August 15, 2016

Honorable Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3295–P
P.O. Box 8010
Baltimore, MD 21244

Submitted electronically to www.regulations.gov

Re: Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

Dear Acting Administrator Slavitt:

On behalf of the American Nurses Association (ANA), we are pleased to comment on the proposed rule, Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care. As the only full-service professional organization representing the interests of the nation's 3.6 million registered nurses (RNs), ANA is privileged to speak on behalf of its state and constituent member associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions, and provide advice and emotional support to patients and their family members. ANA members also include the four advanced practice registered nurse (APRN) roles: nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs).[1] The ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, and outcomes and advance access to health care across the health care continuum.

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-one percent of RNs are employed by hospitals, as staff nurses, administrators, case managers, and in other roles.[2] 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

[1]The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

[2] In 2015, 57.8% of RNs worked in general medical and surgical hospitals. Another 3.5% worked in specialty hospitals. U.S. Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes291141.htm.

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.

## PART 482 – CONDITIONS OF PARTICIPATION FOR HOSPITALS

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

The proposed rule contains a number of important provisions pertaining to patient's rights, including clarification of the requirements concerning the use of restraints and seclusion (including a change in terminology, from "licensed independent practitioner" to "licensed practitioner" with regard to the authority to order restraints and seclusion). ANA agrees with the rationale in the supplementary information for the proposed change in terminology from "licensed independent practitioner" to "licensed practitioner" regarding the authority to order restraints and seclusion and supports this proposed change.

ANA strongly supports the addition of language to the patient's rights regulation "… to establish explicit requirements that a hospital not discriminate on the basis of race, color, national origin, sex, (including gender identity), age, or disability, sexual orientation, or religion and that the hospital establish and implement a written policy prohibiting discrimination on the basis of race, color, national origin, sex (including gender identity), age, or disability, sexual orientation or religion…" in a concerted effort to minimize health disparities. Discrimination has increasingly been recognized as a frequent cause of health disparities and health differences in access to care. The proposed language directly addresses barriers to health and supports ANA's position that health is a universal human right.

### *Proposed Section 482.21: Condition of participation: Quality assessment and performance improvement program*

One proposed change is a new requirement concerning hospital quality assessment and performance improvement programs (QAPI). The proposal would require that hospitals:

> [I]ncorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions."

ANA recommends that the regulatory language be revised to clarify that mandate to report from information already collected from existing programs. With regard to this new proposed requirement, the supplementary information notes that hospitals are already collecting and analyzing data from a number of programs (including the Hospital Inpatient Quality Reporting program, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Condition Reduction Program, the Medicare and Medicaid Electronic Health Record Incentive Programs, and the Hospital Outpatient Quality Reporting program). The supplementary information suggests that it would be efficient and cost-effective to include some of these data in QAPI programs. The supplementary information also

notes that the proposed rule would encourage but not require hospitals to implement information technology systems as part of their QAPI program.

***Proposed Section 482.23: Condition of participation: Nursing services***

CMS proposes to change section 482.23(b), Standard: Staffing and delivery of care. The current rule states:

> (b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

ANA agrees with CMS' rationale to avoid confusion regarding the applicability of this standard by removing the word "bedside" from this standard. ANA fully supports the proposed change in the language of section 482.23(b).

In addition, 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 strong evidence that nurse staffing impacts patient outcomes, and that optimal nurse staffing results in better patient outcomes and improved quality. As noted in the Avalere Report entitled *Optimal Nurse Staffing to Improve Quality of Care and Patient Outcomes*:

> Optimal staffing is essential to providing professional nursing value. Existing nurse staffing systems are often antiquated and inflexible. Greater benefit can be derived from staffing models that consider the number of nurses and/or the nurse-to-patient ratios and can be adjusted to account for unit and shift level factors. Factors that influence nurse staffing needs include: patient complexity, acuity, or stability; number of admissions, discharges, and transfers; professional nursing and other staff skill level and expertise; physical space and layout of the nursing unit; and availability of or proximity to technological support or other resources.[3]

Despite the evidence, 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, and gaps in care seriously impact patient's health and also increase health care costs. Key findings from the Avalere Report address these challenges:

> Published studies show that appropriate nurse staffing helps achieve clinical and economic improvements in patient care, including:
> – Improvements in patient satisfaction and health-related quality of life
> – Reduction/decrease in:
> • Medical and medication errors
> • Patient mortality, hospital readmissions, and length of stay

[3] Avalere. Optimal Nurse Staffing to Improve Quality of Care and Patient Outcomes. Silver Spring, Maryland: American Nurses Association; 2015, p. 4.

