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June 15, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services (CMS),
Department of Health and Human Services
Attention: CMS–1518–P
P.O. Box 8011, Baltimore, MD 21244–1850

RE: CMS–1518–P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates

Dear Dr. Berwick,

The American Nurses Association (ANA) welcomes the opportunity to offer the following comments on the Inpatient Quality reporting (IQR) provisions of the FY 2012 Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and Long-Term Care Hospitals Prospective Payment System (PPS) proposed rule. The ANA, is the only full-service professional organization representing the interests of the nation's 3.1 million Registered Nurses through its constituent/state member associations (CSNA), organizational affiliates (OA), specialty nursing associations, and individual members.

Structural, process, and outcome measures

The ANA supports the use of structural, process, and outcome quality measures (Donabedian, 1988) for performance improvement, public reporting, pay for quality, and program evaluation in acute care hospitals and long term care hospitals. The measures should include accountability measure types that focus on care provided by clinical disciplines (e.g., nursing sensitive care) and inter-professional teams, within setting as well as across settings (ANA, 2010; NQF, 2011).

Participation in a Nursing Sensitive Data Registry and Nursing Sensitive Care Quality Measures

I. Acute Care Hospitals: **Summary of Proposed IQR Program Provisions of the FY 2012 IPPS**

For FY 2013 payment determinations, hospitals are currently reporting on a total of 57 quality measures included in the IQR Program. CMS is proposing refinements to the IQR Program for Acute Care Hospitals for FYs 2014 and 2015, and listed a Possible Future IQR Payment

measures and topics list. CMS is also proposing future evolving alignment of the IPPS and pay for quality programs such as the Hospital Value-based Purchasing program (HVBP) program.

A. CMS Proposed Updates to the IPPS IQR Program FY 2014, FY 2015, and Future IQR Measures/Topics:

CMS's Proposal for Hospital IQR Program FY 2014: ". . . we are proposing to retire 8 measures from the measure set for the FY 2014 payment determination that was finalized in the FY 2011 IPPS/LTCH PPS final rule, and we are proposing to add 4 measures to the measure set for the FY 2014 payment determination: 2 HAI measures collected through the NHSN, 1 claims-based measure (Medicare Spending Per Beneficiary), and 1 structural measure, for a total of 56 measures for the FY 2014 Hospital IQR payment determination." CMS provided a complete list of the proposed IQR Program measures for FY 2014 payment determinations in the Federal Register pages 25,899-25,901.
CMS's Proposal for the Hospital IQR Program FY 2015: ". . . we are proposing to retain all of the FY 2014 measures (56 measures if all of the measures are finalized), to adopt 3 HAI measures, and 14 chart-abstracted measures for a total of 73 measures for the FY 2015 payment determination." CMS provided a complete list of the proposed IQR Program measures for FY 2015 payment determinations in the Federal Register pages 25,908-25,910.
CMS Listed Possible Hospital IQR Program Future Measures and Topics
CMS' Proposal: "…We also invite public comment on the following quality measures and topics set out below that we are considering for the future. We seek to limit the number of chart-abstracted measures and topics in the near future, in order to facilitate the transition to EHR-based reporting. .." Specifically, CMS is seeking comment on an expanded list of additional measures of the IQR Program (i.e., 68 quality measures under 15 topic areas under consideration). CMS provided a complete list of the measures under consideration in the Federal Register pages 25,912-25, 914.

ANA Comments:

1). Participation in a Nursing Sensitive Data Registry FY 2014, FY 2015, and Future Measures

Participation in a Nursing Sensitive Data Registry is proposed for continued inclusion in 2014, 2015, and Future Measures. ANA supports the ongoing inclusion of this measure in FY 2014, 2015, and in future years (i.e., FY 2016 and beyond).

Participation in a nursing sensitive data registry is an important structural support to improve patient safety, providing acute care hospitals unit-level data for quality measurement and reporting. Moreover, the Institute of Medicine (IOM, 2004) report illuminated the importance of utilizing nursing sensitive quality measures within these data registries, including structural measures, to keep patients safe in hospital care and other settings. The ANA's National Database of Nursing

Quality Indicators® (NDNQI®) is the premier national nursing sensitive registry containing data collected at the nursing unit level, across multiple unit types, in all 50 states and the District of Columbia. As of June 1, 2011, 1,765 NDNQI hospitals were submitting quarterly data from over 15,000 nursing units and more than 300,000 nurses responded to the annual RN survey. The NDNQI includes scientifically validated structural, process, and outcome quality measures that are endorsed by the National Quality Forum (NQF) and the Hospital Quality Alliance (HQA). Hospitals and health systems are using quarterly NDNQI data at the unit level for outcome measures including healthcare acquired conditions (HAC), which include multiple healthcare associated infections (HAI) and serious reportable events (SRE's) (e.g., falls with injury and stage 3 and 4 pressure ulcers) as defined by the NQF. Additionally, key structural nursing-sensitive measures are collected annually in a survey (e.g., turnover). The public should be informed of these standardized safety-related outcomes at the unit level through ongoing inclusion of participation in a Nursing Sensitive Care (NSC) database, a structural measure, in the IQR Program and public reporting on Hospital Compare. Moreover, full integration of this structural NSC data registry participation measure should occur in the HVBP Program (i.e., inclusion as well as development and implementation of a scoring methodology).

