

Project Title:

Development of a Measure of Payment for Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

Dates:

- ◆ The Call for Public Comment ran from Tuesday, October 21, 2014 through Friday, November 21, 2014.
- ◆ The Public Comment Summary was posted on January 15, 2015.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with Yale New Haven Health Systems Corporation – Center for Outcomes Research and Evaluation (CORE) to develop a hospital-level measure of risk-standardized, 90-day episode-of-care payments for elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA). The contract name is Development, Reevaluation, and Implementation of Hospital Outcome/Efficiency Measures. The contract number is HHSM-500-2013-13018I-T001 Modification 000002. As part of its measure development process, CMS requested interested parties submit comments on the THA/TKA payment measure.

Project Objectives:

- ◆ To develop a hospital-level measure of risk-standardized, 90-day episode-of-care payments for elective primary THA/TKA.

Information about the Comments Received:

Public comments were solicited by notifying stakeholders and the general public through:

- ◆ Email notification to relevant stakeholders and stakeholder organizations, including:
 - Medical associations and societies: American Association of Hip and Knee Surgeons, American Association of Orthopaedic Surgeons, The Hip Society, The Knee Society, American Hospital Association, American Society of Anesthesiologists, Association of Rehabilitation Nurses
 - Orthopedic registries: The Center for Hip & Knee Replacement Joint Registry- Columbia Orthopaedics, The Center for Research and Education on Therapeutic Registry- Weill Cornell Medical College, Function and Outcomes Research and Comparative Effectiveness in Total Joint Replacement Registry, Global Orthopedic Registry- UMASS, International Consortium of Orthopedic Registries, Kaiser Permanente Total Joint Replacement Registry, Michigan Arthroplasty Registry Collaborative Quality Initiative, Virginia Joint Registry, California Joint Replacement Registry
 - Consumer associations: Consumer Union, Childbirth Connection, Community Alliances
- ◆ Email notification to working group members
- ◆ Email notification to Technical Expert Panel members
- ◆ Posting on CMS Public Comment webpage
- ◆ We received eight comment letters in total, from the American Association of Orthopaedic Surgeons, the Association of Rehabilitation Nurses, the American Society of

Anesthesiologists, the American Health Care Association, the American Physical Therapy Association, the American Association of Hip and Knee Surgeons, Premier Healthcare Alliance, and the Advanced Medical Technology Association. Within these eight comment letters there were 49 comments on the following 14 topics: stakeholder involvement; implementation/use; harmonization; administrative data; measure setting; measure methodology; measure timeframe; risk adjustment; payment outcome; measure reliability and validity; unintended consequences; cost differences between THA and TKA; general support; and miscellaneous/other.

Stakeholder Comments – General and Measure-Specific:

Summary of General Comments

1. Stakeholder Involvement

- One commenter applauded CMS for the involvement of clinical experts on the Technical Expert Panel. The commenter believes that orthopedic surgeons are well suited to inform the development of a measure of the quality and cost of care of musculoskeletal diseases, especially in informing the risk-adjustment process. The commenter expressed hope that this high degree of orthopedic surgeon involvement continues in future measure development initiatives.

Response: CMS appreciates the support of this aspect of the measure development.

- One commenter stated that the current TEP panel underrepresents the perspectives of post-acute providers. The commenter recommended the addition of post-acute providers to the TEP.

Response: The current TEP is comprised of a variety of stakeholders and experts representing a broad array of post-acute providers including rehabilitation nurses, physician assistants, and physical therapists. As a reference, the TEP roster is located on pages 78 and 79 of the Draft Measure Methodology Report.

- One commenter noted that the TEP did not contain representation from the major joint manufacturing industry. The commenter believes 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.

Response: The current TEP represents a group of stakeholders and experts including industry experts such as device manufacturers. As a reference, the TEP roster is located on pages 78 and 79 of the Draft Measure Methodology Report.

2. Implementation/Use

- One commenter expressed hope that this measure be implemented in a judicious and meaningful way.

Response: CMS appreciates this concern.

- One commenter expressed concern that the measure does not provide a full and accurate measure of costs and value associated with THA and TKA as currently constituted, and that it should not be implemented without refinement.

Response: CMS appreciates this concern and has in place a process to refine measures after development.

- One commenter suggested that if the measure is to be used in a formal payment program (e.g., a prospective bundled payment program), the model would need to be re-estimated and recalibrated with untransformed data to obtain useful payment rates (to account for current Medicare rate elements such as wage index differences, teaching status, etc).

Response: Currently, CMS intends to use this measure only for public reporting.

- One commenter expressed concern about the end-usability of the cost data for physicians. The commenter recommended splitting out the data by areas of variability for physician's costs such as: patient placement in skilled nursing facilities, the number of home- or office-based therapy visits, patient readmissions, and the use of inpatient consultations.

Response: CMS appreciates this concern and the suggestion to separate data by post-acute care settings. CMS will consider including this information in future Hospital Specific-Reports so that providers will be able to identify areas of variability.

3. Harmonization

- One commenter supported the alignment of the THA/TKA payment measure with existing THA/TKA quality outcomes measures. The commenter noted that as THA and TKA procedures continue to increase and patients are discharged across the post-acute care continuum, there will be a greater need to standardize quality reporting mechanisms and payment methodology to enhance the coordination of care.

Response: CMS appreciates the support for this aspect of the measure. CMS developed the THA/TKA payment measure in alignment with the NQF-endorsed THA/TKA complication measure.

4. General Support

- Five commenters expressed strong support of the development of this measure and CMS's efforts to improve efficiency and incentivize high quality care for THA/TKA patients across a continuum of care.

Response: CMS appreciates the support of this aspect of the measure development.

Summary of Measure-Specific Comments

5. Administrative Data

- One commenter expressed concern that the administrative claims data used to develop the measure do not include pertinent clinical variables.

Response: CMS appreciates this comment and wants to reassure the public that the administrative data contain many comorbidities and procedures that are clinically relevant to the THA/TKA payment measure. Furthermore, we acknowledge the importance of including clinical variables; however, clinical variables are not available at this time for inclusion in a nationally reported measure such as this. Finally, we believe that using ICD-10 codes may positively impact the ability to evaluate this issue and future measure reevaluation work will consider the impact of ICD-10 codes on the developed measure.