> • Number of preventable events such as patient falls, pressure ulcers, central line infections, healthcare-associated infections (HAIs), and other complications related to hospitalizations
> • Patient care costs through avoidance of unplanned readmissions
> • Nurse fatigue, thus promoting nursing safety, nurse retention, and job satisfaction, which all contribute to safer patient care.[4]

As noted in the Avalere Report, economic restrictions are creating additional pressure to cut nurse staffing in order to balance budgets:

> As nurses comprise the largest clinical subgroup in hospitals, a common reaction to cost containment pressures is to reduce professional nurse labor hours and their associated costs and reduce skill mix. This strategy, however, is shortsighted as appropriate nurse staffing levels are essential to optimizing quality of care and patient outcomes in this era of value-based healthcare.[5]

In light of this compelling evidence on the importance of nursing staffing, ANA urges CMS to add requirements to this section to ensure that hospitals provide adequate numbers of registered nurses and other staff to provide the best quality care to patients. To this end, ANA urges CMS to evaluate ANA's considerations for building an evidence-based staffing framework, set forth in Appendix B of the Avalere Report and detailed in ANA's *Principles for Nurse Staffing.*[6] ANA is available to work with CMS to develop and implement crucial staffing elements to ensure a high standard of nursing care for all Medicare and Medicaid hospital patients.

While not the subject of revision in the proposed rule, ANA notes that the reference to a licensed practical nurse in subsection 482.23(b)(1) appears inconsistent with the waiver provision set forth in section 488.54(c). We understand that unless a waiver is in place (pursuant to section 488.54(c)), a registered nurse must either furnish nursing services or supervise the provision of nursing services, and urge CMS to clarify this point.

A proposed change to the nursing care plan would revise the current section 482.23(b)(4) to add language stating that the current plan *that reflects the patient's goals and the nursing care to be provided to meet the patient's needs.* ANA supports this proposed revision. With regard to section 482.23(b)(6), ANA supports proposed changes to clarify that all licensed nurses providing services in the hospital must adhere to hospital policies and procedures. The proposed rule also states that the director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, or other agreement, or volunteer). We recommend revising this requirement to state:

> The director of nursing service or designee must provide for adequate supervision, evaluation and assessment of the clinical activities of all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).

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[4] *Ibid., p. 5.*
[5] *Ibid., p. 4.*
[6] American Nurses Association. Principles for Nurse Staffing. 2nd Edition; 2012.

Another proposed change to section 482.23 would require hospitals to have "policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present." Such policies and procedures must establish the criteria for such outpatient departments; establish alternative staffing plans; be approved by the medical staff; and be reviewed at least every three years. ANA recommends revising section 482.23(b)(7)(iii) to explicitly require approval by the director of nursing services. While the delivery of patient care takes place in an interdisciplinary setting, it is essential that nurses and nursing leadership fully participate in the development of all policies and procedures impacting nurse staffing. Further, we believe it's essential that RNs are not eliminated or displaced from hospital-sponsored (provider-based) ambulatory clinics.

The new section 482.23(c)(3)(i) addresses the use of verbal orders. The Joint Commission has recently developed guidance on texting orders.[7] ANA recommends that CMS consider addressing the issue of texting orders in this subsection. According to the Joint Commission's: Update: Texting Orders, "The Joint Commission requirements addressing verbal orders (Provision of Care, Treatment, and Services [PC] Standard PC.02.01.03 and Record of Care, Treatment, and Services [RC] Standard RC.02.03.07) outline several issues that may be adapted into the policies and procedures for text orders."

Of specific concern in this update is, "Additionally, organizations need to consider how text orders will be documented in the patients' medical record (that is, does the secure text messaging platform integrates directly with the electronic health record? Or will the texted order be entered manually?)" (Joint Commission Perspectives®, May 2016, Vol 36, Issue 5). A secure text messaging platform that does not integrate directly with the electronic health record (EHR) may introduce potential patient safety risks by circumventing the clinical decision support (CDS) embedded in the EHR. Computerized Physician Order Entry (CPOE) provides real-time information upon order entry to alert the provider of potential medication allergies, drug interactions, lab values, etc. The process of having to manually enter texted orders that do not integrate directly with the EHR raises the concern that nurses will be put in the position of transcribing on behalf of the prescriber who has by-passed the Computerized Physician Order Entry (CPOE) process by texting the order.

ANA is aware that additional guidance from The Joint Commission in collaboration with The Centers for Medicare & Medicaid Services (CMS) is anticipated to be released in September 2016 as reported in Joint Commission Online, June 8, 2016.

While not the subject of revision in the proposed rule, ANA notes that section 482.23(c)(4) of the rule currently requires that blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures. We urge CMS to revise this section to require that such administration be in accordance with nursing and medical staff policies and procedures.

***Proposed Section 482.42: Condition of participation: Infection prevention and control and antibiotic stewardship programs and Proposed Section 485.640: Condition of participation: Infection prevention and control and antibiotic stewardship programs***

[7] See https://www.jointcommission.org/assets/1/6/Update_Texting_Orders.pdf.

