AAHKS
AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

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VIA ELECTRONIC SUBMISSION

Lewis Sandy, MD
Chair
Clinical Episode Payment Work Group
Health Care Payment Learning & Action Network

RE: Comments on Elective Joint Replacement – Draft White Paper

Dear Dr. Sandy:

On behalf of the 2,710 members of the American Association of Hip and Knee Surgeons ("AAHKS"), thank you for the opportunity to comment and offer suggestions on the Health Care Payment Learning & Action Network's ("LAN's") draft white paper, Elective Joint Replacement ("White Paper").

AAHKS is the foremost national specialty organization of physicians with expertise in total joint arthroplasty ("TJA") procedures. Many of our members conduct research in this area and are expert on the evidence based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is also closely engaged in the design and operational questions facing the various Medicare bundled payment initiatives.

AAHKS offers comments on this White Paper, prepared by the LAN Clinical Episode Payment Workgroup ("CEP"), to ensure the LAN benefits from our more broad experience in TJA procedures and bundled payments. Our comments below correspond to the sequence of design elements discussed in the White Paper.

1. **Episode Definition**

"The episode is defined as an elective and appropriate total hip or total knee replacement due to osteoarthritis."

AAHKS accepts, in principle, the White Paper's recommendations that the episode be limited to elective TJAs due to osteoarthritis. This is an improvement over the episode offered in the Medicare Comprehensive Care for Joint Replacement Model ("CJR") commencing shortly. By excluding fractures, the White Paper properly recognizes that elective procedures are a

comparatively controlled clinical event, more subject to provider influence and care, unlike fracture cases. It should also, however, make an effort to exclude TJA for tumors, metastatic cancer, avascular necrosis, inflammatory arthridities such as rheumatoid arthritis and other diagnoses not addressed in the CJR.

The White Paper also recommends that in addition to a routine clinical assessment, a provider use a “standardized, validated functional status assessment tool” to ensure the patient is an appropriate candidate for the procedure. At this point in time, those tools have been used as outcome measure and are validated for measuring the change in status from before and after such episodes. They are not well validated as tools to decide who needs surgery.

We agree with the measuring of outcomes, but are concerned about cost and administrative burden. Functional status assessment tools must be brief and easy to incorporate into existing practice. The more than 40 questions of the HOOS and KOOS assessments become burdensome and unwieldy for routine use in a clinical setting. We appreciate that during the March 22, 2016 LAN webinar discussing the episode, multiple members of the CEP emphasized the need to develop short-form functional status assessments that “get to same good answers with fewer questions” and are therefore realistic for the patient encounter.

We ask the CEP to acknowledge that additional patient exclusion may be necessary as a component of defining the episode. Patient exclusion should occur when the rules and assumptions of the system of care at the heart of the episode cannot be expected to effectively manage the risk associated with their unique set of conditions. If these conditions are defined as modifiable, then their exclusion may be temporary and efforts can be made to correct medical conditions prior to the beginning of the bundle. Such exclusion would be consistent with the White Paper’s principle for limiting the episode to THAs for osteoarthritis, but more explicit definition of such exclusions is needed. Any method of selecting patients for inclusion in the bundle will have wide-ranging impacts, and care must be taken to ensure that adverse selection of at-risk patients does not result in care denial, if such care is medically necessary

2. **Episode Timing**

“For purposes of payment, the starting point for this episode is 30 days pre-procedure, and the stopping point is 90 days post-discharge. Accountability for functional improvement may go beyond the 90 days.”

We do not agree with the White Paper recommendation to frame the episode as beginning 30 days prior to surgery, although we can accept the episode ending 90 days following discharge. This is an appropriate post-discharge window in which to capture most significant complications, after which the ability to impact quality and outcomes is diminished. As the White Paper notes, the appropriateness of the time frame for any episode is determined by which providers and services are included in the episode. An episode with narrowly defined services and fewer participating providers will logically correspond to a shorter timeframe. The

30 days window before surgery is too long and will attribute to the surgeons/hospitals work-up costs that were not in the control of the treating surgeons.

3. Patient Population

"The episode should apply to the broadest-possible pool of patients, using risk and severity adjustment to account for age and complexity."

We agree with and embrace the White Paper's assertion that "Appropriately specified risk and severity adjustment algorithms applied to the episode price are critical." AAHKS believes that inadequate or non-existent risk adjustment is the most significant possible deficiency in an episode or bundled payment design.

If an episode fails to reward hospitals and surgeons who treat high-risk patients at the same level of quality as those treating low risk patients, providers will be driven to treat only low-risk patients. Those treating a greater number of high-risk patients will face perverse financial penalties for taking on the most difficult cases.

For example, the White Paper does not address the differences between primary and revision TJA procedures. AAHKS has found that compared to primary total hip arthroplasty ("THA") for osteoarthritis, conversion THA is associated with significantly more complications, a longer length of stay, and more likely discharge to continued inpatient care, implying greater resource utilization for these patients versus primary THA. Therefore, conversion THA appears to be one procedure for which risk-adjustment is appropriate.

The CEP should acknowledge that multiple methods are available to account for patient variation. Episodes may include risk stratification, exclusion, and other methods depending on what is most appropriate within the entire episode. Development of risk adjustment methods must be done with close consideration of minimizing additional data collection steps for providers. Many important risk factors for adverse patient outcomes currently are either not measurable using available data (e.g., preoperative functional status) or are not consistently reported (e.g., obesity).

4. Services

"All services needed by the patient that are related to the joint replacement procedure should be covered by the episode price."

The White Paper recommends that episode payment should include delivery of all services billed in the time period that are related to the elective joint replacement procedure. The White Paper further notes this may be accomplished through enumerating specific included or excluded services. Such excluded services need to be broad enough to protect the providers from the actuarial risk in the post-operative period of events occurring that are unrelated to the TJA and out of the control of the providers.

AAHKS commends the White Paper for highlighting the challenge of creating such enumerations when considering patients with multiple complex, chronic conditions. Risk adjustment may not completely account for the magnitude of this variation and therefore episodes should also appropriately assign accountability to the provider or entity best able to manage or treat an underlying chronic condition.

5. **Patient Engagement**

"Require use of shared decision-making and patient engagement tools and transparency of the payment model in patient-facing materials to maximize opportunities to engage patients and families in advancing high-value care."

AAHKS agrees that patient engagement is key and supports the White Paper recommendation that providers incorporate shared care planning. The White Paper specifically discusses setting goals prior to the surgery and ensuring that patient, provider, and appropriate family or care givers are included in that discussion. It is helpful that the role of primary caregiver is discussed as a necessary participant in care planning for patients with chronic diseases.

Proper patient engagement includes reviewing the social support and psychological wellbeing of the patient, along with ensuring a home environment conducive to optimal recovery. Providers need to stress the elective timing of surgery and the dramatic impact that modifying risk factors can have on avoiding adverse events or delayed recovery. Modifiable risk factors such as smoking, anemia, diabetes management, and malnutrition should be addressed as inherent risks on the surgical outcome. Finally, delaying surgery, though inconvenient and unsatisfactory, should be considered prudent and preferable to operating on a patient with poorly managed chronic conditions whose risk profile can be altered by appropriate interventions.

The White Paper additionally recommends that prior to surgery, patients be provided with information about the quality and procedure complication rates of possible surgeons and possible acute-care facilities. It is suggested that "such help should be available through clearly designated personnel without conflicts of interest." It is not clear how this recommendation would be operationalized. It seems that the most likely personnel to deliver such information concerning surgeons would be the patient's primary care provider, and that the most likely source of information concerning post-acute care facilities may be the orthopaedic surgeon. The White Paper should be clear if other "designated personnel" are intended and who they may be.

It is not clear that there is an appropriate shared decision making tool that has had been proven to have psychometric validity. It should be noted that the most recent version of the Healthwise tool as provided in 2015 had grossly incorrect information regarding survivorship of modern implants that was based on older literature.

Additional clarity is also needed around the definition of "conflict of interest" that the designated personnel would be free from. While patients may be ultimately free to choose providers, it should be acknowledged that primary care providers, surgeons, hospitals, and post-acute care facilities are increasingly likely to be operating jointly as accountable care organizations or collaborative care networks. Entities within these shared savings arrangements naturally will be incentivized to recommend participating providers with the highest quality and best efficiency, but will such arrangements be considered a conflict of interest?

6. Accountable Entity

"The accountable entity should be chosen based on its ability to engineer change in the way care is delivered to the patient and its ability to accept risk for an episode of care."

AAHKS agrees with the suggestion that clinicians, particularly the orthopaedic surgeons or practice, may be most able to effect change in a joint replacement episode. Many hospitals will not have the capability of managing the episode without substantial additional guidance from surgeons, and could be placed at significant downside financial risk if they fail to turn clinical management over the provider most able to effect change in a joint replacement.

The White Paper also suggests that some physician practices lack the financial resources to assume downside risk as the primary accountable entity under an episode. This is true in some cases and therefore hospitals and physicians should be free to make their own arrangements as to the degree of upside or downside risk to be assumed by either under the episode. It would not be appropriate for a payer to unilaterally make the decision for all parties by, for example, barring orthopaedic surgeons from being in any way the accountable entity.

7. Payment Flow

"Use retrospective reconciliation with upfront payments flowing through an FFS mechanism (APM Framework Category 3)."

The White Paper discusses the alternative benefits and risks of prospective or retrospective fee for service payments in the episode. Regardless, AAHKS supports retrospective payment reconciliation for the episode to determine the actual costs.

8. Episode Price

"Data used to establish the episode price should reflect two years of historical costs and strike a balance between regional- and provider-specific data. The price should acknowledge efficiencies already gained by previous programs and incentivize more efficient levels of practice."

The White Paper succeeds in articulating the interconnected challenges in setting a target episode price through a combination of provider- and regional-specific cost data. If provider-specific costs alone are used, institutions that have already achieved significant efficiencies will be challenged to achieve further savings required under the episode. Similarly, if regional cost data alone is used, those regions that are comparatively efficient as a whole will have a greater number of institutions that are challenged to achieve measureable additional savings in comparison to providers in other regions.

The White Paper proposes a mix of the two types of data, noting that "over time, as performance becomes less variable, it may be useful to lessen the proportion of the episode look-back period that is based on the organization's specific experience." This is very similar to AAHKS' comments on the CMS CJR Proposed Rule, which also commences with a blend of regional- and provider-specific cost data for its episode price. We requested that CMS allow participating hospitals to opt in to regional-only pricing on a more accelerated timeframe lest efficient hospitals be penalized – through lack of payment – for their early efficiency.

We appreciate that the White Paper notes "risk adjustment will also be needed during this process to adjust for the unique characteristics of the population the provider serves." As discussed earlier, proper risk adjustment is essential to account for the real differences in patient population that would not otherwise be appropriately or fairly reflected in regional- or population-specific cost data.

9. Type and Level of Risk

"The goal should be to utilize both upside and downside risk. Transition periods and risk mitigation strategies should be used to encourage broader provider participation."

AAHKS embraces the White Paper recommendation to incorporate both upside and downside risk. We agree with the included qualification that some small providers, such as physician practices, face challenges in taking on downside risk and transitional "phase-in" periods may be necessary.

We appreciate that the White Paper again notes the importance of mechanisms for limiting risk, such as "risk adjusting the episode price, based on the severity within the population." A variety of risk limiting methods are discussed, but what is most important to the success of the episode is that *some adjustment occurs* to limit risk to account for the health status of patients and account for the fact that care is provided by multiple providers across the episode.

10. Quality Metrics

"1) Prioritize use of patient-reported outcome and functional status measures; 2) Use quality scorecards to track performance on quality and inform decisions related to payment; and 3) Use quality information to communicate with and engage patients."

Patient-Reported Outcomes - AAHKS agrees that it is critical to measure the outcomes and patient experience of care to determine whether quality improvements are achieved. We also agree that some metrics, such as patient experience surveys of a hospital experience, and may not be designed to capture key attributes of the patient experience specific to joint replacement. For example, CMS intends to use the HCAHPS survey as one of the measurements to determine a hospital's eligibility for reconciliation payments under the CJR. However, the HCAHPS survey is given to a random sampling of all hospital patients. Therefore, the results that would be reported under the CJR Model would relate to all hospital patients, rather than those whose treatment is subject to the CJR Model. In addition HCAHPS only assesses the patient inpatient experience which does not reflect on the whole 90 day episode of care.

The White Paper notes that the Core Quality Measures Collaborative has released "consensus" orthopaedic measures and is also working towards Patient Reported Outcome and Patient Experience measures. We believe that payers' attention should also be turned to consensus patient-reported outcomes measures suitable for TJA performance measures as developed by AAHKS, the American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry. Specialty Societies should be viewed as a resource with the appropriate experience and expertise to identify patient-reported outcomes that can be integrated into practice and that are reflective of quality. We appreciate the CEP members on the March 22, 2016 webinar discussing how patient reported outcomes measures have value as a process measure for orthopaedic surgeons but that they do not measure provider performance or outcomes.

Quality Scorecards - Any quality scorecards that are used should incorporate adequate risk adjustment to reflect the population served by a provider. AAHKS members have historically been assessed on readmission, re-operations, cost, and length-of-stay, but these measures often inadequately account for the wide variation among patients and therefore lose their comparative value. Whatever measures are developed or adopted, or quality assessments are used, they must be risk-adjusted for factors such as health status, stage of disease, genetic factors, local demographics and socioeconomic factors. These factors represent real variations in patient need and the costs of care. The lack of adequate risk adjustment would also limit the value of data generated by the episode to inform providers of optimal interventions.

11. <u>Additional Operational Considerations</u>

We support the White Paper statement that well-designed payment models must consider the perspectives of payers, providers, and patients, "well as support reliable delivery of care that is provided at the right time in the right setting." Further, regarding the regulatory environment, we believe that federal and state law makers and regulators can do more to modernize existing regulatory frameworks to account for industry-wide progression towards more bundled payments.

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AAHKS appreciates your consideration of our comments. You can reach me at mzarski@aahks.org, or you may contact Joshua Kerr at jkerr@aahks.org.

Sincerely,

Michael J. Zarski, JD
Executive Director
AAHKS