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June 15, 2015

Honorable Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health & Human Services
Attention: CMS–1632–P
P.O. Box 8013
Baltimore, MD 21244–1850

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

Re: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program [CMS–1632–P; RIN–0938–AS41]

Dear Acting Administrator Slavitt:

The American Nurses Association (ANA) welcomes the opportunity to provide comments to the proposed Medicare rule referenced above.

As the only full-service professional organization representing the interests of the nation's 3.1 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, their families and other caregivers as well as the public about various health conditions, wellness, and prevention, 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, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.

ANA requests inclusion of critical safety measures, nurse staffing and skill mix for public reporting be added to the CMS Inpatient Quality Reporting (IQR) Program for timely national reporting

A critical gap in hospital safety measures persists in the CMS Inpatient Quality Reporting (IQR) program. ANA has noted that critical, robust National Quality Forum (NQF)-endorsed structural safety metrics, nurse staffing and skill mix, were not added to FY 2018 or earlier years in this proposed rule. Nursing is a critical core service necessary to deliver quality care. Critical quality metrics, including safety metrics, to evaluate the quality of nursing care through nursing sensitive robust measures is essential to have a complete evaluation of hospital quality and safety (NQF, 2004). The importance of nurse staffing and skill mix to patient safety has been established with over two decades of research. Lower levels of nurse staffing and skill mix are associated with higher rates of death and multiple hospital acquired conditions (HACs). A seminal study (Needleman et al., 2011) published in the New England Journal of Medicine

established causality. The science supporting these NQF-endorsed safety measures is robust (Needleman, 2015, Kane, 2007). ANA supports the right mix of structure, process, and outcomes measures (Donabedian, 1988) as indicated in the Measure Application Partnership (MAP) Measures Selection Criteria (MAP, 2013).

Robust support was voiced and documented in the meeting transcript across the majority of MAP Hospital Workgroup members in December, 2014, for ANA's robust safety structural measures, the staffing and skill mix measures. The nurse staffing and skill mix measures endorsed by NQF were since acknowledged as a floor of safety by the MAP Hospital Workgroup in December, 2015. This Workgroup overturned a "do not support" consent calendar recommendation with a 71 percent vote for "conditional support" pending NQF endorsement at the hospital level reporting. Multiple members, including the chair and co-chair, personally indicated that nurse staffing and skill mix measures are critically important and that these safety measures should be included in CMS's IQR program. Multiple MAP Hospital Workgroup members from different clinical disciplines as well as consumers identified the critical importance of these measures to patient safety. The MAP Coordinating Committee finalized the "conditional support" vote in 2015.

Furthermore, the nurse staffing and skill mix metrics are important, efficient, understandable safety summary metrics to promote transparency and support decision making by consumers, payers and other stakeholders. Specifically, these metrics can be used by consumers and other stakeholders to make decisions based on these metrics as measures of overall patient safety. Consumers and other stakeholders may be overwhelmed by display of HAC data as well as confused when a hospital does well in one HAC and not in another. The existing safety composite, the Agency for Healthcare Research and Quality (AHRQ) PSI-90 has serious weaknesses outlined in the falls measures section below and is not suitable as an efficient summary safety metric across vulnerable acute care hospital populations. In summary, the staffing and skill mix safety measures can best serve as robust safety summary measures currently available for consumers and other stakeholders to use since they are associated with multiple HACs and death across broad populations.

Consumers, payers, multiple clinical team members and other stakeholders have expressed concern in public comments that these metrics have not been included in a timely way in CMS's public reporting program for acute care, the CMS IQR program. These stakeholders, including multidisciplinary team members, understand the critical national safety issue of wide variance in nurse staffing and skill mix, particularly in medical surgical units. Progress has been made in harm reduction. Safety experts on the AHRQ National Advisory Committee on Research and Quality (NAC) in the March, 2015 meeting touted the HAC and readmission reduction trends from 2010 through 2013. However, multiple members voiced concerns that one out of ten Americans are still harmed (*i.e.*, experience a HAC or death) in hospitals. In response to this concern the Director for the AHRQ Center for Quality Improvement and Patient Safety (CQuIPS), Dr. Brady, mentioned nurse staffing as an important factor for consideration in this meeting. The nurse staffing and skill mix measures have been endorsed by NQF for over a decade and are publicly reported by multiple states. It is critical for CMS to identify a timely path for ANA's measures to be publicly reported in IQR in order to reduce variance and empower consumers, payers and other stakeholders to choose wisely.