6. Measure Setting

- One commenter stated that a payment measure should not be utilized within the current fee-for-service payment system and should instead be suited for accountable care organizations or bundled payment programs. The commenter urged CMS to utilize these payment measures in population health-type models and to test the validity of the measures.

Response: CMS appreciates this concern and suggestion; currently, CMS only intends to use this measure for public reporting in the Inpatient Quality Reporting Program.

7. Measure Methodology

- One commenter expressed support of the measure's aim to capture the differences in the payments for patients undergoing THA/TKA.

Response: CMS appreciates the support of this aspect of the measure.

- One commenter supported the inclusion and exclusion criteria used.

Response: CMS appreciates the support of this aspect of the measure.

8. Measure Timeframe

- One commenter supported the measure's aim to use a 90-day measurement timeframe. However, the commenter suggested that in addition to encouraging hospitals and providers to optimize post-discharge care, the measure should also serve to encourage patient pre-habilitation care prior to surgery. Pre-habilitation has the ability to reduce costs by reducing the rate of complications by effectively addressing patient conditions prior to the surgery.

Response: CMS appreciates the support of this aspect of the measure. Although we agree with that pre-habilitation is an important clinical consideration, deciding on an adequate pre-operative period or relevant claims to include was outside of the scope of the measure development work and would not align with CMS's THA/TKA complication measure.

- One commenter also noted that the 90-day measurement period has the ability to effectively capture the cost associated with patient readmissions, which are not currently considered in the 30-day post discharge period included in the Medicare Spending per Beneficiary (MSPB) measure.

Response: CMS appreciates the support of this aspect of the measure.

- One commenter agreed with the TEP's viewpoint that a 30-day measurement timeframe would be insufficient. The commenter cautioned that excluding costs associated with related post-acute services beyond 30-days would artificially deflate predicted expenditures associated with such patients, and could result in adverse patient selection for patients with complex needs if adopted.

Response: CMS appreciates the support of this aspect of the measure.

- One commenter stated that a 90-day episode-of-care length is too long, and that the overarching goal of driving quality improvement within the hospitals will be better served utilizing a 30-day episode length. The commenter noted that in order to align with other inpatient quality measures, CMS should consider utilizing a 30-day timeframe.

Response: CMS appreciates this concern. CMS chose a 90-day measurement timeframe because THA/TKA procedures require ongoing post-discharge care. The 90-day episode window may incentivize hospitals to optimize post-discharge care. In addition, mechanical complications, wound, or joint infections typically present after 30 days, and TEP members felt that including these complications was preferred. Finally, we chose the 90-day timeframe to align with CMS's THA/TKA complication measure which captures complications up to 90 days post discharge.

- One commenter proposed that a multi-year measure would best track long-term clinical outcomes in relation to the joint replacement itself. The commenter recognized that this may not be feasible and suggested that a 180-day measurement timeframe would strengthen the current episode-of-care measure.

Response: CMS appreciates this suggestion. While a longer time period such as 180 days and beyond was considered, 90 days was selected because of feasibility issues surrounding data processing and to align with CMS's THA/TKA complication measure.

9. Risk Adjustment

9.1 Support of Risk-Adjustment Approach

- Two commenters agreed with the risk-standardization and risk-adjustment methodology to account for differences in payments across hospitals, remove variation in payments due to payment adjustments that are not directly related to clinical care, adjust for hospital case mix, and assess relative performance of hospitals.

Response: CMS appreciates the support of this aspect of the measure.

- One commenter supported the risk adjustment for the location of procedure (hip versus knee replacement) as well as the type of procedure (bilateral and staged procedures).

Response: CMS appreciates the support of this aspect of the measure.

9.2 Orthopedic Risk-Adjustment Factors

- Two commenters noted the absence of orthopedic risk-adjustment factors that are not reflected in the billing codes. One commenter requested that patient-specific factors be included in the risk stratification 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. The commenter believes that these patient-specific factors vary from patient-to-patient and can play a very significant role in the post-surgical complication rate.

Response: CMS appreciates this concern; however, the measure data source is administrative claims for Medicare fee-for-service beneficiaries. As such, more nuanced clinical variables are not available at this time for inclusion in a nationally reported measure such as this. In addition, using ICD-10 codes may positively impact the ability to evaluate patient-specific factors and future measure reevaluation work will consider the impact of ICD-10 codes on the developed measure.

9.3 Patient-Reported Data

- One commenter suggested augmenting the risk-adjustment model by including clinician- and patient-reported data to assure sensitive comparisons across clinical and cost metrics.

Response: CMS appreciates this suggestion; however, clinician- and patient-reported outcomes data are not readily available in administrative claims for inclusion in a nationally reported measure such as this.

9.4 Periprosthetic Joint Infection

- One commenter expressed concern that the most serious and potentially preventable complication, periprosthetic joint infection, might not adequately be captured and identified on the complications list under the broad “other infections” field as being directly attributable to the procedure.

Response: CMS appreciates this concern. To clarify, periprosthetic joint infections would be identified during readmissions within 90 days of discharge using the ICD-9 codes located in Table 1 of the Draft Measure Methodology Report. These ICD-9 codes align with CMS’s THA/TKA complication measure identification of wound and joint infections. Furthermore, the payments for readmissions related to wound and joint infections would be included in the risk-standardized payment amount.

9.5 Socioeconomic or Sociodemographic Risk Adjustment

- One commenter encouraged the measure developer to work with NQF in determining whether this measure could benefit from the new sociodemographic risk-adjustment methodology being explored by NQF.

Response: CMS appreciates this suggestion. The measure developer will continue to closely follow the current NQF recommendations regarding risk adjustment for socioeconomic or sociodemographic factors.

- Three commenters noted that the risk-adjustment model fails to include sociodemographic factors that have a substantial impact on the cost of care. One commenter stated that there is a substantial body of evidence that sociodemographic factors – such as patients’ income, housing, education, and race – influence a variety of patient outcomes and some processes that are out of a provider’s control.

Response: CMS appreciates this comment. The measure developer understands that socioeconomic factors may influence a variety of patient outcomes; however, consistent with NQF guidance at the time of measure development, the measure does not include risk-adjustment variables for socioeconomic status (SES). Furthermore, we acknowledge that the association of SES with payment outcomes is complex. Variation in payments associated with SES, race, or ethnicity may indicate differences in the care provided to vulnerable populations, and adjusting for these factors would obscure these disparities. However, CMS will continue to closely follow NQF recommendations regarding risk adjustment for socioeconomic or sociodemographic factors and address this issue going forward as needed.

