March 15, 2019

Mr. Alex Thai
Networking and Information Technology Research and Development
National Coordination Office
National Science Foundation
2415 Eisenhower Avenue
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Re: Comments of the Connected Health Initiative to the National Science Foundation's Networking and Information Technology Research and Development National Coordination Office Regarding New Approaches to Solve the Interoperability Issues between Medical Devices, Data, and Platforms

Mr. Thai:

ACT | The App Association's Connected Health Initiative[1] (CHI) writes to provide comments to the National Science Foundation's Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) in response to its request for information (RFI) on new approaches to solve the interoperability issues between medical devices, data, and platforms.[2]

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their health. This coalition of leading mobile health companies and stakeholders urges Congress, Office of the National Coordinator for Health Information Technology (ONC), the Food and Drug Administration (FDA), the Center for Medicare & Medicaid Services (CMS), and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

[1] http://connectedhi.com.

[2] https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance.

CHI's members are significantly affected by health data interoperability issues and as such work to advance policy solutions that will enable a connected and interoperable continuum of care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called "store-and-forward") technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the integration of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector and help eliminate information silos, data blocking, and barriers to patient engagement.

Interoperability must not only happen between providers, but also between RM products, medical devices, and EHRs. We have consistently urged policymakers, including ONC, to encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This same practice could also be used to measure the interoperability of EHR products.

The success of value-based care models depends heavily on bi-directional interoperability of healthcare data. To reward better outcomes and cost-effective approaches to care, providers must be able to utilize two-way APIs to access, share, and make meaningful use of data about their patients. True interoperability involves not just the ability to access data, but also the ability to use and manipulate it for the user's purposes and the patient's benefit. Knowing the whole story is important for providers and payers to understand the best treatment plan or prevention measures for patients, as well as for patients who seek greater engagement in their own care. Data from previous care settings becomes more important in value-based care because the viability of the provider depends on outcomes. The process to arrive at these outcomes becomes more efficient with care plans tailored to patients' medical history, genetics, and other factors.

This is especially true for providers in rural areas, where there are fewer physicians serving people who live further away from care. Because of these geographic challenges, rural providers need data that shows which care plans or prevention and treatment measures are likely to work—and which are not—for the patients they see as well as to make adjustments to those care plans based on PGHD without requiring the patient to travel to the clinic. Physicians spend about half their time doing paperwork and grappling with EHRs that create friction in their workflow. With fewer caregivers per capita and greater distances between patients and caregivers in the less urban parts of the country, a system that traps physicians in endless stretches of administrative busywork is even more costly for rural patients. Value-based care models enable providers in rural areas to divert resources to where and when they are needed most. The ability to access and analyze data on patients and populations is central to the ability to deliver cost-effective, high-quality care.

The private sector is making strides to assist with the interoperability of data across EHRs and other platforms, and a diversity of APIs are emerging to assist in bringing PGHD into the continuum of care. For example, Health Level Seven International (HL7) is a standards-setting organization comprised of stakeholders from across the healthcare spectrum that has developed the Fast Healthcare Interoperability Resources (FHIR) standard. This is a "light, thin" standard that attempts to homogenize a relatively small subset of data formats and elements across different data users in the healthcare system. The FHIR standard also comes with an API to facilitate the exchange of EHRs. To effectuate the adoption of FHIR, HL7 launched the Argonaut Project, which is also working on standardizing more granular aspects of data formatting and field entries.

Incentives must be aligned in such a way that they encourage the adoption of data field and format standards like FHIR without strict mandates that could lock in standards that fail to keep pace with innovation. Data field and format standardization is likely to change as better data set management develops. Eventually, EHRs and other vendors should provide for two-way APIs that allow software developers to both download data from large sets held by the EHR *and* upload that data into the system. This two-way capability will be central to ensuring that 1) patients will benefit from newer innovations as quickly as possible, and 2) interoperability will evolve more naturally with developments in software and hardware.

Furthermore, as information access and exchange increases, so should efforts to ensure patient data is secure and private. Patients should have meaningful knowledge on the use or reuse of their data, along with commonsense controls over its use. Information moves at the speed of trust; EHRs and other vendors must strengthen patients' and providers' trust placed on the security and privacy of our most sensitive data. Healthcare providers usually work with a wide variety of vendors, from device makers to software companies, and ensuring they all work together to paint an accurate and seamless picture for caregivers is critical, especially for value-based care models.

We also note that interoperability solutions should provide useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must also be positive incentives to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act[3] (MACRA) provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics. We believe positive incentives should include the use of CEHRT, non-CEHRT, or technology that is built on CEHRT. Those incentives should also be calibrated to the need of physician-patient engagement and not directly linked to federal reporting requirements.

[3] Pub. L. 114-10 (2015).

CHI has developed a number of detailed written positions that we believe will assist the NCO in its efforts to solve health data interoperability issues between medical devices, data, and platforms; and which address the specific questions posed in the NOC's RFI. They are as follows, and are appended to this comment letter:

- CHI comments to ONC on its Draft Trusted Exchange Framework and Common Agreement (submitted February 20, 2018)
- CHI comments to ONC on its Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process (submitted February 20, 2018)
- CHI comments to the Department of Health and Human Services (HHS) on its Request for Information Regarding the 21st Century Cures Act Electronic Health Record Reporting Program (submitted October 17, 2018)
- CHI comments to ONC on its Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (submitted January 28, 2019)

Further comments of CHI that address digital healthcare policy issues, including health data interoperability, can be accessed at www.connectedhi.com.

We appreciate the opportunity to submit comments to the NCO on this matter and look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Thank you for your consideration.

Sincerely,

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