AAOS
American Association of Orthopaedic Surgeons

April 26, 2023

Allison Oelschlaeger
Director and CMS Chief Data Officer
Office of Enterprise Data and Analytics
Centers for Medicare and Medicaid Services
Department of Health and Human Services

Dear Director Oelschlaeger:

On behalf of over 39,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we are writing to express appreciation for our valued partnership with the Centers for Medicare and Medicaid Services (CMS). Medicare claims data is integral to our registries' ability to leverage data to help our members improve the value of care they deliver to their patients. With this in mind, we are expressing our concern once again with the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) Section 105(b) requirements for Qualified Clinical Data Registries' (QCDRs) process to obtain Medicare claims data.

As you may be aware, the inability for AAOS to access Medicare claims data easily, regularly, and cost-effectively as a QCDR has been a significant obstacle for the research and quality improvement capacities of our registries. The MACRA included a provision, Section 105(b) "Expanding the Availability of Medicare Data", which was supposed to have taken effect on July 1, 2016, and would have granted QCDRs access to Medicare claims data for quality improvement and studies of patient safety. It is our understanding that CMS chose to instead use an existing process to comply with Section 105(b) due to a lack of new funds for this requirement. CMS later announced that they would not adopt the directive from Congress to grant QCDRs access to Medicare claims data and asked that registries apply to become "Quasi Qualified Entities" to obtain Medicare claims data, a lengthy process which does not satisfy the requirement of MACRA.

The ResDAC program was established to respond to requests from researchers and is inappropriate to meet the continuous and comprehensive access to Medicare claims data required by QCDRs. AAOS originally planned to refresh Medicare claims data quarterly. Currently, due to the lengthy nature of the process and the high direct costs for data acquisition, we can only obtain claims annually. Below are the current steps our QCDRs must take in order to obtain Medicare claims data:

AAOS Registries must submit the following documents and approvals prior to dataset creation (4-5 months)

1. Annual research protocol extension request
2. RIF request letter (summary)
3. Data use agreement update form
4. Data management plan self-attestation questionnaire

5. Data specification and request detail spreadsheet
6. Invoice and updated data specification spreadsheet
7. ResDAC administrative review process
8. CMS approval of final request

Data processing and delivery (1-2 months)

The process detailed above highlights just how significantly CMS' lack of compliance with Congress's directive has impacted the work that QCDRs are doing to surveil and analyze healthcare outcomes. This inefficiency comes at the detriment of Medicare beneficiaries' access to the most advanced, safe, and valuable treatments. For example, AAOS uses this data to analyze and regularly publish device-level survivorship data, thus ensuring that orthopaedic implants are performing as expected. We ask that CMS consider expedient alternatives to the current process which would generate more frequent opportunities for data analysis.

Cost Challenges

The monetary cost of obtaining Medicare claims data through the ResDAC process is nearly prohibitive. AAOS is anticipating that the cost of this data will escalate as the AAOS Family of Clinical Registries grows and the volume of requests increases significantly, both for additional years of claims as well as for new patients in the Registries. As it currently stands, the process costs approximately $80,000-$100,000 per year depending on the data set requested.

Seven years since the law was supposed to take effect, QCDRs are still subject to this time-consuming and costly process for accessing claims data. It is important to incentivize the creation and ease of managing of QCDRs as the U.S. population ages and the health care sector moves to more value-based investments. QCDRs help with improving population health outcomes, effectiveness of care pathways and surveillance of drugs and devices. To create a sustainable future for the Medicare program, policy makers must focus on ease of access and interoperability of Medicare data to aid in decision making and quality improvement.

Specifically, we request that the agency create a pathway for data requests and delivery that fulfills the original directive of the law to create an efficient, affordable, and concise process for continuous access to this data.

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS). Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,

Kevin J. Bozic, MD, MBA, FAAOS
AAOS President

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