9.6 Admission Source

- Two commenters suggested incorporating an adjustment for admission source. One commenter noted that the source of admission provides a strong indication of the acuity of the beneficiary, as well as the potential for comorbidities, which may affect the outcome.

Response: The measure does not adjust for the patient’s admission source because this factor is associated with the structure of the healthcare system and the different care patterns the measure seeks to illuminate. The measure does include risk variables that assess patient frailty, such as protein-calorie malnutrition, metastatic cancer, dementia, and age, and thus likely does capture the clinical risk factors most concerning to clinicians. Furthermore, the THA/TKA payment measure includes only primary, elective procedures.

- One commenter suggested including administrative data on support systems.

Response: CMS appreciates this suggestion. The THA/TKA payment measure utilizes administrative claims data that do not include information on support systems (such as living with a spouse).

10. Payment Outcome

- One commenter recommended clarification and/or revisions to the methodology of determining outpatient therapy expenditures as a component within the payment measure outcome. The commenter specifically was concerned that outpatient therapy services, such as occupational therapists in private practice, speech-language pathologist in private practice, and physician and non-physicians practitioners in office-based settings, are properly identified and calculated.

Response: The THA/TKA payment measure includes all administrative claims filed on behalf of a Medicare beneficiary including outpatient therapy services provided in facility and non-facility settings. Thus, the measure does include all physician, qualified clinician, and non-physician practitioner payments as well as facility payments. We will clarify this in the Measure Methodology Report.

- One commenter requested clarification regarding the proper attribution of all outpatient therapy services at the non-facility rate.

Response: We are aware that outpatient therapy services are reimbursed via the physician fee schedule, using non-facility practice expense Relative Value Units (RVUs). We calculate payments for all outpatient therapy accordingly. The payment diagrams for Physician Services, Comprehensive Outpatient Rehabilitation Facilities, and Outpatient Rehabilitation Facilities can be referenced in Appendix C of the Draft Measure Methodology Report.

11. Measure Reliability and Validity

- One commenter expressed concern that measures of payment have not been tested, and is concerned about the reliability and validity of the measure.

Response: We developed the measure in accordance with NQF criteria for evaluation. In order to meet the criterion of scientific acceptability, a measure must demonstrate adequate reliability and validity. We demonstrated measure reliability using the Intraclass Correlation Coefficient (ICC). The ICC score can be used to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance. We calculated risk-standardized payments (RSPs) using split-sample combined 2010-2012 data. Thus, we obtained two RSPs for each hospital, using an entirely distinct set of patients from the same time period. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure assesses an attribute of the hospital, not of the patients. The agreement between the two independent assessments of each hospital was 0.955, which, according to the conventional interpretation, is “almost perfect”.

We demonstrated validity of the measure by systematic assessment of measure face validity by a Technical Expert Panel (TEP of national experts and stakeholder organizations. Among the 13 TEP members who responded to our face validity question, 2 somewhat agreed, 6 moderately agreed, and 5 strongly agreed that this measure, as specified, will provide a valid assessment of the relative costs of a 90-day hip/knee arthroplasty episode of care for Medicare patients admitted to a given hospital. These strategies and results meet current NQF criteria for scientific acceptability.

12. Unintended Consequences

- One commenter stated that potential unintended consequences on access to care for the most vulnerable of our society may occur if the measure does not adequately account for the complete patient profile, including comorbidities, socioeconomic status, and outcomes.

Response: CMS appreciates this concern and will continue to monitor unintended consequences of the measure.

- One commenter expressed concern that the measure potentially incentivizes undesired provider behaviors in the traditional FFS model but not in ACOs or hospitals in bundled payment programs. The commenter noted that the measure may cause some providers to be more cognizant of the cost of care, and to select the lowest cost approach, as opposed to one that leads to an optimal functional outcome.

Response: CMS appreciates this concern as it illuminates the importance of considering payment and quality together. To that end, the THA/TKA payment measure was developed to align with the NQF-endorsed, publicly reported THA/TKA complication measure. By examining a hospital's payment along with its complication rate, consumers can gain insight into the value of the care that hospital provides.

- One commenter noted that hospitals may become disincentivized to perform necessary elective THA/TKA procedures on patients with cost-predictive factors that have not been adequately risk adjusted.

Response: CMS appreciates this concern. The THA/TKA payment measure includes risk-adjustment variables that are relevant to the measure outcome including patient comorbidities, such as clinical markers of frailty, as well as the procedure location and type. CMS will continue to monitor unintended consequences of the measure.

13. Cost differences between THA and TKA

- One commenter cautioned against conflating THA and TKA payments too closely. Specifically, TKA usually results in significantly more intense acute postoperative pain that limits recovery more than in those patients having THA. TKA and THA are typically treated with different anesthesia techniques. These costs need to be included in payment methodologies for these procedures.

Response: CMS appreciates this concern and suggestion to include the differences in anesthesia payments for regional pain control in the total episode-of-care payment. All anesthesia payments during the index hospitalization are currently captured in the measure calculation. The THA/TKA payment measure also risk adjusts for procedure location (THA versus TKA).

14. Miscellaneous/Other

- One commenter supported the aim to promote shared accountability across multiple specialties and practitioners, including surgeons, anesthesiologists, and other members of a patient's care team who work together to improve surgical outcomes.

Response: CMS appreciates the support of this aspect of the measure development.

- One commenter suggested the measure developer learn more about the development of the Perioperative Surgical Home. The Perioperative Care Clinic concept expands the role of a pre-op clinic into the post-acute, post-discharge setting.

Response: CMS appreciates this suggestion.

- One commenter suggested that CMS consider the significance and development of ICD-9 or ICD-10 codes in the future that could capture patient-specific orthopedic variations. The commenter states that such codes could be added to the risk-adjustment model.

Response: CMS appreciates this suggestion and future work will consider the impact of the ICD-10 codes on the developed measure.

- One commenter supported the measure developer's decision to conduct additional analyses of those patients that were found not to have a CPT code associated with their surgery.

Response: CMS appreciates the support of this aspect of the measure development.

- One commenter urged CMS to consider additional THA/TKA quality measures for revision rates with an episode window of one or multiple years. The commenter noted that a critical measure of joint replacement quality is often considered to be a low revision rate that is measured over a substantial time period.

