ConnectedHealth

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U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
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Re: Comments of the Connected Health Initiative on the Office of the National Coordinator for Health Information Technology's Trusted Exchange Framework and Common Agreement Effort

I. Introduction and Statement of Interest

We write on behalf of ACT | The App Association's Connected Health Initiative (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 and common agreement provisions, as outlined in Section 4003 of the law.[1]

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their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.[2] 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 and keep sensitive health data private and secure.

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

[2] http://connectedhi.com

II. 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 and engage patients 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 interfaces (APIs)[3] 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. Voluntary industry standards, alongside testing and consensus on those standards, to ensure interoperability between EHR systems, medical devices, and healthcare products should be a priority for ONC, and be used to measure the interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not only 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[4] (MACRA) provides that incentive in a value-based environment of health care, one which engages patients, reduces costs, and documents quality metrics.

[3] CMS defines an API as "a set of programming protocols established for multiple purposes…[that] may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current 'patient portals.'" CMS goes on to explain that "[i]f the provider elects to implement an API, the provider would only need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate, and provide supplemental information on available applications which leverage the API." *See* 80 FR 16753. In practice the software application developer community relies on APIs to establish interoperability in a safe and secure manner across contexts. APIs are not just technical specifications regulating how data can be exchanged on a network, but should be understood as a technique for governing the relations these networks contain.

[4] 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.[5] 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.[6] Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RM, including asynchronous technologies.[7] Healthcare providers will also benefit from a growing body of potential cost savings, with a recent study predicting that RM services will help save $36 billion globally by 2018, with North America accounting for 75 percent of those savings.[8] RM has the potential to positively engage patients dealing with chronic and persistent diseases to improve the management of such conditions.

Recognizing the promise of PGHD, ONC has begun to develop a policy framework to identify best practices, service gaps, and opportunities to use PGHD in research and care delivery through 2024.[9] While we have communicated our detailed views and criticism of this effort,[10] we support ONC's efforts to bring PGHD into the continuum of care in a technology agnostic manner. We encourage ONC to sync its efforts within the 21st Century Cures Act with its ongoing PGHD-related efforts and policy changes across the Department of Health and Human Services (HHS) under MACRA.

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

[6] 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.

[7] 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.

[8] 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.

[9] https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data.

[10] Comments of the CHI to ONC on the draft PGHD Framework can be accessed at http://actonline.org/wp-content/uploads/CHI-Comments-to-ONC-re-Draft-PGHD-Framework-White-Paper-052217-w-appendix.pdf.

III. ONC's Trusted Exchange Framework and Common Agreement Efforts Should Prioritize the Connected Continuum of Care Concept

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 help prioritize data generated by patients outside of 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."[11] Moreover, we believe ONC's path to develop the trusted framework should incorporate and build upon the vision it 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 proposed several important changes to the future MACRA-driven Medicare system, which would permit caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries. Our suggested scope for ONC's framework should also be consistent with ONC's policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery.

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

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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