



October 17, 2018

The Honorable Donald Rucker, MD,
National Coordinator for Health Information Technology,
US Department of Health and Human Services
200 Independence Ave. SW
Washington, DC, 20201

Comments submitted at: [Regulations.gov](https://www.regulations.gov)

Re: Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program

Dr. Rucker:

AMIA appreciates the opportunity to comment on Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, public health experts, and educators who bring meaning to data, manage information, and generate new knowledge across the research and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

In reviewing this RFI and based on comments made by ONC officials, we understand the stated purpose of the EHR Reporting Program is to “provide publicly available, comparative information on certified health IT,” to “inform acquisition upgrade, and customization decisions that best support end users’ needs.” Although we do not dispute this interpretation of Cures statute, we do question this constrained scope for the program’s purpose.

AMIA strongly recommends that the EHR Reporting Program measure performance to improve CEHRT security, interoperability, and usability of Certified EHR Technology (CEHRT) in production environments with live patient data, not simply to provide data for “acquisition decision makers.” Especially when viewed alongside the additional provisions in newly developed CEHRT Conditions of Certification,¹ the EHR Reporting Program should be leveraged to bring transparency to how CEHRT performs in production environments with live patient data. ONC should develop an EHR Reporting Program that more closely approximates a post-implementation surveillance ecosystem, not a government-sponsored “consumer reports.” This post-implementation surveillance ecosystem would illuminate CEHRT performance used in production and would generate product performance data automatically, without users having to submit reporting criteria. Making such data publicly available would do far more than inform Dr.

¹ 42 U.S.C. 19 300jj–11 (c)(5)(D)

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Wilson’s next EHR purchase; it would bring competition and market forces to improve the performance of CEHRT security, usability, and interoperability, writ large.

The notion of a post-implementation surveillance ecosystem may seem like a distant and unattainable objective. However, we note that ONC already has a nascent surveillance and oversight program for CEHRT, established through regulation.² This program is supported through an existing set of policies, procedures, and reporting infrastructure that should be leveraged for the EHR Reporting Program. Although the current program focuses on complaint-driven, non-conformities of CEHRT, it would be greatly enhanced by focusing on real-world production data related to interoperability, usability, and security to better understand CEHRT performance in a live environment. We acknowledge that these data may not provide as detailed a picture of performance as would be ideal, but we must also understand what real-world production data are currently available through CEHRT, identify what real-world production data should be available through CEHRT, and work towards building a post-implementation surveillance ecosystem to improve CEHRT security, usability, and interoperability.

We also point to the Food and Drug Administration (FDA) which is endeavoring to have such an ecosystem for Software-as-a-Medical Device (SaMD). According to the FDA’s latest PreCertification Working Model v0.2 for SaMD,³ organizations that wish to market SaMD must commit to monitoring product performance across the lifecycle of the SaMD. The FDA “believes organizations can show excellence...by taking user-centric steps toward continuous improvement through proactive monitoring of [real-world production] data related to their SaMD products.”⁴ In order to be a PreCertified manufacturer of SaMD, the FDA would require organizations to “demonstrate a robust program for monitoring real-world performance data related to their SaMD devices.”⁵

This concept of real-world production data is a reality in most, if not all, CEHRT. For example, one well-known CEHRT developer has the capacity to report how frequently a summary of care record failed to send for an ordered care transition. In this example, users can see if the failure occurred in the ordering workflow (such as if there is no known direct address), if the failure occurred in transit (e.g. a Health Information Service Provider failure), and whether the transaction was received and acknowledged by the recipient system. In another example, we note that one CEHRT developer calculates a Provider Efficiency Profile, which is a tool that provides clinician-level data about workload, system usage, specific number of tools adapted, amount of time in certain activities, and time spent during specific hours of the day, among other data points.

