



PHYSICIAN CLINICAL REGISTRY COALITION

July 9, 2021

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 discussion draft. We applaud the inclusion in the discussion draft of language seeking to increase the use of real-world evidence and supporting the use of patient registries to fulfill post-approval study requirements for products regulated by the Food and Drug Administration.

However, additional, more specific reforms are needed to ensure that clinician-led clinical data registries have meaningful access to Medicare, Medicaid, and State Children’s Health Insurance Program claims data 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 therapies.

Therefore, we respectfully request that you include language in the Cures 2.0 package guaranteeing clinician-led clinical data registries access to Medicare,

Medicaid, and State Children’s Health Insurance Program claims data for quality improvement, patient safety, and research purposes. Such language could take the form of the draft legislative language attached hereto for your consideration.

CMS Has Not Provided Clinician-Led Clinical Data Registries Sufficient Access to Medicare, Medicaid, and State Children’s Health Insurance Program 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 The Centers for Medicare and Medicaid Services (“CMS”) initially refused to implement this mandate, stating that QCDRs could access 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 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 claims data contemplated by Section 105(b) and necessary for QCDRs to effectively link their outcomes data with claims data. The ResDAC option does not provide sufficient access to claims data for quality improvement purposes. The ResDAC process is designed to provide access to claims data for research purposes, which is distinct from utilizing 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 claims data does not provide QCDRs (or other clinician-led clinical data registries) with the long-term, continuous, and timely access to 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 claims data for research purposes without submitting a separate research protocol to ResDAC for review and approval.

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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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 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, Medicaid, and State Children's Health Insurance Program 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 data sets to better track clinical outcomes over time. Accordingly, **we respectfully urge you to include in the Cures 2.0 package language guaranteeing clinician-led clinical data registries access to Medicare, Medicaid, and State Children's Health Insurance Program 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.**

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 claims data, however, the value of health care services cannot be fully measured. Ensuring access to 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 claims data would provide a greater understanding of the real-world impact of breakthrough therapies across numerous patient populations. Real-world evidence holds promise for use across federal agencies, and clinician-led clinical data registries are crucial sources of such evidence. Gaining meaningful access to claims data would enable clinician-led clinical data

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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 This statutory definition is vital for guaranteeing that patient data is transferred only to registries that are fully capable of collecting 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 claims data.

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 or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY – HEAD & NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/CONGRESS OF NEUROLOGICAL SURGEONS
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN SOCIETY OF HEMATOLOGY⁵
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
ASSOCIATION FOR CLINICAL ONCOLOGY
COLLEGE OF AMERICAN PATHOLOGISTS
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE CENTER FOR PROFESSIONALISM & VALUE IN HEALTH CARE
THE SOCIETY OF THORACIC SURGEONS

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

⁵ The American Society of Hematology signed on to this letter after it was submitted to the offices of Representatives Diana DeGette and Fred Upton.

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cc: Sherie Lou Z. Santos, Health Policy Director, Rep. Diana DeGette
(SherieLou.Santos@mail.house.gov)
Mark Ratner, Legislative Director/Deputy Chief of Staff/Policy Coordinator, Rep.
Fred Upton (mark.ratner@mail.house.gov)

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Meaningful Access to Federal Health Plan Claims Data Act Legislative Language

SEC. 1. SHORT TITLE

This Act may be cited as the “Meaningful Access to Federal Health Plan Claims Data Act.”

SEC. 2. FINDINGS

Congress finds as follows:

(1) Clinician-led clinical data registries serve an important role in promoting, facilitating, and conducting medical research and improving quality of healthcare by providing timely and actionable feedback to practitioners on their performance in relation to other practitioners and best clinical practices.

(2) Clinician-led clinical data registries are hindered in their ability to promote medical research and quality improvement by their lack of meaningful access to claims data.

(3) While the Centers for Medicare and Medicaid Services has established programs for providing access to claims data, those programs fail to provide clinician-led clinical data registries with meaningful access to such data.

(4) Ensuring clinician-led clinical data registries meaningful access to claims data will enable such entities 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 therapies.

SEC. 3. ENSURING MEANINGFUL ACCESS TO CLAIMS DATA BY CLINICIAN-LED CLINICAL DATA REGISTRIES

(a) ENSURING MEANINGFUL ACCESS TO CLAIMS DATA.—

(1) ESTABLISHMENT OF A NEW PROGRAM.—The Secretary shall establish a new program (separate from any existing data access programs, including, without limitation, the Centers for Medicare and Medicaid Services Qualified Entity (QE) Program (42 U.S.C. §§ 1395kk(e), 1395kk-2) (also known as the Medicare Data Sharing for Performance Measurement Program) and the Research Data Assistance Center (ResDAC) process) under which the Secretary shall, at the request of a clinician-led clinical data registry, provide timely, broad, and continuous access to a database of claims data to such clinician-led clinical data registry for purposes of research, linking such data with clinical data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety, and other purposes and uses described herein or approved by the Secretary. Access to a database of

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claims data pursuant to this subsection shall not be more restrictive than access to data provided under the QE Program or the ResDAC process.

