



PHYSICIAN CLINICAL REGISTRY COALITION

June 23, 2020

VIA ELECTRONIC MAIL

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Re: Recommendations for Cures 2.0 Legislation

Dear Representatives DeGette and Upton:

The undersigned members of the Physician Clinical Registry Coalition (“Coalition”) write to offer our recommendations for legislative reform to include in the Cures 2.0 package. 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. Most of the members of the Coalition meet the definition of clinician-led clinical data registry under the 21st Century Cures Act and have been approved as Qualified Clinical Data Registries (“QCDRs”) under the Merit-Based Incentive Payment System.

The Coalition commends your leadership in developing legislation to modernize the health care delivery system and better utilize real-world data and real-world evidence across federal agencies. Clinician-led clinical data registries play an essential role in promoting quality of care and are well-positioned to contribute to the legislative efforts described in the Cures 2.0 concept paper. Clinician-led clinical data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities.

Unfortunately, the Centers for Medicare and Medicaid Services (“CMS”) has failed to provide clinician-led clinical data registries with a meaningful way to gain continuous access to Medicare claims data that would further the goals of Cures 2.0. Tying Medicare claims data to clinical outcome information would enable clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide them with the information necessary to assess the cost-effectiveness of alternative therapies. Accordingly, we respectfully request that you include language in the Cures 2.0 package guaranteeing clinician-led clinical data registries access to Medicare claims data for quality

improvement, patient safety, and research purposes. We also urge that Medicare claims data be readily available to clinician-led clinical data registries through the Fast Healthcare Interoperability Resources-based application programming interface and that CMS be required to collect Unique Device Identifiers (“UDIs”) and share that information with clinician-led clinical data registries.

CMS Has Not Provided Clinician-Led Clinical Data Registries Sufficient Access to Medicare Claims Data

Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) directs the Secretary of Health and Human Services 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.”¹ CMS initially refused to implement this mandate, stating that QCDRs could access Medicare claims data through the Research Data Assistance Center (“ResDAC”) process.² After the Coalition and other stakeholders expressed concerns regarding the ResDAC process, CMS provided QCDRs with an alternative mechanism for accessing Medicare claims data, by permitting QCDRs to serve as quasi-qualified entities under the Qualified Entity Program.³

Neither option, however, 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 claims data, and these options provide no access to Medicare claims data for clinician-led clinical data registries that are not QCDRs. 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 is also slow, costly, and cumbersome.

Moreover, CMS’s decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data does not provide QCDRs (or other clinician-led clinical data registries) with the long-term, continuous, and timely access to Medicare claims data required under Section 105(b). The scope of the data provided under the Qualified Entity Program does not satisfy registry needs. QCDRs and other clinician-led clinical data registries generally need data on a provider-specialty specific and nationwide basis; however, quasi-qualified entity status only provides registries access to provider-wide and state-specific data. Quasi-qualified entities also cannot use Medicare

¹ MACRA, Pub. L. No. 114-10, § 105(b)(1)(A), 129 Stat. 87, 136 (2015).

² See Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5,397, 5,408 (Feb. 2, 2016) (proposed rule).

³ Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 44,456 (July 7, 2016).

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data for research purposes without submitting a separate research protocol to ResDAC for review and approval.

In addition, the Qualified Entity Program requirements on eligibility, operations, and governance are extremely lengthy and burdensome. Quasi-qualified entity status only lasts for three years and continued participation in the program requires re-application. Therefore, it does not allow for the continuous access needed for monitoring quality improvement over time.

The ResDAC process and the Qualified Entity Program stand as substantial barriers for QCDRs and other clinician-led clinical data registries to gain timely and meaningful access to Medicare claims data, limiting the ability of such registries to contribute data to determine the value of health care services. These barriers impede progress toward health care delivery modernization.

Cures 2.0 Should Ensure Access to Medicare Claims Data

To perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes, clinician-led clinical data registries require regular, continuous, and sometimes long-term access to large Medicare data sets to better track clinical outcomes over time. In alignment with the letters submitted by the Society of Thoracic Surgeons (“STS”) and The Center for Professionalism and Value in Health Care (“CPVHC”) in response to the Cures 2.0 concept paper, **we respectfully urge you to include in the Cures 2.0 package language guaranteeing clinician-led clinical data registries access to Medicare claims data for quality improvement, patient safety, and research purposes, all of which are necessary to build (or explore) evidence-based models of value-based care to benefit patients.**

In addition, we recommend that Medicare claims data should be readily available in a timely manner to providers through a Fast Healthcare Interoperability Resources-based application programming interface. Doing so will improve patient matching. Patient matching is a critical component of interoperability, data sharing, and the nation’s health information technology infrastructure. The Office of the National Coordinator for Health Information Technology stated that it considers patient matching a quality of care and patient safety issue. Patient matching needs to be addressed in order to have fully functional strategies for data sharing infrastructures. Additionally, we support the standardization of some demographic data, particularly applying the U.S. Postal Service standard to addresses. When the address field is standardized, matching rates improve.

We also believe that the collection of UDIs is pivotal to interoperability and data sharing infrastructure. The Coalition has been a strong advocate for the collection of UDIs within electronic health records (“EHRs”) to support post-market surveillance programs, which would promote early identification of adverse results. The exchange of this data with clinician-led clinical data registries would support the ability to use UDIs for large

scale studies analyzing device effectiveness, examining long-term outcomes, and for quality improvement. Therefore, a provision in Cures 2.0 mandating that CMS collect UDIs in the CMS-1500 form and share that information with clinician-led clinical data registries would dramatically improve our ability to study the safety and effectiveness of medical devices.

Such reform would allow clinician-led clinical data registries to link their outcomes data with CMS claims data in a way that would help ascertain the value of new medical technologies and therapies and assist in the development of effective alternative payment models (“APMs”). As repositories of clinical data, clinician-led clinical data registries can play a key role in developing APMs, particularly in highly specialized areas of care that benefit from cutting edge technologies. In order to develop APMs that are responsive to new technologies and services, it is vital to gain a more comprehensive understanding of health care value, which requires an examination of quality and cost. Without meaningful access to the cost information in Medicare claims data, however, the value of health care services cannot be fully measured. Ensuring access to Medicare claims data would inform the design and development of APMs to align incentives among providers and develop appropriate risk sharing mechanisms.

Reforming clinician-led clinical data registry access to Medicare claims data would provide a greater understanding of the real-world impact of breakthrough therapies across numerous patient populations. We concur with your assertion in the Cures 2.0 concept paper that real-world evidence holds promise for use across federal agencies. Clinician-led clinical data registries are crucial sources of real-world evidence. Gaining meaningful access to Medicare claims data would enable clinician-led clinical data registries to provide greater insight into the value of emerging therapies, particularly in underrepresented and underserved patient populations.

Lastly, such reform would build upon provisions of the 21st Century Cures Act that underscore how clinician-led clinical data registries are uniquely positioned to drive quality improvement initiatives. The 21st Century Cures Act defines the term “clinician-led clinical data registry” as a clinical data repository that is established or operated by a clinician-led or controlled, tax-exempt professional society or other similar organization; designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures; provides feedback to participating data sources; and meets certain quality standards.⁴ As noted by STS and CPHVC, this statutory definition is “particularly important for guaranteeing that [EHR] patient data is only transferred to high-quality registries that are fully capable of collecting, securing, and analyzing patient information for quality improvement.” Consistent with these efforts to improve patient care, we urge you to ensure that clinician-led clinical data registries are afforded meaningful access to Medicare claims data.

⁴ 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180-81 (2016).

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The Coalition appreciates your leadership in developing Cures 2.0, and we stand ready to work with you during this process. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or 202-872-6756).

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY – HEAD & NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY
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SOCIETY OF INTERVENTIONAL RADIOLOGY
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THE SOCIETY OF THORACIC SURGEONS

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