ANA is particularly pleased to see the emphasis on infection prevention as well as infection control. ANA also lauds efforts to better articulate steps needed for robust antibiotic stewardship programs (ASPs) as integral parts of overall infection and control programs, and supports federal efforts not to be too didactic, acknowledging that that vested stakeholders ( CDC, NQF, TJC, SHEA, IDSA) have already outlined exceptional roadmaps by which an individual institution may establish an individualized program. All stakeholders agree, as outlined by the CDC, that ASPs must be an interdisciplinary process that has the buy-in and support of key leadership within the organization, including but not limited to chief medical and nursing officers, QAPI leaders, chief operations and financial officers, systems and informatics analysts, environmental and community leaders, and stakeholders, as well as key institutional and community educators. The focus of any ASP should be on the informed patient/family through the continuum of care.

Strong leadership for the ASPs is essential. While physicians and pharmacists have the expertise in antibiotic management, choosing the right medication is only a part of antibiotic stewardship programs. Leadership of an ASP may ultimately rest on who has the clearest vision of the institutional strengths and knowledge gaps regarding launching an effective, evidenced based program. That leadership may reside in the Systems or Environmental sections, the QAPI team, or the infection preventionists. Each institution should have the latitude to determine how to develop their program.

***Additional ANA comments regarding Part 482***

ANA takes this opportunity to reiterate a prior concern regarding Part 482. Specifically, ANA recommends that CMS revise section 482.22(a) to require hospitals to include practitioners other than physicians on their medical staffs. While CMS took some preliminary steps, in the preamble to the final rule published in 2012,[8] to consider this issue by encouraging hospitals and medical staff to "take advantage of the expertise and skills of . . . non-physician practitioners when making recommendations and appointments to the medical staff," we continue to urge CMS to make this a mandatory requirement. 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. Such a change is also consistent with the landmark Institute of Medicine [now Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine] report, The Future of Nursing: Leading Change, Advancing Health. The report 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.[9]

ANA also recommends adding language to this section to ensure that all practitioners are granted clinical privileges and accorded all categories of medical staff privileges, including voting rights and full due process. While this section of Part 482 is not included in the current proposal, these issues have significant implications for nurses and the nursing profession. ANA urges CMS to reevaluate this issue and consider updating section 482.22(a) during the current rulemaking on Part 482.

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[8] 77 Federal Register 29034, 29047 (May 16, 2012).
[9] Institute of Medicine (IOM). 2011. The Future of Nursing: Leading Change, Advancing (Recommendation 1). Washington, DC: The National Academies Press.

## PART 485 – CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

### *Proposed Section 485.631: Condition of participation: Staffing and staff responsibilities*

The proposed revision to section 485.631(d) addresses the periodic review of clinical privileges and performance. Subsection 485.631(d)(1) states; "*The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH*."

It is essential that the evaluation of the quality and appropriateness of the care provided by all practitioners (including peer review, professional practice evaluations and focused professional practice evaluations) include input from a reviewer (either a staff member or contract provider) with qualifications comparable to the provider under review (such as a practitioner of the same profession or discipline with similar education, training and qualifications who can address the practitioner's skills and clinical judgment). The health care delivery system is undergoing dynamic changes, with growing recognition of the need to utilize all providers to the full extent of their education and training. Ensuring that mechanisms are in place to appropriately evaluate and measure the quality of care that patients receive from their providers is a key element to designing safe and effective health care systems. It is equally important to ensure that the best mechanisms to undertake such evaluations are reflected in CMS' regulations. We welcome the opportunity to meet with CMS to discuss our concerns regarding how best to evaluate the quality and appropriateness of diagnosis and treatment furnished by APRNs and other non-physician providers, and we encourage CMS to include other interested stakeholders, including APRN and physician assistant organizations, in this discussion.

### *Proposed Section 485.641: Condition of participation: Quality assessment and performance improvement program*

The proposed rule contains a number of broad revisions to section 485.641, including the design and scope of the QAPI program as well as changes in governance and leadership. Significant changes include a requirement to use objective measures in evaluating organizational processes, functions and services address outcome indicators related to transitions of care (including readmissions), improved health outcomes, and the reduction of adverse events, errors and conditions acquired while at the CAH.

ANA has a number of concerns with the QAPI proposals as currently drafted, including the time required to implement the changes. Given the broad scope of the proposed changes, CAHs would require significant time to implement the new initiatives. Facilities would require significant technical assistance to successfully develop and implement such programs, including assistance from quality improvement organizations to provide education and training on the appropriate collection of such data. In addition, the low volume of services provided in some CAHs (such as the low volume of surgeries) may make it difficult to collect adequate data for measurement purposes. One option to address this challenge would be to focus on process measures for procedures already in place. Finally, regardless of which form the final rule takes, if the final rule imposes new requirements on these hospitals, it will be essential to ensure that the individuals conducting surveys or certification of CAHs receive additional training to understand the limits facing these hospitals as well as the significant differences among and between these hospitals with regard to activity levels.

We appreciate the opportunity to share our views on this matter. If you have questions, please contact Mary Beth Bresch White, Director, Health Policy (marybreschwhite@ana.org).

Sincerely,

Debbie D. Hatmaker, PhD, RN, FAAN
Executive Director

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President
Marla Weston, PhD, RN, FAAN, ANA Chief Executive Officer