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PHYSICIAN CLINICAL REGISTRY COALITION

May 15, 2024

SUBMITTED ELECTRONICALLY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Physician Clinical Registry Coalition's Comments in Response to the Request for Information on Research Data Request and Access Policy Changes

Dear Administrator Brooks-LaSure:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' ("CMS's") Request for Information on its Research Data Request and Access Policy Changes (the "Policy Change") that impose fees on researchers and discontinue delivery of physical data extracts in support of external research projects.

The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes. CMS's Policy Change will frustrate these goals and force researchers to halt ongoing investigations and pare down research priorities. Therefore, we request that CMS reconsider this Policy Change or make substantial changes that meaningfully engage affected stakeholders like clinical data registries. More generally, we respectfully urge CMS to reform the current Qualified Entity Program ("QE Program") and the Virtual Research Data Center ("VRDC") to ensure clinician-led clinical data registries have meaningful access to Medicare claims data as directed by Congress, particularly in light of the elimination of physical data extracts.

On February 12, 2024, CMS announced that the agency will limit access to Medicare and Medicaid claims data and increase fees imposed on individual researchers who seek to access this data for their investigations. CMS has proposed implementing the Policy Change in two phases, neither of which will become effective before 2025. During the proposed Phase 1, CMS will no longer disseminate physical Research Identifiable File ("RIF") for new research studies, forcing all external research partners to access data within CMS' Chronic Conditions Warehouse VRDC, which does not provide sufficient access to data. Research studies with approved Data Use Agreements ("DUAs") for physical dissemination of RIF data may continue receiving

physical data files in Phase 1, but researchers must pay an annual project fee in addition to the current file dissemination fee to continue to receive physical copies of the data. During the proposed Phase 2, these ongoing studies must end or transition to the VRDC, as CMS will no longer permit any physical RIF data extracts.

CMS cites growing data security concerns and an increase in healthcare data breaches as its justification for the Policy Change. Coalition members, like others in the research community, recognize the sensitivity of this data and take their obligation to protect it very seriously. Accordingly, while the Coalition appreciates that CMS is taking steps to ensure that only authorized users are utilizing sensitive Medicare data, we believe current safeguards ensure this data is well protected. We do not believe the benefits of the Policy Change's security measures outweigh the negative implications it could have on clinical data registries and the Medicare program more broadly.

Background

Most of the members of the Coalition meet the definition of clinician-led clinical data registry under the 21st Century Cures Act[1] (the "Cures Act") and have been approved as Qualified Clinical Data Registries ("QCDRs") under the Merit-Based Incentive Payment System. A QCDR is a CMS-approved entity that "collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients."[2] The comprehensive and valuable measures developed by QCDRs are meaningful and relevant to participating providers and their patient populations. QCDRs collect and analyze data on specified outcomes submitted by physicians, hospitals, and other types of health care providers related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions. QCDRs are major sources of real-world evidence and provide a valuable data collection infrastructure to accomplish numerous objectives, including:

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[1] The 21st Century Cures Act defines a "clinician-led clinical data registry" as:

> [A] clinical data repository— (1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy; (2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures; (3) that provides feedback to participants who submit reports to the repository; (4) that meets standards for data quality including—(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and (B) being subject to regular data checks or audits to verify completeness and validity; and (5) that provides ongoing participant training and support.

21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

[2] CMS, *2016 Physician Quality Reporting System (PQRS) QCDR Training Guide* (Feb. 2017), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2016QCDRTrainingGuide.pdf.

- Improving quality of healthcare by providing timely and actionable feedback to practitioners on their performance and identifying best clinical practices;
- Monitoring the prevalence and trends of specific conditions and diseases;
- Monitoring the effectiveness, cost-effectiveness, and comparative effectiveness of specific devices or treatments;
- Identifying opportunities to research patient outcomes and performing other research; and
- Identifying deficiencies or disparities in care that require corrective action.

Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") 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."[3] Despite this mandate, the agency has not provided the 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 claims data. This limits QCDRs' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes. The Policy Change will only exacerbate this lack of access, contradicting the congressional intent of both MACRA and the Cures Act to promote the effectiveness of and data sharing with QCDRs and clinician-led clinical data registries, respectively.[4]

QCDR Access to Medicare Claims Data

The current options for accessing Medicare claims data are limited. The VRDC is a virtual research environment under which QCDRs can—in theory—access Medicare claims data. The QE Program (also known has the Medicare Data Sharing for Performance Measurement Program) enables organizations approved as "qualified entities" to receive Medicare claims data for use in evaluating provider performance. CMS offers QCDRs the option of becoming "quasi-qualified entities" under this program for purposes of accessing Medicare claims data.[5]

Both the QE Program and VRDC place restrictions on the use of data, allowing registries to access data for very specific research purposes *or* for quality improvement purposes, but not both. In addition, the application processes and associated fees are too costly and cumbersome to provide registries with timely and meaningful access to claims data. Neither the VRDC process nor QE Program provide QCDRs with the type of access to Medicare claims data that satisfies the requirements of Section 105(b).

[3] 42 U.S.C. § 1395kk-2(b)(1)(A).
[4] The Cures Act requires and facilitates data sharing between electronic health records and clinician-led clinical data registries.
[5] *See* Final Rule, "Medicare Program: Expanding Uses of Medicare Data by Qualified Entities," 81 Fed. Reg. 44,456 (July 7, 2016).

Physical data extracts have traditionally allowed researchers to receive shipments of physical data extracts to their institutions. Given the challenges associated with the QE Program and the VRDC, physical data extracts have often been the most reliable source of data for clinical data registries. The imposition of the Policy Change without improving these programs or creating a better pathway for QCDRs to access Medicare data will violate the agency's legal obligation under MACRA.

VRDC

The VRDC process does not provide sufficient access to Medicare claims data for quality improvement purposes for the following reasons:

- The VRDC 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 VRDC 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 VRDC process is slow, cumbersome, and expensive. Data requests can take months and sometimes years to process with no guarantee of approval.

In addition, the VRDC has restrictions on the available coding languages and limited server capacity; it also restricts the number of times researchers can produce outputs. Additionally, researchers must pay additional fees to access other software technologies to conduct their analyses.

QE Program

Treating QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data also 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 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.

Problems with the Policy Change

CMS's current system already fails to provide QCDRs with the meaningful access to Medicare claims data required by MACRA, and the Policy Change will only exacerbate CMS's noncompliance. Elimination of physical data extracts may severely undermine the work of clinical data registries and put CMS in violation of its legal obligation to provide timely, broad, and continuous access to Medicare claims data.

First, the Policy Change's new pricing structure poses significant barriers to researchers, particularly those from organizations that are historically disadvantaged or under-resourced. Regardless of the size or use of data, all entities will face an incredibly steep $20,000 fee for new projects and $10,000 annual renewal fee. This change in pricing structure would significantly increase the cost of accessing Medicare data, which is already a stretch for many nonprofit organizations that sponsor QCDRs. Moreover, the sudden imposition of the $10,000 renewal fee for ongoing research studies that have not yet transitioned away from physical data extracts in Phase 1 could force such projects to shut down, threatening valuable progress.

Second, the Policy Change appears to restrict the ability to download Medicare data with identifiers that facilitate linking with registry data. This limitation severely hinders the effectiveness of research projects and undermines the value of the data itself (for example, researchers cannot follow cancer patients across the care continuum).

Recommendations

The Coalition acknowledges and appreciates that CMS seeks to increase the security of RIF data. However, CMS has not sufficiently considered how the new policy will restrict data access and undermine the work of clinical data registries. Therefore, the Coalition offers the following recommendations to CMS:

- Conduct listening sessions with stakeholders, including clinical data registries, to understand the effects of removing physical data extracts.
- Create a more reasonable fee structure and consider offering waiver applications for students, academics, nonprofits, and other under-resourced organizations.
- Fix the limitations of the VRDC or establish a separate claims data access program that is timely, flexible, and cost-effective.

As to the last recommendation, CMS should establish a viable pathway for accessing data in a timely, comprehensive, and cost-effective manner. This would accomplish the purpose of Section 105(b) of MACRA.[6] 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 and 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, any program should allow for various data set queries including provider-specific claims data, state-specific claims data, and nationwide claims data. More specifically, QCDRs will generally need access to the following information to conduct longitudinal studies:

    - Patient details (name, date of birth, sex, zip code);

[6] 42 U.S.C. § 1395kk-2(b)(1)(A).

  - 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

- 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 should have access to such a dashboard system for a period of at least five years, with the opportunity to reapply for access at the end of such period.

- Using the Medicare claims data in combination with registry data, QCDRs should be permitted to make available to the public reports evaluating the performance of providers of services and suppliers, (ii) conduct additional non-public analyses and provide or charge an access fee for such analyses for non-public use, (iii) provide or charge an access fee for data sets that link claims data with registry data for non-public use, and (iv) provide or charge an access fee for claims data to authorized users for non-public use.

Upon CMS' implementation of a program adhering to these specifications—and QCDRs' utilization of such a program—QCDRs will be able to share the results of their analyses using Medicare claims data with CMS, as well as with other federal agencies, such as the Food and Drug Administration, providing them with invaluable information.

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For the foregoing reasons, the Coalition is concerned that the Policy Change could have detrimental effects on clinical data registries and researchers across the country. Accordingly, the Coalition urges CMS to reconsider the Policy Change and, more generally, to consider additional rulemaking that would provide QCDRs with the meaningful access to Medicare claims data that MACRA Section 105(b) requires and that the VRDC and QE Program fail to provide. The Policy Change's elimination of access via physical data has made this request considerably more pressing. If you have any questions, please contact Leela Baggett or Rob Portman at Leela.Baggett@PowersLaw.com or Rob.Portman@PowersLaw.com.

Sincerely,

The Undersigned Members of the Coalition

American Academy of Dermatology Association
American Academy of Physical Medicine and Rehabilitation
American College of Gastroenterology