANA offers the following recommendations for CMS's consideration, for inclusion in the CoPs. ANA is prepared to work with CMS to further develop and implement these crucial elements to ensure a high standard of nursing care for all Medicare and Medicaid hospital patients:

- A requirement that all hospitals implement a hospital-wide staffing plan that will establish an appropriate number of registered nurses on each unit to meet the needs of the patients and expectations of those units. The plan should take into account factors present on each unit during each shift, such as:

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[16] *Nurse Staffing and Quality of Patient Care*, Structured Abstract. March 2007. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/tp/nursesttp.htm.

  - Number of patients, and level and variability of intensity of care, with consideration to admissions, discharges, and transfers during each shift;
  - Level of education, training, and experience of those registered nurses providing direct patient care;
  - Availability of personnel and services associated with nursing care or augmenting care;
  - Non-patient care-related duties that nurses oversee (e.g. nursing students, orientation of new employees);
  - Competency of nursing staff assigned to particular units to handle patient care needs of those units;
  - Contextual issues, including architecture and geography of the environment;
  - Available technology; and
  - Establishing adjustable minimum numbers of registered nurses based on an assessment of the level and variability of intensity of care required by patients under existing conditions.
- A requirement that hospitals conduct, no less than annually, an evaluation of the staffing plans based upon an assessment of patient outcome data that are nursing sensitive.
- A requirement that hospital staffing plans are made publicly available.[17]

ANA recognizes that rural hospitals, particularly those that are recognized with a 24-hour nursing waiver under section 405.1910(c) of this chapter, might have difficulty meeting these requirements in a timely manner. ANA believes CMS has the capacity to ensure these hospitals do not experience undue burden from these requirements. At the same time, ANA firmly believes appropriate staffing should be a priority for any patient care setting, regardless of the size of a facility, or its resource capacity.

ANA also strongly endorses the position of the Association of periOperative Registered Nurses that CMS should include language in the final rule and regulation to ensure there is a perioperative registered nurse in each operating room, acting as a circulator throughout the duration of each surgical procedure

Proposed Section 482.23(b)(4): Nursing care plan

ANA supports CMS's proposed language requiring a hospital to "ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient." Planning for patient care is one of the core Standards of Professional Nursing Practice for all registered nurses:

> **Standard 4. Planning**
> The registered nurse develops a plan that prescribes strategies and alternatives to attain expected outcomes.
> COMPETENCIES
> The registered nurse:
> - Develops an individualized plan in partnership with the person, family, and others considering the person's characteristics or situation, including, but not limited to, values, beliefs, spiritual and health practices, preferences, choices, developmental level, coping style, culture and environment, and available technology.
> - Establishes the plan priorities with the healthcare consumer, family, and others as appropriate.

[17] American Nurses Association. *Safe Staffing Saves Lives - ANA's National Campaign to Solve the Nurse Staffing Crisis*. http://www.safestaffingsaveslives.org.

- Includes strategies in the plan that address each of the identified diagnoses or issues. These may include, but are not limited to, strategies for:
  - Promotion and restoration of health;
  - Prevention of illness, injury, and disease;
  - The alleviation of suffering, and
  - Supportive care for those who are dying.
- Includes strategies for health and wholeness across the lifespan.
- Provides for continuity in the plan.
- Incorporates an implementation pathway or timeline in the plan.
- Considers the economic impact of the plan on the healthcare consumer, family, caregivers, or other affected parties.
- Integrates current scientific evidence, trends and research.
- Utilizes the plan to provide direction to other members of the healthcare team.[18]

Nursing care plans provide the framework for how RNs care for their patients, and embody several of the core elements of the nursing process – Assessment, Diagnosis, Outcomes Identification, Planning, Implementation and Evaluation. Nursing care plans provide tailored models of nursing care and inform the nursing process for the nurses who spend the most time and provide the most direct care to hospital patients. ANA considers the development, continuation, and valuation of nursing care plans to be a very crucial requirement for all hospitals, and commends CMS for continuing to recognize their value.

CMS has also proposed that "The nursing care plan may be part of an interdisciplinary care plan." ANA fully supports interdisciplinary care and interprofessional collaboration among different types of health care professionals. The team approach to patient care, with care providers of varying backgrounds, education, skills and areas of specialty working together, enhances quality of care.[19] Allowing hospitals to incorporate each patient's nursing care plan into the interdisciplinary plan of care seems an appropriate way to allow other health care providers access to a helpful tool – as long as it is recognized that nurses alone are responsible for development of the nursing care plan.

