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PHYSICIAN CLINICAL REGISTRY COALITION

August 17, 2023

VIA ELECTRONIC MAIL

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5540-NC
7500 Security Boulevard, Mail Stop C4-26-05
Baltimore, MD 21244-1850

Re: File Code CMS-5540-NC: Request for Information; Episode-Based Payment Model

Dear Administrator Brooks-LaSure:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's") Request for Information ("RFI") concerning the design of a future episode-based payment model by the Center for Medicare and Medicaid Innovation ("Innovation Center").[1] 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.

The Coalition's comments are limited to the importance of clinical data registries in the success of innovative payment models. **We respectfully urge the agency to encourage the meaningful use of clinical data registries in any future episode-based payment model.**

Clinical data registries are organized data collection systems operated by or affiliated with a national medical society, hospital association, or other health care association. These registries 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. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. The comprehensive and valuable measures developed by clinical data registries are meaningful and relevant to participating providers and their patient populations. These measures provide important information that is not available from claims data.

[1] Request for Information; Episode-Based Payment Model, 88 Fed. Reg. 45,872, https://www.federalregister.gov/documents/2023/07/18/2023-15169/request-for-information-episode-based-payment-model.

Clinical data registries are uniquely positioned to drive the health care system forward and play an important role in the quality-based payment paradigm. Clinical data registries provide a valuable data collection infrastructure to accomplish numerous objectives, including:

- Improving quality of healthcare by providing timely and actionable feedback to practitioners on their performance and identifying best clinical practices. Quality improvement efforts are typically achieved by developing benchmarks on performance/treatment outcomes from data submitted by all registry participants and sharing those benchmarks with each registry participant.

- Monitoring the prevalence and trends of specific conditions and diseases. The Centers for Disease Control and Prevention ("CDC") and state and local governments rely on registries to provide this data. For instance, the American Academy of Ophthalmology's IRIS Registry® provides data to the CDC's Vision and Eye Health Surveillance System, which creates composite estimates of vision loss and major eye disease prevalence at the national, state, and county level.

- Monitoring the effectiveness, cost-effectiveness, and comparative effectiveness of specific devices or treatments. Real world evidence collected and aggregated by clinical data registries is increasingly being used to develop alternative treatments paths, substantiate whether a service or item is "reasonable and necessary," and support evidence-based guidelines development. For instance, the Food and Drug Administration ("FDA") has been encouraging drug and device manufacturers to work with registries to conduct investigational and post-approval surveillance studies to ensure that both unapproved and approved drugs and devices are safe and effective. In addition, CMS has required participation in registries as a condition of reimbursement for certain medical procedures that involve investigational or off-label (i.e., unapproved) uses of drugs or devices. Participation in the Society of Thoracic Surgeons' and the American College of Cardiology's TVT Registry is a condition of participation for certain Medicare reimbursement purposes, which provides valuable information on the safety and effectiveness of the transcatheter valve therapies.

- Identifying opportunities to research patient outcomes and performing other research. Clinical data registries can be used to identify research opportunities to enhance general knowledge about the safety and effectiveness of various medical procedures, diagnostic tests, treatments, and health care products. Clinical data registries and their robust data sets can enable quicker and less expensive randomized clinical trials, longitudinal studies, and other observational studies. They support innovation and access to care for patients by streamlining and

decreasing the costs of clinical trials for the approval of new drugs or devices by the FDA.

- Identify deficiencies or disparities in care that require corrective action.

Accordingly, meaningful use of registry data should be one of the cornerstones of any innovative quality-based payment program. We also urge the agency to provide meaningful credit/incentivization for clinical data and measure testing participation. Clinician reporting contributes to real world data. However, the Merit-based Incentive Payment System ("MIPS") program currently provides too little credit for submitting data through a clinical data registry. Clinicians must invest time and resources to use registries. Therefore, clinicians are much more likely to pursue these means when there are more significant benefits to making the investment.

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The Coalition appreciates your consideration of our comments. 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 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 Psychiatric Association
American Society of Anesthesiologists/Anesthesia Quality Institute
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons