



January 2, 2023

ELECTRONICALLY SUBMITTED

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Micky Tripathi, Ph.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, Floor 7
Washington, D.C. 20201

Re: Physician Clinical Registry Coalition’s Comments in Response to 21st Century Cures Act: Establishment of Disincentives for Health Care Providers that Have Committed Information Blocking Proposed Rule (RIN 0955-AA05)

Dear Administrator Brooks-LaSure and National Coordinator Tripathi:

The undersigned members of the Physician Clinical Registry Coalition (“the Coalition”) appreciate the opportunity to comment on the Office of the National Coordinator for Health Information Technology’s (“ONC’s”) and the Centers for Medicare and Medicaid Services’ (“CMS’s”) proposed rule to enforce the information blocking provisions of the 21st Century Cures Act (the “Cures Act”) (the “Proposed Rule”).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.²

Clinical data 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

¹ 21st Century Cures Act: Establishment of Disincentives for Health Care Providers that Have Committed Information Blocking 88 Fed. Reg. 74947 (Nov. 1, 2023).

² For more information on the Coalition, see <https://www.registrycoalition.net/>.

procedures, diagnostic tests, and/or clinical conditions. They also conduct research on such data for purposes of evaluating the safety and effectiveness of various medical procedures, drugs, and medical devices. Clinical data registries, acting as Qualified Clinical Data Registries, report medical and clinical data to CMS on behalf of their participating health care providers for purposes of the Merit-based Incentive Payment System (“MIPS”).

Clinical data registries are not considered “health care providers” for purposes of information blocking. Accordingly, the Proposed Rule does not directly apply to clinical data registries that comprise the Coalition. However, the Proposed Rule does directly impact members of registries who are MIPS clinicians. For the reasons discussed below, we respectfully urge ONC and CMS to reconsider its proposed enforcement mechanisms against MIPS clinicians. We also wish to take this opportunity to discuss the continued challenges that clinical data registries face with respect to information blocking. We recognize that the Proposed Rule is confined to enforcement of the information blocking prohibition against a subset of providers. However, as ONC and CMS turn their attention to enforcement, we believe that the agencies should be aware that the existing rules governing information blocking have not been successful in preventing information blocking by electronic health record (“EHR”) vendors. Instead of imposing harsh penalties on MIPS clinicians, ONC and CMS should focus on more vigorously pursuing information blocking violations by EHR vendors.

ONC and CMS Should Reconsider the Proposed Enforcement Against MIPS Clinicians

The Coalition is concerned that the proposed enforcement mechanisms tied to the MIPS program are overbroad and heavy handed. Under the Proposed Rule, the penalty for MIPS eligible clinicians who have been determined to have committed information blocking is a score of zero on the Promoting Interoperability performance category, which is a quarter of the total final composite score. This punitive approach to enforcing the information blocking prohibition does not allow for variation in penalties based on the severity or frequency of information blocking. Instead, ONC and CMS have proposed to automatically impose a “zero” score for the Promoting Interoperability category, which may result in a considerable payment reduction. The lack of enforcement flexibility is unduly harsh and does not provide appropriate incentive for an actor that has committed information blocking to change its behavior during a performance year. Varying penalties based on the seriousness of the alleged information blocking activity would help further discourage bad actors, while distinguishing isolated instances of information blocking from more severe and systemic problematic practices.

We are also concerned that this Proposed Rule would inappropriately penalize an entire medical practice that reports at the group-level in the event that *one* physician commits information blocking. According to the Proposed Rule, if an individual provider commits information blocking, but their MIPS data is submitted as a practice group, the entire practice group would be negatively impacted by that behavior. The Coalition believes that it is unduly harsh to penalize an entire practice for the actions of one provider. Physicians who commit information blocking should be excluded from the group data or be required to separately report data.

Notably, the Proposed Rule does not allow the provider to take corrective action to avoid a disincentive being imposed. We respectfully urge ONC and CMS to prioritize educating

providers on information blocking and work with providers to facilitate corrective action, as opposed to automatically imposing harsh penalties on providers. Allowing providers the opportunity to establish a formal corrective action plan would curb information blocking by ensuring that proper education and systemic practices are appropriately addressed. The Proposed Rule, as currently written, emphasizes arbitrary financial penalties over education and self-correction.

Clinicians—who are already grappling with inflation, workforce shortages, and continued cuts to Medicare reimbursements year after year under the physician fee schedule—should not be subject to automatic, overly harsh, one size fits all penalties associated with information blocking. In fact, we believe that although the majority of alleged information blocking claims are against health care providers, the issue is most likely caused by the provider’s EHR than by the provider themselves, making the potential for automatic, overly harsh penalties even more concerning.

ONC Should Address Information Blocking that Impairs Registry Operations

Notwithstanding our concerns about the Proposed Rule, we applaud ONC’s and CMS’ commitment to addressing information blocking by EHR vendors and hospitals. In order for clinical data registries to accomplish their missions, they must be able to collect data from providers and EHR vendors. Until true interoperability is realized, clinical data registries will fall short of their tremendous potential to improve and progress the quality-based payment paradigm. Unfortunately, despite the previous rules issued by ONC and CMS to prevent information blocking by EHR vendors and hospitals, our clinical data registries continue to encounter roadblocks in gathering critical data elements from these data sources. The Coalition urges the agencies to enhance or more vigorously enforce the existing information blocking rules against EHR vendors.³

EHR vendors, in particular, hinder data transfer to clinical data registries in myriad ways. For example, EHR vendors refuse to enter into negotiations for the transfer of patient information to registries, and therefore are prohibiting registries from any degree of access to such information. EHR vendors also require providers to pay unjustified, large fees to send their data from the EHR to the registry or their software vendor. Further compounding these challenges is a systemic failure to establish a common platform for all proprietary systems to exchange data and information from multiple sources in a language the entire healthcare system can use. If registries are forced to simply import unstructured EHR data, lacking precise and standardized definitions, the integrity and unique value of registry data will be compromised, resulting in stalled innovation and interoperability.

Efforts should be made to develop additional information blocking standards for EHRs and providers that can more effectively support the data needs of specialty registries. We urge ONC to work with our Coalition of clinical data registries and their sponsoring medical specialty societies to establish such standards. Doing so will promote interoperability, information sharing, and quality care.

³ 45 C.F.R. pt. 171.

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The Coalition appreciates the opportunity to comment on the Proposed Rule. If you have any questions, please contact Leela Baggett at Powers Pyles Sutter & Verville PC (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 College of Emergency Physicians

American College of Gastroenterology

American College of Rheumatology

American Society for Gastrointestinal Endoscopy

American Urological Association

Association for Clinical Oncology

Congress of Neurological Surgeons

Outpatient Endovascular and Interventional Society

Society of Interventional Radiology

Society of NeuroInterventional Surgery

The Center for Professionalism and Value in Health Care

The Society of Thoracic Surgeons