

October 16, 2018

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: ONC RFI- Electronic Health Record Reporting Program

Dear Dr. Rucker:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Request for Information (RFI) on the Electronic Health Record (EHR) Reporting Program.

America's hospitals and health systems are committed to utilizing EHRs and other health IT tools. Hospitals and health systems devoted considerable time and resources over the past eight years to implement and use certified EHRs. Increasingly, they are focused on exchanging health information with other providers of care to better support care coordination and transitions across settings of care.¹ Section 4002 of the 21st Century Cures Act, Pub.L.114 – 255, instructs the Department of Health and Human Services (HHS) to develop and to lead a public, transparent process to establish reporting criteria about specific EHR products to enhance transparency and aid providers in evaluating their options. By statute, the EHR Reporting Program must include criteria to address five categories: security; interoperability; usability and user-centered design; conformance to certification testing; and other categories. **Given the high adoption rate of certified EHRs, the EHR Reporting Program should emphasize reporting criteria that indicate how certified EHRs support the safe, efficient and effective collection, exchange and use of electronic health**

¹ Sharing Health Information for Treatment. <https://www.aha.org/guidesreports/2018-03-01-sharing-health-information-treatment>



information rather than static certification criteria on collection of health information. To support that goal, the AHA offers the following recommendations.

REDIRECT REPORTING TOWARD EHR PERFORMANCE IN SUPPORT OF CLINICAL CARE. **The AHA recommends the Office of the National Coordinator for Health IT (ONC) prioritize the development of reporting criteria for the five categories specified in the 21st Century Cures Act that indicate how EHRs support new models of care and patient engagement. In doing so, ONC should leverage existing health IT frameworks and standards to inform the reporting criteria.** Several frameworks from government and private organizations are available to inform the development of EHR reporting criteria. For example:

- The National Institute of Standards and Technology (NIST) Framework for the technical evaluation, testing and validation of the usability of EHRs includes a three part EHR Usability Protocol supporting EHR design evaluation and performance testing in provider settings to encourage user-centered development processes focused on safety.²
- The Association for the Advancement of Medical Instrumentation has developed three of four planned standards to support consistency in health IT implementation with a focus on patient safety, health and security. The standards include concepts and principles for health IT across its lifecycle; quality systems principles and practices; risk management processes to identify and help mitigate patient safety and enterprise risks related to health IT; and health IT usability and the use of human factors engineering to improve its design.³
- The 2014 Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report developed jointly by the Food and Drug Administration (FDA), Federal Communications Commission (FCC) and ONC, known as the FDASIA Report, recognized both the opportunities and risks inherent in using IT systems and emphasized increased learning about the safe development, installation and use of health IT.⁴

The AHA recommends that the reporting criteria advance efforts to promote transparency on the cost of additional software upgrades, interfaces and added services required to support health information exchange in support of care coordination and patient engagement. Hospitals and health systems remain

² <https://www.nist.gov/publications/nistir-7804-technical-evaluation-testing-and-validation-usability-electronic-health>

³ <http://www.aami.org/productspublications/articledetail.aspx?ItemNumber=5470>

⁴ <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>

challenged to collect and share data across settings of care easily or without expensive and cumbersome work-arounds. The repeated and expensive upgrades or tolls for interfaces that are required but not disclosed in certification documentation should cease, or at least be made transparent to purchasers via the EHR reporting program.

The AHA also encourages ONC to work with the new Centers for Medicare & Medicaid Services (CMS) Chief Health Informatics Officer in the development of the reporting criteria. Given the high priority HHS places on promoting interoperability among clinical settings and between patients and their providers, certified EHRs must support related technology use requirements placed on providers. Improved alignment should encourage the consistent implementation of standards and the increased confidence in the shared health information by those making clinical decisions.

UTILIZE DATA CURRENTLY REPORTED FOR INSIGHT ON EHR FUNCTIONALITY AND REPORTING CRITERIA. **The AHA recommends that ONC rely on increased analysis of existing data sources to inform the future EHR reporting criteria and refrain from creating new reporting requirements for providers.** Hospitals generally do not focus on EHRs in isolation, but rather as one technology among many in their complex environment. Hospitals take a holistic approach to the efficient operation of their environment and will consider multiple factors when assessing issues therein. As a result, information that provides insight on EHR performance after implementation may be reported to multiple sources. Identifiable security, interoperability, usability, or certification conformance issues would be reported to EHR vendors or ONC-contracted Authorized Certification Bodies. Other recipients of provider reporting may prove to be additional sources of insight. The CMS electronic clinical quality measure (eCQM) data validation initiative may uncover EHR usability or interoperability issues. Safety concerns could be reported to patient safety organizations where analysis may detect health IT-related safety concerns. Surveys and validation reports about aspects of EHRs use - such as eCQMs, clinical decision support, medication management or computerized provider order entry - submitted to private organizations may identify issues with aspects of EHR functionality and the interoperability of EHR and other clinical or consumer-facing health technology and systems. In order to inform the reporting criteria and foster actionable insight for all stakeholders, we recommend continued collaboration among public and private-sector organizations to expand access to sources of information and opportunities for analysis.

Additionally, we urge ONC to work with EHR vendors, health IT safety researchers and NIST to identify opportunities to leverage audit logs and develop processes that can automate data gathered from clinician-EHR interaction. A requirement that would mandate providers to report technology interaction would distract from their focus on patient care and would increase existing regulatory burdens. Based on an AHA survey to understand the regulatory costs associated with health IT, on average, surveyed hospitals spend \$760,000 annually meeting regulatory requirements, most of which is being used to hire and maintain additional staff.

Hospitals made additional IT investments averaging \$411,000 during the year for the Promoting Interoperability Program, an investment more than 2.9 times larger than that made in any other area.⁵ Small provider organizations or those serving communities with few resources may not be able to afford necessary investment in EHR technology, personnel, and support systems nor the costs associated with additional reporting requirements.

PROVIDER PARTICIPATION IS VITAL TO DEVELOPING REPORTING CRITERIA THAT SUPPORTS SAFE, EFFECTIVE AND EFFICIENT HEALTH CARE DELIVERY. **The AHA recommends that ONC**

prioritize engaging providers in its next steps as it develops reporting criteria.

Hospitals and health systems are prepared to participate in the work to develop reporting criteria for EHRs that includes quantitative and qualitative metrics. Ensuring that EHRs support the culture of patient safety is foundational to future reporting as well as advancing the ability to report, identify, analyze and correct concerns that impact the safe, efficient and effective delivery of health care.

The AHA appreciates your consideration of these recommendations. Please contact me if you have questions or feel free to have a member of your team contact Diane Jones, director of policy, at djones@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy and Policy Development

⁵Regulatory Overload. Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Providers. <https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf>