



October 17, 2018

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

[Submitted online at: <https://www.regulations.gov/document?D=HHS-ONC-2018-0022-0001>]

Re: HHS-ONC-2018-022 – Request for Information Regarding the 21st Century Cures Act Electronic Health Reporting Program

Dear Dr. Rucker:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the opportunity to respond to the Office of the National Coordinator for Health Information Technology's (ONC) request for information (RFI) regarding the Electronic Health Record (EHR) Reporting Program established by the 21st Century Cures Act (the Cures Act).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.

Section 4002(c) of the Cures Act requires the Secretary to develop an EHR Reporting Program and establish reporting criteria for such a program through a public, transparent process.² The Cures Act requires that these reporting criteria address security, interoperability, usability and user-centered design, and conformation to certification testing, as well as other categories as appropriate, which may include those suggested in the statute.³ The Coalition is particularly interested in the interoperability category (including information blocking), as well as the inclusion of a category regarding submitting, editing, and retrieving data from registries such as clinician-led clinical data registries, as suggested in the Cures Act.

¹ Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program, 83 Fed. Reg. 42,913 (Aug. 24, 2018) (EHR Reporting Program RFI).

² 21st Century Cures Act, Pub. L. No. 114-255, § 4002(c), 130 Stat.1033, 1161-62 (2016).

³ *Id.*

1. Categories for the EHR Reporting Program: Interoperability

The lack of interoperability between EHRs and clinical data registries is a serious impediment to data collection.⁴ Owners of EHR systems control the flow of data from registry participants to clinical data registries and the extraction of clinical data from EHRs is the most efficient method of collecting data. 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.⁵ In conjunction with ONC's forthcoming rules to implement the information blocking requirements in the Cures Act, reporting criteria that includes information about how EHRs exchange electronic health information with registries, and the usability of such data will assist efficient exchange of health information and allow providers and clinicians to make informed decisions about their EHR vendors.

It is essential that ONC's reporting criteria measure both the ability of EHR vendors to exchange electronic health information, as well as usability of the exchanged information. For example, it is imperative that the data shared with clinical data registries be sufficient for quality measurement and include the data elements needed to calculate specialty specific quality outcome measures relevant to the physicians using the EHR and participating in a registry. As ONC notes in the cross-cutting topics section of the RFI, user-reported data can help assess interoperability, the usability of information that is exchanged, and the accessibility of that information to end users.⁶ Qualitative data from EHR end-users would be helpful in assessing the ability of EHR vendors to exchange information and the usefulness of that information. To that end, qualitative data from other information recipients, such as clinical data registries, is also essential for assessing interoperability.

ONC points to measures related to health information exchange and interoperability in the Inpatient Hospital Promoting Interoperability Program and the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS) Program as existing data sources for assessing interoperability. The Coalition appreciates ONC's commitment to gathering data in a minimally burdensome manner and we urge ONC to work with the Centers for Medicare and Medicaid Services (CMS) to improve the ways that physicians can share meaningful feedback through these existing reporting mechanisms about ongoing challenges

⁴ 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 (C) does not constitute information blocking" as defined in Section 4004 of the Cures Act. 21st Century Cures Act § 4003(a)(2).

⁵ *Id.* § 4004.

⁶ EHR Reporting Program RFI, 83 Fed. Reg. at 42,915.

with EHR vendors. For example, physicians should have the opportunity to provide direct, qualitative feedback to CMS regarding interoperability and barriers that they face in using EHR when reporting on the Promoting Interoperability performance category of MIPS or while applying for a Promoting Interoperability hardship exemption. The current hardship exemption application contains only checkboxes and does not allow clinicians to describe what is stopping them from meaningfully using an EHR. The Coalition also suggests that ONC work with CMS to offer automatic credit for the Promoting Interoperability category of MIPS to clinicians who engage in a study of barriers to interoperability. Finally, CMS has recently proposed to remove the Public Health and Clinical Data Exchange objective from the Promoting Interoperability performance category of MIPS no later than CY 2022,⁷ as well as the Public Health and Clinical Data Exchange objective and measures from the Inpatient Hospital Promoting Interoperability Program no later than CY 2022.⁸ The Coalition submitted comments opposing the removal of these measures, but if CMS adopts these proposals, these measures will no longer be an adequate data source for measuring interoperability as it affects data exchange between EHR vendors and clinical data registries, as well as for other public health purposes.

