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PHYSICIAN CLINICAL REGISTRY COALITION

January 28, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street NW
Washington, DC 20201

[Submitted online at: https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs]

Re: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Draft for Public Comment

Dear Dr. Rucker:

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) draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*.[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. Most of the members of the Coalition have been approved as qualified clinical data registries (QCDRs) or are working towards achieving QCDR status.

The Coalition greatly appreciates ONC's attention to reducing regulatory and administrative burden relating to the use of health information technology (Health IT) and electronic health records (EHRs). The Coalition is concerned, however, that ONC's draft strategy fails to acknowledge the value of clinical data registries, particularly the important role that QCDRs and other clinical data registries play in enhancing quality improvement activities and reducing administrative burden for clinicians. For the reasons discussed in this letter and as discussed during the Coalition's in-person meeting with ONC last April, the Coalition strongly urges ONC to address the burden associated with the lack of interoperability between EHRs and clinical data registries in its burden reduction strategy.

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[1] ONC, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf.

1. The Importance of QCDRs and Other Clinical Data Registries

Clinical data registries play an essential role in promoting quality of care. The Coalition is concerned that ONC's draft strategy omits any discussion of the important work done by QCDRs and other clinical outcomes data registries (collectively, "CDRs") supported by nonprofit medical societies and other nonprofit entities and claims that most registries are public health registries supported by the Centers for Disease Control (CDC) and other federal and state entities. CDRs provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. CDRs also play an important role in supporting innovation and access to new drugs and therapies for patients by streamlining and decreasing the costs of clinical trials for the approval of investigational new drugs or devices by the Food and Drug Administration (FDA). In addition, CDRs allow for patient-centered, statistically valid, and timely inter-practice and national benchmarking and comparisons. The measures developed by CDRs are meaningful and relevant to participating providers and their patient populations. CDRs reduce overall burden by integrating reporting with providers' clinical work flow. Many non-federal or state-supported CDRs also play an important role in clinical research. As noted in the draft strategy, Section 4001 of the 21st Century Cures Act (the Cures Act) specifically directs ONC to consider EHR-related burden on clinical research in its strategy.

The Coalition appreciates the Department of Health and Human Services' previous efforts, through CMS, to encourage the use of QCDRs for electronically reporting data across quality improvement activities.[2] The ability of QCDRs to access patient information from EHRs is crucial for such registries to achieve their mission of improving quality of care and providing useful analysis to the federal government for quality improvement activities and other purposes. The free flow of data between QCDRs and EHR vendors is also critical to reducing administrative burden for clinicians and to ensuring the success of payment for performance under Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). When EHR vendors erect barriers to sharing information with QCDRs, physicians cannot efficiently report data for the purposes of MIPS.

2. Interoperability between EHRs and Clinical Data Registries

It is essential that ONC's strategy address both the ability of EHR vendors to exchange electronic health information, as well as usability of the exchanged information. As ONC recognizes in its draft strategy, hindrances to interoperability increase administrative burden and expenses for clinicians and divert precious clinical and financial resources from patient care.[3]

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[2] MACRA, Pub. L. No. 114-10, 129 Stat. 87 (2015), requires the Secretary of Health and Human Services to encourage the use of QCDRs and certified EHR technology (CEHRT) for reporting measures under the Quality performance category of MIPS.

[3] The Coalition supports the following definition of interoperability in the Cures Act: "The term 'interoperability', with respect to health information technology, means such health information technology that—(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

Perhaps even more importantly, the lack of interoperability between EHRs and CDRs impedes complete data analyses needed to accurately assess and appropriately improve quality. For example, it is imperative that the data shared with CDRs be sufficient for quality measurement and include the data elements needed to calculate specialty-specific quality measures relevant to the physicians using the EHR and participating in a registry. In conjunction with ONC's forthcoming rules to implement the information blocking requirements in the Cures Act, a strategy that focuses on improving how EHRs exchange electronic health information with CDRs, and the usability of such data will assist efficient exchange of health information and allow providers and clinicians to most effectively make use of QCDRs for reporting under the Merit-based Incentive Payment System (MIPS) Program, as well as the promotion of research, public health, and quality improvement activities by CDRs generally. Further, in an effort to reduce provider burden, the Coalition continues to encourage CMS to provide full credit under the MIPS Promoting Interoperability category to eligible clinicians and groups using an EHR to participate in a QCDR.

The principal impediment to integration of EHR data into CDRs is that some EHR companies refuse to share their data with registries or are charging their customers or registries excessive fees for this data exchange. Owners of EHR systems control the flow of data from registry participants to CDRs and the extraction of clinical data from EHRs is the most efficient method of collecting a large portion of the data collected by registries. Members of the Coalition have experienced major challenges in the exchange of information from EHR vendors, including unreasonably high fees, limited access to data, and a lack of common technical profiles and standards across EHR systems. These barriers interfere with and materially discourage access to information, as well as violate the letter and the spirit of the provisions of the Cures Act that prohibit information blocking.[4]

Finally, many Coalition members continue to encourage ONC to develop common, open-source logic models, implementation profiles, and standards to allow for the ease of sharing data. Currently, EHR vendors maintain data in different logic models, implementation profiles, and standards that create additional barriers for aggregating data. If EHRs were to use certain open source logic models, implementation profiles, and conform the data to Health Level Seven International (HL7) standards, EHRs could transmit data to registries in a more efficient and cost effective manner.

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(C) does not constitute information blocking" as defined in Section 4004 of the Cures Act. 21st Century Cures Act, Pub. L. No. 114-255, § 4003(a)(2), 130 Stat. 1,033 (2016).

[4] *Id.* § 4004.

Thank you for the opportunity to submit these comments. The Coalition appreciates ONC's attention to these important issues. 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 NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY – HEAD AND NECK SURGERY FOUNDATION
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
AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
AMERICAN COLLEGE OF SURGEONS
AMERICAN GASTROENTEROLOGICAL ASSOCIATION
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AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS
NORTH AMERICAN SPINE SOCIETY
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS