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September 4, 2015

Andy Slavitt, Acting Administrator Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services Attention: CMS-5516-P, Mail Stop C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Federal Register 41198 (July 14, 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 14, 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. ¹

ANA appreciates the opportunity to comment on this proposed rule. We initially note that ANA supports the positions and recommendations set forth in the comment letter submitted by the Visiting Nurse Associations of America (VNAA), a national organization that supports, promotes and advances mission-driven, nonprofit providers of home and community-based health care, hospice and health promotion services to ensure access and quality care for their communities. In addition, we offer the following comments, which were developed with input from colleagues with ANA's Organizational Affiliates, the National Association of Orthopaedic Nurses and the Association of Rehabilitation Nurses.

¹The 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.

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Effective Date of the Proposed Rule

Initially we note that the uniform assessment data being collected through the IMPACT Act may be useful to inform the development of a more comprehensive, evidence-based reimbursement policy on changes to the current payment system. We recommend that the Centers for Medicare & Medicaid Services (CMS) consider postponing implementation of the rule and utilize the uniform assessment data being collected through the IMPACT Act.

If this rule is finalized as proposed, the policies would take effect on January 1, 2016. The lead time for implementing the Comprehensive Care for Joint Replacement (CCJR) model is extremely short and may present challenges for some hospital systems. For example, despite the expectation of health information exchange fluidity, sharing of health information from hospital to practices, and to home health agencies (HHA) and Skilled Nursing Facilities (SNFs) varies from provider to provider and state to state. Further, hospital contracts with SNFs and HHAs will need to be revisited. In addition, transparency on costs provided to patients, and the health information technology (HIT) systems needed to bundle costs, may not be ready in advance of the proposed January 1st start date. There is a potential for a decrease in quality of post discharge care in early phases of implementation as post discharge care providers may not be affiliated with a hospital. Further, if systems are not in place in advance of the start date, nurses responsible for coordination of care throughout a 90-day episode may not be able to adequately determine patient status in order to intervene in a timely manner. We are also concerned that there may be delays in designing effective perioperative surgical homes that can effectively provide the care required within the bundle. We urge CMS to reevaluate and extend the current start date for the CCJR model to provide for additional time to prepare for implementation.

Beneficiary Protection

CMS proposes a set of safeguards for beneficiaries receiving care under the CCJR model, including notification for beneficiaries who initiate a CCJR episode. As proposed, the notification would explain the model, inform beneficiaries that they retain their freedom to choose providers and services, explain how patients can access care records and claims data, and advise that all standard beneficiary protections remain in place in this model. We support the proposal to provide comprehensive education to patients regarding this model. It will be essential for hospitals and nurses to be provided with educational materials to help patients and caregivers navigate this new program, as the patient must remain the central partner in this proposal.

The proposed rule indicates that CMS will track case mix and other data to determine if complex patients are being systematically excluded and will publish such information as part of the model evaluation, and will also track medical records and claims data to ensure access to medically necessary services and will incorporate a payment adjustment as a deterrent to offset incentives for providers to delay care. The payment model calls for an adjustment against savings when there are certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode. Monitoring for delayed care will occur in the collection and calculations to determine this adjustment.

We agree with CMS that these aspects of the CCJR model must be carefully tracked and analyzed, and we urge CMS to carefully monitor the potential impact of case mix pre-ruling and post-ruling.

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Although there is an ICD code for joint replacement with comorbidities, some providers may avoid these patients to improve reimbursement. It may be appropriate to consider exclusion criteria for patients who can be pre-operatively optimized within the limitations of their chronic medical conditions. Further, it may be appropriate to limit this model to patients undergoing elective surgery.

Evaluating the Effectiveness of the CCRJ Model

The CCRJ model offers an important opportunity to test and evaluate a new payment model in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for covered episodes of care. The aim of the proposal is to promote quality and financial accountability for certain episodes of care with a goal of "improving coordination and transition of care, improving the coordination of items and services paid for through Medicare Fee-For-Service (FFS), encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care."

We support these important goals, including efforts to fully utilize care coordination and evaluate the potential impact of bundled-payments as a mechanism to improve health. Appropriate and effective care coordination and transitional care 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. Patient and family involvement in a shared decision process will require extensive education to reassure patients that these changes are quality driven, rather than financially motivated. Nurses play an integral role in educating patients and coordinating care and services, and nurses will be critical to the successful implementation of this model.

