AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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September 10, 2018

VIA E-MAIL FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for FY 2019; Quality Payment Program; and Medicaid Promoting Interoperability Program

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 Medicare physician fee schedule ("PFS") proposed rule for fiscal year 2019 (hereinafter referred to as "FY 2019 PFS proposed rule" or "proposed rule").

AAHKS is the foremost national specialty organization of more than 3,600 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 2019 PFS proposed rule:

I. CY 2019 Identification and Review of Potentially Misvalued Services – Section II.E.3

CMS established a process in 2012 for the public to nominate potentially misvalued codes by submitting the alleged misvalued code with supporting documentation each February. In response to the formal CMS process for the public to nominate potentially misvalued CPT codes, one party nominated 7 high volume codes for review, including 27447 (TKA) and 27130

(THA). The anonymous submitter stated that a number of reports by media and federal advisory agencies found "a systemic overvaluation of work RVUs." The submitter argues that overestimates are due to preservice and postservice time (including follow- up inpatient and outpatient visits that do not take place) and intraservice time, and that previous RUC reviews did not capture these overestimates.

We recommend that CMS decline to review 27447 and 27130 under its annual misvalued code process. The anonymous submitter has overstated the findings of GAO and MedPAC regarding time inflation of work RVUs. Most importantly, we note that the RUC and CMS already reviewed and validated the current RVU values most recently in 2013. CMS should not subject professions to code valuations and analysis so frequently. Doing so calls into question the validity of the RUC process in the first place. We suspect that the submitter did not offer documentation supporting why the alleged time inflation has manifested only since 2013. A misvalued code analysis of 27447 and 27130 now would amount to a significant expenditure of time and effort by numerous stakeholders to re-verify values established by CMS and the RUC only 5 years ago.

It is challenging for stakeholders to respond to such requests for comments on anonymous submissions, particularly for those stakeholders most impacted and most knowledgeable. We recommend that CMS revise its 2012 misvalued code nomination process to make public the identity of those nominating codes and to provide access to the documentation submitted by them that allegedly justifies a code review.

II. Lifting Restrictions Related to E/M Code Documentation – Sec. II.I.2.a

We applaud CMS for focusing on an important issue such as addressing provider administrative burden. We appreciate and support the work that CMS has performed through its "Patients Over Paperwork" initiative to identify a range of administrative requirements that are unrelated to patient care or program integrity. Chief among these is the administrative burden attributable to the current documentation guidelines for the new and established outpatient E/M service codes. CMS reports that E/M documentation burden in among the top 3 "red tape/ unnecessary burden" issues reported to it by providers in the last 18 months.

We further appreciate the work CMS has done to foster a dialogue on these proposals with professional societies. Our comments indicate our preferred method for E/M documentation and identify those elements of CMS's proposal which require additional time to refine and analyze.

We endorse the implementation of all of the following proposed changes to E/M documentation standards:

- If physicians choose to continue using the current guidelines, limit required documentation of the patient's history to the interval history since the previous visit (for established patients)
- Eliminate the requirement for physicians to re-document information that has already been documented in the patient's record by practice staff or by the patient
- Eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty
- Remove the need to justify providing a home visit instead of an office visit
- Eliminate the requirement that teaching physicians have to enter a separate note in the medical record.

CMS would allow physicians to determine the level of service based only on either (1) the time spent with a patient or (2) the level of medical decision-making, regardless of the extent of a physical exam or patient history. This expands the current rule, which allows coding based on time only when the majority of the physician's time involves counseling or coordination of care. The acceptable level of documentation would need to satisfy only the requirements for Level 2 (out of the five levels of possible visits), unless the physician based the claim on the time spent with the patient. The Level 2 documentation requirements can be satisfied by completing a problem-focused history, a limited examination, and routine medical decision-making. The same level of documentation would satisfy claims for any service coded as Level 2 through Level 5. The proposal to allow E/M code selection based on medical decision-making eliminates the requirement under current Medicare coding guidelines to document the patient's history and physical exam information.

We support the option to determine level of service based on the level of medical decision-making. The reduced emphasis on documentation of superfluous information is attractive to providers and also serves as an acknowledgement that the push toward EMRs has had unintended consequences. The option also resonates with the experience of many of our members who believe that the intensity of medical decision making is the factor that most distinguishes one patient visit from another.

By eliminating the need to document redundant information about current patients, such as history and examination, which already is in the patient's record from prior visits, physicians would be able to note that there has been no change in the relevant information from the earlier review of systems and history performed on a certain date. Practitioners would only need to note any changes since the prior visit. By reducing required documentation time in this way, physician focus can be better directed towards treating the diagnosis.

CMS should work closely with professional societies to develop guidance on new standards for documenting medical decision making. In the experience of our members, time alone is a poor measure medical decision making. Documentation standards should encompass the complexity of the diagnoses discussed, regardless of whether treatment is required,

complexity of the treatments discussed, and level of risk associated with the medical conditions and treatment options. The effort and scope of decision making involved in working up a primary THA in an otherwise healthy individual is different from that in a medically complex patient or one who has had previous surgeries.

CMS proposes a G-code to be available to certain specialties, but not orthopaedic surgery, to account for medically complex outliers. We question whether the additional documentation burden associated with a G-code will eliminate any value from reducing otherwise superfluous patient information in required E/M documentation requirements.

While we support the simplification of E/M documentation requirements and the use of a medical decision-making standard, we must also express a concern widespread amount our members that the simplification of E/M documentation now, will be used in the future as a justification to reduce reimbursement.

III. Minimizing Documentation Requirements by Simplifying Payment Amounts – Sec. II.I.2.c

Instead of the current progressive levels of reimbursement, CMS would establish a single reimbursement rate for each E & M code for new and established patients for all services coded as Level 2 through Level 5. CMS explained that it wants to set a single rate that aligns with the simplified documentation requirements. CMS explains that by collapsing the different payment levels into a single rate, the need to audit E/M services to determine the appropriate level of service and reimbursement would be eliminated. Under the current methodology, the most common reason for Medicare program audits of E/M coding has been a concern that physicians may be submitting claims with a higher code than is supported by the medical record, which results in overpayment demands or allegations that the physician has filed false claims.

We are aware that CMS is hearing a range of concerns from professional societies regarding this proposal to collapse reimbursement for Levels 2 through 5 in to one rate. Professionals are concerned that, based on the wide variety in practices and patient populations, some providers may see their total reimbursement increase, and others with a higher proportion of complex patients will see significant reductions. The single level payment amounts were determined by (1) weight averaging the work RVUs based on specialty utilization for levels 2-5 and (2) establishing a new E/M practice expense pool. As expected, this proposal resulted in an extremely negative impact on specialties that predominantly bill level 4 and 5 services and an extremely positive impact on specialties that bill mostly level 2 and 3 services. Concerns have been raised if this will lead to the scheduling of multiple visits for one complex patient. Some societies are calling for CMS to withdraw altogether its proposal to simply collapse payment amounts.

We agree that the potential impact on provider practices from the proposed payment changes may vary widely and therefore CMS should proceed extremely cautiously, allowing itself ample time to analyze all concerns and the possible secondary and tertiary impacts. AAHKS suggests that CMS consider collapsing E/M payment into a 3-tier, rather than 2-tier, system. One additional level of patient complexity may address the concerns of those practices that would stand to be significant losers under 2-tiers based on their patient mix.

IV. Recognizing the Resource Costs for Different Types of E/M Visits – Sec. II.I.2.d.i

CMS proposes to reduce payment by 50% for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier –25. Up to now, CMS has allowed standalone E/M visit codes to be billed on the same day as a procedure codes, only if the billing physician specifically indicates that the visit is separately identifiable from the procedure. Now, CMS expresses concern that when a standalone E/M visit occurs on the same day as a 0-day global procedure, there are significant overlapping resource costs that are not accounted for.

The proposed modifier 25 reimbursement reduction policy is unlike the precedent under the 1995 Multiple Procedure Payment Reduction because professional societies and CMS have worked for several years to remove any overlap in the physician work and practice expense for procedures commonly performed during the same encounter as an office visit. Therefore, the proposal would result in an excessive, unjustified reduction in reimbursement because the overlap in physician work and practice expense has already been accounted for in the valuation of these services.

V. Proposed New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years, Selection of MIPS Quality Measures for Individual MIPS Eligible Clinicians and Groups Under the Annual List of Quality Measures Available for MIPS Assessment – Sec. III.H.1.h.2.b

CMS proposes a new measure NQF #2653 at A.3 (Any Change in Functional Status Following Total Knee Replacement). AAHKS supports patient reported outcome (PRO) measures to assess functional status following TKA surgery, but we are concerned with the inclusion of only one PRO based on the Oxford Knee Score. AAHKS supports the use of KOOS Jr and other potential measuring surveys to be available for use. KOOS Jr. and HOOS Jr. were selected as the preferred measurement instruments by the national orthopaedic specialty societies due to the ease of the tools.

We refer CMS to our August 31, 2015 on the Patient Reported Outcomes Summit for Total Joint Arthroplasty convened by AAHKS, CMS, and others. See attached.

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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,

Craig J. Della Valle, MD
President

Michael J. Zarski, JD
Executive Director

AAHKS AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS
AAOS American Association of Orthopaedic Surgeons
AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

Orthopaedic Headquarters | 9400 West Higgins Road | Rosemont, Illinois | 60018-4976

THIS IS A JOINT COMMUNICATION FROM THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS, THE AMERICAN JOINT REPLACEMENT REGISTRY, THE HIP SOCIETY, THE KNEE SOCIETY, AND THE AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

September 8, 2015

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5516-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

Dear Administrator Slavitt:

The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to provide comments on the Comprehensive Care for Joint Replacement Payment Model.

On August 31, 2015, AAHKS convened a Patient Reported Outcomes Summit for Total Joint Arthroplasty in Baltimore, Maryland. 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.

After review of the proposed rule and the discussion of the Summit participants, the comments and rationale below reflect the consensus recommendations of the represented orthopaedic organizations:

1. We propose that CMS require the use of only one general heath questionnaire for the proposed patient reported outcome measure. We recommend that CMS allow hospitals to use either the VR-12 **or** the PROMIS-10 – Global instrument.

2. We also recommend that a disease-specific instrument be used as part of the proposed patient reported outcome measure. The HOOS and KOOS instruments, as outlined in the CMS proposed rule, would be a substantial burden to patients, orthopaedic surgeons and their staff because of the overall length of the instrument. We recommend that the KOOS, JR. instrument be used for total knee arthroplasty (TKA) patients and the HOOS, JR. instrument be used for total hip arthroplasty (THA) patients. We will describe this instrument in detail below.

3. We recommend a staged approach of the candidate risk variables as we suggest that some variables are more clinically relevant and are easier to collect at the present time. We have outlined below our priority list of risk variables, our future desired list of risk variables and risk variables that we recommend should not be included. It is essential that risk adjusted data be collected or access to care for certain patients will be limited in the future.

<u>Patient Reported Outcome (PRO) Measure</u>

The Summit participants discussed both the PROMIS Global instrument and the VR-12 instrument. Both instruments evaluate physical and emotional health. In addition, both instruments have a minimal number of questions (10 or 14) which is important to the orthopaedic community. The group acknowledges that the PROMIS tool is a new instrument and may not have the legacy data that VR-12 has available. However, the National Institutes of Health (NIH) has made a significant investment in the PROMIS surveys and many facilities are starting to collect the PROMIS Global data. It would be redundant for CMS to require both general health PRO instruments. It is recommended that either the PROMIS Global or the VR-12 instruments be used to collect general health information.

The meeting participants also had a lengthy discussion regarding the appropriate disease-specific patient survey instruments for lower extremity joint replacement. In reality, the collection of post-operative patient surveys will be the responsibility of the orthopaedic surgeon and his/her staff. Orthopaedic surgeons are concerned about the number of questions the patients will be required to answer in order to complete the instrument. The HOOS and KOOS instruments, as outlined in the CMS proposed rule, would be a substantial burden to patients, orthopaedic surgeons and their staff. Many surgeons do not collect PRO measure (PROM) data at all at this time and it is unreasonable to expect them to begin collecting such an extensive data set at this

time. The consensus of the Summit participants is that HOOS, JR. and KOOS, JR instruments should be used for the PRO measures.

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). Remaining items were assessed using a Rasch modeling approach to reduce the full HOOS and KOOS to a unidimensional survey of hip or knee "health" comprised of 12 items most relevant and difficult for pre-operative patients undergoing hip and knee arthroplasty. A final Rasch model was performed that reduced the 12 hip items to 6 items (HOOS, JR.) and the 12 knee items to 7 items (KOOS, JR).

In addition to the HSS validation cohort the FORCE-TJR registry was also used to validate these new PROMs. Internal consistency was high for both HOOS, JR. (Cronbach's alpha 0.84) and KOOS, JR. (0.85). The new surveys were highly responsive to joint replacement (standardized response means of 1.7 to 2.4) and there was near-perfect correlation with both the pain and activities of daily living/function domains of the full HOOS/KOOS and the WOMAC (Spearman's correlations 0.80-0.94).

The validation of these 2 new short-form joint-specific surveys was presented at the 2015 AAOS Annual Meeting (HOOS, JR.) and the 2015 International Society of Arthroplasty Registries Annual Meeting (KOOS, JR.). Both publications are currently under review at *Clinical Orthopaedics and Related Research*.

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 the patient reported outcome measures. We believe that this type of data collection is an evolutionary process and the orthopaedic community is prepared to collect more extensive patient data if deemed necessary in the future.

Risk Variables

The Summit participants reviewed the list of candidate risk variables identified in the proposed rule. There was consensus on a priority list of risk variables, a future desired list of risk variables and variables that should not be included. Some of the variables will require additional data collection.

Priority List of Risk Variables

- Body Mass Index – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).
- Race/Ethnicity – Race/ethnicity should be a patient-reported variable and may be recorded in the EHR.
- Smoking Status – Smoking status may be reported through administrative data but additional information may be provided from the EHR.
- Age – Age is reported in administrative data.
- Sex- Sex is reported in administrative data.
- Back Pain – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.[1,2]
- Pain in Non-operative Lower Extremity Joint – Pain in a non-operative lower extremity joint would be patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.[1,2]
- Health Risk Status – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions. In order to identify the patient's comorbid conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.
- Depression/Mental Health Status - The PROMIS Global or VR-12 will collect this variable, as well as the administrative data.
- Chronic Narcotic or Pre-operative Narcotic Use – This variable affects patient outcomes and requires additional consideration. The information should be available in the EHR.
- Socioeconomic Status – This variable affects patient outcomes and requires additional consideration. Further evaluation is required regarding how the data could be collected.

Future Desired List of Risk Variables

- Literacy
- Marital Status
- Live-in Home Support

Risk Variables to Not Include

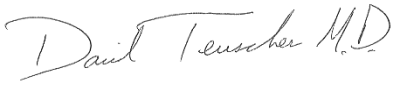
- ASA score
- ROM
- Mode of PROM collection

We appreciate this opportunity to provide these comments to CMS on behalf of the participating organizations in the Patient Reported Outcomes Summit for Total Joint Arthroplasty. For

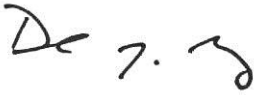
questions or to discuss these comments further, please contact me at (323) 442-8117 or jrlieber@usc.edu.

Sincerely,

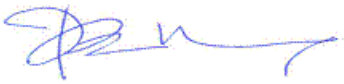
Jay R. Lieberman, MD
President, American Association of Hip and Knee Surgeons



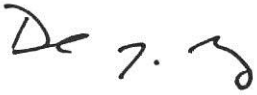
David Teuscher, MD
President, American Association of Orthopaedic Surgeons



Daniel J. Berry, MD
President, The Hip Society



Thomas P. Vail, MD
President, The Knee Society



Daniel J. Berry, MD
Chair, American Joint Replacement Registry Board of Directors

Attachments:

HOOS, JR.

KOOS, JR.

HOOS, JR. HIP SURVEY

INSTRUCTIONS: This survey asks for your view about your hip. This information will help us keep track of how you feel about your hip and how well you are able to do your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Pain
What amount of hip pain have you experienced the **last week** during the following activities?

1. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

2. Walking on an uneven surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living
The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

5. Lying in bed (turning over, maintaining hip position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

6. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

KOOS, JR. KNEE SURVEY

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to do your usual activities. Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Stiffness

The following question concerns the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

1. How severe is your knee stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

What amount of knee pain have you experienced the **last week** during the following activities?

2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

5. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

6. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

7. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

[1]Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. *Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: the need for a musculoskeletal comorbidity index.* J Bone Joint Surg Am. 2013 Oct 16;95(20):1833-7. doi: 10.2106/JBJS.L.01007.

[2] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. *Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: the need for a musculoskeletal comorbidity index.* J Bone Joint Surg Am. 2013 Oct 16;95(20):1833-7. doi: 10.2106/JBJS.L.01007.