(2) STREAMLINED APPLICATION PROCESS.—

(A) INITIAL AND RECERTIFICATION APPLICATION.— Prior to gaining access to a database of claims data under the program established in subsection (a), a clinician-led clinical data registry shall submit to the Secretary an application demonstrating that it is qualified (as determined by the Secretary) to use claims data. Upon the Secretary's approval of a clinician-led clinical data registry's application described in this subparagraph, the Secretary shall provide access to a database of claims data to such clinician-led clinical data registry for a period of at least 5 years. After the expiration of the time period described in this subparagraph, the clinician-led clinical data registry shall reapply to access the database of claims data under the program established in subsection (a).

(B) PROCESS.—The Secretary shall establish a streamlined initial application and recertification application process under which the Secretary shall approve or deny the clinician-led clinical data registry's application described in subparagraph (2)(A) within 60 calendar days after receiving the application unless the Secretary demonstrates a compelling reason for needing additional time to complete the process. If the clinician-led clinical data registry's application described in subparagraph (2)(A) is denied, the Secretary shall provide the reason(s) for denial.

(3) APPEAL RIGHTS.—

(A) OPPORTUNITY TO APPEAL.—The Secretary shall develop and maintain a process by which clinician-led clinical data registries may appeal—

(i) The Secretary's decision to deny the clinician-led clinical data registry's application described in subparagraph (2)(A); and

(ii) The Secretary's failure to approve or deny the clinician-led clinical data registry's application described in subparagraph (2)(A) within a reasonable timeframe established by the Secretary.

(B) DEADLINE FOR DECISION.—The Secretary shall render a decision with respect to an appeal filed by a clinician-led clinical data registry pursuant to subparagraph (3)(A) in a timely manner, not to exceed 60 calendar days after the Secretary receives the clinician-led clinical data registry's request for an appeal. Notice of such decision shall be provided to the clinician-led clinical data registry filing the appeal before the conclusion of such 60-day period.

(4) BROAD AND TIMELY ACCESS TO DATA.—The Secretary shall structure its database of claims data to allow for various data set queries, including, but not limited to, provider-specific claims data, clinical specialty-specific claims data, state-specific claims data, and nationwide claims data. The Secretary shall promptly make available to a clinician-led clinical data registry access to claims data requested by such clinician-led clinical data registry

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within a reasonable timeframe, not to exceed 30 calendar days, after the Secretary approves the request from the clinician-led clinical data registry.

(b) **PERMISSIBLE USES OF CLAIMS DATA.**—Clinician-led clinical data registries may—

(1) Make available to the public reports evaluating the performance of providers of services and suppliers using the claims data provided to such clinician-led clinical data registry under subsection (a) in combination with registry data;

(2) Use claims data received under subsection (a) combined with registry data to conduct additional non-public analyses and provide or sell such analyses to authorized users for non-public use;

(3) Provide or sell data sets that link claims data received under subsection (a) with registry data to authorized users for non-public use; and

(4) Provide or sell claims data received under subsection (a) to authorized users for non-public use.

(c) **FEES.**—

(1) **CLAIMS DATA PROVIDED TO CLINICIAN-LED CLINICAL DATA REGISTRIES.**—Claims data shall be provided to a clinician-led clinical data registry under subsection (a) at a reasonable fee based on the cost of providing such data to the clinician-led clinical data registry. Such fee shall be based at least in part on the number of patients included in the claims data provided to such clinician-led clinical data registry. Any fee collected pursuant to the preceding sentence shall be deposited in the Centers for Medicare and Medicaid Services Program Management Account.

(2) **ANALYSES AND DATA PROVIDED TO AUTHORIZED USERS.**—Clinician-led clinical data registries may charge a reasonable, cost-based fee for providing to authorized users claims data, data sets linking claims data with registry data, or analyses described in subsection (b).

(d) **PROTECTION OF INFORMATION.**—

(1) **PRIVACY, SECURITY, AND DISCLOSURE LAWS.**—The Secretary shall provide access to a database of claims data pursuant to subsection (a) in accordance with applicable information, privacy, security, and disclosure laws, including, without limitation, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the Privacy and Security provisions set forth in Section 13400 of the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5, the regulations promulgated thereunder codified at 45 CFR Parts 160 and 164, and section 105(a)(3)(A)-(B) of Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(a)(3)(A)-(B)).