2) Addition of the Remainder of the Nursing Sensitive Care measures

The ANA supports the inclusion of all the remaining NSC measures proposed for future measures and topics by CMS in the IQR Program. Moreover, ANA respectfully request all these remaining NSC measures being adopted earlier in the IQR Program Measures for FY 2014, FY 2015 IPPS. The results of these unit-based safety quality measures reflecting the care and support of nurses should be both transparent to the public on Hospital Compare and used as levers in pay for quality programs. Thus, the remainder of the scientifically rigorous NSC measures should be added to both the IQR program and the HVBP. A listing of the remaining NSC measures is provided below followed by supporting evidence for these measures.

(a) Full details for the NSC remaining measures including the NSC title, NQF number and description precisely as endorsed by the NQF:

- **NSC Patient Fall Rate (NQF #0141). -** All documented falls, with or without injury, experienced by patients on an eligible unit in a calendar quarter.
- **NSC Falls with Injury (NQF #0202) -** All documented patient falls with an injury level of minor (2) or greater.

- **NSC Pressure Ulcer Prevalence (NQF #0201) -** The total number of patients that have hospital-acquired (nosocomial) stage II or greater pressure ulcers on the day of the prevalence study.
- **NSC Restraint Prevalence (vest and limb only) (NQF #0203) -** Total number of patients that have vest and/or limb restraint (upper or lower body or both) on the day of the prevalence study.
- **NSC (NQF #0204) - Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract)**:
    - NSC-12.1 - Percentage of productive nursing hours worked by RN staff (employee and contract) with direct patient care responsibilities by type of unit
    - NSC-12.2 - Percentage of productive nursing hours worked by LPN/LVN staff (employee and contract) with direct patient care responsibilities by type of unit
    - NSC-12.3 - Percentage of productive nursing hours worked by UAP staff (employee and contract) with direct patient care responsibilities by type of unit
    - NSC-12.4 - Percentage of productive nursing hours worked by contract staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities by type of unit.
    - NSC-13.1 The number of productive hours worked by RNs with direct patient care responsibilities per patient day.
- **NSC (NQF #0205) - Nursing Care Hours Per Patient Day (RN, LPN, and UAP**):
    - NSC-13.1 The number of productive hours worked by RNs with direct patient care responsibilities per patient day.
    - NSC-13.2 The number of productive hours worked by nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities per patient day.
- **NSC (NQF #0206) - Environment Scale-Nursing Work Index (PES-NWI)** is a survey measure of the nursing practice environment; staff registered nurse mean scores on PES-NWI subscales and composite.
- **NSC (NQF #0207) - Voluntary Turnover**:
    - NSC-15.1 Total number of full-time and part-time RN and APN voluntary uncontrolled separations occurring during the calendar month
    - NSC-15.2 Total number of full-time and part-time LPN, LVN voluntary uncontrolled separations occurring during the calendar month
    - NSC-15.3 Total number of full-time and part-time UAP voluntary uncontrolled separations occurring during the calendar month.

(b) Update Supporting Evidence for the remaining NSC measures:

Patient Falls ~ Patient falls in hospitals have been estimated to add $7,118 (2005 dollars) per event (Dall et. al., 2009). Research has shown that fall rates are related to structural measures, such as total nursing hours per patient day, skill mix, RN years of experience, and frequency of risk assessment (Dunton et. al., 2004; Dunton et. al., 2007; Dunton et. al., 2008; Stalhandske et. al., 2008).

Falls with Injury ~ Falls with injury are considered a serious adverse event. Falls may not only result in patient injury and additional expense, they lead to adverse psychological consequences and increase mobility impairments for elderly patients (Savitz et. al., 2005; Lake et. al., 2010). There were almost 10 300 fatal and 2.6 million medically treated non-fatal fall related injuries in older American (≥ 65 years) the US. The total direct medical costs was $0.2 billion dollars for fatal and $19 billion dollars for non-fatal injuries (Stevens et. al., 2006).

Pressure Ulcer Prevalence ~ Persons with pressure ulcers experience a fifty percent increase in mortality (Redelings et. al., 2005). Overall costs for treatment are $9.1 to $11.6 billion per year (Zulkowski et. al., 2005). In the US, patients 65 and older accounted for 56.5 % of the adult population of patients with a principal diagnosis of pressures ulcers (Russo et. al., 2008).

Skill Mix ~ Among the hospital acquired conditions shown to be related to skill mix were infections, pneumonia, pressure ulcers, and falls. In-hospital mortality rate was also shown to be related to skill mix (Kane et. al., 2007). Research demonstrates consensus that skill mix is a standard and important measure of nurses staffing in hospital units (ANA, 1986; Needleman et. al., 2002, Needleman et. al., 2004; Van den Heede et. al., 2007; Blegan et. al., 2007, Dunton et. al., 2007; Sales et.al., 2008). Researchers reported RN skill mix was associated with fewer cases of sepsis ($P < 0.01$) and failure to rescue ($P < 0.05$) (Blegen et. al., 2011).

Hours per patient day ~ RN hours per patient day were negatively related to mortality, in that the higher the RN hours, the lower the mortality risk (Sales et. al., 2008). There is consensus for nursing care hours per patient day as a standard measure of nurse staffing in hospital units (ANA, 1986; Seago et. al., 2006; Kane et. al., 2007; Van den Heede et. al., 2007; Needleman et.al., 2010). Higher total nursing hours per patient day (RN, LPN, and unlicensed assistants) was found by researchers to be associated with lower rates of congestive heart failure mortality ($P < 0.05$), failure to rescue ($P < 0.10$) (Blegen et.al. 2011). Researchers found adult Intensive Care units with higher nurse staffing had lower incidence of Central Line Associated Blood Stream Infection (CLABSI), ventilator-associated pneumonia (VAP), 30-day mortality, and pressure ulcers ($P \leq 0.05$) (Stone et. al., 2007).

Restraint Prevalence ~ …restraint standards for psychiatric settings were in the media spotlight as a result of the *Hartford Courant's* 1998 Pulitzer-prize winning exposé on seclusion and restraint deaths. These articles initiated a U.S. General Accounting Office investigation and Congressional hearings, which ultimately confirmed the *Courant's* findings— that is, that restrained and secluded consumers were traumatized and harmed and that many died as a result of these often violent procedures (leBel, 2008). Moreover, the quality issues and use of physical restraints remains common in the care of older people with multiple chronic illnesses, a growing Medicare population (Ludwig et. al., 2010).

Practice Environment Scale-Nursing Work Index ~ The Practice Environment Scale-Nursing Work Index (PES-NWI) seems to be one of the most promising instruments because of its appropriateness (content validity), its structure, which has a rather good fit (construct validity), its ability to discriminate Magnet hospitals like other NWI derivates (discriminant validity), and it has also been associated in cross-sectional studies with health outcomes, especially nurses' self-assessed mental health but also with patients' health outcomes objectively assessed (concurrent validity) (Bonneterre et.al., 2008). A positive organizational climate (i.e., work environment attributes) has been related to improved patient safety outcomes (Stone et. al., 2008).

Voluntary Turnover ~ Nurse turnover is a statistically significant contributing factor to the
shortage of nurses and has been linked to decreased productivity, poor care quality, heavier workloads for remaining staff, decreased morale, increased potential for injuries, and further turnover (Cavanagh, 2006). The cost of nurse turnover has been reported ranging from approximately $22,000 to over $64,000 (U.S.) per nurse turnover (Jones and Gates, 2007).

B. CMS Proposed Pressure Ulcer Coding Exclusion Change:

Currently, the Complication or comorbidity (CC) Exclusion List prevents a pressure ulcer stage diagnosis code from being designated as a Major Complication or comorbidity (MCC) when a patient is admitted with full thickness pressure ulcer (i.e., stage 3 and 4) (i.e., present on admission [POA]. CMS has proposed pressure ulcers stage 3 and 4 will be removed from CC exclusion list and should be reported as a MCC when reported as a secondary diagnosis. Thus, CMS is proposing to remove diagnosis codes 707.23 and 707.24 from the CC Exclusion List when a principal diagnosis code of one of codes 707.00 through 707.09 is reported to be POA. Additionally, Diagnosis code 707.23 or diagnosis code 707.24 would be designated as an MCC when reported as a secondary diagnosis code with a principal diagnosis code of one of codes 707.00 through 707.09 (Federal Register page 25, 836).

ANA Comments:

Full thickness pressure ulcers, stage 3 and 4, likely require significant healthcare resources. Thus, ANA agrees with CMS's proposed coding changes to support appropriate resources to care for patients admitted with full thickness pressure ulcers. Additionally, ANA suggests that unstageable pressure ulcers (i.e., at least a stage 3 pressure ulcer), diagnosis code 707.25, should also included as an MCC when POA.

C. CMS's Proposal: Alignment of IPPS IQR and Pay for Quality Programs

CMS noted that alignment of the IPPS IQF measures with the Hospital Value-Based Purchasing (HVBP) is a goal in the proposed IPPS 2012 FY rule. Thus, the proposed refinements to update the IQR Program for FFYs 2014 and 2015 may also remove and/or put in place measures for use in the future HVBP Programs. Where it is deemed appropriate, CMS is proposing to simultaneously specify additional measures for both programs (i.e., the FY 2014 HVBP program and the FY 2014 IQR Program). According to statute, measures must have been specified under the Hospital IQR Program and included on the Hospital Compare Website for at least one year prior to the beginning of the performance period in order to be included in the HVBP.

ANA Comments:

ANA supports alignment of the IPPS IQR and HVBP Programs. The structural measure for a nursing-sensitive data base registry is included in the current and proposed IPPS IQR Programs (i.e., FY 2014, 2015, and future quality measures). ANA support both the inclusion of the current IQR structural measure, participation in a nursing sensitive data registry, and integration of the full set of 12 nursing sensitive quality measures into both the IQR and HVBP Programs.

D. CMS's Proposal: Healthcare Personnel (HCP) Influenza Vaccination

CMS has proposed an infection measure for HCP influenza vaccination for FY2015 IQR Program Payment (IPPS) (Federal Register, pages 25,901-903, 25,910, 25-919).

ANA Comments:

In regards to the selection of (3) HCP Influenza Vaccination (NQF # 0431), ANA supports collecting data on this element, as is currently reportable to the Centers for Disease Control and Prevention (CDC). However, ANA notices that there are stark differences between how CMS defines healthcare personnel in the explanation of this rule, and how healthcare personnel are defined in the CDC measures. ANA requests CMS to clearly articulate as part of its rule the definition of healthcare personnel, so that all providers and workers in a facility that have direct patient contact are included in this

rate. ANA's concern is that without this articulation, facilities may only gather data on the providers that employed there, and not include those contractual or otherwise independent personnel in its rate. This would provide an inaccurate rate, as it would negate some provider, volunteers, or other staff that have close contact with patients. ANA encourages CMS to use the definition it has laid out in its rule, but state more clearly how facilities are expected to apply that definition in their reporting. In addition, ANA recommends CMS provide a stipulation for external factors outside of the facilities' control that may impact vaccination rates, in particular a vaccine shortage.

II. CMS Proposed FY 2012 IPPS Changes for Long Term Care Hospitals (LTCH)

A. FY 2014 and Future LTCH Measure Changes:

1) CMS Proposes Adding Urinary Catheter-Associated Urinary Tract Infections (CAUTI)

CMS proposed adding the NQF# CAUTI 1038 measure to all LTCH care units for FY 2014 and beyond (Federal Register pages 25, 983-985).

ANA Comments:

ANA supports the inclusion of the CAUTI measure to the LTCH IPPS FY Program and in future years. Catheter-Associated Urinary Tract Infections are the most common HAI and are preventable with evidence-based nursing care and unit-based performance improvement strategies (Simon et. al., 2009).

2) CMS Proposes Adding Pressure Ulcers

CMS has proposed adding Pressure Ulcers (NQF # NH–012–10) to FY 2014 and beyond. CMS proposes to add the quality measure that includes the percentage of patients who have one or more stage 2–4 pressure ulcers that are new or worsened from a previous assessment. CMS noted "Consistent in our support of the National Quality Strategy principles, mitigating the occurrence or worsening of pressure ulcers is essential in the improvement of patient safety and, therefore, patient care. We recognize NQF endorsement of this measure is limited to short-stay nursing home patients, but believe that this measure is highly relevant and a high priority quality issue for the care of LTCH patients." (Federal Register, pages 25, 985-986)

3) CMS List of Proposed Future Measures and Topics for LTCH IPPS

CMS lists the remainder of the NSC measures detailed for inclusion above for acute care hospitals (pressure ulcers prevalence, falls, falls with injury, skill mix, staffing (hours per patient day), restraint prevalence, turnover, and the PES –

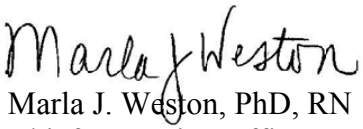
NWI) in the proposed future measures for the LTCH IPPS Quality Reporting Program. (Federal Register, page 25, 987).

ANA Comments:

ANA supports the inclusion of the NSC measures as listed with the measure details as specified above of acute care.

ANA looks forward to continuing activities with CMS related to improving the quality of care provided to all in America. If you have questions, or if the American Nurses Association can be of additional assistance, please contact Maureen Dailey, DNSc, RN, CWOCN, Senior Policy Fellow, by phone (301-628-5062), fax (301-628-) or e-mail **(**maureen.dailey@ANA.org).

Sincerely,



Marla J. Weston, PhD, RN
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Cc: President Karen A. Dailey, PhD, MPH, RN, FAAN

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