September 14, 2015

Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3260–P
P.O. Box 8010
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 80 Federal Register 42168 (July 16, 2015).

Dear Acting Administrator Slavitt:

On behalf of the American Nurses Association (ANA), we are pleased to comment on the proposed rule referenced above, published in the Federal Register on July 16, 2015. As the only full-service professional organization representing the interests of the nation’s 3.4 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, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.

**Comments on Nursing Services (42 CFR 483.35) and Staffing Issues**

The supplemental information provided with this proposed rule notes that CMS recognizes that existing requirements for sufficient staff needs clarification. CMS states that it is developing systems to collect improved staffing data, but notes that there is not sufficient information at this time to impose such a requirement. With regard to this issue the preamble states:

> While we believe that existing requirements for sufficient staff need further clarification, we do not believe that we have sufficient information at this time to require a specific number of staff or hours of nursing care per resident. Furthermore, we do not necessarily agree that imposing such a requirement is the best way to clarify what is “sufficient” to the exclusion of other factors that are important in improving the quality of care for each resident. The American Nurses Association (ANA), in its 2012 Principles for Nurse Staffing, describe

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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.
appropriate nurse staffing as “a match of registered nurse expertise with the needs of the recipient of nursing care services in the context of the practice setting and situation.” The ANA further notes that staffing needs must be determined based on an analysis of healthcare consumer status (for example, degree of stability, intensity, and acuity), and the environment in which the care is provided. Other considerations to be included are: professional characteristics, skill set, and mix of the staff and previous staffing patterns that have been shown to improve outcomes. The International Council of Nurses (ICN) included similar considerations in its 2012 statement of principles of safe staffing levels (http://www.icn.ch/images/stories/documents/pillars/sew/ICHRN/Policy_Statements/Policy_statement_Safe_staffing_levels.pdf). The ICN policy statement includes as one of its key principles that “safe staffing levels must reflect the skills, experience and knowledge required to meet patient care needs, taking acuity levels into account.” A second key principle states that safe staffing “involves a range of factors including (but not limited to) a sufficient number of staff available, an appropriate level and mix of skills, a manageable workload of both teams and individuals; . . .’’. We agree. . . We are concerned that establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population.

The preamble goes on to state:

We also invite comment on the benefits of a mandatory 24 hour RN presence, including cost savings and improved resident outcomes, as well as any unintended consequences of implementing this requirement. We further welcome evidence of appropriate thresholds for minimum staffing requirements (for both nurses and direct care workers) and evidence of the actual cost of implementing recommended thresholds, including taking into account current staffing levels as well as projected savings from reduced hospitalizations and other adverse events.

ANA appreciates CMS’ recognition of ANA’s Principles for Nurse Staffing. However, to cite them in the abstract without taking into account the growing evidence base that supports improved staffing does a disservice to ANA’s principles. We urge CMS to reevaluate the position set forth in this proposed rule in light of current research on staffing issues, and to consider the regulatory steps that can be taken now to address this important issue.

ANA has been collaborating with Avalere health, LLC, to consider safe staffing issues, and the resulting paper on this topic, “Optimal Nurse Staffing to Improve Quality of Care and Patient Outcomes” (August 2015), provides in-depth information on this topic. The methods section of the paper explains that ANA “collaborated with Avalere to explore the clinical case for using optimal nurse staffing models to achieve improvements in patient outcomes.” It continues: “Avalere conducted a targeted review of recent published literature, government reports and other publicly-available evaluations of nurse staffing and patient outcomes. Avalere also convened a panel of leading nurse researchers, thought leaders, managers and those in practice from across the country to provide additional context and to help identify best practices in nurse staffing.” Although the analysis of the paper was focused on acute care hospitals, the resulting principles are applicable to other settings.
The “key findings” section of the paper states:

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.

ANA believes it is essential to begin to address this issue based on current evidence. As highlighted in the paper, published studies show that appropriate nurse staffing helps achieve clinical and economic improvements in patient care. The paper identifies the following benefits:

- Improvements in patient satisfaction and health-related quality of life; and
- Reduction / decrease in the following:
  - Medical and medication errors
  - Patient mortality, hospital readmissions and length of stay
  - Number of preventable events such as patient falls, pressure ulcers, central line infections, hospital-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.

