AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

September 8, 2015

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

RE:	**[CMS-5516-P] Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule**

Dear Acting Administrator Slavitt:

On behalf of the members of the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule "Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule [CMS-5516-P]." The proposed rule presents a payment model for comprehensive care for joint replacement which looks to create a single payment across a 90-day episode of care for lower extremity joint replacement (LEJR).

The AAOS strongly supports efforts by CMS to make appropriately structured alternative payment models available to physicians and other providers, including bundled and episode payment models. We have supported previous efforts by CMS through the Center for Medicare and Medicaid Innovation (CMMI) in the area of musculoskeletal care where current initiatives under the Bundled Payments for Care Initiative (BPCI) address episode-based payment approaches to delivering care to beneficiaries with multiple types of clinical episodes, including musculoskeletal conditions. The Acute Care Episode (ACE) demonstration project also involved musculoskeletal episodes, specifically total knee and total hip replacements. AAOS has supported these initiatives and believes that properly constructed episode of care models and bundled payments have the potential to generate savings for Medicare while having positive effects on patient care. In fact, many AAOS members have been leaders in developing, implementing, and evaluating episode of care payments under the ACE Demonstration Project and the BPCI.

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430

However, these past and current efforts share some features that differ from the current proposal. Namely, these programs were/are voluntary pilot projects and not mandatory as is the current proposal for the proposed locations. In addition, these programs had both physician buy-in and leadership.

The AAOS also notes that while episode-of-care models have shown potential to reduce costs, this potential has not been definitively shown in rigorously tested and validated studies comparing patient outcomes and cost efficiencies under episode-of-care models versus other approaches. Given this lack of rigorous evidence, the AAOS urges extreme caution in undertaking significant changes and alternatively advocates for taking a more systematic, incremental, approach to alternative payment models that maximizes voluntary participation and testing of multiple models to allow for innovation in delivery and payment.

The AAOS has multiple concerns about the proposed rule and we urge CMS to strongly consider significant changes to the program as currently proposed, as we are very concerned about serious unintended consequences for Medicare beneficiaries and physicians. To address our concerns, we have developed detailed recommendations – described in subsequent sections of this letter – to improve the payment model design as currently indicated in the proposed rule:

Our primary concerns with the proposal include:

- Mandatory participation of ALL hospitals located in any of the 75 Metropolitan Statistical Areas (MSAs), pre-determined by CMS which, in effect, mandates participation in the program of all surgeons, providers, facilities, and other parties that provide care surrounding lower-extremity joint replacement (LEJR) procedures and do so in any one of the 75 MSAs;
- The immediate and full implementation of the proposal beginning January 1, 2016;
- A lack of designated physician leadership for episodes-of-care;
- The lack of infrastructure support from CMS necessary to properly administer and undertake the proposed changes;
- The absence of risk-adjustment in the program;
- Inappropriate conditions included in the proposed episodes-of-care;
- Inappropriate proposed patient reported outcome tools and risk variables;
- The retrospective episode payment methodology; and
- Insufficient patient protections and incentives.

We have additional concerns which are detailed in our response letter. We thank the Agency for their attention to these concerns and strongly urge CMS to continue to engage with key stakeholders, particularly professional associations representing musculoskeletal surgeons.

Mandatory Participation

The AAOS strongly supports *voluntary* bundled and episode-of-care pilot projects. We believe the proposal to mandate participation in the model for all surgical episodes in each of the 75 assigned Metropolitan Statistical Area (MSA) is flawed and should be replaced by a voluntary approach for providers and facilities. In effect, any provider practicing in a designated MSA will be mandated to participate in a program that will force many surgeons and facilities who lack familiarity, experience, or proper infrastructure to support care redesign efforts into a bundled payment system.

The proposal to include all episodes and all providers and facilities will severely disadvantage those surgeons, non-physician providers, and facilities that either do not have the proper infrastructure to optimize patient care under episodes-of-care payment models and/or lack adequate patient volumes to create sufficient economies of scale. A voluntary program that allows surgeons, facilities, and non-surgical providers to tailor their episode-of-care models to their particular patient population would lead to far better patient care as well as more accurate and efficient payments.

We strongly urge CMS to revise the mandatory nature of the proposal and instead create incentives for interested participants that would reward innovation and high quality patient care. We believe the program should be voluntary and on a nationwide basis for any set of surgeons, facilities, and providers who seek to collaborate in innovative ways to bring higher quality, improved care coordination, and to lower costs for musculoskeletal care and who have the infrastructure necessary to carry out an episode of care approach to payment and delivery. Specifically, we recommend that CMS require that any participating entity have verifiable interoperability, infrastructure, and agreements between all necessary entities.

Immediate and Full Program Implementation

CMS proposes to initiate the program on January 1, 2016 for all 75 MSAs. Consequently, any changes made by CMS to the proposal would be immediately implemented with no transition time between the deadline for comments on the final rule and implementation. As a result, all Medicare participants and patients in these MSAs would have a maximum of only 60 days to make this significant transition. The AAOS believes this period is far too brief to properly implement and transition into this model, which is compounded by the mandatory participation requirement.

The AAOS recommends the agency postpone the mandatory implementation feature of the program until at least 85% of providers have attained meaningful use or another metric of infrastructure readiness. By basing full implementation on infrastructure readiness, CMS will have time to monitor progress and determine what is and is not working within the voluntary BPCI program. This postponement will also provide surgeons, facilities, and other providers

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430

time beyond that proposed by CMS, which is unrealistic and far too brief. Without taking steps to extend full program implementation, many participants will face significant startup and integration problems, which would make it more difficult to achieve significant improvements in patient quality of care as well as in costs.

Lack of Physician Leadership

CMS proposes to make acute care hospitals the responsible party for managing the episode-of care. The AAOS strongly believes this aspect of the rule requires change to designate that physicians – specifically orthopaedic surgeons – be the primary responsible party, or at least be equivalent in status to the acute care hospital. It is the orthopaedic surgeon who is involved in the patient's care throughout the episode of care, from the pre-operative workup, to the surgery itself, to inpatient post-operative care, to the post-operative care provided in rehabilitation facilities, at home, and in the physician's office. No other party in the total episode of care is as involved in all aspects of the patient's care, and no other party is as important to the final patient outcome as the operating surgeon. Therefore, it is logical that all episodes treated under the program be overseen by orthopaedic surgeons and not an acute care hospital facility. In addition, we believe an orthopaedic surgeon bears the most risk throughout the episode of care and ultimately has the most insight into the best pathways to improving patient care quality and efficiency and should therefore lead the bundled payment initiative.

We recommend revising the proposal to afford the operating surgeons and physician groups the ability to be in charge of the bundle, or explicitly create a mechanism allowing the surgeon or group to participate with a facility or third party to manage the episode, collect payments, recoup overpayments, and return "shared savings" across the spectrum of care. Having the hospital in charge of the bundle gives the hospital inappropriate leverage over surgeons and other participants and could allow some hospitals to exclude surgeons and other care providers if those parties don't wish to meet the hospital's terms. In contrast to the current version of the proposed rule, which allows the hospital to choose to enter arrangements with other providers and facilities to share potential savings and risk, our recommendation to explicitly place a surgeon as head, or co-head, of episodes would significantly reduce barriers to achieving high quality patient outcomes.

In addition, AAOS recommends that hospitals be explicitly restricted, in rulemaking, from putting in place provider restrictions, or from engaging in provider credentialing that limits the ability of physicians to perform total joint replacement procedures, even if those physicians are unwilling to sign an agreement or contract with the hospital. This proposed provision is essential to ensure Medicare beneficiaries have the ability to choose any surgeon or provider for their services.

Lack of Infrastructure Support

The AAOS has significant concerns, as noted above, that full scale implementation within 60 days of final rule publication is unrealistic and likely to cause disruption in normal patient access to care patterns, potentially causing financial harm to physicians and facilities. A more gradual transition from a voluntary to mandatory program would be more realistic and provide ample time for assessing the amount of coordination available and/or necessary, developing clinical pathways, and executing legal agreements between leaders of physician groups and managers of facilities, all factors essential to a successful program.

The timing of the proposal, as noted above, is further exacerbated by the concurrent mandatory adoption of ICD-10, which will likely demand physician and facility focus over the next several quarters. Infrastructural support is incomplete, meaningful use attestation is at 18 and 48% for physicians and hospitals, respectively[1], and EHR vendors have plagued practices with a lack of interoperability and errors in the 2014 PQRS program. Until these glitches are addressed and highly reliable systems are in place, no further mandates should be initiated. Providers continue to require better analytics and support, tools for best practices and ease of reporting, validated patient risk assessment measures, and data sharing with physicians through required transparency by hospitals and payers. While CMS has made progress in some of these areas, it still needs to further strengthen the support and infrastructure for physicians and facilities before adding programs that require significant additional infrastructure investment and development.

Lack of Risk Adjustment

CMS proposes to base adjustments for quality on current Inpatient Prospective Payment System (IPPS) quality measures and future outcome measures for DRGS 469 and 470. However, these measures are not risk-stratified nor risk-adjusted. Analyses of spending during joint replacement episodes have shown there is tremendous variation in post-acute care costs for patients receiving what is ostensibly the same basic procedure. It is clear that some of this variation reflects legitimate differences in patient needs and not "unnecessary" care. Patients with chronic illnesses and/or greater functional or cognitive limitations will generally require rehabilitation for longer periods of time in more expensive settings than "healthier" patients with fewer limitations. The program should be designed to enable teams of providers to redesign care in ways that reduce or eliminate avoidable spending while ensuring that patients with greater needs have access to increased levels of care. Moreover, the program should be designed so that it does not financially penalize providers who perform joint replacement surgeries on patients with greater needs and thereby either discourage providers from performing procedures on such patients or encourage providers to stint on needed care.

Therefore, the proposed episode payment amounts must be risk-adjusted or risk-stratified based on patient characteristics that would be expected to require significantly different types or

[1] Centers for Disease Control and Prevention, http://www.cdc.gov/nchs/data/databriefs/db143.htm. Last accessed 9/4/15.

amounts of services during the complete episode. One of the most important factors determining post-acute care spending is patient functional status, so differentiating patients and associated payments by functional status is essential.

Relying on the current DRG categories to differentiate patient risk, as proposed by CMS, is not adequate for stratifying patients for an entire episode of care. The MS-DRG system is specifically designed to adjust for differences in inpatient hospital spending, not spending in the post-acute care setting. In addition, recent research has shown that functional status can be as or more important than comorbidities in determining total amounts of Medicare spending as well as post-acute care needs following surgery. The two MS-DRGs used to differentiate hospital payments do not incorporate measures of functional status and therefore cannot be used to adjust for longer episodes.

The 90-day episode of care spending measure developed for CMS by the Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation recognizes the need for risk-adjustment beyond DRGs in order to compare episode spending across providers. However, the risk-adjustment methodology included in this approach includes only measures of patient comorbidities, not functional status. The CMS payment systems for post-acute care services delivered by skilled nursing facilities, inpatient rehabilitation facilities, and home health agencies all adjust payment amounts not only by patient health problems but also based on functional measures. Thus, it is illogical to define an episode payment that includes post-acute care services but does not differentiate among patients based on their functional status.

The proposed regulation acknowledges the need for risk-adjustment beyond DRGs but concludes that because there is no standard for the best approach to risk-adjustment, no risk-adjustment will be performed. We believe this is flawed logic and could have significant unintended consequences, particularly since the failure to incorporate any risk-adjustment structure could make it difficult for Medicare patients with higher levels of need to obtain joint replacement surgery under an episode payment model.

As noted above, we recommend a delay in implementing the program, and we recommend that CMS utilize this delay as a developmental phase in which an appropriate risk-adjustment model can be tested and adjusted over time. In addition, CMS can use this time to work with relevant stakeholders to develop the optimal risk-adjustment system for the program that will truly reflect the level of care necessary on a patient level.

Inappropriate Proposed Patient Reported Outcomes and Risk Variables

The AAOS also suggests that CMS amend and clarify the sections of the proposal that deal with patient-reported outcomes and risk variables. The AAOS participated in a one-day summit convened by the American Association of Hip and Knee Surgeons (AAHKS) and attended by entities involved in developing and utilizing hip and knee arthroplasty patient-reported outcomes

and risk variables. The participants in that summit have several specific comments related to the Comprehensive Care for Joint Replacement proposal that are captured in a joint letter from said participants. Please see Attachment A for specific comments.

