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Dr. Donald 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.regulations.gov/document?D=HHS-ONC-2019-0002-0001>]

Re: RIN 0955-AA01 – 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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) proposed rule to implement certain provisions of the 21st Century Cures Act (the Cures Act), including the information blocking provisions (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

I. Interoperability

Section 4005(a) of the Cures Act requires that electronic health records (EHRs) be capable of transmitting data to and, where applicable, receiving and accepting data from clinician-led clinical data registries, in accordance with standards recognized by ONC.³ The Coalition appreciates ONC's attention to exploring multiple approaches to advancing the ability of EHRs to exchange data with registries. Access to patient information from EHRs is crucial for registries to achieve their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. The free flow of data between registries and EHR vendors is also critical to reducing administrative burden for

¹ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Fed. Reg. 7,424 (Mar. 4, 2019).

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

³ 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180 (2016).

clinicians and to ensuring the success of payment for performance under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

It is essential that ONC address both the ability of EHR vendors to exchange electronic health information (EHI), as well as the usability of the exchanged information. Lack of interoperability between EHRs and other health IT and registries impedes the collection and analysis of data needed to accurately assess and appropriately improve quality of care. While many registries have found methods to work around this lack of interoperability, such efforts have required significant investments of time and resources. Improved interoperability would allow registries to conduct their work more efficiently and effectively and devote more time and resources to analyzing data to identify best practices and improve patient care. A regulatory framework that focuses on improving the exchange of EHI with registries and the usability of such data will assist efficient exchange of information and allow providers and clinicians to more effectively make use of registries 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 registries. The Coalition supports ONC's proposed Conditions of Certification related to Communications that implement the Cures Act prohibition on health IT developers restricting communications on the usability, interoperability, security, and user experience of their products, as well as information about the business practices of developers of health IT related to exchanging EHI. The Coalition believes that this is a step in the right direction toward promoting transparency and improving usability of EHI and the interoperability of health IT.

In the Proposed Rule, ONC specifically seeks information about how ONC's proposed new standards and capabilities for certified application programming interfaces (APIs) to aid bidirectional exchange of data with registries, as well as use cases where an API using FHIR Release 4 might support improved exchange between a provider and a registry. While the bulk data exchange capability contained in FHIR Release 4 could potentially be valuable for exchanging data with registries, the Coalition wishes to emphasize that FHIR Release 4 would not be valuable to registries without a very large bulk data extract capability, given the large volume of unique patient data contained in registries. This approach appears to still be in the early stages of development—as a result, the Coalition would like to see real life implementation of the scalability of data extract capabilities before this approach is implemented for exchanging data with registries.

The Coalition is also concerned that the goal of semantic interoperability through APIs will only go so far without natural language processing or human curation of clinical notes, both of which are resource intensive and often unsuccessful. ONC has skipped straight to APIs and FHIR as the solution to interoperability challenges, but many entities lack standardized and codified data elements. Development of these resources is often very costly and requires technical support. As a result, the Coalition urges ONC to provide technical assistance for organizations looking to develop HL7 standards. Furthermore, the Coalition emphasizes that any efforts to standardize the exchange of data with registries should not create incentives for EHR vendors to limit the data that they provide to registries on behalf of providers.

Finally, the Coalition urges ONC to adopt the definition of “clinician-led clinical data registries” included in the Cures Act in future rulemaking to implement Section 4005 of the Cures Act.⁴ The Coalition looks forward to working with ONC as it implements the registry provisions of the Cures Act.

II. Information Blocking

In addition to enhancing the ability of clinical data registries to access patient information from EHR vendors, it is just as critical that ONC develop policies for policing information blocking by EHR vendors that otherwise have the capability to share their data with clinical data registries. The Coalition supports ONC’s proposed definition of information blocking, as this definition is consistent with Section 4004 of the Cures Act. The Coalition strongly advocated for the information blocking language included in the Cures Act and appreciates ONC’s adherence to the statutory language in implementing and enforcing the information blocking provisions. The Coalition encourages ONC to publish additional examples of practices that may constitute information blocking through sub-regulatory guidance.

The Coalition has significant concerns about ONC’s proposed definitions of health information networks (“HINs”) and health information exchanges (“HIEs”). Specifically, the Coalition is concerned that the breadth of ONC’s proposed definitions of HINs and HIEs is inconsistent with the meaning and intent of the information blocking provisions adopted by Congress. As previously mentioned, the Cures Act creates “clinician-led clinical data registry” as a defined term.⁵ Yet this term is conspicuously not included in the actors that Congress explicitly listed as covered by the information blocking provisions. If Congress wished to apply the information blocking provisions to clinical data registries, it would have done so. Instead, Congress applied the information blocking provisions to health IT developers, HINs, HIEs, and health care providers. In addition, there is little indication in the language of the Cures Act that Congress felt HINs and HIEs were separate and distinct entities—these terms are used interchangeably throughout Section 4004 of the Cures Act, including in Section 4004(b)(1)(C). Instead, as state and regional health information exchange networks refer to themselves using a number of different terms, Congress was endeavoring to ensure that such entities were covered by Section 4004 (the information blocking provisions). Any definition of HIN or HIE adopted by ONC must reflect Congress’s intent by not including clinical data registries.

Furthermore, it is inappropriate to include clinical data registries in the definition of HINs or HIEs because registries serve a fundamentally different purpose from these other entities. While HINs or HIEs are primarily just facilitators of information exchange between a number of providers and organizations, clinical data registries serve to collect and analyze data to identify best practices and improve patient care. The Coalition urges ONC to exclude clinical data registries from its definitions of HINs and HIEs in order to reflect the fundamentally different purpose that these entities serve.

⁴ 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1180-81 (2016).

⁵ *Id.*

a. Adverse Effect of Information Blocking on Registries

As ONC recognizes in the Proposed Rule, EHR vendors often erect barriers to sharing information with registries. 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 registries excessive fees for this data exchange. For example, as described in one of the examples of information blocking offered in the Proposed Rule, an EHR developer may inappropriately claim that a registry is infringing on the developer's copyright in its database because the interface incorporates data mapping that references the table headings and rows of the EHR database in which the EHI is stored. As the Coalition has described at length in its previous comments on information blocking, members of the Coalition also report other barriers to 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.⁶ 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. Imposing these impediments to the exchange of data are particularly inappropriate given that EHR vendors are just holding the data for the health care providers who seek to submit the same data to clinical data registries. The EHR vendors have no inherent right to withhold that data from such registries.

Many clinicians also need access to data from hospital systems for the purpose of reporting on quality measures. As the Centers for Medicare and Medicaid Services (CMS) eliminates claims-based measures, clinicians that rely on data from their hospital's EHRs or Laboratory Information Systems (LISs) are disadvantaged because it is difficult or impossible to access the hospital's data. Many clinicians need data from hospitals to support their ongoing participation in MIPS or Alternative Payment Models (APMs). Data from hospitals may include critical information such as laboratory tests and utilization, images and other diagnostic information, emergency department care, etc. Without these data elements, many measures cannot be fully calculated and scored.

Clinicians working in and supporting hospitals should have access to all of a patient's data from the hospital's EHR and LIS. In many cases, however, this does not occur or is made extremely difficult. As a result, a large number of clinicians using clinical data registries to report quality measures do not receive any data from their hospitals. While hospitals often claim that they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from sharing this information with clinicians. In addition, because each hospital has its own unique legal and administrative framework for potentially accessing data, clinicians and registries currently must invest significant resources in attempting to access data from multiple hospitals. As a result, the lack of data availability from hospitals is a significant resource problem for the system as a whole. In light of this serious issue for hospital-based clinicians, the Coalition encourages both ONC and CMS to come up with

⁶ The Coalition's prior comments on information blocking are available here: <https://www.registrycoalition.net/registry-resources/>.

potential solutions to help improve the flow of information between hospital EHRs, LISs, imaging systems, and registries.

b. Enforcement of the Information Blocking Prohibition

The Cures Act empowers the HHS Office of Inspector General (OIG) to investigate claims of information blocking and provides for referral processes to facilitate coordination with other relevant agencies, including ONC, the HHS Office for Civil Rights (OCR), and the Federal Trade Commission (FTC). Based on ONC's description in the Proposed Rule, the Coalition understands that ONC and OIG may coordinate their respective enforcement activities, as appropriate, by sharing information about claims or suggestions of possible information blocking or false attestations (including violations of Conditions and Maintenance of Certification that may indicate that a developer has falsely attested to meeting a condition). In the final rule, the Coalition urges ONC to more specifically address how it plans to coordinate with the OIG to enforce the information blocking provisions of the Cures Act. For example, the Coalition requests that ONC clarify the circumstances under which ONC will coordinate its review of a claim of information blocking with the OIG versus deferring to the OIG to lead a review of such a claim. Effective enforcement of the information blocking provisions is essential to ensuring that Congress's intent to prohibit information blocking is fully realized.

c. Proposed Exceptions to the Information Blocking Prohibition

It is essential that ONC's proposed exceptions to the information blocking prohibition be narrowly tailored to the purpose that ONC seeks to achieve and not inappropriately interfere with Congress's goals in including the information blocking provision in the Cures Act. The Coalition cautions ONC against creating broad exceptions that undermine the rules against information blocking. In addition, for each of these exceptions, the Coalition encourages ONC to publish additional examples of practices that may fall within each exception through sub-regulatory guidance. The Coalition's comments on each of these proposed exceptions are laid out below.

i. Proposed Exception: Preventing Harm (§ 171.201)

The Coalition supports ONC's exception to the information blocking prohibition for practices necessary to prevent harm to patients. The Coalition further supports ONC's definition of "harm" to include corrupt or inaccurate data being recorded or incorporated into a patient's EHR, as well as the misidentification of a patient's EHI. It is essential to the work of registries that the information included in a patient's EHR be accurate.

ii. Proposed Exception: Promoting Privacy of EHI (§ 171.202)

The Coalition supports ONC's efforts to promote the privacy of EHI. Coalition members are concerned, however, that EHR vendors may inappropriately deny access to their health care provider outcomes data based on the false premise that such transfer of data somehow violates the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Accordingly,

Coalition urges ONC to advise EHR vendors that HIPAA compliance is not a justification for withholding data from clinical data registries and other similar parties if such registries are in compliance with all applicable HIPAA Rules. The Coalition further requests that ONC urge parties to work together in good faith to address any privacy concerns.

iii. Proposed Exception: Promoting Security of EHI (§ 171.203)

As with the proposed exception to promote the privacy of EHI, the Coalition supports ONC's efforts to promote the security of EHI, but is concerned that EHR vendors may inappropriately deny access to their health care provider outcomes data based on the false premise that such transfer of data somehow violates HIPAA. As above, the Coalition urges ONC to advise EHR vendors that HIPAA compliance is not a justification for withholding data from clinical data registries and other similar parties if such registries are in compliance with all applicable HIPAA Rules. The Coalition further requests that ONC urge parties to work together in good faith to address any security concerns.

iv. Proposed Exception: Recovering Costs Reasonable Incurred (§ 171.204)

As stated earlier in this letter and in the Coalition's prior comments to ONC regarding information blocking, unreasonably high fees charged by EHR vendors are one of the principle impediments to the exchange of information between registries and EHRs. The Coalition supports ONC's proposal to limit an actor's ability to charge fees to the recovery of costs reasonably incurred to provide access, exchange, or use of EHI, based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. The Coalition further supports ONC's efforts to prohibit the charging of fees based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor.

