AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

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March 24, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5061-P
P.O. Box 8010
Baltimore, MD 21244-1850

Subject: Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

Dear Acting Administrator Slavitt:

The American Joint Replacement Registry (AJRR) appreciates the opportunity to review and comment on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities published in the Federal Register on February 2, 2016. The proposed rule solicits input on the implementation of new statutory requirements that would expand how qualified entities may use and disclose data under the qualified entity program to the extent consistent with applicable program requirements and other applicable laws, including information, privacy, security and disclosure laws.

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, 650 hospitals, and 4,500 surgeons. AJRR collects Level I (patient, hospital, surgeon, and procedure info), 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 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 Qualified Clinical Data Registry (QCDR). AJRR was designated a QCDR in FY 2014 and FY 2015.

AJRR commends CMS for soliciting input on the implementation of expanding the uses of Medicare data by Qualified Entities (QEs) but is disappointed that CMS proposed not to adopt new policies or procedures regarding QCDRs access to Medicare claims data for quality improvement or patient safety research.

Data sharing policies and procedures should include matching Medicare claims data to the Social Security Death Masterfile (SSDMF) to improve the accuracy of QCDR clinical outcomes data. There are limitations, lengthy program requirements and high costs associated with the QE program that may prevent potential entities from exploring the possibility of becoming a QE.

Qualified Clinical Data Registries (QCDR)

CMS is proposing not to adopt any new policies or procedures regarding QCDR access to Medicare claims data for quality improvement or patient safety research. This is contrary to Congressional intent. Under Section 105, as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), beginning July 1, 2016, the Secretary of HHS must provide Medicare claims data upon request to QCDRs for the purpose of linking such claims data with clinical outcomes data to perform risk-adjusted, scientifically valid analysis and research to support quality improvement.

However, in the proposed rule, CMS decided not to issue a rulemaking on this section of the law based on its assertion that QCDRs can currently request Medicare claims data through the Research Data Assistance Center (ResDAC) data request process. Congress enacted section 105(b) knowing that Medicare claims data was available through the ResDAC process. Releasing Medicare claims data for quality improvement and patient safety purposes, as requested by Congress, is distinct from using Medicare claims data for research. Limiting QCDRs to the ResDAC process would inhibit their ability to use Medicare claims data to track clinical outcomes over the long-term. AJRR is respectfully requesting that CMS grant access to Medicare claims data as instructed by the MACRA legislation.

AJRR further requests that CMS match the Medicare claims data to the state-reported death data in the Social Security Death Masterfile (SSDMF) when releasing Medicare claims data for QCDRs. Matching the SSDMF data to Medicare claims data before releasing it to QCDRs for quality improvement and patient safety purposes would greatly enhance the ability of QCDRs to verify patient death status and track patient outcomes over time.

Limitations on the Qualified Entities (QE) with Respect to the Sale and Provision of Non-Public Analyses

CMS is seeking comment to define a minimum cohort that would be expected in a given target region before a QE could provide non-public analyses. The AJRR suggests that there be a CMS requirement to clearly disclose the percent of the entire cohort that is contributing to the data in any non-public or public report. This leaves the entity that was soliciting or paying for the report and anyone viewing the report in a position to determine if that level of sampling was sufficient for statistical purposes.

Confidential Opportunity to Review, Appeal and Correct Analyses

CMS proposes to generally require QE to comply with the same error corrections process and timelines as are required for public performance reporting when sharing analyses that individually identify a provider or supplier. AJRR recommends that providers or suppliers that are identified in "non-public analyses" not review and request corrections before the QE provides or sells the non-public analysis. The concern is that a provider or supplier could potentially receive information that they are not entitled to receive (essentially every report in which they are identified). If the analyses are non-public, the recipient paying for the report should have the right and responsibility to judge the statistical validity and request comment or share data with the supplier or provider.

Data Use Agreement (DUA)

CMS proposed a number of provisions that addresses the privacy and security of the combined

data and/or the Medicare claims data and/or non-public analyses that contain patient identifiable data. The AJRR agrees that QE need to contractually bind authorized users using the Qualified Entity Data Use Agreement (QE DUA) to protect patient identifiable combined data and/or Medicare data, any patient identifiable derivative data, and/or non- public analyses that contain patient identifiable data, with the privacy and security protections under HIPAA Privacy and Security Rules. This encourages transparency as well as performance improvement in the provision of health care services and provides information for employers, consumer groups, patients, and caregivers to assist them in making more informed health care decisions.

Additional Data

CMS is proposing not to expand the data available to QE from CMS because there are difficulties in using data from the Medicaid and CHIP Statistical Information System (MSIS). CMS states that the data from the MSIS is incomplete, not contemporary, data collections are not synchronized, costs cannot be readily determined and reports are questionable and subject to interpretation.

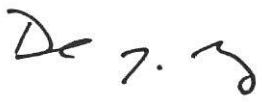
Due to these reasons, CMS designed a Datamart strategy that will provide a new set of data for the user community as part of the *Transformed MSIS (T-MSIS) project*. All states were expected to have demonstrated operational readiness to submit T-MSIS files, transition to T-MSIS and submit timely T-MSIS data as of July 1, 2014.

Section 105(c) of MACRA states that, at the discretion of the Secretary, the data that the Secretary may make available to QE, including standardized extracts of claims data under titles XIX (Medicaid) and XXI (the Children's Health Insurance Program, CHIP) for one or more specified geographic areas and time periods as may be requested by the QE. T-MSIS was not mentioned in the proposed rule. Instead of allowing QE access to T-MSIS, CMS proposed that QE get data directly from State Medicaid Agencies.

If CMS forces QE to get data from State Medicaid Agencies, each state would have to be contacted individually. This creates an administrative burden, is time consuming and may be costly. The AJRR suggests providing QE with access to data from the T-MSIS project that will follow the law's requirement to expand data to QE.

The AJRR appreciates this opportunity to provide comments on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities proposed rule. 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