ConnectedHealth

June 3, 2019

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, District of Columbia 20201

RE: *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* (Docket No. CMS-9115-P)

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Office of the National Coordinator for Health Information Technology's (ONC) proposed rule to implement certain provisions of the 21st Century Cures Act. This includes conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking.[1]

CHI represents a broad consensus of stakeholders across the healthcare and technology sectors whose mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients' and consumers' experience and health outcomes. We seek to partner with the Department of Health and Human Services (HHS) in realizing the benefits of an information and communications technology-enabled American healthcare system. In particular, CHI is committed to advancing an interoperable healthcare continuum that enables the bidirectional flow of necessary health data between provider and patient, as well as between other important stakeholders who have a role in improving care coordination and decision-making.

The efficacy of precision medicine, population health, clinical decision support—and AI driven tools in particular—is dependent in large part on the availability of massive data sets. The free flow of information and interoperability are therefore important and potentially life-saving for patients. CHI is committed to advancing health data interoperability throughout the continuum of care.

[1] https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and.

ONC's proposed information blocking rules come at an important time. There is no disputing that interoperability and patient access to health information are preventing timely and informed care coordination and decision-making. Further, electronic health information and educational resources are critical tools that empower and engage patients in their own care. CHI strongly believes that a truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from connected medical devices to general wellness products) with open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement. Interoperability must not only happen between providers, but also between remote patient monitoring (RPM) products, medical devices, and EHRs.

While our full comments on the draft ONC information blocking rules are attached, key viewpoints and recommendations from our community include:

- CHI is generally supportive of ONC's efforts to prevent information blocking and facilitate greater data access throughout the care continuum. However, ONC's electronic health information (EHI) and information blocking proposals are too vague. A logical, objective approach is necessary to reduce confusion. ONC should align its information blocking requirements with the certified capabilities of health IT vendors, i.e., the U.S. Core Data for Interoperability (USCDI) and APIs. Information blocking should be evaluated through the lens of access, use, and exchange of the USCDI.
- CHI notes its concern with the proposed definition of a Health Information Network (HIN). At present, the definition is written so broadly that it may sweep in any developer of healthcare technology (as opposed to a developer of certified health IT). Finalizing the HIN definition as it is proposed would expand the rules past those who are developing technology intended to be certified through this rule and would make differentiations in other definitions (such as categorizing other developers as developers of certified health IT). We strongly recommend that the definition of HIN be narrowed to include only entities that are an actual network (or formalized component of an actual network) and have an actual operational role and responsibility for the network.
- While this ONC proposal contemplates four different options as far as the use of the Fast Healthcare Interoperable Resources (FHIR) standard, we support requiring the adoption of FHIR Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides. We believe using one version of the FHIR that it will be much more conducive to realizing an interoperable healthcare ecosystem.

- While CHI supports reliance on the USCDI, we ask ONC to consider a few limitations with USCDI Version 1.0. USCDI Version 1.0 does not fully support the necessary elements for payer to member, payer to payer, and payer to provider information exchanges (which are required in the CMS Proposed Rule). CHI urges ONC to prioritize its effort to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.
- With further details and some exceptions noted in our detailed comments, CHI generally supports ONC's proposed API conditions and maintenance of certification provisions. We appreciate ONC's efforts to address excessive fees charged by EHR vendors to connect their products with other health IT systems, health information exchanges, and third-party applications. ONC's proposal fee policy attempts to address most scenarios, but the resulting framework is complex and has limited usefulness. We suggest a more practical approach that includes a tiered fee structure for APIs.
- CHI generally supports ONC's proposed approach to health IT developer attestations.
- CHI supports making data available to patients needed to promote transparency and fair market competition. Generally, such information's availability will advance Congress' goals for transparency, benefitting patients and consumers. However, we urge ONC to focus on providing patients with information that is useful to patients consistent with Congress' intent. Defining electronic health information (EHI) to include various types of price information that entities subject to the rule do not hold is inappropriate.
- CHI is generally supportive of the proposed information blocking exceptions subject to specific input we provide in our detailed comments. However, ONC should create policies that identify bad actors that systematically and unjustifiably reject data requests without considering the considerable burden they may place on the rest of the health care system. ONC should clarify that a provider exercising his or her best judgement when providing information to a requestor will not be considered an information blocker.
- We urge ONC to provide affected stakeholders with adequate time to address technical and operations capabilities needed to address compliance with new information blocking rules. To prevent significant confusion, we strongly recommend ONC refrain from adjusting the 2015 Edition Base EHR definition, create separate timelines for developers and provider adoption, and recommend naming a new certified health IT Edition.

We also emphasize that it is crucial for ONC to ensure that its interoperability rule is as aligned as possible with the interoperability rules being developed by the HHS Centers for Medicare and Medicaid Innovation (CMS). Should the rules diverge, stakeholders may be put into a position where they are forced to violate one rule (e.g., meet the requirements of the CMS interoperability rule but face ambiguities as to whether the requirements of an exception to ONC information blocking is being satisfied). CHI acknowledges ONC's (and CMS') efforts to coordinate and supports those efforts.

CHI appreciates the opportunity to submit its comments, highlighted in this letter, and attached in full, to ONC. We look forward to assisting ONC in realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

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