AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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June 15, 2015

VIA ELECTRONIC FILING

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1632-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment System Proposed Rule for FY 2016 (CMS-1632-P)

Dear Mr. Slavitt:

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 proposed rule to make changes to the Medicare hospital inpatient prospective payment system (IPPS) policies and rates for fiscal year (FY) 2016 ("Proposed Rule").

AAHKS is the essential organization of more than 2500 hip and knee specialists, functioning to serve the needs of patients, care providers and policy makers regarding hip and knee health, including hip and knee replacement surgery. AAHKS's mission is to advance and improve hip and knee patient care through leadership in education, advocacy and research.

Our comments focus on the following provisions of the Proposed Rule:

- AAHKS recommends that CMS modify or establish a new MS-DRG for total hip arthroplasty (THA) cases involving patients with hip fracture.

- CMS is soliciting comments on potential changes to the Bundled Payments for Care Improvement Initiative (BPCI). AAHKS believes that it is critical for CMS to adopt modifications to recognize the different cost profile associated with hip fracture patients that are currently included in the Major Joint Replacement of the Lower Extremity Clinical Episode. As noted, AAHKS recommends that CMS establish a new MS-DRG THA cases involving patients with hip fractures, so that these cases in this new MS-DRG can be excluded from the BPCI. Alternatively, CMS could establish an exception policy for these cases as part of the BPCI. We offer several other suggestions for refinements to the BPCI to further program goals.

- With respect to implementation of Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA measure for use in the Hospital Inpatient Quality Reporting (IQR) Program, AAHKS supports inclusion of adjustments to include prior use of health services, admission source and administrative data on support systems as well as demographic data because these factors can be used as proxies for clinical complexity.

- We continue to have concerns about the validity and appropriateness of two measures previously-adopted for the Hospital IQR Program and the Hospital Value Based Payment program: Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty (NQF 1550); and 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty (NQF 1551).

- AAHKS agrees that CMS should continue to refine MS-DRG crosswalks to reflect the transition to ICD-10-CM.

- AAHKS shares CMS's concern regarding the data presented to date in support of the new technology add-on payment application for the VERASENSETM Knee Balancer System (VKS).

I. MS-DRG Assignment for Hip Fracture Cases

AAHKS requests that CMS modify or create a new MS-DRG for hip arthroplasty cases that involve patients with hip fractures represented by diagnosis codes 820.0-820.9. These cases are currently assigned to either:

- 469 Major joint replacement or reattachment of lower extremity w MCC, or
- 470 Major joint replacement or reattachment of lower extremity w/o MCC

These cases involve more fragile patients than the typical patient undergoing an elective hip or knee replacement, who are also assigned to these MS-DRGs. These patients may have significant comorbidities not present in elective THA cases.

CMS recognized the appropriateness of differentiating hip fracture patients needing non-elective THA from other hip replacement patients undergoing elective THA when it excluded such patients from the Hospital Readmissions Reduction Program THA/TKA Readmission Measure.

Based on our analysis, total hip replacement cases with fracture have higher standardized mean costs than patients with no fracture in both MS-DRGs 469 and 470 and longer lengths of stay. While the difference in inpatient costs may be moderate, an American Association of Medical Colleges (AAMC) analysis shared with CMS underscores how costly these cases are when considering a broader bundle of services including post-acute care.

This issue has tremendous implications for successful participation in the BPCI initiative because clinical episodes track to the MS-DRG assignment, and the Major Joint Replacement of the Lower Extremity Clinical Episode encompasses MS-DRGs 469 and 470. Because of the higher total care costs associated with hip fracture cases, BPCI participants are penalized for treating hip fracture patients. Without a remedy, potential BPCI participants will be discouraged from selecting to offer these MS-DRGs given the uncertain risk, or Medicare beneficiaries with hip fractures could encounter access issues. We believe that establishing a specific MS-DRG assignment for hip arthroplasty with hip fracture cases is the most straightforward solution. Alternatively, CMS could move all hip fracture cases to MS-DRG 469 to recognize the more significant adverse health profile of these cases.

We understand that CMS typically does not consider the broader costs of care associated with a hospitalization case as part of the IPPS. However, the Agency has challenged the health care industry to look beyond narrow payment silos in its call for accelerated adoption of alternative

payment models, such as bundled payment arrangements.[1] CMS must give providers the tools they need to effectively operate in this transformed payment systems – including the coding that is necessary for hospitals and their partners to accurately assess and address patient risk and costs.

II. Refinements to Bundled Payments for Care Improvement Initiative

CMS is soliciting comments on potential changes to the Bundled Payments for Care Improvement Initiative. AAHKS supports this initiative, and is proud of the major role that orthopaedic surgeons are playing.

