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PHYSICIAN CLINICAL REGISTRY COALITION

# Qualified Clinical Data Registry Access to Medicare Claims Data

## 1. Introduction

Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directs CMS to provide Medicare claims data to qualified clinical data registries (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." The Centers for Medicare and Medicaid Services (CMS) initially issued refused to implement this mandate, stating that QCDRs could access Medicare claims data through the Research Data Assistance Center (ResDAC) process.[1] When the Physician Clinical Registry Coalition (the Coalition) and others complained that the ResDAC process was too slow, costly, and cumbersome to provide QCDRs with timely and meaningful access to Medicare claims data, CMS offered QCDRs the option of becoming a quasi-qualified entity for purposes of accessing Medicare claims data.[2] For the reasons provided below, neither option provides QCDRs with the type of timely, broad, and continuous access to Medicare claims data contemplated by Section 105(b) and necessary for QCDRs to effectively link their outcomes data with Medicare data.

## 2. CMS Has Not Provided Sufficient QCDR Access to Medicare Claims Data

Neither the ResDAC process nor quasi-qualified entity status provides QCDRs with the type of access to Medicare claims data that satisfies the requirements of Section 105(b).

- The ResDAC process does not provide sufficient access to Medicare claims data for quality improvement purposes:
    - The ResDAC process is designed to provide access to Medicare claims data for research purposes, which is distinct from utilizing Medicare claims data for the broad quality improvement and patient safety purposes contemplated by Section 105(b).
    - The ResDAC process provides for the release of a defined set of data only for discrete research projects. QCDRs require long-term and continuous access to large Medicare data sets to better track clinical outcomes over time.
    - The ResDAC process is slow, cumbersome, and expensive. Data requests can take months and sometimes years to process with no guarantee of approval.

[1] *See* Notice of Proposed Rulemaking, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities," 81 Fed. Reg. 5397, 5408 (Feb. 2, 2016).
[2] See Final Rule, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities,"81 Fed. Reg. 44,456 (July 7, 2016).

- CMS's decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data does not provide QCDRs with the long-term, continuous, and timely access to Medicare claims data required under Section 105(b):

    - Quasi-qualified and qualified entity status only provides QCDRs access to provider-wide and state-specific data. QCDRs generally need data on a provider-specialty specific and nationwide basis. Thus, qualified entity status would provide QCDRs with both more and less data than they need to link Medicare Claims data with provider-level clinical outcomes data.

    - Quasi-qualified and qualified entity status can only be obtained after an extensive application process. For example, it took one Coalition member eighteen months to complete the qualified entity application process. QCDRs already have to pass through an extensive CMS review process to obtain their status. Requiring them to also apply for quasi-qualified entity status, with no guarantee of approval, will delay their access to Medicare data and is fundamentally contrary to Congress' intent in passing Section 105(b).

    - Quasi-qualified and qualified entity status is only approved for a three-year period, after which CMS requires re-application. Therefore, it does not allow for the continuous access needed for monitoring quality improvement over time.

    - Quasi-qualified and qualified entities must pay for each set of data they receive, which can become cost prohibitive over time. Because of qualified entities only have access to provider-wide 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, which will involve unnecessary cost and delay.

    - 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.

**3. Medicare Claims Data Requested for Measuring Quality Improvement**

For QCDRs and other clinical data registries, longitudinal analysis is one of the most valuable research tools for measuring quality improvement. These studies involve tracking patients over time and across different providers, as the majority of patients receive care from several different settings (e.g., hospitals, physician offices, skilled nursing facilities) and do not necessarily return to the same provider or care setting for follow-up care. QCDRs need timely, cost-effective, and continuous access to Medicare claims data to perform longitudinal studies, The following are some of the specific features of a data access program necessary to allow QCDRs to adequately

link their clinical outcomes data to perform longitudinal and other analyses for quality improvement (as well as research) purposes:

- QCDRs need access to either direct patient identifiers or probabilistic matching to link to their patient-level clinical outcomes data. This capability can provide insight into the health status of patients, their historical utilization of medical services and risk-adjusted clinical outcomes, and variation in uses and costs among providers relevant to a complete episode of care. These data elements can also inform the design and development of alternative payment models to align incentives among providers and develop appropriate risk sharing mechanisms.

- While the specific data elements needed by each QCDR will vary, QCDRs will generally need access to the following information to conduct longitudinal studies:

    - Patient details (name, date of birth, sex, zip code);
    - Provider details (provider/organization name, provider/organization National Provider Identifier (NPI), claim operating physician, claim operating physician NPI, zip code);
    - Procedural information (admission date, discharge date, procedure data, claim procedure codes, claim diagnosis);
    - National mortality data;
    - Patterns of surgery including various surgical combinations (by DRG, CPT);
    - Medical versus surgical management of disease;
    - Device tracking/surveillance;
    - Frequency of visits;
    - Frequency of exacerbations both pre-and postoperatively;
    - Re-interventions or revisions;
    - Co-morbidities

- QCDRs need, and we believe Section 105(b) requires, CMS to establish a separate process for QCDR data queries that is timely, flexible, and cost-effective. The current Medicare claims data files are extremely complex and require expert data analysts and programmers familiar with these data to narrow down the data elements to those specifically of interest to QCDRs. After signing appropriate data use and other agreements, QCDRs should automatically be eligible to submit queries for data sets that will permit linking outcomes and claims data in a timely manner. The fees for such access should be reasonable and scaled to the nature of the data request. CMS could establish a dashboard system to which QCDRs would have access and would allow them to review and link with Medicare claims data on a real-time basis, much the same way that QCDRs give their participants access to QCDR data.

- QCDRs are willing to share the results of their analyses using Medicare claims data with CMS, as well as other federal agencies, such as the Food and Drug Administration.

## 4. Requested Action

The Coalition requests additional rulemaking separate from the ResDAC process and quasi-qualified entity status to provide QCDRs the necessary access to Medicare claims data. If you have any questions, please contact Rob Portman at rob.portman@ppsv.com or 202-872-6756.