Response: CMS appreciates this suggestion. CMS's complication measure captures revision procedures associated with wound and joint infections within 90 days of the admission date. Furthermore, capturing revision procedures beyond a 90 day timeframe would become increasingly challenging to attribute to the hospital where the index THA or TKA was performed.

- One commenter recommended 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. The commenter suggested that supporting the AJRR registry as an alternative for meeting quality reporting requirements would provide an invaluable resource to improve patient outcomes.

Response: CMS appreciates this suggestion.

Proposed Action(s):

The measure developer reviewed all comments carefully and discussed the raised issues. The measure developer did not make changes to any of the current measure specifications based on the public comments received. The measure developer will include greater details in future Hospital-Specific Reports based upon the public's comments.

Preliminary Recommendations:

The measure developer is not recommending any changes to the measure specifications in response to public comments.

Overall Analysis of the Comments and Recommendations to CMS:

CMS appreciates the public's comments. At this time, CMS is not recommending any changes to the measure but will take the comments into consideration during the annual measure reevaluation process and other future work.

Hospital-Level, Risk-Standardized Payment Associated with THA/ TKA Verbatim Public Comment Form

Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-mail Address	Type of Organization	Recommendations/ Actions Taken
11/01/14	THA/ TKA Payment	<p>The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the development of measures of payment for total hip and knee arthroplasty (THA and TKA, respectively). The AAOS is committed to high-quality and efficient care for patients with musculoskeletal conditions and is supportive of the Centers for Medicare and Medicaid Services (CMS) efforts to ensure that this care is sustainable for Medicare beneficiaries in the future.</p> <p>TECHNICAL EXPERT PANEL FOR MEASURE DEVELOPMENT The AAOS is pleased to see such a high degree of physician involvement in the Technical Expert Panel (TEP) convened for the development of the proposed cost measure and the similar efforts in outcome measure development for THA and TKA. We believe that orthopaedic surgeons are best suited to be the leaders of a patient care team that provides high-quality care and efficient use of resources. We also believe this leadership in patient care suits orthopaedic surgeons well and makes them particularly central to informing the risk-adjustment process in measures of outcomes and costs. Orthopaedic surgeon involvement in developing measures of the quality and cost of care for musculoskeletal diseases is critical to ensuring that the most positive change can be affected for patients.</p> <p>MEASURE METHODOLOGY While we are supportive of the effort to develop this payment measure, we have a specific concern about the end-usability of the cost data being collected for adjustment in this measure, particularly for physicians. There appear to be four primary areas of variability for physician costs: patient placement in a skilled nursing facility, the number of home- or office-based therapy visits, patient readmissions, and the use of inpatient consultants. We hope that cost data collected on these factors would be split out for physicians to see and take</p>	<p>Anthony Wheeler, PhD Senior Manager, Health Policy</p> <p>American Academy of Orthopaedic Surgeons/ American Association of Orthopaedic Surgeons</p>	wheeler@aaos.org	Professional Society	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

Date Posted	Measure Set or Measure	Comments	Name, Credentials, and Organization of Commenter	E-mail Address	Type of Organization	Recommendations/ Actions Taken
		<p>action on. Without the ability to see these data, we fear physicians may not have the granularity necessary to make change.</p> <p>IMPLEMENTATION OF THE MEASURE OF PAYMENT The AAOS is broadly supportive of CMS's efforts to improve patient care and efficiency through quality measurement and payment evaluation. We hope that this measure is implemented in a judicious and meaningful way. We believe that the present effort of convening a TEP to inform the development of a thoughtfully risk-adjusted payment measure alleviates some of our concerns. However, our reservations surrounding the aforementioned methodology issues remain and we hope that consideration of these issues continues through the final stages of this measure's development and ultimately on its way to implementation.</p> <p>FUTURE MEASURE DEVELOPMENT The AAOS is pleased to see such a high degree of involvement of orthopaedic surgeons in the development of the present measure of payment for THA and TKA. We hope that orthopaedic surgeons will be afforded the same opportunity to participate in the process via a TEP or similar group in future measure development initiatives with CMS and the Yale-CORE group. We also hope that the methodological concerns expressed in our letter are taken into consideration as this measures' development continues. We look forward to continuing to be a positive contributor to the measure development process. Thank you for considering our comments on these important matters.</p>				
11/05/14	THA/TKA Payment	<p>On behalf of the Association of Rehabilitation Nurses (ARN) – representing 5,700 rehabilitation nurses that work to enhance the quality of life for those affected by physical disability and/or chronic illness, I am pleased to submit this letter of support for the Hospital-Level Measure of Risk-Adjusted Episode-of-Care Payments for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).</p> <p>ARN supports efforts to ensure patients with physical disabilities and chronic illnesses have access to comprehensive, quality care in the most appropriate care setting. ARN's mission is to promote and advance professional</p>	<p>Jordan Wildermuth, MSW Manager, Health Policy & Advocacy Association of Rehabilitation Nurses</p>	<p>jwildermuth@connect2amc.com</p>	Professional Society	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>rehabilitation nursing practice through education, advocacy, collaboration, and research to enhance the quality of life for those affected by disability and chronic illness. Rehabilitation nurses take a holistic approach to meet patients' nursing and medical, vocational, educational, environmental, and spiritual needs. Rehabilitation nurses begin to work with individuals and their families soon after the onset of a disabling injury or chronic illness and work to promote the independence and/or maximum level of function of patients. Rehabilitation nurses also provide continuous patient and caregiver education to ensure patients' success when they return home, to work, or school.</p> <p>We agree that the growth in Medicare spending highlights the need to incentivize high-value care while maintaining that all patients receive the right care at the right time in the right setting. ARN supports the methodology used to develop this measure and believes that it successfully captures the aims of the measure, including capturing the differences in the payments for patients undergoing THA/TKA, accounting for differences in the payments across hospitals, removing variation in payments due to payment adjustments that are not directly related to clinical care, adjusting for hospital case mix, assessing relative performance of hospitals, and aligning with THA/TKA quality outcome measures. As THA and TKA procedures continue to increase and patients are discharged across the post-acute care continuum, there will be a great need to standardize quality reporting mechanisms and payment methodology to enhance the coordination of care.</p> <p>ARN is pleased to support this measure and we stand ready to work with other stakeholders. We are eager to partner with you to ensure that patients continue to have access to quality rehabilitation care in the setting most appropriate for their needs</p>				
11/20/14	THA/TKA Payment	On behalf of the American Society of Anesthesiologists® (ASA), I am pleased to comment on the development of the Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Payment Measure. The measure under development highlights the high cost of care in the post-acute setting and the challenges faced by practitioners to return the patient to functionality. ASA supports the Centers for Medicare &	Matthew Popovich, Director of Quality and Regulatory Affairs	M.Popovich@asahq.org	Professional Society	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to