However, we have some concerns with the model as currently structured. For example, a determination of the need for intensive rehabilitation is necessarily dependent on the effects of a patient's injury or illness, including impairments, functional deficits, and achievable goals, rather than simply the patient's diagnosis. Basing a site-neutral determination on an acute discharge diagnosis-related group prevents the assessment of function – an essential component in determining the proper post-acute setting. In addition, failure to appropriately determine the site of care for post-acute services may contribute to avoidable hospital readmissions. It is important to ensure that authorized level of care matches the patients' clinically assessed needs, and to ensure that services are provided at the appropriate level of intensity – in the right setting and at the right time – to meet the patient's individual needs. We are also concerned with proposals to regulate post-acute care reforms that bundle episodes of care, impose financial incentives to treat patients in the least intensive setting, or otherwise limit rehabilitation benefits under the Medicare program.

When evaluating the implementation and effectiveness of this model, we urge CMS to carefully evaluate a number of factors. At the outset it is hard to ascertain how the financial impact of the CCJR model will affect reimbursement in hospitals, and how this in turn will impact nursing resources within facilities. For example, the role of a nurse care manager or nurse navigator will be pivotal to the success of these patients throughout the 90-day episode of care. Expanding the number of certified orthopaedic nurses to provide comprehensive and competent care will be

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essential to effectively implement this model. However, this will require participating hospitals to recognize and make the financial commitment necessary to prepare staff for these roles. Not all hospitals are able to make these investments, particularly if they do not see the value of investing in the resources necessary to fill these roles. If this model is implemented, we urge CMS to carefully monitor its impact.

In addition, it will be important to monitor the impact of patient access to orthopaedic joint care if some hospitals decide not to pursue redesigning their orthopaedic service lines and either eliminate or limit services. Such actions would require patients to travel outside their communities or postpone surgery. It will also be important to closely monitor and evaluate the use of existing electronic health records (EHR) and evaluate the extent to which existing EHR systems can be effectively utilized to coordinate care and transitional services.

A number of additional factors should be carefully examined when evaluating the effectiveness of this model. Under this model, hospitals are responsible for the financial burden but have no ability to drive patients to post-acute care providers (PAC) with best quality and value records. The choice is left to patients who may choose PAC providers based on geography, referral of family or friends, and not on quality of care. Home health providers in rural areas may need to bolster their available nursing and therapy services if fewer patients are referred for more costly SNF services. We also note that without recommended standards and best practice recommendations, variations in care will still occur. For example, in order to make the care cost effective, some joint replacement programs may use lower cost alternatives or forgo other enhancements to the patient experience. If this model is finalized as proposed, we urge CMS to carefully monitor these aspects of the implementation.

Waivers-Subpart G

There are a number of waivers that are highlighted in the Proposed Rule, involving "incident to" billing, telehealth requirements, etc. However, the Proposed Rule omits a waiver that should also be considered in examining bundled payment for CCJR. Advanced practice registered nurses are currently not allowed to certify hospitalized patients for home health care services. This often produces delays when the attending physician is not on-site. Given the DRG based payment there are no direct savings to Medicare but there are costs imposed on the hospital in maintaining the patient for extra days of care. If hospitals could reallocate resources in those cases, some part of such cost savings could offset above average cost episodes that would be expected during the demonstration. With 75 jurisdictions involved under this Proposed Rule, as many as one third should be allowed to waive the physician only home health certification to assess changes in quality and cost.

ANA is concerned, in general, that the existing system of "incident to" law, regulation, and experience contributes to making the delivery of services to patients opaque rather than transparent. In this regard, execution of the demonstration should require more specific identification of the clinicians whose services are billed incident to and documentation of the specialties of those clinicians. A patient episode that included nine post-discharge visits billed to a physician practice NPI only establishes total approved charges—rather than describing the process of care or actual care coordination. Some logical method of identifying those services must be

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developed for the evaluation of this aspect of the demonstration. In response to previous Proposed Rules ANA has advocated for the development and use of specialty specific incident to modifiers to track services provided and billed as incident to a physician service. ANA is also concerned that authorization of general supervision for such services could allow non-qualified clinicians to provide follow-up care supervised only by a hospital contractor.

Another waiver would allow telehealth visits to originate in a beneficiary's home rather than from a certified telehealth facility. There have been more than a sufficient number of demonstrations that telehealth can be an important adjunct to on-site care so this is not an important part of the demonstration. However, if the originating site requirements are to be waived, it should be incumbent upon the demonstration evaluators to contemporaneously collect information on the alternative patient or family costs avoided by not having to transport the patient from home to an established site of an available telehealth facility.

We appreciate the opportunity to share our views on this matter. If you have questions on the comments concerning waivers, please contact Peter McMenamin, Health Economist (peter.mcmenamin@ana.org; 301.628.5073). For other questions, contact Jane Clare Joyner, Senior Policy Fellow (janeclare.joyner@ana.org; 301.628.5083).

Sincerely,

Debbie D. Hatmaker, PhD, RN, FAAN

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Executive Director

cc: Pamela Cipriano, PhD, RN, NEA-BC, FAAN, ANA President Marla Weston, PhD, RN, FAAN, ANA Chief Executive Officer