June 25, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims [CMS-1694-P | RIN 0938-AT27]

Dear Administrator Verma:

The American Nurses Association (ANA) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Fiscal Year 2019 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System proposed rule. Through this comment letter, we express our general support for CMS' Meaningful Measures Initiative, but urge CMS to use caution and deliberation when using its removal factors (especially the proposed eighth removal factor included in this proposed rule) to make changes to any of its public reporting programs, particularly in the case of the proposed removal of the safe surgery checklist measure from the Hospital Inpatient Quality Reporting (IQR) Program. ANA is also extremely disappointed that CMS chose not to include ANA's two nurse staffing measures for public reporting in the Hospital Inpatient Quality Reporting (IQR) Program and urge CMS to reconsider this decision. Finally, ANA conditionally supports the inclusion of the Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM) for voluntary reporting through the Hospital IQR Program.

ANA is the premier organization representing the interests of the nation's 4.0 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and

wellness of nurses, and advocating on health care issues that affect nurses and the public. 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 including essential self-care, and provide advice and emotional support to patients and their family members. ANA members also include the four advanced practice registered nurse roles (APRNs): nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs) and certified registered nurse anesthetists (CRNAs).[1] ANA is dedicated to partnering with health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

I) Support for the Meaningful Measures Initiative with caution on a proposed eighth measure removal factor and removal of the safe surgery checklist measure
(Section I.A.2 - Improving Patient Outcomes and Reducing Burden Through Meaningful Measures; and Section VIII.A.4 – Hospital Inpatient Quality Reporting (IQR) Program)

ANA supports CMS' Meaningful Measures Initiative (MMI)'s stated goal in Section I.A.2 of the proposed rule to "identify highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes." As well as the Hospital Inpatient Quality Reporting (IQR) Program's stated goal in Section VIII.A.1.a of the proposed rule to "put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures".

ANA's official position statement on Electronic Health Records states that "ANA strongly supports efforts to further refine the concept and requirements of the patient-centric EHR, including the creation of standards-based electronic health records and supporting infrastructures that promote **efficient and effective** inter-professional and patient communications and decision-making wherever care is provided." This same official position statement also states that nurses and patients must be integral participants in the design, implementation, and evaluation phases of the electronic health record.

[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.

ANA appreciates the fact that CMS has developed a series of seven removal factors for Hospital IQR Program measures (through the FY 2016 IPPS/LTCH PPS final rule) to ensure that the IQR Program is comprised of an optimal suite of measures. These seven removal factors ensure that CMS is thoughtful and thorough when considering the removal of any measure from the program. ANA supports CMS' efforts to harmonize measures between the Hospital IQR Program, the Hospital Value-Based Purchasing (VBP) Program, the Hospital-Acquired Conditions (HAC) Reduction Program, and the Hospital Readmissions Reduction Program through the FY 2019 IPPS/LTCH PPS proposed rule. Such harmonization of measures moves the health system toward greater efficiency and parsimony and reduces burden on providers.

While ANA understands the proposed addition of an eighth removal factor related to costs versus benefits, we urge CMS to be thoughtful and cautious in applying this factor (and indeed all seven other removal factors) when considering whether to remove a measure from the Hospital IQR Program and to consider potential adverse impacts, particularly if the measure in question is not captured in any of the other three IPPS quality programs listed above. The proposed removal of the safe surgery checklist measure for FY 2020 onward is an obvious example of this.

Surgery providers use checklists to reduce morbidity and mortality worldwide. Safe surgery checklists were developed to decrease errors and adverse events, and increase teamwork and communication in surgery. Despite widespread adoption and use of safe surgery checklists, never events that the checklist was designed to prevent still occur in the United States at an alarming frequency. In fact, wrong-site, wrong-procedure, and wrong-patient surgeries still occur nearly 40 times per week. Root cause analyses of these events most often show that effective communication among team members would have prevented the harm.

A recent AHRQ study found that 62% of wrong site surgeries could have been prevented by appropriate use of a pre-procedure verification, site marking, and a surgical time out before the procedure. Yet CMS's proposal to eliminate the checklist reporting measure cites checklist use at 96-97% percent, indicating that the measure is "topped out". ANA agrees with the assertion of our colleagues at the Association of periOperative Registered Nurses (AORN) that while perhaps being used in a cursory and rote manner at 96%, meaningful implementation and use of safe surgery checklists is nowhere near topped out, given the current never event statistics from our nation's operating rooms. ANA urges CMS to ensure that the critically important outcomes that this safe surgery checklist measure achieves – namely, avoiding wrong site surgeries – can be adequately monitored through another IPPS quality program in order to avoid unintended, negative patient outcomes.