Payroll data is electronically available in administrative databases for national reporting using these NQF-endorsed metrics. Thus, data collection is not burdensome and is available to national reporting according to CMS directed standards. The Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) provides requirements, standards and a data dictionary, for hospital reporting of infection measures. Similarly, CMS can require national standards for electronic data submission including adherence to a designated data dictionary. This can expedite efficient national standardized staffing and skill mix data reporting to CMS. Hospitals report data to calculate infection measures to CDC via NHSN without regard to whether the data is collected via electronic health records or via paper charts. The same approach can be utilized by CMS for the nurse staffing and skill mix data.

Furthermore, the NQF-endorsed nurse staffing and skill mix measures are not eMeasures. MAP did not recommend that eMeasures be developed for these structural safety measures in the 2015 MAP deliberations. A requirement by CMS to retrieve these data from the electronic health record (EHR) would seriously delay public reporting and significantly increase the cost and burden of a path to national public reporting. ANA agrees with CMS that collection of data through EHRs as electronic clinical eMeasures (eCQMs) is preferable when feasible. Process and outcome measures should be pulled seamlessly via EHRs as a byproduct of documenting clinical care. However, it is not appropriate to develop the ANA staffing and skill mix as an eMeasure through the EHR. These data are already reported efficiently through administrative databases in hospitals. Rather the path for timely, efficient national reporting of the NQF-endorsed staffing and skill mix measures, in a standardized format and a common data dictionary, is urgently needed. This can be accomplished to advance patient safety in a manner similar to that specified by CDC that hospitals use to report infection safety. This is essential in order to save lives and prevent harm through the reduction of multiple HACs and death.

Nurse staffing and skill mix measures are critical safety measures for public reporting across care settings. CMS has indicated the importance of nursing workforce metrics for patient safety in skilled nursing facilities. CMS's new Payroll-Based Journal (PBJ) Data Collection System will be open for voluntary nurse staffing reporting in 2015 and mandatory reporting beginning July 1, 2016 (CMS, Center for Clinical Standards and Quality/Survey & Certification Group 2015). On the PBJ website it is noted that "CMS has long identified staffing as one of the vital components of a nursing home's ability to provide quality care. Over time, CMS has utilized staffing data for a myriad of purposes in an effort to more accurately and effectively gauge its impact on quality of care in nursing homes. Staffing information is also posted on the CMS Nursing Home Compare website, and it is used in the Nursing Home Five Star Quality Rating System to help consumers understand the level and differences of staffing in nursing homes." (CMS, 2015). ANA applauds CMS's leadership in patient safety by working with stakeholders to improve the quality of nurse staffing data currently posted on CMS's Nursing Home Compare. ANA is committed to working with CMS to have ANA's NQF-endorsed staffing and skill mix measures posted timely via CMS's IQR.

A pathway for consumer-friendly display was discussed in the MAP Hospital Workgroup meeting. ANA staffing and skill mix measures could be displayed via the five star rating system if chosen as part of the subset of IQR measures for inclusion on CMS's Hospital Compare. The five star rating system is recognized as understandable to consumers. Consumers have not

indicated checkbox type structural measures (e.g., participation in a type of data registry) as important for display on Hospital Compare. Consumers have indicated that nurse staffing and skill mix are robust metrics that will provide consumers essential safety data. Once included in IQR, these measures can be considered by consumers for prioritization for display on Hospital Compare. The NQF Safety Practices (NQF, 2010) in place from 2010 through 2014 recommended in the nursing workforce section (safety practice number nine) that public reporting of nurse staffing be done using the NQF-endorsed ANA staffing measure. The MAP built on this core NQF safety work by indicating that staffing and skill mix measures were both robust NQF-endorsed safety metrics for timely inclusion in CMS's IQR program, by conditionally supporting these measures pending NQF endorsement at the hospital level. Both measures are included in the NQF Safety Measures Steering Committee for review at the hospital level and maintenance endorsement on June 17, 2015.

