AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

March 29, 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:

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed rule "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.

The AAOS supports efforts by CMS to expand how qualified entities may create non-public analyses and provide or sell such analyses to authorized users, as well as how qualified entities may provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users. The AAOS welcomes the expansion of the Qualified Entity (QE) program and also supports the implementation of certain privacy and security requirements, and imposed assessments on QE.

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 AAOS recommends not requiring a minimum criteria, but instead making it 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 analysis. It also stimulates greater reporting, rather than limit reporting.

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc

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 identify a provider or supplier. AAOS 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, in accordance with the error correction requirements in section 1874(e)(4)(C)(ii) of MACRA. Our suggestion is that there be no requirement for prior review and correction requests before release of non-public analyses.

This proposal could open an opportunity for a provider or supplier to receive information that they are not entitled to receive (essentially every report in which they are identified) and enable the release of these non-public reports to be entangled in further non-public private discussions regarding the nature and validity of claims related to errors in the data that should be a question of general concern. 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 vendor.

If data would be released and made public, the opportunity to correct errors should be required. The QE would request corrections or changes before or after the release of a public report allowing the QE the discretion to decide on sharing the report if public reporting has identifiable supplier or provider information.

Limitations on the Qualified Entity Regarding Data Disclosure

CMS proposes to require that a QE impose certain contractually binding use/re-disclosure requirements as a condition of providing and/or selling combined data and/or providing Medicare claims data to an authorized user. The AAOS recommends revising the proposal to identify what "certain contractually binding use/re-disclosure requirements" are when providing Medicare claims data. These requirements should be defined.

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.

317 Massachusetts Avenue NE
Suite 100
Washington, D.C. 20002-5701
PHONE 202.546.4430
www.aaos.org/dc

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 AAOS suggests providing QE with access to data from the T-MSIS project that will follow the law's requirement to expand data to QE.

Financial Impact on Qualified Entities

In the proposed rule, CMS estimates that the total impact on a QE for the first year of the program will be $27,925,198.00. That cost estimate is representative of what is believed to be the cost of each qualified entities' activities to analyze the Medicare claims data, design and calculate performance measures and produce public provider performance reports.

There has been no mention of the cost to become a QE. The understanding is that the costs to become a QE depend largely on the sum of Medicare claims data the entity is requesting and is based on the number of beneficiaries in the geographic region as well as the number of different claims types the entity needs. To obtain more specific cost information, CMS has requested that potential entities register on the QE Certification website. Registering on the QE Certification website requires that each potential entity essentially complete an application and review the Qualified Entity Certification Program (QECP) Phased Application Process. The AAOS agrees with expanding the use of Medicare data by QE but the process and costs associated with becoming a QE need to be transparently defined, convenient, timely and affordable.

In the proposed rule, CMS also anticipates the number of QE to increase slightly but does not anticipate significant growth in the QE program given the QE program requirements, as well as other existing programs that allow entities to obtain Medicare data. CMS has created a lengthy application and review process for potential entities to become QE.

The QE program requirements are explained in the Operations Manual and consist of four phases that include that the organizational structure of an entity be examined, that the QE comply with data security and privacy requirements established by the program, that the QE comply with its related measurement, reporting and corrections and appeals process and lastly, public reporting, during which a QE engages providers in the corrections and appeals process and releases its public performance reports. This process can be very time consuming and burdensome. This is not representative of the Congressional intent in the MACRA legislation.

The AAOS respectfully recommends that the proposed rule on expanding the use of Medicare data by QE be carefully revised to reflect a process that does not entail lengthy program requirements and that allows potential entities to explore the possibility of becoming a QE without a complicated process.

The American Association of Orthopaedic Surgeons (AAOS) thanks you for your time and for considering our concerns and comments on the "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities." Should you have questions on any of the above comments, please do not hesitate to contact AAOS' Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,

Gerald R. Williams, Jr., MD

President, American Association of Orthopaedic Surgeons

cc: Karen Hackett, FACHE, CAE, AAOS Chief Executive Officer
William O. Shaffer, MD, AAOS Medical Director
Graham Newson, AAOS Director of the Office of Government Relations

Additional signatories on AAOS' comments on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities include the following organizations:

Cervical Spine Research Society
American Association of Hip and Knee Surgeons
North American Spine Society
J. Robert Gladden Orthopaedic Society
Arthroscopy Association of North America
Limb Lengthening and Reconstruction Society
Society of Military Orthopaedic Surgeons
American Orthopaedic Foot and Ankle Society
Scoliosis Research Society
American Orthopaedic Society for Sports Medicine
American Society for Surgery of the Hand
American Shoulder and Elbow Surgeons