Catholic Health Association of the United States

A Passionate Voice for Compassionate Care

September 8, 2015

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G
Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS-5516-P

Re: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule (Vol. 80, No. 134), July 14, 2015

Dear Acting Administrator Slavitt:

On behalf of the Catholic Health Association of the United States, the national leadership organization of the Catholic health ministry, representing the largest group of not-for-profit providers of health care services in the nation, I would like to offer the following comments on the referenced proposal by the Centers for Medicare and Medicaid Services (CMS) to create a Comprehensive Care for Joint Replacement (CCJR) Payment Model.

The Catholic health ministry is committed to providing safe, effective, patient-centered, timely, efficient and equitable care to all patients. We strive to improve the quality and safety of the care that we provide every day. CHA welcomes the continued movement of our health care system towards one that rewards providers for high-quality patient care in a manner that focuses on quality and outcome rather than volume. CHA has expressed its support for programs such as the Medicare Shared Savings Program/Accountable Care Organizations, Value Based Purchasing and Readmission Reductions, and we welcome CMS' proposal to move forward with a new bundling model in the form of the CCJR. As with the other programs, our goal in offering comments to the current proposal is to contribute to its successful implementation in a way that avoids unintended consequences such as increasing disparities in care or creating disincentives to serve low-income or vulnerable patients.

- **Episode of Care Definition/Risk Adjustment/Exclusions**

An episode of care in the CCJR model would be triggered by an admission to an acute care hospital paid under MS-DRG 469 (major joint replacement of reattachment of lower extremity with major complications or comorbidities) or MS-DRG 470 (major joint replacement or reattachment of lower extremity without major complications or comorbidities) in the inpatient prospective care system (IPPS). The episode of care would end 90 days after discharge from the hospital. The episode would include all related care under Medicare Parts A and B, including inpatient, outpatient, physician, inpatient rehabilitation, skilled-nursing and home health services. Certain unrelated services (unrelated hospital admissions and Part B services; drugs paid outside the MS-DRG; and IPPS new-technology payments) would be excluded. The model would last for five years, beginning January 1, 2016 and ending December 31, 2020.

Both MS-DRG 469 and 470 include elective and non-elective procedures. Our members see important differences in clinical pathways, complexity and functional impairment between elective and non-elective procedures. Including fractures and trauma cases in the episode of care without accounting for differences among hospitals in their mix of these services is problematic. We are also concerned about the lack of adjustment for patient-specific clinical indicators or differentiation for the procedure mix within a given DRG (e.g., partial hip, total hip, or knee). Our members' experience has shown that hip fracture patients are significantly more expensive, especially for post-acute care. Without making such adjustments trauma centers or hospitals that serve a more frail elderly population will have a higher proportion of fracture-related episodes compared to the "average" hospital and will have much higher post-acute care costs. Adjusting for these factors will also assure access to care for high-cost patients and guard against, or offset the effect of, patient steering. For these reasons, **CHA strongly urges CMS to include a method to adjust for these differences and if it chooses not to, then to exclude non-elective procedures from the CCJR bundle.**

While we appreciate the exclusion from the model of certain services, we urge CMS to consider other exclusions. **CMS should consider possible exclusions related to ongoing care for chronic or certain unrelated conditions.** For example, commercial joint bundling programs in which our members participate exclude conditions such as active cancer, HIV and ESRD. We also note that no exclusions are proposed for services provided in a post-acute care setting. For example, while an unrelated hospital readmission would be excluded, subsequent post-care care services would be included. **CMS should consider appropriate exclusions related to post-acute care.** Similarly, when a patient dies during the triggering hospitalization that case would not be included in the CCJR model. No similar proposal is made in the case of the patient's death during the 90-day post-discharge period. **We urge CMS to exclude all cases when a patient dies, whether that occurs during hospitalization or the post-discharge period.**

- **Updating the data set of three historical years every other year**

CMS proposes to use three years of historical CCJR episodes for calculating CCJR target prices and to update the set of three historical years every other year. For performance years one and two, CMS would use historical episodes that started prior to the CCJR model—January 1, 2012 and December 31, 2014. For performance years three and four CMS would use historical episodes that started between January 1, 2014 and December 31, 2016. This would include two years of historical data prior to the CCJR model and one year of data after implementation. By performance year five, all historical episodes would reflect spending occurring during the CCJR model – January 1, 2016 through December 31, 2018.

CHA urges CMS not to finalize this proposal, and instead to maintain an historical base for the five-year period and then update the three-year baseline if the model continues beyond 2020. Our concern is that updating the baseline every other year, will make it very difficult for hospitals to achieve savings and put them at higher risk for making payments to CMS, particularly in the latter performance years when data in the baseline would include data from the early performance years and any savings the hospitals generated. This approach would penalize hospitals for success in generating savings and improving quality. In its final rule for the MSSP program (published June 9, 2015), CMS modified its benchmark methodology by making an adjustment to reflect the average per capita amount of savings earned by the ACO in its first agreement period. We strongly urge CMS to consider a similar approach if CMS chooses to update the set of three historical years every other year or such an approach could be used if the model extended beyond 2020 into a second 5-year period.

- **Quality Measures**

In order to be eligible to receive reconciliation payments, hospitals must first meet or exceed a minimum performance threshold on three specified quality measures currently used in the hospital IQR program: Elective hip and knee replacement readmissions, Elective hip and knee replacement complications rates, and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) results. While we appreciate CMS' attention to quality and its proposal to use existing measures, we have two concerns. First, the readmission and complications measures reflect only elective procedures while the CCJR population will include those undergoing both elective and non-elective procedures. This mismatch could be solved by excluding non-elective procedures from the CCJR, which we suggest CMS do if it does not include risk adjustment in the final rule.

Second, neither of these measures includes adjustment for sociodemographic factors such as income, education, race, homelessness and language proficiency, which have been shown to have a significant relationship to health outcomes. **We strongly support incorporating sociodemographic adjustments in quality measures used in reporting or pay for performance programs, and again urge CMS to do so.** Such an adjustment is particularly important when, as is proposed here, a hospital is held accountable for what happens to the

patient post-discharge. Many factors beyond the control of the hospital can affect the recovery and health of patients, such as whether a patient can afford medications, has access to healthy food and safe places to exercise, and has housing and living conditions conducive to healing. Failing to adjust for these factors in performance-based payment incentive programs can result in unnecessary and inappropriate payment reductions for providers that serve a high percentage of disadvantaged patients, harming both the patients and the providers by depriving them of the resources they need to make sure every patient receives quality care.

- **Waivers**

CHA supports CMS' proposal to waive certain Medicare program rules under the CCJR. These waivers include the "incident to" direct supervision requirement for home health visits and the geographic site limitations on telehealth payments.

CMS also proposes to waive the skilled nursing facility (SNF) three-day rule but only beginning in the second year of the program. **CHA urges CMS to waive the SNF three-day rule in the first year as well.** While hospitals do not face downside risk in year one, they will be setting up their program procedures including discharge procedures and relationships. It makes better sense to have this rule in place from the beginning than to wait to introduce it in the second year. The waiver will only apply with respect to SNFs that have at least a three-star rating on Nursing Home Compare. We strongly support efforts to ensure that patients receive high-qualify SNF care. However, we are concerned that in some areas there may not be a sufficient number of SNFs with three-stars or more. Thus some patients who could be safely released to SNF care in fewer than three days would have nowhere to go for appropriate care. The lack of a three-star SNF in the area means the patient either stays in the hospital longer than necessary, which runs counter to the goals the model is seeking to achieve, or is denied access to Medicare-covered SNF services. We ask CMS to consider this possibility and propose an alternative solution that both emphasizes quality and allows for exceptions when necessary.

