AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

OFFICE: 847.698.1200 • FAX: 847.698.0704 • WEB: aahks.org
9400 W Higgins Road, Suite 230 • Rosemont, IL 60018-4976

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VIA REGULATIONS.GOV

Centers for Medicare & Medicare Services
U.S. Department of Health and Human Services
Attention: CMS-1716-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates

The American Association of Hip and Knee Surgeons ("AAHKS") appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") on its hospital inpatient proposed payment systems ("IPPS") proposed rule for fiscal year 2020 (hereinafter referred to as "FY 2020 IPPS proposed rule" or "proposed rule").

AAHKS is the foremost national specialty organization of more than 4,000 physicians with expertise in total joint arthroplasty ("TJA") procedures. Many of our members conduct research in this area and are experts in using evidence based medicine to better define the risks and benefits of treatments for patients suffering from lower extremity joint conditions. In all of our comments, AAHKS is guided by its three principles:

- Payment reform is most effective when physician-led;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus.

Our comments focus on the following provisions of the FY 2020 IPPS proposed rule:

I. Changes to Calculations of Technology Add-On Payment – Section II.H.9.

Under IPPS, a Technology Add-On Payment provides additional payment, based on the cost to the hospital, for high-cost cases involving relevant new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. In the proposed rule, CMS will change the technology payment calculation for the hospital to make an add-on payment equal to the lesser of: (1) 65% of the costs of the new

medical service or technology; or (2) 65% of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment would be limited to the full MS-DRG payment plus 65% of the estimated costs of the new technology or medical service.

AAHKS is supportive of CMS' proposal to change the calculations of the Technology Add-On Payment. AAHKS is encouraged by CMS efforts to foster the use of new technology that can ultimately help increase efficacy, effectiveness, and overall quality of patient care. This measure will reduce price barriers that previously may have disincentivized physicians and hospitals from using the most innovative technology or devices during TJA procedures. AAHKS supports proposals that reduce barriers that keep surgeons from using the latest innovative products that surgeons believe are clinical appropriate.

II. Request for Information on the New Technology Add-On Payment Substantial Clinical Improvement Criterion – Section II.H.6

In the applications for the IPPS new technology add-on payment CMS lists several criteria that it uses to determine whether a new medical service or technology would represent a substantial clinical improvement, including whether use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments. CMS is requesting feedback on whether new or changed regulatory provisions or new or changed guidance regarding additional aspects of the substantial clinical improvement evaluation process would be helpful. CMS asks whether it should provide more specificity or greater clarity on the types of evidence or study designs that may be considered by the agency in evaluating substantial clinical improvement. CMS asks:

- What data should be used to demonstrate whether the use of the technology substantially improves clinical outcomes for patients relative to existing technologies?
- What clinical outcomes data and patient reported measures data should be assessed to demonstrate substantial clinical improvement?

AAHKS believes that in collecting data to assess clinical improvement of outcomes, CMS should rely upon patient reported outcome tools that have already been developed with care by stakeholders. A forefront example is the Patient Reported Outcomes Summit for Total Joint Arthroplasty hosted in August 2015 by representatives from orthopaedic organizations (AAHKS, American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, and American Joint Replacement Registry), Centers for Medicare & Medicaid Services (CMS), Yale-New Haven Health Services Corporation Center for Outcomes Research and Evaluation (Yale/CORE), private payors and other stakeholders participated in the Summit. The Summit's goal was to obtain a consensus regarding the patient-reported outcomes (PRO) and risk variables suitable for total hip and knee arthroplasty performance measures.

The consensus of the Summit participants is that HOOS, JR. and KOOS, JR instruments should be used for the PRO measures specific to hip and knee arthroplasty. The HOOS, JR. and

KOOS, JR. surveys are short-forms developed using an evaluation of the data obtained from the Hospital for Special Surgery joint replacement registry. A cohort of patients undergoing unilateral THA and TKA who completed both pre-operative and 2 year post-operative HOOS and KOOS hip and knee specific PROMs were identified for the development and validation of these new joint replacement specific short-forms. All HOOS and KOOS items were first assessed for relevance (pre-arthroplasty patients were asked to rate the importance of each item), difficulty (based on pre-operative scores in patients undergoing joint arthroplasty), redundancy (5 Pain domain items on both the HOOS and KOOS overlap with Activities of Daily Living and/or Sports & Recreation items), and missingness (items in which more than 10% of respondents skipped the item were excluded).