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		<p>Medicaid Services (CMS) goals and that of the measure developer to improve efficiency and reduce cost in health care delivery by developing and using measures that are high value, impactful and meaningful for practitioners and patients alike.</p> <p>Physician anesthesiologists promote rapid early mobilization by their choice of anesthetic technique and patient-centered care by delivering superior postoperative pain management. ASA cautions against conflating THA and TKA payments too closely. TKA usually results in significantly more intense acute postoperative pain, which limits recovery more than in those patients having THA. TKA is commonly treated with peripheral nerve analgesic techniques, including continuous peripheral nerve catheter analgesia. These techniques are not typically employed for THA. Continuous catheter techniques greatly benefit patients undergoing TKA by improving analgesia and facilitating mobilization postoperatively. These costs need to be included in payment methodologies for these procedures.</p> <p>ASA has an acute interest in this particular measure since it will impact many of our members who participate in alternative payment models and Accountable Care Organizations. The measure contributes to our desire for a physician anesthesiologist's actions to be recognized at the hospital level. We support measures that promote shared accountability across multiple specialties and practitioners, including surgeons, anesthesiologists and other members of a patient's care team who work together to improve surgical outcomes. Anesthesiologists add significant value, both in providing patient-centered care and decreasing healthcare costs, to the hospitals and facilities where we work.</p> <p>Physician anesthesiologists are uniquely positioned to reduce the post-acute care costs that are often as high as 60% of the total cost for hip and knee surgery. Recently, the ASA has promoted the development of the Perioperative Surgical Home (PSH) and the concept of a "Perioperative Care Clinic." PSH is an innovative, patient-centered model of care achieved through shared decision-making and seamless continuity of care from the time of decision for surgery through the patient's recovery post-discharge.^{1,2} Although the measure</p>	American Society of Anesthesiologists			the measure in response to public comment recommendation.

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		<p>addresses, from a payment perspective, an episode of care that is triggered by admission, the underlying assumption allows for additional exploration of clinician workflows and their interactions and communication with the patient. We invite the measure developer to learn more about the ASA PSH by visiting www.asahq.org/psh.</p> <p>By way of example, the Perioperative Care Clinic concept expands the role of a pre-op clinic into the post-acute, post-discharge setting. Part of the reasoning behind this measure includes a discussion on the 90-day “episode of care” and how a 90-day period would “incentivize hospitals to optimize post-discharge care.” But the measure should also serve to encourage hospitals and other providers to optimize the patient prior to surgery. Many of the same care providers who establish a relationship with the high-risk patient in the pre-op clinic can and do follow-up with the same patient in the first few weeks after discharge. Optimization or pre-habilitation has the ability to reduce costs by reducing the rate of complications by effectively addressing patient conditions prior to surgery. If the care team can help make this a reality for a hospital, then anesthesiologists can share in the savings of the post-acute care costs than account for a majority of the total cost for hip and knee surgery.</p> <p>The 90-day measurement period has the ability to effectively capture the costs associated with patient re-admissions, which are not currently considered in the 30-day post discharge period included in Medicare Spending Per Beneficiary (MSPB) measures. At the same time, if and when the measure is approved for use, we request that the measure undergo additional review and testing to ensure that the measure is carefully analyzed, reviewed and appropriately updated to reflect all of the contributions our members deliver to these patients.</p> <p>We appreciate your consideration of our submitted comments on this measure.</p>				
11/21/14	THA/TKA Payment	<p>Dear Dr. Kim:</p> <p>The American Health Care Association (AHCA) appreciates the opportunity to respond to the Centers for Medicare and</p>	James Michel American Health Care Association	jmichel@ahca.org	Provider Association	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are

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		<p>Medicaid Services (CMS) Quality Measures Public Comment Page call for public comment regarding two documents prepared under the <i>Development, Reevaluation, and Implementation of Hospital Outcome/Efficiency Measures</i> project being conducted by its contractor, Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE) under contract number HHSM-500-2013-12018I.</p> <p>The specific report titles are: <i>Draft Summary of Technical Expert Panel (TEP) Evaluation of Measure Risk-Standardized Payment Measures: Hip/Knee Episode of Care, September 22, 2014, and Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0), 2014 Draft Measure Methodology Report, September 2014</i></p> <p>AHCA is the nation's leading long term care organization. AHCA and its membership of over 12,000 non-profit and proprietary centers are dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing care centers, assisted living communities, subacute centers and centers for individuals with intellectual and developmental disabilities.</p> <p>As CMS describes in its call for public comments, the Agency has contracted this project to develop an outcomes measure that can be used to support quality improvement, and that this public comment period provides an opportunity for the widest array of interested parties to provide input to the measure under development as comments from the public can offer critical suggestions in addition to those identified by the measure contractors and their technical expert panel (TEP).</p> <p>AHCA appreciates CMS for its efforts in reaching out to stakeholders to solicit feedback regarding issues that may have been otherwise overlooked. As the proposed outcome measure includes post-acute services furnished within the</p>	Senior Director, Medicare Research & Reimbursement American Health Care Association			provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>episode of care window for the identified THA/TKA measure cohort, our AHCA member facilities play a critical role in the successful post-acute management of the subject patient population. From our unique perspective we have identified a number of issues within the two documents provided that we wish to offer in the following comments.</p> <p><i>Comments Pertaining to Draft Summary of Technical Expert Panel (TEP) Evaluation of Measure Risk-Standardized Payment Measures: Hip/Knee Episode of Care, September 22, 2014</i></p> <p>General Comments Pertaining to TEP Feedback</p> <p>AHCA recommends that the 30-day outcomes measure window is not sufficient</p> <p>AHCA agrees with the TEP member feedback on page 8 that the 30-day outcomes measure window is not sufficient, particularly related to capturing post-acute services furnished for more complex THA/TKA cases that require services beyond the 30-day index hospitalization window. Excluding costs associated with directly related post-acute services beyond 30 days would artificially deflate predicted expenditures associated with such patients, and could result in adverse patient selection for patients with complex needs if adopted.</p> <p>AHCA recommends the addition of post-acute provider representation to TEP</p> <p>The TEP comments on page 11 indicate that the TEP members did not expect the proportion of post-acute care payments for THA/TKA to be as high as it was (60%). This may be an indicator that the current TEP panel underrepresents the perspectives of post-acute providers, including skilled nursing facilities (19.5% of all post-acute payments). In today's healthcare environment, patients undergoing such elective procedures typically have a relatively short length of acute care stay. However, THA/TKA patients often require extensive post-acute rehabilitation services, including SNF-based physical therapy (PT) and occupational therapy (OT) in order to restore functional mobility and self-care to prior levels to enable return home, or to the highest practicable level within</p>				

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		<p>the patient's facility-based living environment. Post-acute provider insight on the TEP is necessary to inform the measure development contractor of the setting-specific patient care issues related to the study population.</p> <p><i>Comments Pertaining to Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0), 2014 Draft Measure Methodology Report, September 2014</i></p> <p>Calculation of the Payment Outcome</p> <p>AHCA recommends clarification and/or revisions to the methodology of determining outpatient therapy expenditures as a component within the payment measure outcome</p> <p>AHCA is concerned about the described methodology of determining outpatient therapy expenditures as a component within the payment measure outcome. Outpatient therapy services can be a significant component of post-acute post-surgical rehabilitation care delivery and outcomes for THA/TKA patients. We have identified specific areas where the described methodology makes it unclear whether outpatient therapy services are properly identified and calculated:</p> <p>Medicare outpatient therapy services are identified under statute and regulation as physical therapy, occupational therapy, and/or speech-language pathology services that may be furnished in facility settings (hospital, skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), outpatient rehabilitation facility (ORF), critical access hospital (CAH), home health agency(HHA)) as well as by qualified clinicians in office-based settings (physical therapist in private practice (PTPP), occupational therapist in private practice (OTPP), speech-language pathologist in private practice (SLPP), physician, and non –physician practitioners [physician assistant, nurse practitioner, clinical nurse specialist]).</p> <p>The description of calculating payments for different care settings, services, supplies (section 2.5 pg. 19-30) describes</p>				

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		<p>various payment systems; however, the only sections that mention outpatient therapy services are 2.5.2.2 for CORFs and ORFs. Per the June 2013 MedPAC report to Congress¹, only eleven percent of outpatient therapy services in 2011 were attributed to CORF, ORF and HAA combined. He remaining 89 percent of outpatient therapy spending was attributed to SNF (37%), PTPP (30%), Hospital <i>[not OPFS]</i> (16%), Physician, non-physician practitioners, OTPP, and SLPP combined (7%). Have the CORE investigators overlooked including payments from these outpatient therapy settings, or is the omission just in the report description details?</p> <p>If outpatient therapy procedures are included from all of the applicable settings described above, have the CORE investigators properly attributed all outpatient therapy procedure practice expense RVUs at the non-facility rate? Per Medicare regulations, outpatient therapy services furnished by facilities or office-based providers are reimbursed at the non-facility rate, regardless of the place of service. The description of the approach for stripping payments for physicians, physician extenders, and social work services (section 2.5.4 pg. 29-30) does not appear to permit this specific policy when attributed to outpatient therapy services as the section differentiates facility versus non-facility practice expense RVUs.</p> <p>Risk-Adjustment Methodology</p> <p>* AHCA recommends that the approach to risk adjustment be modified to include prior use of health services, admission source, and available administrative data on support systems.</p> <p>The description of the approach to risk adjustment (section 2.7 pg. 31-32) describes that <i>the goal of risk adjustment for this measure is to account for patient and procedure characteristics and comorbid conditions that are clinically relevant and have strong relationships with the outcome, while illuminating important quality differences between hospitals</i>. The description further indicates that comorbidities reported within 12 months prior to the index hospitalization</p>				

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		<p>are utilized in the risk-adjustment methodology based upon clinical relevance and statistical significance.</p> <p>In addition, the measure developers indicate that <i>the measure does not adjust for the patient's admission source or discharge disposition (for example, a skilled nursing facility) because these factors are associated with the structure of the health care system and the different care patterns the measure seeks to illuminate.</i> In addition, patient demographic data is excluded from risk-adjustment as <i>variations in payments associated with these characteristics may indicate differences in the care provided to vulnerable populations, and adjusting for these factors would obscure these disparities.</i></p> <p>However, AHCA contends that when the outcome measure is cost, and not clinical outcome, then factors including prior use of health services admissions source, and available administrative data on support systems are clinically relevant and have a strong relationship with the cost outcome. These factors can and should be utilized as proxies for clinical complexity that cannot otherwise be identified in available administrative data. The following provides examples: Elective THA/TKA patients that required acute and/or post-acute services in the 12 months prior to the index hospitalization may have significant predictable cost differences from patients with similar comorbidities that only received ambulatory care services in the prior 12 months.</p> <p>Admission source may also be significant predictable cost variables for elective THA/TKA patients. The post-acute rehabilitation potential and goals, and therefore associated costs can vary significantly for patients with similar comorbidities if they were admitted from a SNF versus from a community-based environment. For example, a THA/TKA patient admitted to a SNF for post-acute care that was previously residing in the SNF may have limited functional rehabilitation goals and limited costs, while a similar patient admitted to a SNF for post-acute services but expecting to return home to a two-story walkup home may have more extensive rehabilitation goals which would result in higher costs.</p>				