² 45 CFR 170.556

³ Food and Drug Administration. Software Precertification Program: Working Model – Version 0.2 – June 2018. Available at: <https://www.fda.gov/medicaldevices/digitalhealth/digitalhealthprecertprogram/default.htm>

⁴ Ibid. pg. 29

⁵ Ibid. pg. 29

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Beyond this reorientation of EHR Reporting Program goals, AMIA offers the following recommendations:

- (1) ONC should develop interoperability reporting criteria for the EHR Reporting Program by building on previous RFIs meant to “measure interoperability.”** Past efforts to determine nationwide interoperability – as required by the Medicare Access and CHIP Reauthorization Act of 2015 – and ONC’s “Proposed Interoperability Standards Measurement Framework,” should inform development of interoperability reporting criteria for this aspect of Conditions of Certification.
- (2) ONC should view health IT safety as a measurable byproduct of usable CEHRT deployed in live environments.** To understand CEHRT usability performance in situ, ONC should supplement user-reported measures with measure concepts that reflect the safety of health IT.
- (3) ONC should prioritize an additional measure that demonstrates CEHRT’s capability to provide patients with “a complete copy of their health information from an electronic record in a computable form,” as required by Cures.⁶** A focus on this aspect of CEHRT would align with top-level HHS priorities to improve patient access to their data and enable development of a longitudinal health record.
- (4) ONC should ensure alignment between the EHR Reporting Program and other aspects of the Cures-mandated Conditions of Certification.** Compliance with the EHR Reporting program constitutes one of seven distinct aspects of new Conditions of Certification, so ONC should look for ways to enable participation in this program to meet these additional requirements.

Below we offer additional details regarding our recommendations. AMIA is committed to working with ONC to ensure that this aspect of Cures is impactful and leads to material improvements in CEHRT performance, rather than add to the crowded space of health IT “consumer reports.” Should you have any questions or require additional information, please contact AMIA Vice President for Public Policy Jeffery Smith at jsmith@amia.org or (301) 657-1291 ext. 113. We, again, thank ONC for the opportunity to comment and look forward to continued dialogue.

Sincerely,



Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Enclosed: Detailed recommendations re: Electronic Health Record Reporting Program RFI

⁶ 42 U.S.C. 19 300jj–11 (c)(5)(D)

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To be successful and to impact the performance of CEHRT used by clinicians, AMIA recommends ONC:

- (1) Reorient the focus of the EHR Reporting Program away from a consumer reports for “acquisition decision makers” and seek to enhance a nascent post-implementation surveillance ecosystem;
- (2) Focus efforts to identify comparable reporting criteria for measures mandated by Cures in Section 3009A, reflecting interoperability, usability and user-centered design, security, conformance to certification testing; and providing patients with “a complete copy of their health information from an electronic record in a computable form;” and
- (3) Ensure the EHR Reporting Program aligns with broader Conditions of Certification by enabling compliance with this program to count towards requirements for CEHRT to “successfully test the ‘real world use’ of the technology for interoperability in the type of setting in which such technology would be marketed.”⁷

1. Reorient the focus of the EHR Reporting Program away from a consumer reports for “acquisition decision makers” and seek to enhance a nascent post-implementation surveillance ecosystem.

As described in the body of our response letter, AMIA encourages ONC to leverage the EHR Reporting Program for a more meaningful purpose. In our members’ experience, a deficit of information regarding which CEHRT to purchase is not a core problem. Rather, a deficit of capability related to interoperability, usability, and security is.

ONC currently has a nascent surveillance program, supported through an existing set of policies, procedures, and reporting infrastructure that should be leveraged. ONC’s surveillance and oversight duties require Authorized Certification Bodies (ONC-ACBs) to determine if a Complete EHR or Health IT Module they certified continues to function as required. Further, results of these surveillance activities are made available through the Certified Health IT Products List (CHPL). 45 CFR 170.556, “In-the-field surveillance and maintenance of certification for Health IT,” elucidates the current policy, which provides a mechanism to implement the kind of EHR Reporting Program we recommend ONC pursue.

We note that as of as of September 21, 2017, ONC is exercising enforcement discretion with regard to the regulatory requirement at 45 CFR 170.556(c)(2) that ONC-ACBs conduct randomized in-the-field surveillance for, at a minimum, two percent of the health IT certifications they have issued. According to a footnote on its website, “ONC will not, until further notice, audit ONC-ACBs for compliance with randomized surveillance requirements or otherwise take administrative or other action to enforce such requirements against ONC-ACBs, nor will it consider lack of implementation of these requirements by an ONC-ACB to be a violation of its Program compliance requirements under 45 CFR 170.523, the Principles of Proper Conduct for ONC-ACBs, or good standing under

⁷ 42 U.S.C. 19 300jj–11 (c)(5)(D)(v)

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45 CFR 170.560.”⁸ We recommend this complaint-driven-only approach be revisited as part of this EHR Reporting Program.

2. Focus efforts to identify comparable reporting criteria for measures mandated by Cures in Section 3009A, reflecting interoperability, usability and user-centered design, security, conformance to certification testing; and providing patients with “a complete copy of their health information from an electronic record in a computable form.”

We note that this RFI seeks information on a wide array of questions beyond the core areas required by Cures. We recommend that ONC focus its limited resources on constraining the focus to reporting criteria for measures mandated by Cures, reflecting interoperability, usability and user-centered design, security, conformance to certification testing; and providing patients with “a complete copy of their health information from an electronic record in a computable form.”

Interoperability

AMIA recommends ONC develop interoperability reporting criteria for the EHR Reporting Program by building on previous RFIs meant to “measure interoperability.” These reporting criteria should: (1) Be automated wherever possible; (2) initially, target high-value standards/use cases; and (3) deliver value to those stakeholders being measured. As we articulated in response to RFIs in 2016 and 2017, AMIA supports a blended approach of automated reporting and retrospective reviews to determine CEHRT interoperability performance.

In 2016, AMIA strongly recommended that ONC develop a measurement strategy that is patient-centric, and one that can be expanded and refined over time. In response to an RFI meant to inform implementation of Section 106(b)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. No. 114–10), we articulated an approach that would seek to understand where interoperability is needed, and then assess whether it is occurring. Our measurement strategy relied on claims data and statistical samples to conduct retrospective reviews, examining if expected interoperable data sharing occurred for patients with health conditions that necessitated receiving care from multiple providers. We argued that this approach would help ONC assess the availability of data and the impact of interoperability where it is likely to influence the care of patients most – among the clinicians and organizations that treat them routinely.

These recommendations were field-tested in a recent study published in the *Journal of the American Medical Informatics Association*.⁹ According to the findings, only 63 percent of hospitals routinely exchange patient data with the hospital they share the highest volume of patients with. These data stand in contrast to ONC data indicating 97 percent of respondents are classified as routinely sending information electronically in federal measures. While this study may not have developed

⁸ ONC-ACB Surveillance Program. Available at: <https://www.healthit.gov/topic/certification-ehrs/onc-acb-surveillance>

⁹ Everson J, Adler-Milstein J. Gaps in health information exchange between hospitals that treat many shared patients, *Journal of the American Medical Informatics Association*, Volume 25, Issue 9, 1 September 2018, Pages 1114–1121, <https://doi.org/10.1093/jamia/ocy089>

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automated measures that could be easily used by ONC for the EHR Reporting Program, it revealed important information for policymakers interested in improving interoperability. If ONC proceeds with survey-based methods to understand interoperability, it should consider more robust methodologies like the one exhibited in this study.

In 2017, ONC issued a Request for Comment on a “Proposed Interoperability Standards Measurement Framework,” wherein it outlined ways to measure the use of interoperability standards by end users to meet specific interoperability needs. One proposed measurement area would “track the use of standards by end users in deployed systems (i.e., which standards are most commonly being used and understand how often and in what manner standards are customized during implementation).” As the use of compatible standards are pre-requisite for interoperability, it stands to reason that automated measures developed for this purpose could also be used for purposes of EHR Reporting Program’s interoperability reporting criteria.

Usability and User-Centered Design

AMIA recommends ONC view health IT safety as a measurable biproduct of usable CEHRT deployed in live environments. While we acknowledge and support efforts such as the usability and user-centered design (UCD) evaluation framework developed by Medstar Health’s National Center for Human Factors in Healthcare,¹⁰ this kind of framework relies on data acquired during certification. In addition to relying on certification-derived data, the EHR Reporting Program must include data on how systems perform in production.

