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PHYSICIAN CLINICAL REGISTRY COALITION

August 31, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013

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

Dear Mr. Slavitt:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) are writing to express our concerns about the "quasi-qualified entity" provisions of the recently-issued final rule, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities" (the Final Rule).[1] 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 Program and its implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10). The Coalition was disappointed, however, that CMS initially chose, in the notice of proposed rulemaking in this proceeding (the Proposed Rule), not to develop new policies and procedures to implement Section 105(b) of MACRA.[2] Under Section 105(b), Congress directed CMS to make Medicare claims data available to QCDRs at their request to support their quality improvement, research, and patient safety efforts. However, CMS initially 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.

[1] 81 Fed. Reg. 44,456 (July 7, 2016).
[2] 81 Fed. Reg. 5397, 5408 (Feb. 2, 2016).

In response to the comments of the Coalition and others, CMS decided in the Final Rule to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data. While we appreciate CMS's effort to provide QCDRs with an alternative means of accessing Medicare data, treating QCDRs as quasi-qualified entities will not provide them with the type of access contemplated by Section 105(b) of MACRA.

Section 105(b) 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." 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 specifically directed CMS to provide QCDRs with Medicare claims data "for purposes of linking such data with clinical outcomes data."

Significantly, if Congress had wanted CMS to treat QCDRs as qualified entities for purposes of data access, it easily could have said so in Section 105(a), which addresses data access issues for qualified entities. Instead, it created a completely separate section and mandate for CMS to provide QCDRs with access to Medicare data.

Moreover, offering QCDRs the opportunity to apply for quasi-qualified entity status does little to give QCDRs the long-term, continuous, and timely access to Medicare claims data required under Section 105(b). Qualified entity status only lasts for three years and continued participation in the program requires re-application by submitting documentation of any changes to the original application. If the re-application is denied, CMS will terminate its relationship with the qualified entity. In addition, Medicare Fee-For-Service files are released quarterly on an approximate 5.5 month lag. Qualified entities must pay for each set of data they receive, which can become cost prohibitive over time.

While the new qualified entity regulations contain some provisions that may help expand QCDRs' access to claims data, the onerous requirements and lengthy application process required to become a qualified or quasi-qualified entity stand as a substantial barrier for QCDRs to gain access to the data mandated by Section 105(b). For example, it took one Coalition member eighteen months to complete the application process. The Qualified Entity Certification Program (QECP) rejected the application, even though the Coalition member had extensive communication with QECP staff throughout the application process about its eligibility, and QECP staff provided the Coalition member with advice about the details of its application. In addition, CMS's lack of guidance on what is required to become a quasi-qualified entity raises confusion as to how QCDRs can take full advantage of this option.

The data provided under the Qualified Entity Program is both over- and under-inclusive. The data available to qualified entities is provider-wide and state-specific. In fact, what QCDRs generally need is national data sets that are either procedure- or specialty-specific. In order to

receive nationwide data, QCDRs will have to pay for the entire set of data across all providers and then narrow down the data itself to the particular clinical specialty.

In addition, the regulations do not provide enough guidance on the meaning of a quasi-qualified entity. CMS provided no precise definition, no description of how to apply to become a quasi-qualified entity, and no separate procedures for a quasi-qualified entity to follow. Since the regulations require a quasi-qualified entity to meet "all the requirements in this subpart" except for § 401.707(d), we can only assume that CMS means it does not intend to establish any separate application requirements or procedures. The only guidance that currently exists on quasi-qualified entities is from the QECP FAQ, which states "[a]ny QCDRs that meet these requirements may request access to QE Medicare data as a quasi QE. To apply to become a quasi QE, QCDRs should register on the QECP public website … and complete a registration form."[3] Currently, the registration form does not mention quasi-qualified entities.[4]

CMS seems intent on keeping the Qualified Entity Program extremely small. In the final rule, CMS estimates that five new qualified or quasi-qualified entities will join the program under the new rules, increasing the total number of qualified entities from 15 to 20.[5] This suggests that it will be very difficult for QCDRs to qualify for quasi-qualified entity status. Yet, the intent of Section 105(b) is for all QCDRs to have continuous and timely access to Medicare data to support their quality improvement, patient safety, and research efforts.

Lastly, we must also state our concern that CMS included the quasi-qualified entity concept in the Final Rule for the first time without providing any opportunity for public comment. It was never mentioned in the Proposed Rule. By including the quasi-qualified entity approach in the Final Rule without any notice or opportunity for public comment, CMS has clearly violated the requirements of the Administrative Procedure Act at 5 U.S.C. § 553(b).

For these reasons, the undersigned members of the Coalition have strong reservations about CMS's decision to meet its obligations under Section 105(b) by offering QCDRs the option of becoming quasi-qualified entities. This approach does not provide QCDRs with the kind of continuous, timely, and affordable access to Medicare claims data contemplated by Congress. At a minimum, CMS should have provided an opportunity for public comment on the quasi-qualified entity concept.

[3] QECP, *FAQ #8*, https://www.qemedicaredata.org/SitePages/faq.aspx (last accessed August 12, 2016).
[4] QECP, *Registration Form*, https://www.qemedicaredata.org/SitePages/register.aspx (last accessed August 12, 2016).
[5] 81 Fed. Reg. at 44,473.

We would appreciate the opportunity to meet with you and other appropriate CMS representatives to convey our concerns in person. Please contact Rob Portman at 202-872-6756 or rob.portman@ppsv.com to let us know if you are willing to meet with representatives of the Coalition.

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY- HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/ NEUROPOINT ALLIANCE
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY/GIQUIC
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
AMERICAN JOINT REPLACEMENT REGISTRY
AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF ANESTHESIOLOGISTS/ ANESTHESIA QUALITY INSTITUTE
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
NORTH AMERICAN SPINE SOCIETY
SOCIETY FOR VASCULAR SURGERY
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROIINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS