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May 30, 2019

Don Rucker, MD
National Coordinator
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services (HHS)
Mary E. Switzer Building, Mailstop: 7033A
300 C Street SW
Washington, DC 20201

Attention: 21st Century Cures Act: Interoperability, Information Blocking,
and the ONC Health IT Certification Program Proposed Rule (NPRM)
RIN 0955-AA01

Submitted electronically to:
<https://www.regulations.gov/>

Dear Dr. Rucker:

The eHealth Initiative (eHI) welcomes the opportunity to submit comments on the proposed rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*.

This proposed rule is cited by HHS as a key step in the “digital data revolution to empower America’s patients.” We are pleased to see patients and healthcare consumers at the center of the transformational changes in this proposed rule. eHI’s two decades of work and its diverse, powerful membership have worked towards this goal and built needed momentum to move the health IT field forward at critical junctures. We are prepared to do so again as these rules are finalized and move into practice.

Overall, eHI appreciates the proposed rules’ role in moving healthcare forward and the increased emphasis on the lynchpins of:

- Improving the interoperability of electronic health information;
- Enhancing care coordination;
- Promoting patient access to and control over their health information;
- Providing a detailed implementation framework for implementing the information blocking provisions of the *21st Century Cures Act*.

We urge ONC however to carefully consider the adequacy of current health care infrastructure and systems to support proposed changes, reasonable implementation timeframes, as well as any potentially negative and disruptive impacts on current, successful infrastructure and practices, especially in the case of interoperability.

eHI is in a unique position to comment and offer insight on this proposed rule as a Washington DC-based, independent, non-profit organization whose mission is to drive improvements in the quality, safety, and efficiency of healthcare through information and information technology. We are the only national organization that represents all stakeholders in the healthcare industry and regularly “convene healthcare’s best.” Working with its membership, eHI advocates for the use of health IT that is practical, sustainable and addresses stakeholder needs, particularly those of patients, www.ehidc.org. eHI’s work and its membership have built needed momentum and moved the health IT field forward at critical junctures.

A timely example of this is three active, impactful eHI workgroups to improve care for patients with chronic conditions. These workgroups include:

- Value & Reimbursement
- Technology & Analytics
- Workflow for Provider and Patient Engagement

The workgroups’ mission includes looking at closing gaps in data, removing barriers to sharing information, educating patients and providers about consent to share data, incentivizing data sharing and patient engagement. Many of these same issues are addressed by ONC’s proposed regulation. Our organization also tackles timely issues such as electronic medication adherence, prior authorization in healthcare, and technical solutions to cost transparency and using social determinants of health (SDOH) data to improve patient and population outcomes. On-going eHI workgroup dialogue and deliverables --including best practices and recommendations for policy and industry -- enable our organization to have valuable insights for ONC as elements of this proposed rule proceed ahead.

eHI’s extensive *eHealth Resource Center* -- a clearinghouse of success stories, reports, surveys and other material -- can also provide important context and guidance as ONC moves forward. This information hub can be accessed at: <https://www.ehidc.org/resources>.

We look forward to working with you and other key federal government players towards better patient care, provider flexibility and truly value-based care for all. Below are eHI’s observations and recommendations. If you have any questions or need clarifications, please contact me at Jennifer.Covich@ehealthinitiative.org.
Sincerely,



Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative

Response on Specific Issues

Overarching

Agency Coordination – eHI urges ONC to work practically and thoughtfully with other federal partners in implementing programs related to this proposed rule, particularly in the area of interoperability and enhancing care coordination.

IV. Updates to the 2015 Edition Certification Criteria (Patient Access)

Promoting Patient Access to and Control over Health Information

Comments: eHI supports ONC’s strategy to anchor this proposed rule around fostering innovation that promotes patient access to and control over their health information. This principle has long been at the heart of the eHI mission. Indeed, *eHI’s 2020 Roadmap* lays out our shared vision to transform care delivery with patient-centric care and calls for: (1) timely and relevant patient-focused information and health IT tools available to all; and (2) high quality and efficient patient care through the use of interoperable health IT. Key recommended tools to support this vision in the *eHI 2020 Roadmap* include meaningful incentives that promote patient-focused care, as well as information and tools that enable informed patient-consumer action and decision making, working hand-in-hand with healthcare providers. ONC’s proposed rule gives implementation impetus to these broad goals and we look forward to working with you and other relevant agencies towards achieving these aims.

eHI’s June 2018 comments to HHS on the “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates” proposed rule are also relevant here that, “Patient self-efficacy is critical in value-based payment and patient engagement/education is fundamental to that success. Also, free-market innovation in health care is best empowered through initiatives and standards that support the consumer/patient access to records, interoperability for patients and the tools that increase their knowledge.”

IV. Updates to the 2015 Edition Certification Criteria (Scope of Electronic Health Information)

Broad Definition of Electronic Health Information – eHI commends ONC for seeking to advance a patient-driven health care system better via better connectivity and more well defined information practices. In its proposed rule, ONC lays out a broad definition of electronic health information (EHI), to which the information blocking prohibition applies and that includes data that is electronic protected health information (EPHI) under the HIPAA regulations, as well as other electronic individually identifiable health information. More specifically ONC defines EHI to mean:

- (i) Electronic protected health information; and (ii) any other information that—
- is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103;
 - identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
 - relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of

health care to an individual. This definition of EHI includes, but is not limited to, electronic protected health information and health information that is created or received by a health care provider and those operating on their behalf; health plan; health care clearinghouse; public health authority; employer; life insurer; school; or university.

Comments: Given that the electronic health information (EHI) definitions will form the basis for both action and penalty in our healthcare system, we urge ONC to further define and appropriately focus and specify the electronic health information definition for the final rule.

VII. Conditions and Maintenance of Certification (APIs)

APIs – ONC proposes to adopt a new API criterion in § 170.315(g)(10), which would replace the “application access – data category request” certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This would be the new “standardized API for patient and population services” certification criterion and would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications. It would also require health IT developers to support API-enabled services for data on a single patient and multiple patients. Specifically required would be API access to and search capabilities for all data proposed as part of the United States Core Data for Interoperability (USCDI) for a single patient and multiple patients. The API technology would need to be able to establish a secure and trusted connection with apps that request data.

Comments: eHI agrees that “this approach would provide a stable and consistent direction in which the industry can go when it comes to deploying (g)(10)-certified APIs that support data access to the USCDI” and that API functionality is critical for better electronic access to health information for patients and providers and in achieving interoperability. eHI commends ONC for selecting an innovative and flexible suite of standards and associated resources, including HL7® Fast Healthcare Interoperability Resources (FHIR®). We urge that prior and ongoing interoperability lessons and successes --both private and public-- should be leveraged. eHI is the nation’s most diverse coalition of health care stakeholders and stands ready to provide insight on these issues.

As with the proposed information blocking provisions, we also urge caution given our concerns about complex and costly compliance, documentation, patient education and healthcare stakeholder risk issues related to the proposed API provisions. All parties will need to undertake significant steps to implement APIs and all stakeholders will need to work together to ensure a measured, secure, informed and realistic approach to this transition.

eHI registers concern regarding the proposed rules’ API provisions and the associated app and attestation process, which could present risk to both providers and patients. Specifically, according to the ONC proposed rule:

- APIs should require a “yes” attestation by the app that patients are provided meaningful notice and control over how their protected health information (PHI) is used to connect to the API.

eHI believes that this traditional “click yes to continue” model likely isn’t enough to communicate to the patient the risk managing that data might have or to give confidence to providers concerned that patients understand the risks and benefits of this data use. Healthcare providers and others should be assured that patients comprehend the risk prior to using their data in apps and in choosing using the API.

We urge ONC to evaluate for future certification criteria, ways in which certified health IT can gather and store information specific to a patient's understanding of the use of the data, drawing as appropriate on elements of the Model Privacy Notice created by ONC.

