



PHYSICIAN CLINICAL REGISTRY COALITION

December 2, 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: Support for Sections 309 and 411 of the Cures 2.0 Act

Dear Representatives DeGette and Upton:

The undersigned members of the Physician Clinical Registry Coalition (“Coalition”) write to express our strong support for the inclusion of Section 411 in the Cures 2.0 Act, ensuring 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. We also applaud the inclusion of Section 309, which seeks to increase the use of real-world evidence and support the use of data from clinical care data repositories and patient registries to fulfill post-approval study requirements for products regulated by the Food and Drug Administration.

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. 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. Unfortunately, the Centers for Medicare and Medicaid Services (“CMS”) has not provided clinician-led clinical data registries sufficient access to Medicare, Medicaid, and State Children’s Health Insurance

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Program claims data. The current lack of timely and meaningful access to claims data limits the ability of clinician-led clinical data registries to contribute data to determine the value of health care services.

The Cures 2.0 Act would ensure 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.

This legislation 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”). 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.

The Cures 2.0 Act 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 registries to provide greater insight into the value of emerging therapies, particularly in underrepresented and underserved patient populations.

Lastly, the Cures 2.0 Act builds upon provisions of the 21st Century Cures Act that underscore how clinician-led clinical data registries are uniquely positioned to drive quality improvement initiatives. In particular, we applaud the fact that Cures 2.0 incorporates the 21st Century Cures Act’s definition of “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.¹ 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.

On behalf of the Coalition, we thank you for championing the inclusion of Sections 309 and 411 in the Cures 2.0 Act, and we look forward to working with your offices and others in Congress to enact them into law. 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).

¹ 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180-81 (2016).

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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
American College of Emergency Physicians
American College of Gastroenterology
American College of Radiology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists/Anesthesia Quality Institute
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons

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)