AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

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June 15, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt:

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the *Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models* published in the Federal Register on April 27, 2016. The proposed rule solicits input on the new regulations related to Qualified Clinical Data Registries (QCDRs) and Clinical Data Registries (CDRs). Many MIPS eligible clinicians will be able to use the qualified registries and QCDRs for all MIPS submission (not just for quality submission) and QCDRs will be able to provide innovative measures that address practice needs. CMS is encouraging the use of QCDRs and CDRs and is looking to promote quality and accurate data.

AJRR is the only national hip and knee arthroplasty Registry collecting data in all 50 states, and is the largest orthopaedic Registry with over 400,000 procedures, 700 hospitals, and 5,000 surgeons. AJRR collects Level I (patient, hospital, surgeon, and procedure info), some Level II (patient risk factors, comorbidities, 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 Level III (patient-reported outcome measures). AJRR also has a mechanism in place for orthopaedic professionals to submit their Physician Quality Reporting System (PQRS) data to CMS through our QCDR. AJRR was designated a QCDR for FY 2014, FY 2015, and FY 2016.

AJRR strongly supports the use of QCDRs, Qualified Registries (QRs), and Certified EHR Technology. Registries provide the data collection platform that allows for benchmarking, linking measurement to performance, and the improvement of quality of care.

Qualified Clinical Data Registries (QCDRs)

Under Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) , Congress explicitly directed CMS to provide real time Medicare claims data to QCDRs for quality

improvement and patient safety purposes. CMS instead chose not to adopt policies and procedures to implement this provision, claiming that the existing Research Data Assistance Center (ResDAC) program is already available to QCDRs to obtain Medicare claims data, and that a new program is not needed. In so doing, CMS ignored the fact that Congress was aware of the ResDAC process when it passed Section 105(b) of MACRA. Congress would not have adopted this provision if CMS was successfully providing QCDRs with sufficient access to Medicare data. AJRR commends CMS for encouraging the use of QCDRs to promote quality and accurate data but the provisions set forth in the proposed rule have negatively impacted our Registry operations and this is disappointing.

The ResDAC process, which was established to respond to discrete requests for Medicare data from researchers, is inadequate to meet the continuous and comprehensive access to Medicare claims data required by QCDRs. The Medicare claims data provided by ResDAC is not "real-time" Medicare data- it is at least two years old and is presented in a format appropriate for research purposes and this is not what QCDRs and other registries need to provide essential longitudinal information related to implant and patient outcomes to the public and to all stakeholders. QCDRs require "real-time" Medicare claims data in order to conduct longitudinal quality comparison studies of patients and medical devices in the pursuit of improved patient care.

Data Completeness Criteria

CMS is proposing that MIPS eligible clinicians or groups submitting data on quality measures using QCDRs, qualified registries, or via EHR need to report on at least 90% of the clinician or group's patients that meet the measure's denominator criteria, regardless of payer for the performance period. The expectation of CMS is to receive quality data for both Medicare and non-Medicare patients, yet CMS has chosen not to provide access to real-time Medicare claims data, as requested by Congress and the provider community.

Real-time Medicare claims data are needed to link claims data with clinical outcomes data to perform risk-adjusted, scientifically valid analysis and research to support quality improvement. AJRR urges CMS to initiate additional notice and rulemaking to establish a process for QCDRs to access real-time Medicare claims data for quality improvement purposes, rather than refer QCDRs to the ResDAC program. This is a real and critical need for the AJRR and other patient outcome registries, and the current proposal will impede our progress to be able to provide thousands of orthopaedic surgeons with risk adjusted data on hundreds of thousands patients with hip and knee replacements.

CPIA Data Submission Criteria

CMS proposes to recognize clinicians for activities that contribute to advancing patient care, safety and care coordination in the Clinical Practice Improvement Activities (CPIA) category. CPIAs will be weighted as high (20 points each) or medium (10 points each) based on alignment with CMS national priorities and programs for a total score of 60 points in this category. All QCDR activities in the CPIA category have been weighted as medium.

AJRR commends CMS for encouraging the use and participation of QCDRs but with QCDR data submission activities being weighted as medium it will be difficult for small groups (15 or fewer clinicians) and eligible clinicians and groups located in rural areas to obtain 60 points in the CPIA category for participating in/or using a QCDR. AJRR recommends that registry related activities be weighted as high (20 points) so that clinicians are able to get the highest possible weight for registry related activities which will lead to increased participation and use of QCDRs.

Request for Comments on Use of QCDRs for Identification and Tracking of Future Activities

CMS contends that for future years, QCDRs will be allowed to define specific CPIAs for specialty and non-patient-facing MIPS eligible clinicians or groups through the already-established QCDR approval process. CPIA standards are not nationally recognized and there is no CMS program for CPIAs. Due to the undefined nature of activities, AJRR agrees that QCDRs should be allowed to define specific CPIAs. QCDRs can provide the capability to gather data on the feasibility of performing CPIAs and it is important that CPIAs are correctly identified and tracked. As stated by CMS, the proposed data submission methods will allow for greater access and ease in submitting data, as well as consistency throughout the MIPS program.

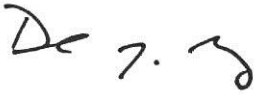
Qualified Clinical Data Registries (QCDRs)

CMS proposes to expand the capabilities of QCDRs by allowing QCDRs to submit data on measures, activities, or objectives for three of the MIPS performance categories: quality, CPIA, and Advancing Care Information. AJRR agrees that CMS should expand the capabilities of QCDRs to allow reporting for all MIPS performance categories. This alleviates the need for individual MIPS eligible clinicians and groups to use a separate mechanism to report data for these performance categories.

CMS proposes that data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3% of the total number of MIPS eligible clinicians submitted by the QCDR may result in notations on CMS qualified QCDR posting of low data quality and would place the QCDR on probation. It would be virtually impossible for most QCDRs to meet the 3% error rate requirement. AJRR recommends that CMS review the proposal for a 3% error rate and adopt an error rate that is more feasible for QCDRs to achieve at this early stage in their development.

The AJRR appreciates this opportunity to provide comments on the Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models. We look forward to continuing to work with CMS to provide guidance and input on issues related to the clinical data registries. If you have 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