VIII. Information Blocking

Information Blocking Actors – The Proposed Rule identifies those parties subject to the information blocking prohibition (referred to as “actors”), including: health care providers, health IT developers, HIEs and HINs. ONC proposes to define HIN broadly enough to include health systems or other health care providers that enable, facilitate or control the flow of information among unaffiliated individuals and entities. Different penalties apply to different categories of actors. Under the proposed rule, health IT developers, HIEs and HINs are potentially subject to fines of up to \$1 million per violation while health care providers are potentially subject to “appropriate disincentives,” which can include penalties associated with CMS Promoting Interoperability programs. Health care providers that meet ONC's broad definition of HIN, however, would face the same significant civil monetary penalties as health IT developers and HIEs.

Comments: eHI urges a review of the very broad definitions of health care actors related to information blocking, particularly health information networks and health information exchanges. We also register caution and concern about complex and costly compliance and documentation related to the proposed information blocking provisions. Support for health information exchanges has been a critical tenet of the eHealth Initiative since its early days and indeed, we count many of the nation's leading HIEs among our membership. We have much knowledge to impart gained through our *Connecting Communities Collaborative*, a public-private sector consortium creates and disseminates best practices, business cases and policy recommendations for sustainable HIE models, among other goals. eHI also has at its fingertips archived information on HIEs as a result of our yearly data exchange survey which tracks the growth and progress of data exchange efforts across the United States. eHI stands ready as a leading, multi-stakeholder national HIE resource to work with ONC on HIE issues as they evolve and grow within ONC program purview.

X. Patient Matching Request for Information

Patient Matching RFI – Both ONC and CMS are requesting feedback about how agency authority can be leveraged to improve patient identification and safety to encourage better coordination of care across different healthcare settings while advancing interoperability.

eHI offers our organization as a robust, multi-stakeholder forum to gather feedback on this critical issue. Our membership contains leading voices on patient matching that provide a diversity of views. A full eHI member list can be accessed at: <https://www.ehidc.org/members>.

In addition, eHI supports ONC's intent to identify additional opportunities in the patient matching space and explore ways that ONC can lead and contribute to coordination efforts with respect to patient matching. As AHIMA emphasizes in their comments, today, there is no consistent approach to accurately matching a patient to their health information which has led to significant costs to hospitals, health systems, physician practices, long-term, post-acute care (LTPAC) facilities, and other providers. And, there are critical patient safety implications when data is matched to the wrong patient and when essential data is lacking from a patient's record due to identity issues.

eHI also supports other key points detailed below related to the patient matching RFI questions in this NPRM that are expressed by AHIMA and other organizations:

Patient Matching Solutions Involving Patients

We agree with ONC that involving patients in patient matching could be a viable and effective solution to increase the accuracy of matching while giving patients access to their own clinical information. We recommend that as ONC explores different methods and technical platforms that seek to include patients it take into consideration key barriers that may inhibit certain patient populations from being able to participate in the capture, update and maintenance of their own demographic and health data including race and ethnicity, age and socioeconomic status.

Effect of Data Collection Standards on the Quality of Health Data and Patient Matching

We recommend that ONC support the adoption of well-tested demographic data standards to improve patient matching including requiring the use of the US Postal Service standard for "address" under the USCDI. Additionally, there are a number of standardized primary and secondary data attributes that could help facilitate accurate patient matching including NCVHS' "Core Health Data Elements," Accredited Standards Committee X12 (ASCX12)'s Basic Character Set, and CAQH standards. We also recommend that ONC work with industry to identify other well-tested data collection standards that could be adopted under the USCDI.

Requirements for EHRs to Assure Accurateness and Completeness of Data Collected for Patient Matching

Standardized data fields that do not limit the number of characters or that do not allow users to bypass certain required demographic elements (including those elements collected at the time of registration) could increase the likelihood of accurate data capture.

Data that Could be Added or Constrained in the US Core Data for Interoperability (USCDI) to Support Patient Matching

eHI recommends that ONC work with industry and experts to identify other regularly collected demographic data elements that could be incorporated into the USCDI.

Finally, eHI urges ONC to pay careful heed to the answers received in response to the patient matching RFI.