II) Advocate for inclusion of two nurses staffing measures for public reporting through the Hospital IQR Program
(Section VIII.A.4 – Hospital Inpatient Quality Reporting (IQR) Program)

ANA is disappointed that CMS did not propose to include ANA's two National Quality Forum (NQF)-endorsed nurse staffing measures – NQF #0204 – Nurse Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract) and NQF #0205 – Nurse Hours per Patient Day – for public reporting in either the Hospital Inpatient Quality Reporting (IQR) Program through the FY 2019 IPPS/LTCH PPS proposed rule. ANA strongly believes that these measures contribute to the Meaningful Measures Initiative's stated objectives, contribute significantly to improved patient outcomes, empower patients and their families and caregivers, increase transparency with respect to care decisions, and, do not present an additional or significant reporting burden for providers.

These two nurse staffing measures achieve several of CMS' stated objectives of the Meaningful Measures Initiative outlined in Section I.A.2 of the proposed rule. ANA's nurse staffing measures undoubtedly address high-impact measure areas that safeguard public health and are patient-centered and meaningful to patients. Nurse staffing plays an important role by ensuring that the nurse is provided adequate time and resources to prepare each patient for discharge. Lower nurse-to –patient ratios hold promise for preventing unnecessary hospital readmissions for all patients through more effective pre-discharge monitoring of patient conditions and improved discharge preparation (Tubbs-Cooley HL, Cimiotti JP, Silber JH, Sloane DM, Aiken LH, 2013):

- Each additional patient added to a nurse's average case load increases odds of 30-day readmission 6-9% due to poor nurse working environment and staffing (McHugh MD, Ma C, 2013 & Mitka M, 2015). Conversely, patients who receive care in "better" nurse work environments have lower odds of readmission (Ma C, McHugh MD, Aiken LH, 2015).
- Hospitals staffed with 8 RN hours per adjusted patient day have 25% lower odds of receiving readmissions penalties when compared to similar hospitals staffed with 5.1 RN hours per adjusted patient day (McHugh MD, Berez J, Small DS., 2013).
- Missed standard nursing care activities during a patient's hospitalization, such as teaching, care-coordination, care planning, and treatments, are associated with increased odds of readmission of 2-8%, after adjusting for patient and hospital characteristics. This suggests that providing nurses with sufficient time and resources to

address various patient needs can help reduce readmission rates (Carthon JMB, Lasater KB, Sloane DM, Kutney-Lee A, 2015).

- Higher RN non-overtime staffing decreased the odds of readmission of medical/surgical patients by 50% and reduces post-discharge emergency department visits. Hospitals could potentially reduce post-discharge utilization costs and readmissions by increasing investment in nursing care hours to better prepare patients to manage their care at home prior to discharge (Weiss ME, Yakusheva O, Bobay KL, 2011).

ANA notes that with respect to reporting burden, over half of all inpatient hospitals in the nation already collect and report these measures voluntarily, pointing not only to their value but also to the lack of burden for providers to do so. Furthermore, 51% of respondents to a 2015 National Database of Nursing Quality Indicators (NDNQI) survey – used as part of the initial NQF endorsement of both measures – indicated that it **took less than one full, eight hour day per quarter** to collect and report data on the measure, followed by 27% indicating that it took less than two full, eight hour days per quarter, and 10% stating that it took three full, eight hour days per quarter. Collecting and reporting data on these important nurse staffing measures is not unduly burdensome, and in January 2018, ANA corrected the NQF Measure Information Forms for each measure through the Annual Update process to accurately reflect the reporting time and effort.

CMS places a premium on measures which provide clear costs over benefits, demonstrated by the fact that it is proposing a cost-benefit measure removal factor for measures in the Hospital IQR Program in this very proposed rule. These measures would provide enormous benefits through better data collection, while exacting minimal additional costs. As detailed above, adequate nurse staffing in hospitals has a significant positive impact on reducing patient readmissions. Such readmissions can be avoidable – and very costly. An NCBI report (McIlvennan C, Eapen Z, Allen L, 2015) notes that the Medicare Payment Advisory Commission (MedPAC) estimated in 2008 that reducing avoidable readmissions by even 10% would save Medicare $1 billion. Given the impact that nurse staffing has on reducing such avoidable readmissions, this is a clear benefit to including these measures for public reporting in the Hospital IQR Program.