Nevertheless, we believe that it is critical for CMS to adopt modifications to recognize the that hip fracture patients currently included in the Major Joint Replacement of the Lower Extremity Clinical Episode have a far different cost profile than elective hip replacement patients. They require significantly more post-operative costs, and they cannot be effectively managed pre-operatively as can elective joint replacement patients. The proportion of patients who may present with a hip fracture cannot be accurately predicted by a BPCI participant based on historical data, according to the experience of BPCI participants. Nevertheless, the implications for meeting financial targets are significant, given the dramatically higher post-operative costs and readmission risks associated with these patients.

As noted above, AAHKS recommends that CMS establish a new MS-DRG for THA cases involving patients with hip fractures (or otherwise reassign these cases), so that these cases can be excluded from the BPCI Major Joint Replacement of the Lower Extremity Clinical Episode. This is would be the most effective way for encouraging continued and new participation in the BPCI and any follow-on initiatives. Alternatively, these cases could automatically be assigned into MS-DRG 469, which would recognize higher overall complications/comorbidities and mitigate the risks for BPCI participants.

More generally, we urge CMS to continue to look for ways to enhance risk-sharing metrics, including socio-economic risk, within alternative payment methodologies like the BPCI, and otherwise address high-cost, low-volume cases. We also encourage CMS to continue to enhance flexibility in payment distribution arrangements, and to maximize physician input and flexibility in patient site of care for total joint procedures.

III. Hospital Inpatient Quality Reporting (IQR) Program Measures

A. Proposed New Measures: Elective THA/TKA Episode-of-Care Payment

CMS is proposing a series of updates to the measures used in the Hospital IQR Program for the FY 2018 payment determination and subsequent years, including the addition of the following THA/TKA payment measure:

> Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based)

CMS is adopting a claims-based measure Risk-Standardized Payment Associated with an Episode of Care for primary elective THA/TKA for use in the Hospital IQR Program. AAHKS appreciates CMS's move to limit this measure to "elective" procedures as recommended. Moving forward, we believe that this measure should be refined to adequately consider prior use

[1] http://www.hhs.gov/news/press/2015pres/01/20150126a.html.

of health services, admission source and administrative data on support systems as well as demographic data because these factors can be used as proxies for clinical complexity. The NQF agrees that socioeconomic risk adjustment should be considered. We understand the NQF is going to pilot a project involving socioeconomic risk adjustment and we strongly support this initiative. AAHKS feels strongly that factors related to SES do impact cost of care and therefore when the outcome measure is cost and not clinical outcome, these factors are clinically relevant and have a strong relationship with the cost outcome. AAHKS is concerned that excluding such factors could result in adverse patient selection for patients with complex needs.

The literature also supports concerns regarding the accuracy of administrative data sets used for measure development.[2] CMS cites as justification for this measure the fact that quality measures for THA/TKA, such as: (1) Hospital-level risk-standardized complication rate (RSCR) following elective primary THA/TKA (NQF #1550) and (2) Hospital-level risk-standardized readmission rate following elective primary THA and/or TKA (NQF #1551), are already adopted in the Hospital IQR Program. As discussed below, however, we continue to question the validity and appropriateness of these specific measures, and do not believe their availability enhances the utility of the data that would be collected under the new THA/TKA payment measure.

In addition, as CMS is also aware, this is a non-NQF-endorsed measure, which CMS intends to adopt under its exception authority. We do not believe that adoption of an episode of care payment measure – that does not seek to assess quality or clinical patient care factors – merits bypassing the usual, established NQF endorsement process.

Finally, *if* CMS proceeds in this area in the future, we agree with the Measure Application Partnership (MAP) recommendation of "harmonizing and determining the most parsimonious approach to measures the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies.'

B. Previously-Adopted Measures: NQF 1550 & 1551

We also continue to have concerns about the validity and appropriateness of two measures previously-adopted for the Hospital IQR Program (and the Hospital Value Based Payment program):

- Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty (NQF 1550).

  30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty (NQF 1551)

As noted, the literature questions the accuracy of administrative data sets underlying both of these measures.[3] The C-statistic for the risk adjustment model is only 0.64 for NQF 1550 and

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[2] See Losina, et al. Accuracy of Medicare claims data for rheumatologic diagnoses in total hip replacement recipients. J Clinical Epidemiology, 56, 2003 515-519; Cima, et al. How best to measure surgical quality? Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicators (AHRQ-PSI) and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) postoperative adverse events at a single institution. Surgery, 150(5), November 2011 943-949; Lawson, et al. A Comparison of Clinical Registry Versus Administrative Claims Data for Reporting of 30-Day Surgical Complications. Annals of Surgery, 256(6) December 2012 973-981.