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(2) PROHIBITION ON USING ANALYSES OR DATA FOR MARKETING PURPOSES.—An authorized user shall not use analyses or data provided or sold under subparagraphs (b)(2)-(4) for marketing purposes.

(3) NO REDISCLOSURE OF ANALYSES OR DATA.—An authorized user in receipt of an analysis or datum provided or sold under subparagraphs (b)(2)-(4) shall comply with section 105(a)(5) of Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(a)(5)).

(4) OPPORTUNITY FOR PROVIDERS OF SERVICES AND SUPPLIERS TO REVIEW.—Prior to a clinician-led clinical data registry using, providing, or selling claims data, data sets linking claims data with registry data, or analyses described in subsection (b), to the extent that such data, data sets, or analyses would individually identify a provider of services or supplier who is not being provided or sold such data, data sets, or analyses, such clinician-led clinical data registry shall confidentially make available such data, data sets, or analyses to such provider of services or supplier and provide such provider of services or supplier with the opportunity to appeal and correct errors.

(e) DATA USE AGREEMENT.—A clinician-led clinical data registry and an authorized user shall enter into a data use agreement regarding the use or disclosure of any claims data or data sets that link claims data with registry data that the clinician-led clinical data registry is providing or selling to the authorized user under subparagraphs (b)(3)-(4). Such agreement shall include the requirements and prohibitions described in section 105(a)(4) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(a)(4)).

(f) ASSESSMENT FOR A BREACH.—

(1) IN GENERAL.—In the case of a breach of a data use agreement, the Secretary shall impose an assessment on the clinician-led clinical data registry and the authorized user.

(2) ASSESSMENT.—The assessment under subparagraph (f)(1) shall be in an amount up to \$100 for each individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under part B of such title for whom the clinician-led clinical data registry provided data on to the authorized user.

(3) DEPOSIT OF AMOUNTS COLLECTED.—Any amounts collected pursuant to this subsection shall be deposited in the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. § 1395t).

(g) DISCOVERY OR ADMISSION AS EVIDENCE.—Claims data released to a clinician-led clinical data registry under section (a) shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without consent of the applicable provider of services or supplier.

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SEC. 4. REPORT TO CONGRESS

Not later than 2 years after the date of enactment of this Act, and every year thereafter, the Secretary shall submit to Congress a report on the extent to which clinician-led clinical data registries are afforded meaningful access to claims data.

SEC. 5. DEFINITIONS

In this Act:

(1) **AUTHORIZED USER.**—The term “authorized user” shall have the meaning ascribed to it in section 105(a)(9)(A) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(a)(9)(A)), as well as a government agency or other governmental entity, researchers, entities that seek data for purposes of complying with regulations or other requirements of the Federal Food and Drug Administration, and other entities approved by the Secretary.

(2) **CLAIMS DATA.**—The term “claims data” shall have the meaning ascribed to the term “data” in section 105(b)(1)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. § 1395kk-2(b)(1)(B)).

(3) **CLINICIAN-LED CLINICAL DATA REGISTRY.**—The term “clinician-led clinical data registry” shall have the meaning ascribed to it in section 4005(b) of the 21st Century Cures Act.

(4) **DATA USE AGREEMENT.**—The term “data use agreement” means an agreement described in subsection (e) of section 3.

(5) **NON-PUBLIC USE.**—The term “non-public use” means for the purposes of promoting, facilitating, and conducting medical research; assisting providers of services and suppliers to improve patient safety and to develop and participate in quality and patient care improvement activities, including developing new models of care; assisting clinician-led clinical data registries in developing quality measures; educating a government agency or other governmental entity; supporting clinical trials and other activities necessary to comply with pre- or post-market approval or adverse event reporting requirements or conditions imposed by the Federal Food and Drug Administration; and other purposes approved by the Secretary.

(6) **PROVIDER OF SERVICES.**— The term “provider of services” shall have the meaning ascribed to it in section 1861(u) of the Social Security Act (42 U.S.C. § 1395x(u)).

(7) **SECRETARY.**—The term “Secretary” means the Secretary of Health and Humans Services.

(8) **SUPPLIER.**— The term “supplier” shall have the meaning ascribed to it in section 1861(d) of the Social Security Act (42 U.S.C. § 1395x(d)).

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SEC. 6. REGULATIONS

The Secretary shall promulgate not later than 1 year after the enactment of this Act, final regulations to implement the provisions of this Act.

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