AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

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September 8, 2015

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

Subject: CMS-5516-P Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services.

Dear Mr. Slavitt:

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the Centers for Medicare & Medicaid (CMS) *Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services*, published July 14, 2015 in the Federal Register.

The AJRR is the only national hip and knee arthroplasty registry with collection from all 50 states, and is the largest with over 300,000 procedures, 565 hospitals, and 4,200 surgeons. AJRR collects Level I (patient, hospital, surgeon, and procedure info) and some Level II (patient risk factors, co-morbidities, post-operative complications, and surgical approaches) data on patients, surgeons, medical devices, and revision complications reported under the procedural codes for primary hip and knee arthroplasty. And, by the time the CCJR program is implemented, AJRR will have the ability to collect Level III (Patient Reported Outcomes) data. AJRR also has a mechanism in place for orthopaedic professionals to submit their Physician Quality Reporting System (PQRS) data to CMS through our Qualified Clinical Data Registry (QCDR); this is our second year that we received this designation from CMS and the only national orthopaedic registry as such.

We commend CMS for addressing the expenditures of Medicare while attempting to preserve and enhance the quality of care for Medicare beneficiaries. We have had the opportunity to review the proposed rule and have the following comments.

Implementation Period:
AJRR urges CMS to reconsider the start of the implementation period. Many hospitals are not prepared to enter into a bundled payment model at this time. The CCJR rule will not be final until November 1, 2015, and CMS expects to begin implementation on January 1, 2016. For hospitals new to integrated care and bundled payment, this time window is short.

Regarding the Financial Incentives for Hospitals:
AJRR is encouraged to see CMS's proposal to financially incentivize hospitals that link required data measure submissions with additional patient-reported outcome measures. This methodology shows promise in the ability to curb healthcare inflation. However, we strongly encourage CMS to extend incentives further and include surgeons who are responsible for interacting with patients and collecting PROM data. It's the individual practitioner who maintains the follow-up appointments after surgery. We agree that payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of improved care redesign between hospitals and other providers.

Inappropriate Proposed Patient Reported Outcomes and Risk Variables:
AJRR suggests that CMS amend and clarify the sections of the proposal that deal with patient reported outcomes and risk variables. The AJRR participated in a one day summit convened by the American Association of Hip and Knee Surgeons (AAHKS) and attended by entities involved in development and utilization of hip and knee arthroplasty patient reported outcomes and risk variables. The participants in that summit have several specific comments related to the Comprehensive Care for Joint Replacement proposal that are captured in a joint letter from said participants. Please see attachment A for those specific comments.

Measure Development:
CMS is developing a measure to assess the improvement in patient-reported outcomes following total hip arthroplasty (THA) and total knee arthroplasty (TKA). The hospital-level performance measures of patient-reported outcomes following elective primary THA and/or TKA are under development. During development, CMS is indicating that they would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopaedists.

For the purpose of the voluntary patient-reported outcome measures, AJRR strongly suggests that CMS accept data that is reported by a hospital to a Qualified Clinical Data Registry. AJRR currently collects lower extremity joint replacement data from hospitals in 50% of the Metropolitan Statistical Areas (MSAs) designated in the CCJR proposed rule. Efforts are underway to collect more data in these MSAs and we hope to increase our coverage in these cities as time goes on. AJRR will be prepared to provide a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data that is consistently collected at the hospital level and contains risk variables identified by orthopedists. Additionally, AJRR's Registry has the ability to provide national benchmarks against demographics of the United States.

AJRR remains committed to working with CMS on patient-reported outcomes data reporting. Our leadership is collaborating with the Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE) team in order to move forward measure testing for CMS. In sum, we hope that CMS would consider releasing further information on what data and information is needed for testing the measure to build the risk adjustment model. As a CMS-approved Qualified Clinical Data Registry, we will include any additional information or data if we are not already collecting it. We favor prioritization of the development of risk adjustment models. We hope that CMS will devote sufficient resources to studying the issues related to overlap/interaction among measures, feasibility of data collection in various healthcare settings, appropriate risk adjustment methods, and fairness.

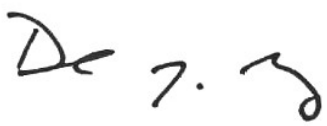
Current Data Sources & Selection Bias Due to Issues Related to Selective-Reporting/Under-Reporting:

In its proposal, CMS states that "current data sources are not consistently collected nor collected in a uniform process and in a standardized format (data elements are not consistently defined across different data sources.) Currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements."

We understand that the CMS will use measures to compare quality across providers and/or hospitals. Since proposed measures are not collected universally, we believe an ongoing evaluation of selection bias is essential, both in terms of differences across hospitals as well as within hospitals. For example, patients who are less likely to benefit from surgery may be selectively excluded from the pool of patients with both pre- and post-surgery assessments, leaving a biased sample of patients with complete data (i.e., cherry-picking). Similarly, variation across hospitals in terms of data collection, scoring methodology, and risk adjustment are important methodological factors that may limit the utility of these measures.

The AJRR appreciates this opportunity to provide input on this new payment model initiative and we look forward to continuing to work with CMS and providing guidance and input on issues applicable to registries, specifically Qualified Clinical Data Registries. Ultimately, we look forward to CMS using AJRR as the national database to collect hospital-level performance measures of patient-reported outcomes. If you have any questions regarding our comments, please do not hesitate to contact our Executive Director, Jeffrey P. Knezovich, CAE at (847) 430-5036 or at knezovich@ajrr.net.

Sincerely,



Daniel J. Berry, MD
Chair
American Joint Replacement Registry

cc: Jeffrey P. Knezovich, CAE, Executive Director
David G. Lewallen, MD, Medical Director