Incorporation of the nursing care plan as part of the interdisciplinary care plan aligns with recommendations of two expert panels. In 2003, the Institute of Medicine issued a report, *Health Professions Education: A Bridge to Quality.* The report included the recommendation that health professions students and working professionals develop and maintain proficiency in five core areas including working as part of interdisciplinary teams. In 2011, the Interprofessional Collaborative Expert Panel, *Core competencies for Interprofessional Collaborative Practice: Report of an Expert Panel*. The core competencies recommended in the report were developed to promote interprofessional collaborative practice as key to safe, high quality, accessible patient-centered care.[20]

Proposed Section 482.23(c): Preparation and administration of drugs

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[18] American Nurses Association. 2010. Nursing: Scope and Standards of Practice, 2nd edition, 36. Silver Spring, MD: American Nurses Association.

[19] Josiah Macy, Jr. Foundation, ABIM Foundation, Robert Wood Johnson Foundation. (2011). Team-Based Competencies: Building a Shared Foundation for Education and Clinical Practice. Washington, DC. Macy Foundation. http://www.josiahmacyfoundation.org/publications.

[20] Board on Health Care Education. 2003. Health professions education: A bridge to quality. Washington, D.C.: The National Academies Press. Interprofessional Education Collaborative Expert Panel. (2011). *Core competencies for interprofessional collaborative practice: Report of an expert panel.* Washington, D.C.: Interprofessional Education Collaborative.

ANA commends CMS for the changes in proposed section 482.23(c)(1)(i), which specifically allow that drugs and biological to be ordered by practitioners other than those "responsible for the patient's care . . . if such practitioners are acting in accordance with State law, including scope of practice laws, and . . . if the hospital has granted them privileges to do so."

This proposed revision would add needed flexibility regarding which practitioners can write orders for a particular patient, increasing efficiency and access to care. It would allow APRNs and other qualified providers who care for the patient to write medication orders, rather than limiting that ability only to the admitting physician or other healthcare provider. The proposed language recognizes and accommodates the complex web of multiple and varying types of providers who are currently involved in delivering and ensuring the quality of care for hospital patients in today's health care delivery system.

ANA also commends CMS for recognizing the value of standing orders and protocols. Standing orders are an evidence-based and valuable tool to increase efficiency in patient care, which allow hospitals to capitalize on the competency of professional nurses. ANA concurs with CMS's conclusion that the literature provides a rationale for these changes, particularly for streamlined patient care in the emergency department and improving immunization rates.

However, with respect to proposed section 482.23(c)(3), ANA questions why CMS retained the language "With the exception of influenza and pneumococcal vaccines . . ." ANA is concerned that while CMS' intent is to expand the types of immunizations that can be administered under standing orders, this phrase will impede hospitals from doing so. **ANA suggests that this language be revised to read, "With the exception of immunizations recommended by the Advisory Committee on Immunization Practices,"** which would suggest that any recommended vaccine can be administered using standing orders. This would greatly improve hospitals' ability to improve access to vaccines, and overall vaccination rates for many populations.

ANA also recommends the following revision be made in both section 482.24(c)(3)(i) and (iii): deletion of the phrase "in consultation with the hospital's..." following the word "staff" and preceding the word "nursing." The revised CoP would read "Establishes that such orders and protocols have been reviewed and approved by the medical staff, nursing, and pharmacy leadership." Nursing and pharmacy leadership should be full partners in considering standing orders policies to ensure they are as effective as possible.

Proposed Section 482.23(c)(4): Blood transfusions and intravenous medications

ANA supports reference to, and reliance upon, State law and hospital policies and procedures regarding the administration of blood transfusions and intravenous medications, but with a caveat. Those state laws and regulations, and hospital policies must provide adequate safeguards to prevent errors in administration. Such errors can have severe, even fatal, repercussions. Therefore, we believe that the person administering these should be an RN or APRN, and we support adding language to that effect.

CMS has proposed to eliminate the requirement for special training, and require only that "Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures." The potential for errors in administration is significant. RNs and APRNs are educated and experienced regarding the utmost necessity of ensuring safe administration of IV medications and blood transfusions, potential contraindications, and the dire consequences that can ensue rapidly as a result of errors in administration. Sadly, this is an area where

numerous errors continue to occur, largely due to human error, with tragic consequences of morbidity and mortality. Thus ANA has serious concerns if the types of personnel allowed to administer IV medications and blood transfusions are expanded beyond RNs and APRNs.

