February 20, 2018

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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
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Re: Comments of the Connected Health Initiative Regarding the Office of the National Coordinator for Health Information Technology's Draft Trusted Exchange Framework for the Interoperable Exchange of Electronic Health Information U.S. Core Data for Interoperability and Proposed Expansion Process

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) to inform its efforts related to implementation of the 21st Century Cures Act's trusted exchange framework, specifically on its Draft U.S. Core Data for Interoperability (USCDI) and its proposed expansion process (draft USCDI).[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CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their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, 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 using interoperable data while keeping sensitive health data private and secure.

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[1] http://connectedhi.com.

[2] https://oncprojecttracking.healthit.gov/wiki/display/INTEROP/Common+Agreement+and+Exchange+Framework.

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

ONC's support for the 21st Century Cures Act's trusted exchange framework and common agreement provisions comes at an important time. 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 RM products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks can be seen in the communications technology industry, which has flourished globally. 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[3] (MACRA) provides that incentive in a value-based healthcare environment, one which engages patients, reduces costs, and documents quality metrics.

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[3] 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.[4] 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.[5] 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.[6] Healthcare providers will also benefit from the potential of RM's cost savings. A recent study predicted the use of RM services will help save $36 billion globally by 2018, with North America accounting for 75 percent of those savings.[7] RM has the potential to positively engage patients 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."[8] 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 includes PGHD would also be consistent with 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.[9] ONC's framework should augment CMS' new rules that bring PGHD into the continuum of care.

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

[5] 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.

[6] 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.

[7] Juniper Research, *Mobile Health & Fitness: Monitoring, App-enabled Devices & Cost Savings 2013-2018* (rel. Jul. 17, 2013), *available at* http://www.juniperresearch.com/reports/mobile_health_fitness.

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

[9] http://www.connectedhi.com/blog/2018/1/2/recognition-reimbursement-results-why-2017-was-a-win-for-connected-health.

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

Under the Trusted Exchange Framework and Common Agreement (TEFCA), 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 provide data classes in the USCDI and to establish a process and structure by which the USCDI will be updated and expanded.

CHI supports the USCDI's proposed Version 1 Data Classes, which reflects the same data classes referenced by the 2015 Edition Common Clinical Data Set (CCDS) definition and includes Clinical Notes and Provenance. CHI further supports the proposed USCDI expansion process, which would occur annually based on stakeholder input. We also support the "glide path" for additions to the USCDI which should reflect technology and competitive neutrality principles as it incrementally expands data classes.

From a process perspective, however, we do not recommend that the TEFCA or the USCDI be finalized and implemented until the related ONC information blocking rulemaking is completed. Ultimately, the definition of information blocking and how the HHS Office of the Inspector General will enforce against information blocking will be needed to inform the formalized TEFCA and USCDI. Therefore, we urge ONC to pause its ambitious timeline to formalize the USCDI's Version 1 Data Classes until *after* the ONC information blocking rulemaking is completed and seek further public comment on the USCDI after that time.

As ONC does establish the process and structure needed to update the USCDI in the future, we also urge for flexibility in the USCDI's expansion. Different data classes may need more (or less) time for development, and ONC's should work with the connected healthcare stakeholder community to ensure that its timelines and expectations are realistic.

CHI also notes that testing is completely omitted from the draft USCDI, though ONC does note that "once the final [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."[10] 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.

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[10] Draft USCDI at 6.

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.

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,

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