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June 25, 2012

Honorable Marilyn B. Tavenner, MHA, RN
Centers for Medicare & Medicaid Services (CMS),
Department of Health and Human Services
Attention: CMS-1588-P
P.O. Box 8011
Baltimore, MD 21244-1850

Submitted electronically via: <http://www.regulations.gov>

Re: CMS-1588-P, Medicare Program; Proposed Changes Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers

Dear Administrator Tavenner,

The American Nurses Association (ANA) welcomes the opportunity to offer the following comments on CMS's proposed rule: Changes Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (LTCHPPS) and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers. 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 important and rigorous structural, process, and outcome quality measures (Donabedian, 1988) that are effective tools in performance improvement, public reporting, pay for quality, and program evaluation in acute care hospitals and long term care hospitals. The measures should include patient-centric, team-based measures for use within settings, and when appropriate across settings as recommended by the Measures Application Partnership to CMS.

Effective Patient-centric, Team-based Measures

I. Acute Care Hospitals: Measures for Payment Determinations for FYs 2014, 2015 and 2016 FY 2015 IPPS IQR and VBP

CMS is proposing refinements to the Inpatient Quality Reporting (IQR) Program for Acute Care Hospitals for FYs 2014, 2015, and 2016. CMS is also proposing further alignment of measures between IPPS and the pay for quality program, the Hospital Value-based Purchasing program (VBP) program.

A. CMS Proposed Updates to the IPPS IQR Program FY 2014, FY 2015, and HVBP programs; and HAC Present on Admission (POA):

CMS's Proposal for IQR Measure Removal in 2015 including CMS's Hospital Acquired Conditions (HACs):

“Seventeen measures are proposed for removal from the hospital IQR program measure set for FY 2015 and subsequent payment determinations” which include “the SCIP–VTE–1 measure, eight HAC measures, three Agency for Healthcare Research and Quality (AHRQ) IQI measures, and five AHRQ PSI measures from the Hospital IQR measures for FY 2015 payment determinations in the Federal Register (pages 28035-28036).

ANA Comments:

- 1) The ANA notes the importance of adding important NQF-endorsed safety measures to the IPPS program in FY 2014 to prepare for the removal of the retrospective hospital acquired conditions (HACs) measures in 2015, in order to close an important safety measure gap.**

The ANA supports removal of the retrospective CMS HAC measures in FY 2015, which were not National Quality Forum (NQF) endorsed measures, and are being removed related to the reliability and validity problems with the measures. The ANA's National Database of Nursing Quality Indicators® (NDNQI®) is the premier national registry for nursing sensitive care, containing team-based data collected at the nursing unit level, across multiple unit types, in all 50 states and the District of Columbia. The NDNQI is a powerful tool employed by 1 of every three hospitals, 1,852 hospitals, and in 18,894 units in the U.S. to provide actionable, unit-level metrics to interprofessional health care teams to reduce HACs. Specifically, the NDNQI reports on NQF-endorsed measures including measures that effectively address HACs reductions via scientifically rigorous measures, such as the NQF-endorsed pressure ulcers and falls measures used in NDNQI. The ANA presented the NDNQI national pressure ulcer and falls reduction results at the April 30, 2012 Partnership for Patients update meeting, which were later presented by CMMI leaders to senior White House staff. Thus, the ANA specifically requests that CMS add the following NQF-endorsed pressure ulcer and falls measures used in NDNQI be added

to the IQR and HVBP in 2014: 1) NQF #0201 (nosocomial prevalence of pressure ulcers), 2) falls measures NQF # 0141 and NQF # 0202 (i.e., falls and falls with injury rates).

B. CMS' clinical advisors analyzed CMS data and did not support changing the severity of the pressure ulcers diagnosis code (707.25) for unstageable pressure ulcers. The CMS interpretation is that an unstageable pressure ulcer is not definitively a stage III or IV ulcer. Thus, CMS is proposing unstageable pressure ulcers should continue to be classified as a non- complication or comorbidity (CC).