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		<p>Support systems may also be significant predictable cost variables. The post-acute rehabilitation potential and goals, and therefore associated costs can vary significantly for patients with similar comorbidities but different available support systems. For example, a THA/TKA patient admitted to a SNF for post-acute care but expecting to return home without support systems may have more extensive rehabilitation goals which would result in higher costs than a similar patient that had support systems at home. While administrative data only contains limited information related to support systems (e.g. lives with spouse), such information should be considered within the measure.</p> <p>AHCA is concerned that if the hospital-level, risk-standardized payment measure associated with a 90-day episode of care for elective THA/TKA does not address these cost-predictive variables, and if the measure is adopted for quality or payment policy purposes in the future, then patient access to such services may be compromised. Hospitals may become dis-incentivized to perform necessary elective THA/TKA procedures on patients with these factors that have not been adequately risk-adjusted.</p> <p>On behalf of our members, AHCA thanks you for the opportunity to submit these comments regarding the Development of Measures of Payment for Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).</p>				
11/21/14	THA/TKA Payment	<p>To Whom It May Concern:</p> <p>On behalf of the American Physical Therapy Association (APTA), I would like to thank the Yale New Haven Health Services Corporation/ Center for Outcomes Research and Evaluation (CORE) for the opportunity to comment on the development of hospital-level measure of risk-standardized, 90-day episode-of-care payments for elective primary THA/TKA. APTA is a professional association representing physical therapists, physical therapist assistants, and students of physical therapy.¹ APTA's goal is to foster advancements in physical therapy practice, research, and education. The mission of APTA is to further the profession's role in the prevention, diagnosis, and treatment of movement</p>	<p>Heather Smith, PT, MPH Director, Quality</p> <p>American Physical Therapy Association</p>	Heather.smith@apta.org	Professional Association	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>dysfunctions and the enhancement of the physical health and functional abilities of members of the public.</p> <p>Physical therapists are an essential member of the health care team who provide evaluation and treatment for individuals following total hip and/ or total knee arthroplasty (THA and or TKA). Physical therapists treat individuals in a variety of practice settings, including hospitals, skilled nursing facilities, home health agencies, rehabilitation agencies, and private practice outpatient clinics. Physical therapists integrate essential elements of evaluation and management with a person- centered focused based on the best available evidence to optimize outcomes. For individuals with THAs and TKAs, physical therapists provide various interventions with the goals of improving muscle performance, activity and participation, and promoting physical activity to decrease the risk of subsequent disability.</p> <p>Physical therapy interventions are designed to restore and promote maximal physical function for people following THAs and TKAs. The physical therapy model of practice as delineated in the Guide to Physical Therapist Practice is patient-centered, incorporating patients' needs and goals across a continuum of care. Physical therapist interventions for people following THAs and TKAs aim to reduce pain; increase and maximize joint mobility, muscle strength, flexibility, and aerobic capacity; and prevent functional loss. Interventions may include: therapeutic exercise; manual therapy; functional training in self-care, home management, and work; physical agent modalities; and use of orthotic, assistive, adaptive, protective, and supportive devices, combined with patient-related instruction/education. APTA supports the goal of improving the quality of health care. Physical therapists are committed to providing high-quality, timely care and to the promotion of evidence-based practice and patient-centered practice. APTA is pleased to see development of a hospital level measure of risk-standardized, 90-day episode-of-care payments for elective primary THA/TKA. APTA supports the inclusion and exclusion criteria for this measure, as well as the risk adjustment methodology. APTA would encourage the measure developer to work with NQF in determining whether this measure could benefit from</p>				

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		<p>the new sociodemographic risk adjustment methodology being explored by NQF.</p> <p>In conclusion, APTA would like to thank CORE for the opportunity to comment on the development of hospital-level measure of risk-standardized, 90-day episode-of-care payments for elective primary THA/TKA. We look forward to working with CORE in the future to ensure quality measures are representative of the identified patient populations.</p>				
11/21/14	THA/TKA Payment	<p>Dear Dr. Kim:</p> <p>The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to provide comments on the 2014 Draft Measure Methodology Report. As you are aware, AAHKS is the essential organization of more than 2300 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.</p> <p>AAHKS members value our relationships with both the Centers for Medicare & Medicaid Services (CMS) and Yale New Haven Health Services Corporation and the Center for Outcomes Research and Evaluation (YNHHSC/CORE), which we have worked to strengthen. Evidence of that partnership was evident earlier this week when our members had a conference call with members of YNHHSC/CORE to collaborate on risk adjustment issues.</p> <p>After review of the Yale-drafted Measure Methodology Report and the Draft Summary of the Technical Expert Panel, AAHKS makes the following comments and recommendations:</p> <p>We understand the need to develop a hospital-level, risk-standardized, 90-day episode of care measure of payment. The measure as currently constituted does not provide a full and accurate measure of costs and value associated with TKA and THA, however, and it should not be implemented without refinement.</p>	<p>Krista M Stewart Membership & Advocacy Coordinator</p> <p>American Association of Hip and Knee Surgeons</p>	krista@aaahks.org	Professional Association	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>We are concerned that the data used to develop the measure included CMS administrative data only, and it does not include pertinent clinical variables. It is clear that there are limitations to the use of administrative data, and it follows that expenditure data is likely flawed.</p> <p>The risk-adjustment model used in the development of the measure fails to include sociodemographic factors that have a substantial impact on the cost of care.</p> <p>As we discussed in our conference call with Yale-CORE this week, the risk-adjustment model used in the development of the measure fails to account for orthopaedic-specific risk factors that are not reflected in the billing codes. For instance, surgeons treating patients with multiple comorbidities may be disproportionately affected in public reporting if risk models do not address the complete comorbid profile, including musculoskeletal conditions. AAHKS and the national FORCE-TJR registry demonstrated that patient-reported function and assessments of osteoarthritis in knees, hips, and low back are important to these models.</p> <p>Clinician and patient-reported data, including outcomes information, should be used to augment risk-adjustment models to assure sensitive comparisons across clinical and cost metrics.</p> <p>According to the Draft Measure Methodology Report, the measure is intended to facilitate the profiling of hospital value and encourage the most efficient delivery of high-quality care, and it is not intended to be used in payment programs. To the extent that the measure is at any point to be used in a formal payment program (e.g., a prospective bundled payment program for THA/TKA for a given payor / provider in a specific locale), AAHKS believes that the model would need to re-estimated / recalibrated with untransformed data to obtain useful payment rates (to allow for accounting of current Medicare rate elements such as wage index differences, teaching status, etc.).</p> <p>AAHKS is concerned about the potential unintended consequences on access to care for the most vulnerable of</p>				

