AAHKS
AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

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March 30, 2015

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Contract Number HHSM-500-2013-13011I/HHSM-500-T0001 - Electronic Clinical Quality Measures Development and Maintenance for Eligible Professionals -- •Functional Status Assessment and Improvement for Patients who Received Total Hip and Total Knee Replacements

Dear Measure Developer:

The American Association of Hip and Knee Surgeons (AAHKS) welcomes the opportunity to comment on the development of a measure for risk adjusted improvement in functional status after total hip and knee replacement. In its current form, the measure is an early start towards a possible ECQM and we fully support this concept. However, our organization does have several issues of concern.

We support the development of measures to assess patient outcomes, but we believe that it is essential for the data to be meaningful and collected in a cost-effective manner. Although the measure is intended to meet the requirements for reporting incentives, our concern is that it inevitably will be used for public reporting and payment adjustments similar to the evolution of the hospital based total joint measures. Therefore, the administration of these patient reported outcomes tools across broad populations will need to meet strict standards regarding usability, reliability, validity, and reportability given the absence of such an application to date.

Another major concern is related to the specific measures that are being selected. At the present time most joint replacement surgeons are not collecting any data in a prospective fashion so it may not be feasible from either a patient flow or economic standpoint for surgeons to be expected to collect data at this time using multiple measures. We believe that a joint specific tool and a general health measure (i.e. the NIH PROMIS or VR-12) should be considered. We also have concerns that requiring the complete HOOS and KOOS to be used will be too onerous for both patients and surgeons. Our organization is presently collaborating with the Yale New Haven Health System Center for Outcome Research and Evaluation to identify updated and more user friendly measures to be used to evaluate outcomes.

Another critical issue is that the language of the measure expects the surgeon to pick only one of the potentially three-per-case outcomes tools. This could create six different reporting scenarios with differing expected scales and proportions of change over time. It is advised that the developers require both a joint specific tool as well as a general health measure, and make this uniform so that comparisons can be made more readily. This might require deciding on either PROMIS or VR-12 as the exclusive general health measure. Of course, in the future other measures could be added as needed but we believe that the initial goal should be to obtain the essential information in an efficient manner for the patient and surgeon.

We concur with the intent of assessing functional improvement through patient reported outcomes. We were encouraged to see a broader set of risk factors including orthopedic specific and socio-demographic parameters in Table 1. We agree that it is difficult to establish a fair risk adjustment model through administrative data sets only, as pertinent orthopedic risk variables currently are not collected. We are encouraged that many of the orthopedic variables that we consider critically important have been included to support the development of a fair risk adjustment model. The collection of these variables is hampered by the lack of diagnostic codes for many of the variables that orthopaedic surgeons consider important. Therefore, either new diagnostic codes need to be developed or an adequate reporting interface needs to be constructed for the individual surgeon. Ideally all this data could be collected by a National Outcomes Registry. However, this is currently not available, nor is there any consideration for the reporting burden on the individual physician. Until this process is clarified, AAHKS is asking our members to collect 11 orthopedic-relevant variables that currently have ICD-9 codes so that these variables can be tested to determine if they improve the current risk model. We believe that this data could eventually be collected in a registry. In addition, neurologic, hepatic, renal and cardiac disease are left unmentioned, yet all might significantly affect the delta of function between before and after arthroplasty.

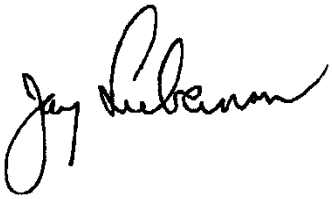
Additionally the mechanism of capturing the variations in socio-demographic status is not described. It is suggested that race and average census income by home zip codes might be automated retrievals. Obesity also needs to be better defined as a continuous variable of body mass index or stated as ranges of the same. There is also no mention of volume criteria. The developers will need to address sample size in order to avoid harm through potentially wider standards of deviation in the practices of surgeons with smaller volumes. There has been resistance to breaking out individual surgeon data from large registries for similar reasons.

One other issue that is not addressed in the proposal is how to evaluate the patient who has two or three joint replacements in one year. If attempting to capture the improvement from the first knee replacement at eleven months, are the outcomes of the surgeon to be jeopardized because the patient is then only several weeks status post the contralateral total knee? Is it appropriate to capture the pre-procedure functional status of the second procedure only one or two months after the first? Perhaps it would be most reasonable when faced with multiple total joint replacements within a year to utilize for both procedures the pre-op functional status before the initial procedure and utilize as the outcome for both procedures the final status up to a year after the second procedure. This would measure how well the surgeon is caring for the patient as a whole, not the joints as somehow being isolated separate parts.

Finally, this measure development started as a parallel process to a similar measure being developed for hospital reporting. The development and timing of implementation of these measures need to be harmonized in order to facilitate accurate data collection and to reduce costs.

Again, we appreciate the opportunity to comment on this proposed measure. We support the concept of developing a measure to evaluate total joint arthroplasty patients in an outpatient setting. To our knowledge, neither AAHKS nor the American Academy of Orthopaedic Surgeons participated in this process with Mathematica. Given that total hip and knee replacement combined represent the single greatest procedural cost to CMS, we would encourage CMS and Mathematica to consider making further refinement of this measure with assistance from orthopaedic surgeons.

Sincerely,



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