



March 29, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-FC, P.O. Box 8013
Baltimore, MD 21244-8013.

Re: [CMS-5061-P] – Medicare Program: Expanding Uses of Medicare Data by Qualified Entities

Dear Mr. Slavitt:

The Physician Clinical Registry Coalition (the Coalition) welcomes the opportunity to comment on the Medicare Program: Expanding Uses of Medicare Data by Qualified Entities Proposed Rule (Proposed Rule). The Coalition is a group of more than 20 medical societies and other physician-led organizations that sponsor clinical data registries that collect identifiable patient information for quality improvement and patient safety purposes to help participating providers monitor clinical outcomes among their patients. We are committed to advocating for policies that enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of these outcomes. Over half the members of the Coalition have been approved as qualified clinical data registries (QCDRs) and most of the others are working toward that goal.

The Coalition commends the Centers for Medicare & Medicaid Services (CMS) for continuing to promote transparency as to Medicare claims data through its development of the Qualified Entity (QE) program and its implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). The Coalition is disappointed, however, that CMS chose not to develop new policies and procedures to implement Section 105(b) of MACRA. Under Section 105(b), Congress directed CMS to make Medicare claims data available to QCDRs at their request to support their quality improvement and patient safety efforts. However, CMS chose not to issue new regulations addressing Congress' directive as part of the Proposed Rule, stating that QCDRs can already access Medicare claims data through processes outlined on the Research Data Assistance Center (ResDAC) website.

In declining to issue regulations implementing Section 105(b) of MACRA, CMS has ignored the fact that Congress was well aware of the ResDAC processes for accessing data and yet chose to pass Section 105(b) anyway. Congress must have intended for CMS to create processes for accessing Medicare claims data in addition to those that were already available. In fact, Section 105(b) is primarily intended to allow QCDRs access to Medicare claims data for quality

improvement and patient safety purposes, instead of for the discrete research purposes for which the data is already available through the ResDAC processes. The Coalition therefore respectfully requests that CMS issue regulations implementing Section 105(b) of MACRA. We further request that such data sharing policies and procedures include matching of the Medicare claims data to the Social Security Death Masterfile (SSDMF) data before its release to improve the accuracy of QCDR clinical outcomes data.

1. Congress Intended CMS to Issue Regulations Governing the Release of Medicare Claims Data to QCDRs

CMS' decision not to issue regulations implementing Section 105(b) of MACRA is contrary to the plain language of the statute. Section 105(b) explicitly requires that CMS make Medicare claims data available to QCDRs for quality improvement and patient safety purposes. The Coalition advocated for this provision of MACRA so that the clinical outcomes information gathered by QCDRs could be tied to Medicare claims data to better track these outcomes over time. Congress was aware of these benefits when it passed MACRA. It also knew that Medicare claims data was already available to QCDRs for research purposes, yet chose to direct CMS to create an additional avenue for accessing Medicare data for quality improvement purposes. In choosing not to issue regulations implementing this provision, CMS would render Section 105(b) superfluous, an interpretation that is clearly contrary to Congress' intent, the plain meaning of the statute, and longstanding principles of statutory construction.

2. CMS Must Provide QCDRs With Access to Medicare Claims Data for Quality Improvement and Patient Safety Purposes

Congress drafted Section 105(b) specifically to allow QCDRs access to Medicare claims data for quality improvement and patient safety purposes. Section 105(b) is titled "Access to Medicare Claims Data by Qualified Clinical Data Registries to Facilitate Quality Improvement" and the language of the statute explicitly directs CMS to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research *to support quality improvement or patient safety.*" (Emphasis added). In declining to issue regulations implementing this provision, CMS fundamentally misunderstands Congress' intent in passing Section 105(b) of MACRA. According to the preamble to the proposed rule, CMS believes that "[t]he CMS research data disclosure policies already allow qualified clinical data registries to request Medicare data for [Section 105(b)'s] purposes, *as well as other types of research.*" (Emphasis added) However, releasing Medicare claims data for quality improvement and patient safety purposes, as requested by Congress, is distinct from using Medicare claims data for research. Moreover, the distinction drawn by Congress is consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) distinction between research and quality improvement activities with respect to patient identifiable data.

To perform data analysis for quality improvement purposes and patient safety, QCDRs require long-term and continuous access to large Medicare data sets to better track clinical outcomes over time. In drafting Section 105(b) of MACRA, Congress was aware of this need and as such

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specifically directed CMS to provide QCDRs with Medicare claims data “for purposes of linking such data with clinical outcomes data.” The ResDAC process that CMS believes addresses this need is cumbersome and provides for the release of data only for discrete research projects. Limiting QCDRs to this process would inhibit their ability to use Medicare claims data to track clinical outcomes over the long-term. Congress instead intended to make Medicare claims data available to QCDRs by virtue of their having met the requirements of the QCDR qualification process. CMS would still need to provide a mechanism for QCDRs to apply to CMS and identify their specific data needs, but this mechanism should be wholly separate from the ResDAC procedures, which are designed to address discrete research projects.

3. SSDMF Data Should be Matched with Medicare Claims Data Before Being Released to QCDRs

In releasing Medicare claims data for QCDRs, CMS should match that data to the state-reported death data in the SSDMF to allow QCDRs to verify the “life status” of patients who otherwise may not be available for follow-up after treatment. The Social Security Administration (SSA) used to have a policy of sharing this data but withdrew it in 2011 for legitimate privacy concerns and as a protection against identity theft. However, the Secretary of Health and Human Services (HHS) also has the authority under 42 U.S.C. § 405(r)(9) to match data held by the SSA to data held by HHS. 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.

Conclusion

CMS’ decision not to implement Section 105(b) of MACRA and provide QCDRs with continuous and timely access to Medicare claims data for quality improvement and patient safety purposes is contrary to congressional intent and the plain language of the statute. The ResDAC procedures for accessing Medicare claims data are insufficient to address QCDRs needs. We respectfully request that CMS establish a mechanism for QCDRs to request Medicare claims data for purposes of linking to clinical outcomes data in support of the quality improvement efforts of QCDRs consistent with Section 105(b). We also respectfully request that the Medicare claims data accessed through this process be matched with SSDMF data before it is shared with QCDRs.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Rob.Portman@ppsv.com or 202.466.6550.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY

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SOCIETY OF NEUROINTERNTIONAL SURGERY
SOCIETY FOR VASCULAR SURGERY
THE SOCIETY OF THORACIC SURGEONS