ConnectedHealthInitiative

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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building
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Re: Comments of the Connected Health Initiative Regarding the Office of the National Coordinator for Health Information Technology's Draft v3 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 (v3) 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CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their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 RM products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks is 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.

Further, CHI urges ONC to support the use of health data and PGHD through artificial intelligence (AI) in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. ONC's policies should contribute to the investment in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value, ultimately offering a pathway for the voluntary adoption and integration of AI systems throughout the care continuum.

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 of federal health plans and the beneficiaries they serve now 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.

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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.

A scope that increasingly includes PGHD is also consistent with the Department of Health and Human Services' (HHS') health technology policy. CMS has continued to advance 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' rules that bring PGHD into the continuum of care (in both the fee-for-service and value-based care context).

III. Connected Health Initiative's Specific Comments on ONC's Proposed Version 3 U.S. Core Data for Interoperability (USCDI)

The USCDI is 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 to update and expand the USDCI as appropriate.

CHI supports the USCDI's proposed Version 3's 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 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) with scaled security and privacy risk management practices that recognize the sensitivity of SDOH data that may be shared or disclosed. This includes incorporating SDOH data that considers social and environmental factors of patients' lives outside of the health care system in the USCDI with adequate safeguards, which requires ONC to coordinate with the HHS' Office for Civil Rights, standards development organizations, and other impacted stakeholders, which we support and encourage.

CHI reiterates our request that ONC clarify the role of testing and/or certification in the success of the Trusted Exchange Framework and Common Agreement (TEFCA) and in the establishment and development of the USCDI. ONC has previously noted that once the final TEFCA is published, Qualified Health Information Networks (HINs) and their participants will be required to update their technology to support all the data classes included in USCDI 21 in accordance with the requirements in the final TEFCA.

CHI also requests that ONC include the Average Blood Pressure (ABP) Level 2 data element in the USCDI v3. High blood pressure impacts more than 120 million people in the United States and is the leading modifiable risk factor for preventing death from cardiovascular disease. The accurate measurement and interpretation of blood pressure is vital for diagnosing high blood pressure and assessing effectiveness of treatment. With over 20 years of clinical evidence and guidelines, proper estimation of an individual's blood pressure requires multiple blood pressure measurements---in other words, obtaining two or more blood pressure readings and then averaging. This is true regardless of whether a patient is in an office setting or measuring their blood pressure at home. Moreover, consistent communication of ABP is critical for addressing

hypertension nationwide. Including ABP in the USCDI will make it easier for physicians and other healthcare providers to diagnose high blood pressure and assess blood pressure control more accurately. Physicians need health information technology systems that can store and exchange ABP, separate and apart from individual readings. This can help with documentation and enable physicians to use ABP information in their clinical decision making. This position is widely supported with the U.S. Centers for Disease Control and Prevention, the National Association of Community Health Centers, the American Hospital Association, the American Heart Association, and the American Medical Association, all in agreement with CHI that including a standardized ABP data element within the USCDI v3 is necessary.

Lastly, CHI supports the coordination of the annual review process for the USCDI 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 finalizing.

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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