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		our society if the episode of care payment measure does not adequately account for the complete patient profile, including comorbidities, socioeconomic status, and outcomes. Based on our past and current work in the development of clinical performance measures for hip and knee arthroplasty, we recommend that CMS and CORE engage in a partnership with AAHKS in the development/refinement of payment and clinical measures for medical conditions related to the hip and knee. More specifically, AAHKS members would be pleased to meet with CMS and Yale-CORE representatives regarding changes needed to the THA/TKA payment measure to preserve access and ensure that this care is sustainable for Medicare beneficiaries in the future.				
11/21/14	THA/TKA Payment	<p>Dear Dr. Kim:</p> <p>On behalf of Premier, Inc., a leading healthcare improvement company, uniting an alliance of more than 3,000 U.S. hospitals and nearly 110,000 other providers to transform healthcare, we appreciate the opportunity to comment on the payment measures being developed associated with Total Hip Arthroplasty and Total Knee Arthroplasty. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Our comments primarily reflect the views of our owner hospitals and health systems, which, as service providers, have a vested interest in the development of sound payment measures, particularly those that will be ultimately used by the Centers for Medicare & Medicaid Services (CMS).</p> <p><i>Measure setting and testing</i></p> <p>While we recognize there is a need for the development of episodic, longitudinal payment measures that can be used to support quality improvement, we do not believe these types of measures are sufficiently tested and refined to be utilized within the current fee-for-services payment system. We are privileged to work with many organizations who are implementing some form of population health management, such as accountable care organizations or bundled payments. The payment measure under development is better suited for these types of payment and delivery models. Hospitals not</p>	<p>Seth Edwards, MHA Director, Federal Affairs</p> <p>Premier Healthcare Alliance</p>	<p>Seth_Edwards@PremierInc.com</p>	Healthcare Improvement Company	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>participating in accountable care or bundled payment models may find it difficult to track a patient over 90 days, coordinate with post-acute providers and to use the results to drive quality improvement. Many of these non-integrated hospitals may not even have formal relationships with post-acute providers that would allow for some level of control by the hospital over the 90 day duration of the episode. Moreover, we are concerned that this type of measure has not been tested, we have concerns as to reliability and validity, and is thus not ready to be included in payment. While we recognize that the measures were developed utilizing two years of data, we believe that it would be beneficial to test the measures through a demonstration project, in order to more fully understand the impact on care, particularly in a non-integrated setting. To address these issues, Premier urges CMS to utilize these payment measures in population health-type models, and to run a demo to test the validity of the measure.</p> <p><i>Episode length</i></p> <p>Premier believes that defining the episode as 90 days is too long, and the overarching goal of driving quality improvement within the hospitals will be better served utilizing a 30-day episode length. CMS currently utilizes the 30-day episode length in several other measures, for example the Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older (NQF #0230), a part of the Inpatient Quality Reporting program. In order to align with other inpatient measures, CORE should utilize the 30-day length.</p> <p><i>Risk adjustment</i></p> <p>We continue to believe in the need to incorporate social determinants of health, in particular socioeconomic status (SES), into the risk adjustment methodology for measures such as these measures. SES is critical in this type of measurement, as social determinants can hinder access to rehabilitation. Comparing hospital performance between markets of widely varying SES, without taking the SES of the populations served into account, is flawed. Social</p>				

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		<p>determinants play a major role in influencing health and wellness. There is a substantial body of evidence that sociodemographic factors—such as patients’ income, housing, education and race—influence a variety of patient outcomes and some processes that are out of a provider’s control. As noted by Christine Cassel, “not adjusting for patients’ sociodemographic factors might actually harm patients, exacerbate disparities in care, and produce misleading performance scores for a variety of providers, which means that no one has accurate information to use for comparison.”¹ Moreover, the National Quality Forum Board (NQF) of Directors voted on July 23, 2014 to initiate a trial period for assessing the impact and implications of risk adjusting relevant quality measures for sociodemographic factors. This vote follows an NQF technical report that recommends adjusting for sociodemographic factors the performance measures used to determine provider payment.² A robust risk-adjustment approach will strengthen the reporting process and help to minimize the potential for unintended consequences.</p> <p>In addition, we believe that the measures should incorporate an adjustment for admission source. The source of admission provides a strong indication of the acuity of the beneficiary, as well as the potential for comorbidities, which may affect the outcome.</p> <p><i>Incentives</i></p> <p>While we agree that measures such as the THA/TKA payment measure are useful for integrated delivery and payment models of care, e.g., ACOs and bundled payments, we are concerned this measure raises the risk of unintended consequences in terms of potentially incenting undesired provider behaviors. In ACOs, there is a counter-balance to this type of payment measure by requiring the ACOs to meet quality performance thresholds in order to be able to share in the savings generated. A similar dynamic exists in the Bundled Payment for Care Improvement initiative. However, in the traditional FFS payment model, there is nothing to counteract the incentives underlying these measures. It could cause some providers to be more cognizant of the cost of care, and</p>				

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		<p>to select the lowest cost approach, as opposed to one that leads to an optimal functional outcome. For example, rehabilitation at home can be much less expensive than utilizing other post-acute providers, such as a rehabilitation facility, but it can also lead to worse functional outcomes. Since the incentives are tied to lowering costs, how does CMS plan to manage this dynamic?</p> <p><i>Conclusion</i> In closing, Premier greatly appreciates the opportunity to submit these comments on the hospital-level measures being developed associated with Total Hip Arthroplasty and Total Knee Arthroplasty.</p>				
11/21/14	THA/TKA Payment	<p>Dear Administrator,</p> <p>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.</p> <p>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.</p> <p>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</p>	<p>Steven J. Brotman, M.D., J.D Senior Vice President Payment and Health Care Delivery Policy</p> <p>The Advanced Medical Technology Association</p>	sbrotman@advamed.org	Trade Association	Stakeholder comments reviewed by measure developers and will be reviewed with the Technical Expert Panel; detailed responses are provided in the Public Comment Summary Document. No change to the measure in response to public comment recommendation.

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		<p>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.</p> <p>A. Episode Window</p> <p>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.</p> <p>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</p> <p>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.</p> <p>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</p>				

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		<p>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.</p> <p>B. Risk Stratification</p> <p>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.</p>				

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		<p>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. 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.</p> <p>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.</p> <p>C. Joint Registry Data</p> <p>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.</p> <p>Finally, it is noteworthy that the Technical Expert Panel (TEP) does not contain representation from the major joint</p>				

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		<p>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.</p> <p>AdvaMed appreciates the opportunity to provide these comments. We would be pleased to answer any questions regarding these comments.</p>				