CMS itself clearly recognizes that the role of the registered nurse – and subsequently nurse staffing patterns – is critical in patient care and outcomes. As CMS notes in its comments in the FY 2018 IPPS/LTCH PPS final rule, numerous studies have clearly and consistently shown a link between appropriate nurse staffing and care quality and patient outcomes. Increased nurse

staffing is clearly associated with a reduction in hospital-related mortality and adverse patient events, such as respiratory failure, cardiac arrest, and hospital-acquired infections. Studies have also found that increased nurse staffing is associated with reduced patient length of stay, reduced rate of readmissions, and reduced hospital costs. CMS also acknowledges that over 2,000 inpatient hospitals currently report this data.

ANA is currently in the midst of the NQF re-endorsement process for these two nurse-staffing measures. As we did following the publication of the FY 2018 IPPS/LTCH PPS final rule, we look forward to engaging with CMS to ensure that the value of nursing in patient care is transparent and available to patients, their families and caregivers when considering hospital care and emphasize the immense value and minimal burden in reporting these measures.

III) ANA conditional support for initial voluntary adoption of the Hospital Harm – Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM)
(Section VIII.A.9.b – Potential Future Inclusion of the Hospital Harm – Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM))

ANA conditionally supports the initial voluntary adoption of the Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM). As CMS notes in the proposed rule, hospital-harm events due to the administration of opioids are a major concern in hospital care, as they increase lengths of stay, costs, and the risk of readmissions, and lead to significant numbers of in-hospital cardiac arrests.

ANA appreciates the recognition by CMS that this measure's specifications are complicated by the influx of opioid overdose patients who present in emergency departments and have been administered naloxone. An important distinction is made between patients who are administered naloxone within the first 24 hours to be an instance of harm, where administrations of naloxone is likely due to a community overdose event, and those who are administered naloxone after 24 hours, which would indicate a hospital-harm event. Given that the intent of this eCQM is to measure hospital harm opioid-related adverse events, it would make no sense to include in the measure instances in which naloxone was administered due to a community overdose; including such instances would place unwarranted blame on inpatient hospitals.

ANA conditionally supports the initial voluntary adoption of this measure for public reporting in the Hospital IQR Program. It would be inappropriate to designate a measure that is undergoing additional testing and has several outstanding questions, including whether it incentivizes

providers to avoid using naloxone in the event of a hospital harm opioid-related event, for mandatory public reporting or to adopt it into the existing eCQM measure set.

ANA urges CMS to ensure that these questions are answered before making a decision to either make reporting mandatory or for the measure to be included in the existing eCQM measure set. As with any measure, and particularly with the focus on patient-centered outcomes under the Meaningful Measures Initiative, we ask CMS to always consider the maxim of "first do no harm" in patient care when considering the removal or inclusion of any publicly reported quality measure.

ANA welcomes an opportunity to further discuss the Meaningful Measures Initiative, the publicly reported safe surgery checklist Hospital IQR Program measure, ANA's two NQF-endorsed nurse staffing measures, or the proposed inclusion in the Hospital IQR Program of the Hospital Harm – Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM). If you have questions, please contact Cheryl Peterson, MS, RN, Vice President, Nursing Programs at 301-628-5089 or at Cheryl.Peterson@ana.org.

Sincerely,

Debbie Hatmaker, PhD, RN, FAAN
Executive Director / Executive Vice President

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President
Loressa Cole, DNP, MBA, RN, NEA-BC, FACHE, ANA Chief Executive Officer

Organizations signing on to this letter:

American Nurses Association-Illinois
American Nurses Association-Massachusetts
Alabama State Nurses Association
California Nurses Association
Colorado Nurses Association
New Hampshire Nurses Association
North Carolina Nurses Association
Texas Nurses Association
Academy of Medical-Surgical Nurses
American Association of Critical-Care Nurses
American Association of Neuroscience Nurses
American Holistic Nurses Association
Association of periOperative Registered Nurses
Emergency Nurses Association