In summary, prolonged delay of national reporting via CMS's IQR of nurse staffing and skill mix will impede patient safety performance improvement and contribute to persistent critical safety gaps in transparent public reporting. Timely inclusion in IQR and employment of the public policy reporting lever is important. Public reporting is one of nine levers identified in the National Quality Strategy (AHRQ, 2015, p.24). CMS has noted the effectiveness of the public reporting policy lever in their quality measure evaluation report (CMS, 2015). Public reporting is an essential lever to reduce the current staffing and skill mix variation, particularly in medical-surgical units to improve patient safety and reduce avoidable harm and cost. ANA stands ready to assist CMS to develop a plan to expedite national standardized public reporting of nurse staffing and skill mix.

ANA requests inclusion of critical safety measures, falls and falls with injury for public reporting in the CMS Inpatient Quality Reporting (IQR) Program for timely national reporting, or, timely CMS support for electronic clinical measures (eCQM) development to occur

It is essential for CMS to include a robust set of falls metrics in IQR. A persistent falls measure gap has been identified by multiple stakeholders. ANA, along with consumers, purchasers, clinical team members and other stakeholders, has identified a gap in a robust set of falls metrics in IQR. Specifically, the falls injury metric is narrow in the AHRQ PSI-90 and seriously under-reports injuries related to falls as described below. Multiple stakeholders have asked CMS to consider ANA's falls metrics.

CMS had signaled in previous rules that eCQMs are preferred for additions to the IQR. ANA was pleased that CMS recognized the importance of these measures and the falls measures gap and supported ANA's NQF-endorsed falls and falls with injuries measures on the MUC list for the 2015 MAP evaluation. The deliberations began with the MAP Hospital Workgroup in 2014. The MAP Hospital Workgroup conditionally supported the ANA falls measures for inclusion in CMS's IQR upon the condition of NQF-endorsement at the hospital-level reporting. This vote was finalized by the MAP's Coordinating Committee in 2015. These falls measures will be reviewed in the NQF Safety Measures SC on June 17, 2015, for hospital level reporting and three year maintenance endorsement.

Given that most hospitals already collect falls and injuries from falls in electronic databases, data reporting via a similar system CDC uses for infection reporting is feasible (e.g., requirements common standards and data dictionary). Thus, timely uptake of ANA's current falls measures is ANA's first preference to close the current measure gap.

If CMS prefers to report falls and falls with injuries as de novo eMeasures, ANA respectfully requests CMS prioritize development of clinically meaningful, clinically enriched eCQMs that capture nursing data. This data is essential for a learning health system. Specifically, national reporting can be expedited through funding support for development of eMeasures informed by the current NQF-endorsed falls measures. Robust falls measures that are clinically enriched with nursing data better evaluate the quality of care and can be employed as a public reporting policy lever via CMS's IQR. ANA is committed to working collaboratively with CMS and the Press Ganey eMeasure development team to develop a de novo set of falls metrics.

There are multiple weaknesses described below with AHRQ PSI-90 safety composite and falls metric included in this narrow safety composite. Additionally, CMS and AHRQ noted there is no harmonization issue between the AHRQ falls metric included in the PSI-90 and the ANA falls measures at the MAP Hospital Workgroup voting meeting in 2014. Given the persistent robust falls measures gap and lack of harmonization issue, it is essential for CMS to consider including the current ANA falls measures in IQR, or, fund timely development of robust falls eCQMs that include clinical data from nursing.