Inappropriate Conditions Included in the Program

CMS proposes to include all lower extremity joint arthroplasty procedures within DRGs 469 and 470. These include elective hip and knee arthroplasty procedures (total or partial) caused by osteoarthritis or similar conditions, but also include ankle arthroplasty, as well as arthroplasty for fracture repair such as hip hemiarthroplasty or total hip arthroplasty for hip fracture. The AAOS strongly recommends that CMS revise the conditions included in the program and specifically exclude all arthroplasty procedures for fracture conditions as well as any conditions for ankle replacement. This program revision would not be complicated as CMS is able to track patients by ICD-10 diagnosis code and could easily structure the program to exclude fracture or acute diagnoses or any diagnosis codes below the knee.

We believe the program should be limited to truly elective hip and knee arthroplasty procedures and to include other conditions only increases the burden on systems and exacerbates the likelihood of adverse selection. The inclusion of higher cost and more variable conditions like hip fracture also increases the possibility of significant variation both longitudinally and geographically.

CMS acknowledges the difficulty of including hip fractures in particular in the proposed rule where they discuss that Hip Fracture has been excluded from BPCI bundled projects due to the rationale noted above. Accordingly, it is less complicated and appropriate to exclude it as part of the program entirely.

We request that CMS remove hip fracture surgery from the list of conditions included in the program as well as ankle replacement and that in all future rulemaking, CMS make explicit that both conditions are excluded entirely. It is essential that CMS specifically include this language in rulemaking and in a direct fashion so as to provide clarity to all participants.

Retrospective Payment Approach

CMS proposes to pay all surgeons, facilities, other physicians and non-physicians, and other entities across the episode of care in a normal fashion, and then retrospectively apply a "total target expenditure" and seek to reconcile actual expenditures against the target expenditures.

The AAOS is supportive of the retrospective approach as proposed, as the prospective bundles under BPCI (Model II) for total joint arthroplasty faced significant logistical difficulties administering the prospective payments. Retrospective episode-of-care payments are akin

to "virtual" bundles, and help minimize many of the legal hurdles inherent in contracting across a diverse spectrum of care providers.

We believe CMS is correct to apply the experiences under BPCI Model II for total joint arthroplasty, whereby all four of the sites that started under Model II ultimately either dropped out of the BPCI initiative, or converted to the retrospective bundled model (Model IV). This demonstrates why it is critical the program be executed voluntarily and based on rigorous analysis of the results for patients, providers, and payers. As drafted, the proposal lacks the evidenced-based approach necessary to truly leverage best practices in managing payments and delivery across the healthcare system.

Lack of Patient Protections and Incentives

CMS' current proposal does not address the role of the patient in the process, and does not propose methods to empower patients to seek out the highest quality joint care. We believe this is a missed opportunity and that CMS should revise the proposal to add incentives and pathways for patients to be more actively involved in the care process. There are numerous ways CMS could provide incentives to patients, from reducing or waiving deductibles to providing benefits for accelerated recovery and participation in therapy.

AAOS believes the best way to provide real choice to patients is to give them the benefit of meaningful choices regarding where and with whom they receive joint care. In light of this important consideration, a voluntary approach would provide patients with much stronger signals about which facilities and physicians are seeking new models of care and delivery and further reinforces the need for the program to be voluntary rather than mandatory.

CMS also could take advantage of the opportunity to test different models and approaches to delivery system reform inherent in the proposal to also offer physicians and patients additional options for payment, specifically the option of balance billing and physician/provider contracting. The AAOS supports efforts to extend direct contracting arrangements and balance billing arrangements and urges CMS to consider the proposed program as an opportunity to test the ability of such arrangements to drive patients to the highest quality providers of musculoskeletal care.

Additional Comments

In addition to the issues previously addressed, the AAOS also wishes to recommend the following amendments to the CMS proposal:

- AAOS recommends that CMS include a waiver for the three-night-stay minimum required for DRG 469 and 470 in order for the patient to be discharged to a rehabilitation facility. In the proposed rule, CMS indicated they were considering this as a possible

additional action under the proposed program and the AAOS supports this action. We believe a waiver of the three-night minimum would allow participating entities to reduce inpatient costs and risks associated with longer inpatient stays for patients who can be safely discharged earlier than 72 hours post-operatively;

- AAOS recommends patients not be home-bound in order to qualify for home health care under the program. This would allow patients to receive home healthcare services if the care team determines this is the best place for post-operative care, even if the patient isn't technically defined as home-bound;

- AAOS recommends that providers across the episode of care potentially be paid for telehealth or home-based services delivered to patients under the program;

- AAOS recommends that surgeons, physicians, and other non-physician providers be permitted to provide patients under the program in-kind services or to reimburse patients for costs of activities or services associated with the episode;

- AAOS recommends that CMS eliminate all limits on gainsharing among providers to give providers the flexibility to allocate the CMS payment among the members of program teams in ways that maximize incentives for each specific team, as opposed to a one-size-fits-all model. Prohibiting compensation to any provider designed to reward them for increases in the number of joint replacement procedures they perform must continue, but there would be no ban on payments that help control costs within a CMS episode;

- AAOS recommends that current BPCI participants be allowed to participate in the CMS program should they choose to do so. The proposal calls for BPCI initiatives for DRG 469 or 470 to be exempted from the program. We believe it is better for those BPCI arrangements to opt to either transition into the proposed program or remain as part of BPCI. We don't believe it makes sense to have BPCI initiatives that are largely similar to the joint replacement initiative not be part of the program and it would be more streamlined to offer physicians and facilities the option to join the joint replacement program or remain under BPCI. This would also be consistent with our recommendation to make it a strictly voluntary program;

- AAOS recommends that participation in the program be considered demonstration of alternative payment model (APM) participation for the purposes of complying with the statutory requirements under the 2015 Medicare Access and CHIP Reauthorization Act (MACRA). CMS has indicated their statutory authority to propose this program comes from the 2010 Patient Protection and Affordable Care Act (PPACA) that authorized CMMI. Given this citation, we believe it is inconsistent to not identify the proposed program as an APM and thus program participants as APM adopters; and

- AAOS recommends that CMS make participation in a data registry a requirement for all participants in the program. We recommend CMS designate the American Joint Replacement Registry (AJRR) as one of the primary collectors of data for the proposed program. The AJRR is the only registry collecting joint replacement data for the entire country and therefore is an essential partner for CMS in developing and tracking outcomes in joint replacement.

****

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on this important and groundbreaking proposed rule. The AAOS looks forward to working closely with CMS on further refining the program and to improving the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact AAOS' Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,

David Teuscher MD

David D. Teuscher, MD
President, American Association of Orthopaedic Surgeons

cc: Karen Hackett, CAE, AAOS Chief Executive Officer
William Shaffer, MD, AAOS Medical Director
Graham Newsome, AAOS Director of the Office of Government Relations

Additional signatories to AAOS' comments on CMS' Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Proposed Rule [CMS-5516-P] include the following organizations:

J. Robert Gladden Orthopaedic Society
American Association for Hand Surgery
Orthopaedic Trauma Association
Arthroscopy Association of North America
American Orthopaedic Society for Sports Medicine
American Orthopaedic Foot and Ankle Society
American Society for Surgery of the Hand

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430

Attachment A

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.

Patient Reported Outcome (PRO) Measure

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

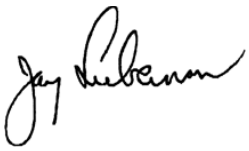
Risk Variables to Not Include

- ASA score
- ROM
- Mode of PROM collection

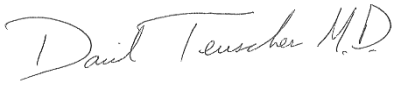
We appreciate this opportunity to provide these comments to CMS on behalf of the participating organizations in the Patient Reported Outcomes Summit for Total Joint Arthroplasty. For

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

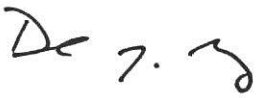
Sincerely,



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

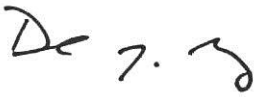


David Teuscher, MD
President, American Association of Orthopaedic Surgeons



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
☐	☐	☐	☐	☐

Attachment A

[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.