Proposed Section 482.23(c)(6): Self-administration of medications

Proposed section 482.23(c)(6) would, for the first time, permit hospitals which have well-defined policies and procedures in this regard to allow patients to self-administer certain medications, those which are hospital-issued, and/or those which the patient brought into the hospital. **ANA generally supports this provision, only if hospitals are kept to very high standards in their required policies, and nurses retain the flexibility to determine which patients are capable of doing this on their own.** Used properly and with the right patients, self-administration can be an extraordinarily helpful tool for teaching self-care as a patient and his or her family begin the transition back home or to less-intensive care settings. It is primarily nurses who are responsible for educating patients and families about medications after discharge, to ensure a sufficient level of understanding to prevent errors, confusion, and potential re-admissions that may result from non-compliance with medical regimens. Many hospital nurses also serve as a point of contact for questions regarding medications after discharge, particularly post-surgery.

Proposed Section 482.24 Condition of participation: Medical record services

ANA applauds CMS's proposal to end the controversial policy requiring that verbal orders be physically signed or otherwise authenticated within 48 hours. The 48-hour policy has proved impractical, with limited demonstrated efficacy and effect. It creates a significant and substantial burden for the ordering practitioner as well as the hospital – and particularly the nursing staff often charged with the responsibility of ensuring that the ordering practitioner complies with this requirement.

We also commend CMS for allowing flexibility in who can sign medication orders, however we believe even more flexibility is needed to reflect the realities of practice. Two subparts of proposed section 482.24(c) are pertinent. Section 482.24(c)(2) and (3)(iv) refer to authentication by "the ordering practitioner or another practitioner responsible for the care of the patient *as specified under section 482.12(c)* and authorized to write orders by hospital policy in accordance with State law" (emphasis added). **ANA recommends that this additional qualification (482.12(c)) for a practitioner responsible for the care of a Medicare patient be eliminated.**

Section 482.12(c) addresses the condition of participation governing body and, in particular, contains a limited list of practitioners providing care to Medicare patients. This list precludes the possibility of considering Medicare patients who are the responsibility of other practitioners. Given the increasing prevalence of the interdisciplinary care team providing care to Medicare patients, CMS would limit itself and create undue barriers to care by retaining this rigid list of practitioners, particularly as it pertains to the proposed sections regarding authentication of orders. The language of 482.24(c)(2) and (3)(iv) should be consistent with that in proposed section 482.23(c)(1), regarding who may write orders for the administration of drugs and biologics. This would permit any qualified practitioner to authenticate all orders, including verbal orders, "in accordance with State law, including scope of practice laws, and only if the hospital has granted them privileges to do so." Should CMS decide against this recommendation, ANA alternately proposes that APRNs be added to the list of practitioners who may authenticate all orders.

The limited list of practitioners in Section 482.12(c) reflects an approach to patient care that is quickly becoming outmoded. It is not consistent with healthcare initiatives, particularly by CMS, to encourage

interdisciplinary team based models of care. ANA proposes that CMS undertake a rigorous review of where else in the Conditions of Participation section 482.12(c) is referenced. These other references might similarly limit patients' access to services and practitioners, as well as create unnecessary barriers to administrative efficiencies. ANA welcomes the opportunity to join CMS in this review. In the interim, CMS should address this problem, at a minimum, by adding APRNs to the list of practitioners who may, in accordance with state law and hospital policy, authenticate all orders.

ANA is also concerned about that the proposed language, "authenticated promptly in the patient's medical record," may be misinterpreted. ANA believes CMS's intent is to ensure that standing orders appear in an individual patient record. However, this language could be interpreted to mean that *each individual patient* must have his or her own standing order for certain drugs or biologicals. Clearly, this would defeat the purpose of a standing order, if an ordering practitioner must create individual standing orders tailored to each patient. We do not believe this is the agency's intent, and urge CMS to add clarifying language to the regulation in the final rule. Otherwise, the administrative burden on RNs would be substantial. Imagine, for instance, requiring an RN to obtain an ordering practitioner's authentication for an order, each and every time an influenza vaccine is to be given. RNs are fully capable of assessing a patient for eligibility for influenza vaccine and, under a hospital-wide standing order, administer and document the vaccine.

Section 482.25: Conditions of participation: Pharmaceutical services

We agree with the intent of section 482.25 (b)(6), which requires immediate reporting of drugs errors, adverse effects and incompatibilities. However, we suggest rewording to recognize that the appropriate person to receive such reporting is the provider responsible for the patient, who may or may not be the attending physician. We suggest CMS consider the following revision (underlined) for the final rule:

> Proposed § 482.25(b)(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician <u>or other provider responsible for the patient</u> and, if appropriate, to the hospital's quality assessment and performance improvement program.

For example, this would facilitate timely reporting to a Certified Nurse Midwife caring for a patient during labor and delivery, or to a nurse practitioner or physician assistant caring for a patient in the emergency room.

Proposed Section 482.42: Condition of participation: Infection control

ANA supports CMS's proposal to allow infection control officers to develop their own system "for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel." The vast majority of infection control officers within hospitals are registered nurses -- who take their roles and responsibilities very seriously, and exhibit a high level of professionalism and vigilance. It is important to recognize their contributions and ability to design systems that make the most sense for their hospitals. Infection control policies and procedures should be tailored to the physical environment, resources, services and patient population unique to each hospital. ANA appreciates CMS permitting flexibility in this important area, which could will significantly reduce the administrative burden for a facility and maintain or enhance quality of patient care.

PART 485—CONDITIONS OF PARTICIPATION SPECIALIZED PROVIDERS

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

ANA applauds CMS's proposed changes to the CoPs for critical access hospitals. The proposed revisions appear to offer CAHs increased flexibility in their operation and employment of key personnel, particularly clinical nurse specialists, with inherent benefits for CAH patients as well.

Proposed Section 485.604: Personnel qualifications

ANA fully supports and endorses the position and comments of its organizational affiliate, the National Association of Clinical Nurse Specialists (NACNS). NACNS, the leading organization representing clinical nurse specialists, recommends the following language in lieu of the proposed language of the notice of proposed rulemaking:

> Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)
> § 485.604 Personnel qualifications.
> * * * * *
> (a) *Clinical nurse specialist.* A clinical nurse specialist (CNS) is a registered nurse with a nursing degree at the master's or doctoral level from an accredited educational institution that is authorized to practice as a CNS based on state nurse licensing laws and regulations.

Proposed Section 485.639: Conditions of participation: Surgical services

ANA supports CMS's modification of section 485.639, clarifying that surgical services are optional for CAHs. ANA has a longstanding history of advocating for government policies which increase and support access to health care resources for all patients, particularly underserved populations or those in remote or rural areas. CAHs are designed to serve that sector of patients who lack a wide array of choices for health care. We believe that granting CAHs the flexibility to provide surgical services – or not – can serve to increase the development of CAHs and the ability of certain hospitals to serve as CAHs, which in turn would increase choices for patients. However, we urge CMS to be vigilant regarding unintended consequences, particularly whether this rule may lead to certain CAHs eliminating surgical services from their current portfolio without given thought to an alternative source for such services.

Regulatory Impact Analysis

ANA applauds CMS for recognizing the importance of effective utilization of the workforce, particularly the nursing workforce. These estimates are indicative of the potentially significant savings to the healthcare system by more effective utilization of the workforce.

Registered nurses account for approximately 40% of staff compensation in hospitals. Increasing the efficiency of the system by allowing registered nurses to perform to the highest level of their capabilities will increase quality, maintain current output, and could free nursing resources for such additional functions as care coordination.

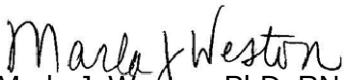
It is true that APRNs are typically paid lower salaries than physicians, and there are significant savings to hospitals that can be achieved by increased substitution of APRNs for physicians. For hospitals paid on a DRG basis, the substitutions described in the NPRM would generate no savings to Medicare Part A. Part B reimbursement, however, works under different rules. With respect to Medicare Part B ANA strongly endorses equity in reimbursement. A particular service, e.g., hospital discharge day management (CPT 99238), provided by a qualified clinician should be reimbursed at the same rate regardless of the clinician specialty; be that a physician, nurse practitioner or any other APRN.

CMS notes that their estimates of the effect of this regulation are subject to significant uncertainty and therefore they "welcome comments on ways to better estimate the likely effect of these reforms." ANA would recommend that CMS distill more refined data from its transactions with hospitals. The IOM Report on the Future of Nursing clearly recommended the collection of better data on registered nurses and the nursing workforce. CMS should be at the forefront of better and more specific data collection to reduce the uncertainty currently associated with its proposed new hospital regulations.

Conclusion

We appreciate the opportunity to provide our views regarding this important proposed rule. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Eileen Carlson, RN, JD, at eileen.carlson@ana.org or 301-628-5093.

Sincerely,



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