[3] Ibid.

0.65[4] for NQF 1551. The validity of these measures was based on only one correlation of the acquired administrative data and a relatively small chart review. There was discordance of 97 of the 644 cases reviewed. That chart review did not report on the concordance of risk factors; it is not known from that chart review if they are adequately and accurately captured, especially given their capture over the year prior to the index procedure. The underpinning statistical analysis again references previous work concentrating on cardiovascular disease that may not be replicable in elective total joint arthroplasty.

Neither of these measures is adjusted for socio-demographic factors, which are known to have significant correlation with the variability of outcomes. The measures' authors dismiss the need for socioeconomic risk adjustment based on internally prepared work that used as a comparator the population of the hospital as a whole rather than the specific population requiring arthroplasty. Such socio-demographic risk adjustment refinements, which have been endorsed by the NQF, are critically necessary to prevent the creation of disincentives that could compromise patient access to key orthopedic procedures based on clinical and socioeconomic factors.

The underlying coding data for these measures also is known to underreport significant comorbidities, particularly obesity. Given the potential for such cases to skew Medicare metrics – particularly under the VBP -- the current composition of this measure could result in problems with access to total joint surgery for certain classes of patients, including but not limited to the obese, lupus patients, and transplant patients. In fact, in the original publically available version of these measures, the creators stated; "Given this is an elective procedure, there exists the potential that publicly reporting the measure could reduce access to care for certain patient groups who may be healthy enough to undergo the procedure but who carry a higher risk for complications." While the authors posited that they "do not anticipate this result," we are not aware of efforts to monitor whether such access impact has been occurring.

IV. Revision of Hip or Knee Replacement: Proposed Revision of ICD-10 Version 32 Logic

In the Proposed Rule, CMS addresses comments that the logic for ICD-10 MS-DRGs Version 32 does not work the same as it does for the ICD-9-CM based MS-DRGs Version 32 for joint revisions. In response to specific recommendations, CMS is proposing that cases that have a spacer removed prior to the insertion of a new joint prosthesis be assigned to ICD-10 MS-DRG 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively), as is the case with the ICD-9-CM MS-DRGs.

CMS is also proposing that joint revision cases that involve knee revisions with cemented and uncemented qualifiers be assigned to ICD-10 MS-DRGs 466, 467, and 468. Additionally, CMS examined joint revision combination codes that are not currently assigned to MS-DRGs 466, 467, and 468 in ICD-10 MS-DRGs Version 32. CMS identified additional combinations that

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[4] With the addition of five more non-administrative risk factors, the C-statistic goes up to 0.79%. David C. Ayers, MD, Thomas K. Fehring, MD, Susan M. Odum, PhD, and Patricia D. Franklin, MD, MBA, MPH. Using Joint Registry Data from FORCE-TJR to Improve the Accuracy of Risk-Adjustment Prediction Models for Thirty-Day Readmission After Total Hip Replacement and Total Knee Replacement. J Bone Joint Surg Am. 2015;97:668-71.

also should be included so that the joint revision ICD-10 MS-DRGs have the same logic as the ICD-9-CM MS-DRGs.

AAHKS supports these proposed assignment changes to ensure that the ICD-10 MS-DRGs capture the appropriate ICD-10 procedure codes. We encourage CMS to continue to review the ICD-10 MS-DRGs for the full range of orthopaedic procedure codes, both before and after the transition to ICD-10.

V. New Tech Add-On Payment Request: VERASENSE™ Knee Balancer System (VKS)

CMS discusses an application for new technology add-on payments (NTAP)for the VERASENSE™ Knee Balancer System (VKS), which is a sterile, single patient use device to intraoperatively provide a means to dynamically balance the patient's knee during total knee arthroplasty (TKA) surgery. CMS notes a number of concerns regarding the technology's eligibility for NTAP and solicits comments.

In general, AAHKS supports and encourages efforts develop technological advances that improve outcomes during orthopaedic surgery, particularly technologies that can facilitate transmittal of data to joint registries. We share CMS's concern, however, regarding the data presented to date supporting substantial clinical improvement, particularly with regard to the accuracy of this technology compared to manual adjustments made by the surgeon.

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AAHKS appreciates your consideration of our comments. You can reach me at mzarski@aahks.org, or you may contact Krista Stewart at krista@aahks.org.

Sincerely,

Michael J. Zarski, JD
Executive Director
AAHKS