

June 3, 2019

Dr. Donald Rucker  
National Coordinator for Health Information Technology (ONC)  
Office of the Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Re: RIN 0955-AA01

Dear Dr. Rucker:

The Personal Connected Health Alliance (PCHAlliance), a non-profit membership association, appreciates the opportunity to provide comment on the proposed rule, titled “21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program”, published in the Federal Register on March 4, 2019. Our comments are brief and focused on elements essential to advancing personal connected care and connected health, the PCHAlliance mission. PCHAlliance works to advance evidence-based two-way digital communications between patients, their caregivers, and providers through the development of open technical standards, real-world testing, and health plan coverage of evidence-based connected care.

Interoperable, connected health requires a broad ecosystem of shared digital health information. PCHAlliance members span this ecosystem and include entities that: manufacture the devices patients, and providers use to measure biophysical data; provide health insights and increase the usability of clinical decision support; provide care; operate the networks that communicate patient-generated data between patients and providers; and represent consumer perspectives on connected health. PCHA’s member list is available at <http://www.pchalliance.org>.

PCHAlliance appreciates ONC’s extensive work to develop consensus around interoperability standards via the US Core Data for Interoperability (USCDI) and the Interoperability Standards Advisory (ISA). Consensus-based standards, certification programs, and policies comprise the essential backbone to enable interoperability and the broad sharing of health care information to support and improve health care delivery, decision making, and operations. PCHAlliance supports policies that lower the barriers to interoperability, and we note that the creation of standards, like the USCDI and specification of FHIR based APIs, is essential to provider and patient access to the information needed for health care delivery, health care decisions, and health care operations. We call on ONC and HHS to move forward with policies, including requiring the use of FHIR based APIs, the USCDI, along with clearly defined and specified exceptions to information sharing. We note that these are baseline, initial functions for the patient-centered connected health at the heart of personal connected health, but comprise only the first steps as they remain silent on and do not establish a two-way system of interoperability essential to the consumer - provider communications of personal connected health care. While there is nothing in this proposed rule that prevents two-way interoperable information exchange, the proposed rule is largely silent on personal connected health care. And, to ensure we move toward including personal connected care and the two-way interoperability as a component of health care delivery, we request that ONC:

- Publicly articulate, possibly in the preamble of the final rule, that future rulemaking will address standards to permit patients to contribute data not just retrieve data.
- Ensure that this rule, when published in final form, contain no barriers to two-way communication between providers and patients, specifically, that there are no barriers to inclusion of patient-generated health data and that the USCDI will support patient-provider two-way information sharing.

Ideally, after API certification for information requests to support treatment and patient retrieval functionality is established and operating, then certification would take the next step and support voluntary certification of two-way transfer and transport of patient-generated health information from medical devices enabled by FHIR-based APIs.

In addition, to our request that ONC ensures and commits to a future pathway for personal connected health and standards that support and enable two-way consumer-provider communication. PCHalliance notes the following three items that its members flagged as posing what are likely unintended barriers to their work on interoperable, two way, interoperability:

**The definition of Health Information Network (HIN) is broad and is likely to include technology platforms that simply transmit EHI between unaffiliated entities.** For example, it will capture vendors or contractors engaged in transmitting information, that have no relationship with the consumer, and that have no input to health care delivery, health care decision-making, or health care operations. We believe the intent of this rule is to ensure information exchange between providers and data retrieval by patients to enable health care delivery, health care decisions, and health care actions. We recommend that the definition of HIN be narrowed so that it is focused on provider information systems that collect, maintain, and share patient health information to enable health care delivery, health care decisions, and health care actions.

Additionally, we are concerned that this proposed broad HIN definition will stifle innovation in the HIT technology market as it will chill entry of new technology and new entities supporting health care data exchange across payers, providers and patients. This broad definition makes entry into this market complex, costly and adds costly functionality that is duplicative. Most of these technology companies are not engaging in information blocking practices, rather they use open standards and open API programs, but they are doing so as vendors or contractors to make a complex health information technology system function. With a narrower HIN definition, one that focuses information exchange used to enable health care delivery, health care decisions, and health care actions, there will be clarity that will allow for robust innovation, and when that innovation supports and is used for health care delivery, decisions and actions, it will have to comply with these standards.

**The privacy and security OR the feasibility exception to information sharing should be clarified and we note two exceptions that we believe will be instrumental to innovation and smooth implementation of interoperability:**

1. *Allow business associates (BAs) to meet the terms of the business associate agreements (BAAs).*

21st Century Cures allowed but did not require BAs to provide patients access or retrieval rights. BAAs typically include provisions that allow the covered entity with the direct patient relationship to fulfill and meet its privacy and security policy (which is publicly posted). It is also possible that fulfilling a BAA and following the privacy and security policies of the BAA that then allow a covered entity to meet its privacy and security policy would make sharing data unfeasible. But, it would be far clearer to clarify that the privacy and security exception allows BAs to meet and fulfill the terms of their BAAs.

2. *Clarify that ALL ACTORS follow the specified information sharing restrictions associated with research.*

All Actors engaged in research being conducted with blinded or masked study designs must be permitted to follow information sharing that supports the study design. The current exception would only allow Covered Entities (CEs) and Business Associates (BAs) to follow information sharing in a manner aligned with research design, yet many entities that would be defined as HINs may be engaged in research and we note that under HIPAA the data used for research flows using a HIPAA authorization, not business associate agreements.

The proposed privacy and security exception states “An actor that is a covered entity or business associate may deny an individual’s request for access to their protected health information in the circumstances provided under 45 CFR 164.524(a)(1), (2), and (3) of the HIPAA Privacy Rule.” This provision includes a very narrow exception for CEs and BAs that permits CEs and BAs to NOT share information when that information is part of clinical research with a blinded or masked designed. This information is typically ‘tagged’ as part of a blinded or masked research. And, in the case of device or PGHD, the PCHAlliance’s Continua Design Guidelines address this topic, providing tagging so that the research information can remain masked or blinded while the research is underway.

We are delighted to provide support for interoperability, identify important future functions and functionality of ONC standards to achieve interoperability that supports personal connected health. Please contact me if you need any additional information or have questions. The Personal Connected Health Alliance welcomes the opportunity to work with ONC as these and other exciting regulatory and policy changes are under consideration.

Sincerely,



Robert Havasy

Managing Director

Personal Connected Health Alliance