The AHRQ PSI-90 weaknesses include 1) significant undercounting of multiple nursing-sensitive HACs, such as pressure ulcers and falls due to coding errors driven from discharge data collected only from physician documentation, 2) lack of timely data for consumer, purchaser, provider, clinician team, and other stakeholder decision making for performance improvement purposes. For example, the 2013 results from this measure were published in December, 2014 (ARHQ, 2014), and 3) lack of robust clinical data provided by the largest group of health care professionals in acute care and the proximal caregivers, nurses. These weaknesses limit the clinical meaning to clinicians for use in performance improvement and robustness of the quality evaluation in transparent public reporting via CMS's IQR.

Furthermore, the AHRQ PSI-90 measure did not pass the NQF maintenance re-endorsement review in the 2014 NQF Safety Measures Steering Committee review due to reliability and validity issues. The AHRQ PSI-90 measure has since been adjusted with three new metrics for consideration in the NQF Safety Measures Steering Committee. AHRQ has also submitted the composite measure for review as a surgical safety composite evaluating safety limited to the surgical population. The population was narrowed to improve the scientific acceptability of the measure as recommended by the Safety Measures Steering Committee in 2014. These metric changes will be reviewed for the AHRQ PSI-90 endorsement consideration in the June, 2015 NQF Safety Measures Steering Committee. Given the identified problems in the current metric and proposed narrowed surgical population focus, there is a no reliable, valid and timely safety measure of the quality of large proportion of acute care patients in CMS's IQR program. The gaps include prevalent, vulnerable populations that do not undergo surgical procedures. This is important since the MAP Dual Eligible Workgroup has identified the vulnerable populations that

are dual eligible have a higher risk for harm. Thus, the MAP Dual Eligible Workgroup identified safe nurse staffing as important to dual eligible population.

National data using data collected with the ANA's NQF-endorsed falls metric was used as a lever to inform performance improvement and for evaluation in CMS's Partnership for Patients (PfP) initiative. National evaluations have demonstrated reduction in falls related injuries. It is important that national robust falls metrics, falls and falls with injury, be included in IQR so there is alignment with robust safety metrics currently employed in effective performance improvement programs and initiatives. Specifically, clinically meaningful and robust metrics should be transparently available for consumers and other stakeholders to view for decision making. National data collection via the falls eCQMs can be the future pathway for robust, standardized clinical measures with low burden that are essential to inform a Learning Health System. The measures identified by the PfP "2.0" contract proposal posted on Federal Business Opportunities (https://www.fbo.gov) include the ANA's falls measure. It is important for CMS to employ effective public reporting levers through the use of robust safety outcome metrics that are high impact, clinically relevant, and understood by consumers and other stakeholders.

ANA Recommends High Impact Robust Safety Structure Measures for IQR

Although the MAP supported a "building block" check box type measure for evaluating safety culture, this measure is not ready for the IQR program. ANA supports the direction of such a measure, but notes that this measure is not endorsed by NQF and is not robust for inclusion as a safety structural measure in IQR. Rather, ANA respectfully recommends that CMS consider a metric in which hospital level scores are indicated. Moreover, a climate survey measure may be more appropriate as culture is more effectively evaluated via survey metrics by evaluating safety climate. Specifically, culture and microcultures (e.g., safety cultures) is best evaluated as climate (e.g., safety climate) since safety culture is played out as climate within teams at the "sharp end of care." The priority for addition to IQR for safety measures is not the easy check box measures, rather, they are more robust safety measures. Specifically, nurse staffing and skill mix has a robust body of evidence to support expedited inclusion in CMS's IQR program.

We appreciate the opportunity to share our views on this matter and welcome the opportunity to discuss these issues in greater detail. If you have questions, please contact Maureen Dailey, PhD, RN, CWOCN, Senior Policy Fellow, ANA Health Policy, at 301.628.5062 or maureen.dailey@ana.org.

Sincerely,

Debbie Hatmaker

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

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