CHA urges CMS to waive provisions of the civil money penalty (CMP) law, the federal anti-kickback statute and the physician self-referral law that could inhibit the formation of financial relationships needed to make the CCJR succeed. Alternative payment models, such as accountable care organizations (ACOs) and bundled payments, require substantial clinical and financial integration among institutional providers of services, physicians and other practitioners. Some of these financial arrangements either run afoul of the physician self-referral law or do not clearly fit into an existing exception to the law, especially in the case of provider groups who provide the continuum of care across settings.

In order for these alternative payment models to be successful, CMS has in the past recognized that certain provisions of Title XI and Title XVIII of the Social Security Act must be waived to permit the parties to form the arrangements required to provide quality care and better manage the conditions of the Medicare beneficiary population. While these waivers have been helpful in establishing some of the arrangements under the alternative payment models, the self-referral

law still imposes substantial barriers for hospitals, other institutional providers of services and physicians to create the legal relationships and arrangements necessary to improve care quality, care coordination and efficiency for the Medicare population.

Additionally, the proposed start date of January 1, 2016 poses an unreasonable burden on providers, physicians and practitioners who must negotiate arrangements that meet the many regulatory and subregulatory requirements of the model. Without some certainty as to what CMS intends to provide in the form of waivers (be they waivers currently in effect under an ACO model or additional waivers to alleviate the burden of self-referral law barriers to integration), participating hospitals and prospective CCJR collaborators will be entering into agreements for purposes of a mandatory program without fully understanding the legal landscape in which they must operate. This lack of information and planning will stifle the very innovation CMS and CMMI hope to encourage, and puts providers and physicians at risk of inadvertently violating fraud and abuse laws in their efforts to coordinate and improve care quality and efficiency under the Medicare program.

CMS should also waive discharge planning requirements that prevent hospitals from recommending preferred high-quality post-acute care settings. While beneficiary choice is a very important principle, in the context of the CCJR it must be considered in light of the hospital's financial accountability for the entire episode of care. Hospitals must have reliable guidelines giving them the flexibility to help patients choose high-quality post-acute care.

- **Timing and Data**

CMS is proposing to begin the CCJR program January 1, 2016, after finalizing its rule in October 2015. However, CMS states that baseline data will not be available "sooner than 60 days after January 1, 2016, the effective date of the model." This is much too late. CMS is using historical baseline data from prior years to determine price targets and other measurements. **We strongly urge CMS to release this data to CCJR- participating hospitals as soon as the rule is finalized.** Providing historical claims data before the effective date of the CCJR program will enable hospitals to engage in the critical analysis necessary to focus their efforts. It will provide our members with an improved ability to undertake care re-design, identify system weaknesses and plan improvements.

- **Enforcement**

CMS proposes to use enforcement mechanisms to ensure compliance with the requirements and provisions of the CCJR model that are consistent with enforcement mechanisms for violations of requirements applicable to other CMMI models, especially BPCI Model 2. CMS would enforce the requirements of the program though warning letters, corrective action plans, payment penalties, and, on rare occasions, termination from the model. CMS indicates that its potential exercise of termination authority would be rare, and that it could terminate the program due to reasons other than provider noncompliance.

The CCJR model imposes a new care delivery structure with complex requirements on a vast number of institutional providers of service and suppliers, some of which have little or no experience with these models, and it does so on a mandatory basis. We would encourage CMS to limit its use of this proposed money penalty authority to egregious circumstances, such as knowing and willful violations and patterns of violations of requirements that directly impact the safety and health of patients. Additionally, we would urge CMS to afford participating hospitals and CCJR collaborators the option to pay civil money penalties with respect to a performance period over several years.

In closing, thank you for the opportunity to share these comments on the CCJR proposed rule. We look forward to working with you on these and other issues that continue to strengthen the country's hospitals and health care system. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

Michael Rodgers
Senior Vice President
Public Policy and Advocacy