The HOOS, JR. and KOOS, JR. surveys represent efficient and reliable short-form alternatives to the full HOOS and KOOS surveys. We believe the forms should be used for assessing the clinical improvement attributable to any proposed new technology impacting lower joint replacement.

III. Hospital Quality Programs

a. Hospital Readmissions Reduction Program - Section IV.G.3

In the proposed rule, CMS seeks to establish a sub-regulatory process to address any potential future non-substantive changes to the payment adjustment factor components in the Hospital Readmission Reduction ("HRR") Program. Additionally, CMS will adopt a measure removal policy that aligns with the removal policies previously adopted in other quality reporting and quality payment programs to ensure consistent and uniform quality measurement and the discarding of superfluous measures.

AAHKS appreciates the opportunity to comment on the development of such a sub-regulatory process. As CMS develops this new process, CMS should reach out to relevant specialty society groups to incorporate their expertise of how the HRR program can impact clinical actions by physicians. AAHKS is willing to cooperate with CMS to determine the most effective and less burdensome way to incorporate these insights into sub-regulatory policy development. Furthermore, AAHKS is supportive of efforts that will reduce unnecessary burdens on physicians that hinder physicians from focusing on delivering optimal care to their patients. Additionally, we support the consistency and streamlining of the measure removal policy because it improves stakeholders understanding of how the Hospital Quality Programs operate.

b. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures – Section IV.G.11

CMS provides hospitals with confidential hospital specific reports ("HSRs") containing stratified results in the hope that hospitals can use their results from the disparity methods to identify and develop strategies to reduce disparities in the quality of care for patients through targeted improvement efforts. In the FY 2019 IPPS final rule, the pneumonia readmission

measure was the only measure, using both disparity methods that was made available to hospitals during a month-long confidential reporting period in late summer of 2018. In the proposed rule, CMS proposes to add to the confidential HSR for claims-based measures and the confidential reporting of disparity results for 5 additional claims-based measures which includes the Elective Primary THA and/or TKA (NQF #1551) (THA/TKA Readmission measure).

AAHKS is appreciative of CMS' decision to assess disparities in the quality of care concerning elective primary THA and/or TKA as a performance measure. AAHKS believes that adequate risk adjustment is vital to appropriately incentivize providers. AAHKS anticipates that the information shared in the confidential HSR should help hospitals and CMS make appropriate decisions as it relates to the disparities and risk adjustment.

c. <u>Hospital Inpatient Quality Reporting Program – Section VIII.A.5</u>

In the proposed rule, CMS seeks to adopt 2 new opioid-related electronic clinical quality measures ("eCQMs") beginning with the CY 2021 reporting period/FY 2023 payment determination: (1) the Safe Use of Opioids – Concurrent Prescribing eCQM, which focuses on concurrent prescriptions of opioids and benzodiazepines at discharge, in an area of high-risk prescribing; and (2) the Hospital Harm Opioid-Related Adverse Events eCQM, which seeks to reduce adverse events associated with the administration of opioids in the hospital setting by assessing the administration of naloxone as an indicator of harm.

AAHKS is grateful for the Administration's consistent attention to the opioid addiction crisis. We appreciate that these measure focus specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and that may bring a patient into the emergency department. AAHKS encourages CMS to initially introduce both measures as *voluntary* for hospitals. As such, CMS will have the opportunity to gather evidence based information on these measures to determine if the measures inappropriately disincentivize the use of benzodiazepines before the measure is incorporated more widely or made mandatory. For example, while naloxone may be a surrogate indicator of opioid overdose, some have expressed a concern that labeling the use of naloxone as an indicator of harm may deter hospitals from accurately reporting or using this important treatment which helps patients recover from overdose. We believe that standard clinical procedures to reduce opioid-related adverse events are rapidly emerging and will place clinicians and hospitals in a better position to manage clinical behavior under this measure soon. As these developments emerge, we don't want to unintentionally detract from our concerted efforts to treat and respond to opioid addiction and overdoses.

We additionally wish to share that AAHKS members are working to reduce opioid use through effective care management. We believe there could be value in developing a MIPS quality measure for opioid-sparing approaches to managing pain. With the opioid crisis in mind, AAHKS intends to develop an opioid-sparing pain management quality measure applicable to TJA. Our overall goal is to develop or identify three process, three structural, and three outcomes-based measures for the physician to use at their discretion to satisfy various reporting

requirements. We request that these measures be reviewed and validated by appropriate entities within HHS after they are developed.

d. Remove Claims Based Hospital Wide All-Cause Readmission Measure with Hybrid Hospital Wide Measure - Section VII.A.5.b

In the proposed rule, CMS seeks to remove the Claims-Based Hospital-Wide All-Cause Readmission measure and replace with the proposed Hybrid Hospital-Wide All-Cause Readmission ("HWR") and require reporting beginning with the FY 2026 payment determination after 2 years of voluntary reporting of the Hybrid HWR measure. The HWR measures estimates the hospital-level, risk-standardized rate of unplanned, all-cause readmission after admission for any eligible condition within 30 days of hospital discharge. The Hybrid HWR measure uses a combination of administrative data and a set of core clinical data elements extracted from hospital EHRs for each hospitalized Medicare FFS beneficiary over the age of 65 years, which is why it is referred to as a "hybrid" measure.

AAHKS is committed to improving outcome reporting to increase accuracy and utility, such that what is collected is useful to patients and decision makers, but doing so with a reduction in the administrative burdens on physicians. As such we appreciate CMS' view point of implementing this measure on a voluntary basis before requiring reporting. During the voluntary time period, CMS should evaluate the effectiveness of the Hybrid HWR measure before requiring the measure on all hospitals.

IV. Medicare and Medicaid Proposed Promoting Interoperability Program - Section VIII.D.3

In the proposed rule, CMS will continue to use the Query of the Prescription Drug Monitoring Program ("PDMP") measure as optional and available for bonus points instead of being required as was finalized last year. Further, CMS will remove the Verify Opioid Treatment Agreement measure beginning in CY 2020 from the Promoting Interoperability Program because of received feedback from stakeholders that this measure presents significant implementation challenges, leads to an increase in burden, and does not further interoperability.

AAHKS is supportive of CMS actions towards PDMP measure and the Verify Opioid Treatment Agreement. AAHKS supports the use of quality measures to improve the quality of care for our patients. Thus, AAHKS is supportive of CMS decisions to continue to use PDMP as an optional measure that is available for bonus points instead of requiring the measure. Furthermore, AAHKS is appreciative of CMS listening to feedback from stakeholders that the Verify Opioid Treatment Agreement measure presents significant implementation challenges.

V. Proposed New Category: Social Determinants of Health (1) Proposed Social Determinants of Health Data Collection To Inform Measures and Other Purposes – Section VIII.C.7.f

We support CMS' proposal to add social determinants of health to the data collected under the Long-Term Care Hospital Quality Reporting Program. AAHKS eagerly awaits CMS action to further implement the provisions of the IMPACT Act to improve risk adjustment based on socioeconomic factors. Providers of all types have become more aware of the impact of socioeconomic factors on clinical outcomes. We are grateful for CMS' appropriate focus on these factors which can shed more light on our patient population, particularly those in post-acute care.

In the inpatient setting, 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. Health status, stage of disease, genetic factors, local demographic and socioeconomic factors significantly impact the quality and outcomes of surgeries performed. Without properly recording and measuring all of the factors that impact quality, providers may be subject to future payment adjustments that are reflective of the patient population and not reflective of the actual quality of care provided. We support collection of this data in any possible care settings to ensure that CMS policy making and any future risk adjustment proposals are informed by and responding to descriptive characteristics of the patient population.

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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,

Michael P. Bolognesi, MD
President

Michael J. Zarski, JD
Executive Director