The Coalition is concerned, however, that EHR vendors may attempt to use this proposed exception as a loop hole to continue to charge unreasonably high fees. As explained in the Coalition's previous comment letters regarding information blocking, Coalition members report that unreasonably high fees are one of the biggest problem areas when working with EHR vendors. The Coalition also notes that there is currently significant variation among the fees charged by EHR vendors. The Coalition urges ONC to require actors to disclose the methodology behind their fees.

v. Proposed Exception: Declining to Provide Access, Exchange, or Use of EHI in a Manner that is Infeasible (§ 171.205)

The Coalition cautions ONC that EHR vendors may attempt to use this proposed exception to inappropriately deny access to EHI for registries. As a result, the Coalition urges ONC to strongly enforce the requirement that an actor timely respond to all requests relating to access, exchange, or use of EHI and, in the event that the actor determines that providing EHI in a particular manner is not feasible, provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request. The Coalition further strongly

encourages ONC to enforce its proposed requirement that the actor work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the EHI.

vi. Proposed Exceptions: Licensing Interoperability Elements (§ 171.206)

The Coalition supports ONC's proposal to require actors to negotiate with requestors in a reasonable and non-discriminatory fashion to identify any interoperability elements that are needed and offer an appropriate license with reasonable and non-discriminatory terms. The Coalition cautions, however, that the ability to charge reasonable royalties to license interoperability elements may present an opening for EHR vendors to charge unreasonably high fees for exchanging information with registries. As a result, the Coalition urges ONC to require actors to disclose the methodology behind their fees.

vii. Proposed Exceptions: Maintaining and Improving Health IT Performance (§ 171.207)

The Coalition supports an actor's ability to make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the practice is for a period of time no longer than necessary and implemented in a consistent and non-discriminatory manner. The Coalition urges ONC to require that, if feasible, actors provide advance notice that health IT will be temporarily unavailable in order to perform maintenance or improvements.

III. Complex Framework of Federal and State Privacy Laws

HIPAA covered entities and their business associates must comply with a complex framework of laws and regulations that includes the HIPAA regulations, the Common Rule, the FTC Act, and state privacy laws and security standards. While the Coalition appreciates ONC's efforts to consult with OCR to develop the information blocking provisions consistent with the HIPAA Privacy, Security, and Breach Notification rules,⁷ the lack of harmonization within this vast framework of laws can create uncertainty or confusion for HIPAA covered entities and their business associates that want to exchange health information. The Coalition strongly urges ONC and CMS to work with OCR, the Office of Human Research Protections, and the FTC to eliminate conflicts or duplication between HIPAA, the Common Rule, the FTC's enforcement efforts, and this new regulatory scheme. Given that many privacy and security regulations were not created within the scope of the current digital landscape and may be outdated, there is an urgent need to align the various regulatory frameworks applicable to data privacy and security. The Coalition looks forward to working with each of these agencies and departments on this important issue.

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⁷ Proposed Rule, 84 Fed. Reg. at 7,527,

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The Coalition appreciates the opportunity to comment on the Proposed Rule. We urge ONC to adopt the Coalition's suggestions to facilitate and promote the use of clinician-led clinical data registries and implement the information blocking provisions of the Cures Act. The Coalition's goal is to allow the use of registries to grow and ultimately result in even greater improvements in the quality of patient care. In light of the critical role that registries play in improving patient outcomes and quality of care, we encourage ONC to work closely with CMS to adopt consistent policies across the board to further incentivize interoperability and electronic exchange of data between providers and clinical data registries.

Thank you for the opportunity to submit these comments. 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,

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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
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AMERICAN COLLEGE OF RADIOLOGY
AMERICAN COLLEGE OF RHEUMATOLOGY
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SOCIETY OF NEUROINTERVENTIONAL SURGERY
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