November 21, 2014

Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE)

Via e-mail to: paymentmeasure@yale.edu

RE: Hospital-Level Risk-Standardized Payment Measure for a 90-day Episode of Care for Elective THA/TKA

Dear Administrator,

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the measure currently in development by the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE): Hospital-Level Risk-Standardized Payment Measure for a 90-day Episode of Care for Elective THA/TKA.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies, including orthopedic implantable device companies that supply the vast majority of hip and knee implants used worldwide.

AdvaMed supports the need to develop relevant inpatient quality measures related to patients undergoing these replacement procedures and understands the potential problems and complex issues involved in data collection and analysis. Risk-standardizing payment measures for joint replacement offers an important opportunity to improve the efficiency of health care delivery to these patients. Modern joint replacement prostheses contribute to the solution and as such their continued innovation should be supported, especially since joint replacement surgery has demonstrated quality of life gains in all evaluated ages of Medicare patients.1 These implants also lead to lower costs.

While we support this effort, we have several concerns with the proposed measure and several statements in the Summary of Technical Expert Panel (TEP) Evaluation of Measures. Our comments will address these issues below.

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A. **Episode Window**

AdvaMed applauds the effort by CMS to evaluate expenditures across an episode of care for joint replacement surgery. It is important to develop a quality measure that tracks the many components of Medicare spending across a continuum of care, rather than strictly focusing on implants as the driver of cost.

Still, a measure that captures only a 90-day episode of care should not be viewed by CMS as the ultimate determinant of “high-value care” because implant performance characteristics drive many of the clinical and societal benefits of joint replacement surgery. A critical measure of joint replacement quality is often considered to be a low revision rate that is measured over a substantial time period and the most common measurement target applied is ten (10) years. This is because many global markets, among them the United States, demand that clinical outcomes from joint replacement surgery are measured over a multi-year period in relation to the joint replacement prosthetic device itself. While we realize this time frame is unrealistic in developing and testing quality measures, we urge CMS to consider how to best track long-term clinical outcomes of THA/TKA.

AdvaMed believes a longer time frame of 180 days would strengthen this episode-of-care measure, and we would urge CMS to consider additional quality measures that would still be practicable, such as one or possibly two-year revision rates for THA/TKA.

In summary, joint replacement surgery delivers patient benefits that vastly exceed the episode of care considered under this measure. Focusing on just short-term process improvement can yield short-term outcome gains, but overemphasizing these metrics could stifle innovation that can enhance the long-term value patients and society derive from joint replacement. While we strongly support efforts to identify variation, encourage efficient post-acute care and bolster quality, this measure would be improved by increasing the episode of care to 180 days, and additional measures should be considered for revision rates, which are currently the accepted standard for determining the value of joint prostheses innovations.

B. **Risk Stratification**

AdvaMed has serious concerns regarding various facets of the risk stratification method that is proposed in the measure. CMS is proposing to stratify risk based on Medicare administrative claims information. Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider as many relevant variables as possible in developing this model.

Notably absent from the discussion on determination of risk stratification factors are individual patient measures in the orthopedic context such as functional/range of motion status, presence or absence of specific orthopedic pre-operative deformities, and other indicators and/or disorders involving variability of bone quality, including diseases/disorders affecting bone
growth/functions and medications affecting mineral absorption and bone quality. AdvaMed believes that these patient–specific factors should be included in the risk stratification for the measure, as they vary from patient-to-patient and can play a very significant role in the post-surgical complication rate. This is highlighted by the concern of one individual on the TEP that using CMS CCs to group ICD-9 codes would mask the effect of individual ICD-9 codes on the outcome. Additionally, CMS might consider the significance and development of ICD-9 (or ICD-10) codes in the future that could capture these same patient-specific orthopedic variations and which could be included in the risk adjustment model.

One of the most serious and potentially preventable complications that may occur after total joint arthroplasty (TJA) is periprosthetic joint infection (PJI). PJI is reported to occur in 1-4% and 0.59-2% of patients who have undergone total knee and hip arthroplasty, respectively.² ³ The cost of treating an individual PJI is reported to be in excess of $50,000 and if the offending organism is antibiotic resistant, i.e. Methicillin-resistant Staphylococcus aureus (MRSA), the cost can surpass $100,000.⁴ ⁵ Therefore, in a measure of this type, it is important to correctly recognize and capture all cases of infectious complications. We are concerned that these infections might not adequately be captured and identified on the complications list under the broad “other infections” field as being directly attributable to the procedure.

AdvaMed also supports the actions of the TEP members to risk adjust for type of procedure (hip versus knee replacement), as well as index bilateral and staged procedures. Additionally, AdvaMed shares concerns with several of the TEP members that the payment outcome was not fully accounting for the impact of patients who do not have CPT codes associated with their index hospitalization. AdvaMed supports CORE’s decision to conduct additional analyses of those patients that were found not to have a CPT code associated with their surgery.

C. Joint Registry Data

AdvaMed recommends that CMS support hospital participation in the American Joint Replacement Registry (AJRR) in order to further advance the development of quality measures related to THA/TKA. Supporting the AJRR registry as an alternative for meeting quality reporting requirements would provide an invaluable resource to improve patient outcomes. The joint registry will allow the tracking of implant performance from the time of the index procedure and the identification of any complications or issues that may be related to the care of the patient with that device.

Finally, it is noteworthy that the Technical Expert Panel (TEP) does not contain representation from the major joint manufacturing industry. We believe that having an industry member serve on the TEP would enhance the overall measure development process by bringing a body of essential unique perspectives and providing invaluable input and feedback.

AdvaMed appreciates the opportunity to provide these comments. We would be pleased to answer any questions regarding these comments. Please contact me if we can be of further assistance.

Sincerely,

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