To understand CEHRT usability performance in situ, ONC should look towards measure concepts developed by the National Quality Forum (NQF) in 2016 and the SAFER Guides, as well as endeavor to develop new measure concepts. The NQF report, “Identification and Prioritization of Health IT Safety Measures,” identified dozens of measure concepts across nine key health IT safety areas, such as clinical decision support, user-centered design, and system downtime, that could be adapted into the EHR Reporting Program.¹¹ Likewise, the SAFER Guides could identify high-priority functions necessary for safe and usable CEHRT and inform decisions over how to measure the availability or performance of these function(s).¹² Finally, we point to simulation tools like the Leapfrog CPOE Tool,¹³ which ONC could use to examine the usability of factors related to medications, such as drug allergy alerts, therapeutic duplication, and dose limits.

¹⁰ Ratwani R, Hettinger AZ, Kosydar A, et al. A framework for evaluating electronic health record vendor user-centered design and usability testing processes, *Journal of the American Medical Informatics Association*, Volume 24, Issue e1, 1 April 2017, Pages e35–e39, <https://doi.org/10.1093/jamia/ocw092>

¹¹ National Quality Forum, “Identification and Prioritization of Health IT Patient Safety Measures, Final Report,” (2016) http://www.qualityforum.org/Publications/2016/02/Identification_and_Prioritization_of_HIT_Patient_Safety_Measures.aspx

¹² Office of the National Coordinator for Health Information Technology, “Safety Assurance Factors for EHR Resilience,” (2018), <https://www.healthit.gov/topic/safety/safer-guides>

¹³ The LeapFrog Group, “CPOE Evaluation Tool (V3.) User Instructions (For Adult and General Hospitals Only),” 2017, http://www.leapfroggroup.org/sites/default/files/Files/CPOE_Instructions_2017_0_0.pdf

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Conformance to Certification

We believe that data currently collected as part of ONC’s surveillance program would be sufficient to satisfy this requirement of the EHR Reporting Program. We recommend this data continue to be made available through the CHPL.

Other categories, as appropriate to measure the performance of electronic health record technology Cures requires the EHR Reporting Program to include reporting criteria across four prescriptive measure categories and a fifth, optional “other categories as appropriate to measure the performance of electronic health record technology.” We recommend ONC prioritize a measure that provides the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format. Recent policies established by CMS seek to improve patients’ access to their data through APIs. However, this access will only provide a limited data set (currently the common clinical data set) which is insufficient to be considered a complete copy. Policy efforts should be made to define what a complete copy is, and technical requirements should deliver this newly defined concept to patients in a computable format, so that their data can be used once made available.

3. Ensure the EHR Reporting Program aligns with broader Conditions of Certification by enabling compliance with this program to count towards requirements for CEHRT to “successfully test the ‘real world use’ of the technology for interoperability in the type of setting in which such technology would be marketed.”

Cures Section 4002 includes a new set of requirements known as the Conditions of Certification. There are seven distinct subsections to which CEHRT must comply and the EHR Reporting Program is only one of these. Another key aspect of these Conditions is found at 42 U.S.C. 19300jj–11 (c)(5)(D)(v) stating that the health IT developer “has successfully tested the real world use of the technology for interoperability (as defined in section 300jj of this title) in the type of setting in which such technology would be marketed.”

AMIA recommends that CEHRT complying with the EHR Reporting Program would also be in compliance with the subsection (v) of the Conditions. Reporting on high-value interoperability use cases, or on the use of high-value interoperability standards, would not only provide a window into CEHRT performance for purposes of the EHR Reporting Program, but also demonstrate real world use of the technology in the type of setting which the CEHRT is marketed. If the CEHRT preforms satisfactorily (vis-à-vis the interoperability reporting criteria), then it would meet this requirement of the Conditions of Certification. If not, the CEHRT would need to meet this requirement of the Conditions through other means or risk its certification status.