The paper continues:

Organizations such as ANA support state and federal regulation and legislation that allows for flexible nurse staffing plans. In addition to promoting flexible staffing plans, ANA and like-minded constituents support public reporting of staffing data to promote transparency and penalizing institutions that fail to comply with minimal safe staffing standards.

Further, ANA has introduced a legislative model in which nurses themselves are empowered to create staffing plans. Optimal staffing is much more than just numbers, and direct care nurses are well equipped to contribute to the development of staffing plans.

To conclude, appropriate nurse staffing is associated with improved patient outcomes. With the increased focus on value-based care, optimal nurse staffing will be essential to delivering high quality, cost-effective care. Implementation of a legislative model will help set basic staffing standards and encourage transparency of action through public reporting and imposing penalties on institutions that fail to comply with minimal standards.

While ANA is supporting legislative steps to address safe staffing, we believe that there are regulatory steps that CMS can currently take, based on existing literature set forth in the ANA/Avalere paper, to address this issue. We welcome the opportunity to meet with CMS to discuss these findings in greater detail.
With regard to these issues, CMS also notes that a “competency-based staffing approach would require the facility to evaluate its population and its resources. . .” The additional specificity is welcomed, but lacking a comprehensive enforcement with penalty program the likelihood that this will result in improved staffing is minimal. ANA urges CMS to be proactive in evaluating whether this approach has actually increased the total nursing care hours per resident day. In addition, ANA supports the recommendations submitted by Harrington, et al., with regard to specifying that violations of Section 483.35 result in the issuance of an automatic G-level violation for harm and jeopardy to any facility found to have inadequate staffing levels to meet the needs of patients. Further, ANA supports the recommendation from Harrington, et al., recommending that CMS require an automatic hold on admissions in facilities with inadequate staffing levels until the facility increases the staffing to an acceptable level. We also urge CMS to consider either eliminating waivers or limiting them to emergency situations only, and closely monitoring the health and safety of residents until standards are met, as discussed by Harrington, et al.

With regard to safe staffing, ANA also urges CMS to require facilities to engage the services of at least one RN 24-hours per day, 7-days a week. Such a step is essential to achieving the goals of coordinating care and reducing the incidence of unnecessary hospitalizations.

**Resident Rights (§483.10)**

ANA supports the proposal to add a new requirement concerning residents’ rights to participate in the care planning process, to request meetings or changes to the person-centered care plan, to receive services included in the care plan and participate in its development, and to self-administer medications if clinically appropriate. ANA supports the right of a resident to share a room with his or her roommate of choice and receive visitors of his or her choice as well as the right of residents to choose their attending physician. We also support the proposal to incorporate the ability of the resident to access medical records in the form and format as requested including in electronic form.

**Transitions of Care (42 CFR 483.15)**

The proposed rule contains significant changes concerning transitions of care. CMS describes these changes as reflecting quality concerns related to the care of a resident who is being transitioned between settings. The proposed rule addresses admissions, transfers and discharges, bed-hold policies, and therapeutic leave policies.

ANA supports the recognition and discussion of this important topic and efforts to fully utilize care coordination as a mechanism to improve transitions of care. For many years ANA has stressed the fundamental importance of care coordination and transitional care for patients and residents, and the pivotal role that RNs and APRNs in improving care coordination and transitional care services. Such services are essential to advancing the delivery of health care and furthering the priorities of the National Strategy for Quality Improvement in Health Care: better care; better health; and reduced costs.
We appreciate the opportunity to share our views on this matter. If you have questions regarding the safe staffing issue, please contact Mary Jo Assi, Director of Nursing Practice and Work Environment (maryjo.assi@ana.org). For other questions, contact Jane Clare Joyner, Senior Policy Fellow (janeclare.joyner@ana.org).

Sincerely,

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Senior Director, Nursing Programs

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President
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