ConnectedHealth

April 15, 2021

Micky Trapathi
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

Re: Comments of the Connected Health Initiative Regarding the Office of the National Coordinator for Health Information Technology's Draft v2 U.S. Core Data for Interoperability

I. Introduction and Statement of Interest

We write on behalf of ACT | The App Association's Connected Health Initiative[1] (CHI) to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) on its Draft (v2) U.S. Core Data for Interoperability (USCDI) and its ongoing USCDI expansion process (draft USCDI).

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their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, ONC, the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation using interoperable data while keeping sensitive health data private and secure. CHI is a longtime supporter of ONC in its efforts to establish rules prohibiting illegal information blocking, which are critical to realizing a connected care continuum.

[1] http://connectedhi.com.

II. The Need for Interoperable Exchange of Health Information Throughout the Continuum of Care

ONC's continued efforts to provide health data interoperability are as important as ever. Electronic health information and educational resources are critical tools that empower patients to engage in their own 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 formats with interoperability 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 deficient patient engagement.

Interoperability must happen between providers, as well as between remote monitoring (RM) products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks can be seen in the communications technology industry. In addition to testing and finding consensus on voluntary industry standards, ONC should prioritize encouraging implementation of those standards to ensure interoperability between EHR systems, medical devices, and healthcare products, and use such standards to measure the interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must also be an incentive to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act[2] (MACRA) provides that incentive in a value-based healthcare environment, one which engages patients, reduces costs, and documents quality metrics.

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

Remote monitoring of PGHD is integral to the future of the American healthcare system. The demonstrated benefits of RM services include reduced hospitalizations and cost, avoidance of complications, and improved care and satisfaction, particularly for the chronically ill.[3] The Department of Veterans Affairs provides a compelling use case for the use of virtual chronic care management, which ultimately resulted in a substantial decrease in hospital and emergency room visits.[4] Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RM and asynchronous technologies.[5] Healthcare providers will also benefit from the potential of RM's cost savings. RM demonstrably improves patient engagement dealing with chronic and persistent diseases to improve the management of such conditions.

We believe ONC shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized through the trusted framework. We strongly encourage ONC to ensure their efforts prioritize data generated by patients outside the traditional care setting. Providers serving the beneficiaries of federal health plans will come to expect access to seamless and secure patient data across the care continuum, where "[i]ndividuals are able to seamlessly integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service terms."[6] Moreover, we believe ONC's path to develop the trusted framework should incorporate and build upon the vision set forth in its Interoperability Roadmap and PGHD framework.

A scope that increasingly includes PGHD is also consistent with the Department of Health and Human Services' (HHS') health technology policy. CMS has recently advanced several important changes to the future MACRA-driven Medicare system, which will permit caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries. ONC's framework should augment CMS' new rules that bring PGHD into the continuum of care (in both the fee-for-service and value-based care context).

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[3] *See* Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4.

[4] Darkins, Telehealth Services in the United States Department of Veterans Affairs (VA), *available at* http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf.

[5] The global wearable medical devices market is expected to progress from US$2.73 bn in 2014 to US$10.7 billion by 2023, predicted to progress at a 16.40% CAGR from 2015 to 2023. See http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2023-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html.

[6] ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* at 73.

III. Connected Health Initiative's Specific Comments on ONC's Proposed U.S. Core Data for Interoperability (USCDI) and Expansion Process

The USCDI and its expansion process are central to enhanced interoperability of healthcare data by specifying a common set of data classes required for exchange and identifying a predictable, transparent, and collaborative process. We appreciate ONC's work to update the USCDI and its establishment of a process and structure by which the USCDI will be updated and expanded.

CHI supports the USCDI's proposed Version 2 Data Classes, which build on the data classes referenced by the 2015 Edition Common Clinical Data Set (CCDS) definition and includes Clinical Notes and Provenance. CHI further supports proposed USCDI expansion, consistent with technology and competitive neutrality principles. CHI notes its support for the expansion of the USCDI to include social determinants of health (SDOH) paired with scaled security and privacy risk management practices that recognize the sensitivity of SDOH data that may be shared or disclosed. Including SDOH data in the USCDI with adequate safeguards will require ONC to coordinate with the HHS' Office for Civil Rights, standards development organizations, and other impacted stakeholders, which we support and encourage.

CHI also notes that testing is omitted from the draft v2 USCDI, though ONC has noted in the past that once the final Trusted Exchange Framework and Common Agreement (TEFCA) is published, Qualified HINs and their Participants will be required to update their technology to support all of the data classes included in USCDI v1 in accordance with the requirements in the final TEFCA.[7] We reiterate our request made on the draft TEFCA that ONC clarify the role of testing and/or certification in the success of the TEFCA and in the establishment and development of the USCDI.

In addition, we request that the annual review process for the USCDI be coordinated with the Interoperability Standards Advisory (ISA) annual review process and urge ONC to explain the relationship between the USCDI and ISA within the USCDI before it is finalized.

[7] Draft USCDI at 6.

IV. Conclusion

We appreciate the opportunity to submit comments to ONC 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,

Brian Scarpelli
Senior Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005