"We received a request to consider changing the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from its current classification as a non-CC to an MCC." CMS examined claims data in the FY 2011 MedPAR file and the analyses were more supportive of a complication or comorbidity (CC) than a major complication or comorbidity (MCC). CMS' clinical advisors did not support changing the severity of this diagnosis code because: "It would be inappropriate to assume that a pressure ulcer reported with diagnosis code 707.25 might be a stage III or IV pressure ulcer". Thus, CMS proposed unstageable pressure ulcers should continue to be classified as a non-CC and is not proposing any change, Federal Register Page 27910.

ANA Comments:

The ANA notes the importance of adding or revising hospital acquired conditions (HACs) measures to close an important safety measure gap.

The ANA, including the ANA NDNQI and National Center for Nursing Quality (NCNQ) certified wound, ostomy, and continence nurse experts, believe CMS's interpretation that: "It would be inappropriate to assume that a pressure ulcer reported with diagnosis code 707.25 might be a stage III or IV pressure ulcer" is incorrect given the current evidence-based guidelines. According to the 2009 international guidelines on pressure ulcers, an unstageable pressure ulcer is either a stage III or stage IV pressure ulcer. The full definition per these internationally expert guidelines follows:

"Unstageable pressure ulcer - Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV." (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel, 2009).

Full thickness pressure ulcers, stage 3 and 4, are a significant cause of human suffering, costly, and identified as a serious adverse event (NQF, 2011). ANA agrees with the National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel guidelines that unstageable pressure ulcers are full thickness, which would be either a stage III or IV ulcer. Patients developing these full thickness ulcers need extensive care support and appropriate resources for care. Thus, ANA suggests

that unstageable pressure ulcers (i.e., at least a stage 3 pressure ulcer), diagnosis code 707.25, should also be reclassified as an MCC when POA by CMS.

C. CMS Structural Measures Prevent and Proposed for IPPS IQR and Gap in VBP

CMS finalized participation in a nursing-sensitive data registry in the IQR and made the following comments in the 2012 final VBP regulations.

“We believe these measures require further analysis of how they could be scored, and how they would impact a hospital’s total performance score before they can be adopted for the Hospital VBP program. We intend to consider these issues as the Hospital VBP program evolves. Federal Register / Vol. 76, No. 88 / Friday, May 6, 2011, Page 26501.

ANA Comments:

It’s clear from the national-level results achieved in pressure ulcer and falls reduction that NDNQI, the largest nursing-sensitive data registry, is an effective team-based structural support in acute care at the unit level. Nurses are the proximal caregiver, which provides most of the direct care in hospitals. Thus, participation in a systematic clinical database registry for nursing-sensitive care should continue to be included in both IQR and VBP programs as a quality measure. The ANA also requests that participation in a nursing-sensitive data registry be added to the 2014 VBP and scoring methodology as a lever to reward hospitals that are effectively using team-based, unit data a powerful tool to reduce harm and avoidable harm and keep patients safe.

Additional Important Structural Measures Gaps Persist in CMS’s IQR and VBP Program Key to Patient Safety:

Evidence-based Staffing Measures

The ANA emphasizes the importance of unit-based structural safety quality measures reflecting the care and support of nurses, the largest group of healthcare professionals, should be both transparent to the public on Hospital Compare and used as levers in pay for quality programs. The ANA specifically requests the following additional NQF-endorsed structural measures, which were developed by ANA, are included in NDNQI, and are effectively used nationally by hospitals be added to the FY 2014 IQR and VBP and beyond. Strong supporting evidence provided to NQF for these structural measures is presented in Appendix 1.

- **NQF #0204 - Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract):**
 - Percentage of productive nursing hours worked by RN staff (employee and contract) with direct patient care responsibilities by type of unit
 - Percentage of productive nursing hours worked by LPN/LVN staff (employee and contract) with direct patient care responsibilities by type of unit
 - Percentage of productive nursing hours worked by UAP staff (employee and contract) with direct patient care responsibilities by type of unit

- Percentage of productive nursing hours worked by contract staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities by type of unit.
- The number of productive hours worked by RNs with direct patient care responsibilities per patient day.
- **NQF #0205 - Nursing Care Hours Per Patient Day (RN, LPN, and UAP):**
 - The number of productive hours worked by RNs with direct patient care responsibilities per patient day.
 - The number of productive hours worked by nursing staff (RN, LPN/LVN, and UAP) with direct patient care responsibilities per patient day.

The ANA also supports the following structural measures used effectively in NDNQI and is NQF endorsed:

- **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.

CMS is proposing to adopt a surgical checklist structural measure for the Hospital IQR Program for FY 2016.

CMS proposed a surgical checklist as a structural measure (Haynes, A.B.; Weiser, T.G.; Berry, W.G. et al., 2009), which is not endorsed by NQF, is proposed by CMS to improve patient safety, Federal Register, Page 28049.

ANA Comments:

The ANA agrees that the Secretary should support measures that are crucial to patient safety, as supported by statute, even if the measure is not yet endorsed by a national consensus body. The ANA is fully supportive of the following comments of the Association of periOperative Registered Nurses (AORN), an ANA organizational affiliate:

“AORN is also fully supportive of CMS’s proposal to assess whether acute care hospitals are using a safe surgery checklist to ensure effective communication and patient focused safe practices are being performed prior to the administration of anesthesia, prior to incision, and prior to the patient leaving the operating room. AORN was an early endorser and remains a strong advocate for use of a safe surgery checklist to prevent wrong site, wrong side, wrong patient surgeries and increase optimal surgical outcomes for all patients.”

- D. CMS proposes adding two conditions to the list of hospital acquired conditions (HACs) for 2013: surgical site infection following cardiac implantable electronic device (CIED) and iatrogenic pneumothorax with venous catheterization for the HAC payment provisions for FY 2013.**

Per the Affordable Care Act (ACA), under section 1886(d)(4)(D) inpatient facilities do not receive higher MS-DRG payments for patients with complications or major complications caused by the conditions on the HAC list. “We are proposing to add two additional conditions for FY 2013, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. The projected savings estimate for these two conditions is less than \$1 million, with the total estimated savings from HACs for FY 2013 projected at \$24 million dollars, Federal Register Page 27879, 27881, 27894-27895.

ANA Comments:

- 1) The ANA notes the importance of adding hospital acquired conditions (HACs) measures to close an important safety measure gap.**

The ANA full supports the comments of the AORN:

“AORN believes that if hospitals and other facilities follow standard operating room procedures regarding surgical attire, hand hygiene, sterile technique, sterilization, traffic patterns, environmental cleaning, maintaining a sterile field, preoperative skin antisepsis, and retained surgical items in all areas and settings where CIEDs are inserted, the chance of a SSI is greatly reduced. AORN believes that the addition of SSI following CIED to CMS’s HAC list for FY 2013 will prompt hospitals to follow well-established standards of practice in all areas of the hospital where invasive procedures are performed, and not limit these standard successful practices to only the surgical suite.”

II. CMS is proposing additional quality measures for Cancer Exempt Hospitals

CMS added five quality measures for Cancer Exempt hospitals for the new cancer hospital quality reporting program to begin in FY 2014, Federal Register, Page 28065.

ANA Comments:

The ANA agrees with the comments provided by the Oncology Nursing Society (ONS), an ANA organizational affiliate. The ONS noted:

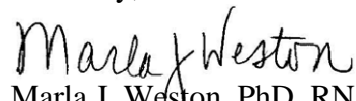
PPS-Exempt Cancer Hospitals, like other healthcare institutions concerned with providing high quality cancer care, should participate in public reporting programs of important, scientifically sound and meaningful measures. The NQF and the MAP provided a thorough review of existing endorsed measures, and the 5 that are put forward are broadly appropriate for this activity as a starting place. Two of the five proposed are sensitive to nursing interventions, the largest group of healthcare providers, and the most proximal caregiver on the acute care team. The ONS notes the importance of patient-centric, team-based (interprofessional) measures. Nurses must have significant voice in the planning, conduct, and execution of quality-related

activities, and the implementation of evidence-based interventions to improve team-based practice as indicated by the evidence.

The ANA and ONS look forward to the evolution and further development of additional patient-centric, team-based oncology care measures over time. This will best occur with appropriate interprofessional team representation in the national quality measurement enterprise and priority measure development funding to fill current important measures gaps.

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) or e-mail (maureen.dailey@ANA.org).

Sincerely,

A handwritten signature in black ink that reads "Marla J. Weston". The signature is written in a cursive, flowing style.

Marla J. Weston, PhD, RN
Chief Executive Officer

cc: President Karen A. Dailey, PhD, MPH, RN, FAAN

References

- Donabedian, A. (1988). The quality of care: How can it be assessed? *Journal of the American Medical Association*, 260, 1743-1748.
- Haynes, A.B.; Weiser, T.G.; Berry, W.G. et al. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. *New England Journal of Medicine*, 360, 491–499.
- National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. (2009). Prevention and treatment of pressure ulcers: clinical practice guideline. Washington DC: National Pressure Ulcer Advisory Panel.
- National Quality Forum (NQF). (2011). *Serious Reportable Events in Healthcare: 2011 Update*. Washington, DC: Author.

Appendix

Table 1. Evidence of the Association between Nursing Hours per Patient Day and Patient Outcomes

Patient Outcome	Author (year)	Staffing measure	Result
Falls	Blegen & Vaughn (1998)	Total nursing HPPD	NS
	Cho et al (2003)	Total nursing HPPD	NS
	Dunton et al (2004)	Total nursing HPPD	(-)
	Dunton et al (2007)	Total nursing HPPD	(-)
	Lake et al (2010)	RN HPPD	(-)
		LPN HPPD	(+)
		NA HPPD	(+)
Pressure Ulcers	Blegen et al (2011)	Total nursing HPPD	(-) Adult intensive care units only
	Cho et al (2003)	Total nursing HPPD	(+)
	Dunton et al (2007)	Total nursing HPPD	(+)
Failure to rescue	Blegen et al (2011)	Total nursing HPPD	(-)
	Needleman et al (2002)	RN HPPD	(-) Surgical patients only
Mortality	Blegen et al (2011)	Total nursing HPPD	(-)
	Needleman et al (2002)	RN HPPD	NS
Length of stay	Blegen et al (2011)	Total nursing HPPD	(-) Adult general units only
	Needleman et al (2002)	RN HPPD	(-) Medical patients only
Urinary tract infection	Cho et al (2003)	Total nursing HPPD	NS
	Needleman et al (2002)	RN HPPD	(-) Medical patients only
Pneumonia	Cho et al (2003)	Total nursing HPPD	NS

KEY. (-) statistically inverse relationship between nursing hours per patient day and patient outcomes (higher staffing is related to lower rates of the patient outcomes); (+) statistically positive relationship between nursing hours per patient day and patient outcomes (higher staffing is related to higher rates of the patient outcomes); NS = results were not significant; HPPD = hours per patient day; RN = registered nurses; LPN = licensed practical nurses; NA = nurse aides.

Table 2. Evidence of the Association between Nursing Staff Skill Mix (% of Hours Supplied by RNs) and Patient Outcomes

Patient Outcome	Author (year)	Result
Falls	Blegen & Vaughn (1998)	(-)
	Cho et al (2003)	NS
	Dunton et al (2004)	(-)
	Dunton et al (2007)	(-)
Pressure Ulcers	Blegen et al (2011)	NS
	Cho et al (2003)	NS
	Dunton et al (2007)	(-)
Mortality	Blegen et al (2011)	NS
	Estabrooks et al (2005)	(-)
Length of stay	Blegen et al (2011)	NS
	Needleman et al (2002)	(-) Medical patients only
Urinary tract infection	Cho et al (2003)	NS
	Needleman et al (2002)	(-)
Pneumonia	Cho et al (2003)	(-)
	Needleman et al (2002)	(-) Medical patients only

KEY. (-) statistically inverse relationship between RN skill mix and patient outcomes (higher proportion of nursing hours provided by RNs is related to lower rates of the patient outcomes); (+) statistically positive relationship between RN skill mix and patient outcomes (higher proportion of nursing hours provided by RNs is related to higher rates of the patient outcomes); NS = results were not significant; HPPD = hours per patient day; RN = registered nurses.