Finally, many in the Coalition 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 and clinical data registries 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. Developing these models, profiles, and standards is critical to enabling registries to aggregate sufficient data, achieve meaningful results, and extrapolate such results to improve the quality of care. Whether EHRs implement such logic models, implementation profiles, and standards would also be useful information for comparing EHR vendors within the interoperability category.

2. Categories for the EHR Reporting Program: Other Categories for Consideration

We urge ONC to prioritize the inclusion of the “submitting, editing, and retrieving data from registries, such as clinician-led clinical data registries” category in the EHR Reporting Program. Clinical data registries play an essential role in promoting quality of care. QCDRs and other clinical outcomes data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. In addition, QCDRs and other clinical outcomes data registries allow for patient-centered, statistically valid and timely inter-practice and national benchmarking and comparisons. The measures developed by QCDRs and other clinical outcomes data registries are meaningful and relevant to participating providers and their patient populations.

The principal impediment to integration of EHR data into clinical data registries is that some EHR companies refuse to share their data with registries or are charging their customers or

⁷ CY 2019 Physician Fee Schedule, Medicare Shared Savings Program Requirements, Quality Payment Program, and Medicaid Promoting Interoperability Program Proposed Rule, 83 Fed. Reg. 35,704, 35,930 (July 27, 2018).

⁸ FY 2019 Inpatient Prospective Payment Systems Proposed Rule, 83 Fed. Reg. 20,164, 20,520 (May 7, 2018).

registries excessive fees for this data exchange. As discussed above, Coalition members have reported that some EHR vendors refuse to enter into negotiations for the transfer of patient information to clinical data registries, and therefore are prohibiting clinical data registries from any degree of access to such information. Meanwhile, other EHR vendors have negotiated with Coalition members and their third party database vendors, but some of these vendors require providers to pay a large fee to send their data from the EHR to the clinical data registry or their software vendor, or require purchasing intermediary software systems owned by the EHR. As a threshold matter, it would be helpful for clinicians to know which EHR vendors are willing and able to submit data to registries. In addition, the fees that EHR vendors charge providers to send their data from the EHR to the clinical data registry or their software provider would be a useful data point for comparison purposes. Whether the EHR vendor requires the purchasing of certain intermediary software systems owned by the EHR would also be helpful information when comparing EHR vendors.

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. The ability of clinical data registries to access patient information from EHRs is crucial for such registries to achieve their mission of improving quality of care and to provide useful analysis to the federal government for quality improvement activities and other purposes. The free flow of data between QCDRs and EHR vendors is critical to the success of payment for performance under Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).⁹ The inability to exchange information with EHR vendors hampers the ability of registries to conduct analyses for quality improvement purposes, resulting in smaller sample sizes and skewed results. When EHR vendors erect barriers to sharing information with QCDRs, physicians cannot efficiently report data for the purposes of MIPS. As a result, the ability to compare whether and how different EHR vendors exchange information with QCDRs and other clinical data registries is critical information for many clinicians.

* * * * *

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 ORTHOPAEDIC SURGEONS
AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

⁹ MACRA, Pub. L. No. 114-10, 129 Stat. 87 (2105), 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.

Dr. Don Rucker, M.D.

October 17, 2018

Page 5

AMERICAN ASSOCIATION OF NEUROLOGICAL 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
AMERICAN SOCIETY FOR RADIATION ONCOLOGY
AMERICAN SOCIETY OF ANESTHESIOLOGISTS
AMERICAN SOCIETY OF CLINICAL ONCOLOGY
AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
AMERICAN SOCIETY OF PLASTIC SURGEONS
AMERICAN UROLOGICAL ASSOCIATION
COLLEGE OF AMERICAN PATHOLOGISTS
SOCIETY OF INTERVENTIONAL RADIOLOGY
SOCIETY OF NEUROINTERVENTIONAL SURGERY
THE SOCIETY OF THORACIC SURGEONS