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 Regarding the Office of the National Coordinator for Health Information Technology's Draft Trusted Exchange Framework for the Interoperable Exchange of Electronic Health Information

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 the implementation of the 21st Century Cures Act's trusted exchange framework and common agreement provisions, as outlined in Section 4003 of the law.[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CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their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 and keep sensitive health data private and secure.

[1] http://connectedhi.com.

[2] https://oncprojectracking.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, 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. 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 industry standards, ONC should prioritize encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products. This practice could also be used 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.

[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 the end of 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 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."[8] Moreover, we believe ONC's work 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 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 Trusted Exchange Framework and Common Agreement

Based on the above, CHI offers the following comments on the specifics of the Draft TEFCA:

- ***Process/timing concerns with the expeditious path forward proposed by ONC, and the need for further comments on a more-developed TEFCA.*** We appreciate ONC's issuance of the draft TEFCA for public comment, which is the second call for input on this matter to date. However, the TEFCA is undeniably linked to ONC's ongoing efforts to address information blocking under the 21st Century Cures Act, which will include an enforcement role for HHS' Office of the Inspector General. The TEFCA must be able to reference what does and does not constitute information blocking, and explain TEFCA's definition of a stakeholder in relation to the information blocking rulemaking. Therefore, we strongly recommend that the finalization of TEFCA does not precede the completion of ONC's information blocking rules. TEFCA should incorporate the meaning of information blocking as clarified in the information blocking rulemaking and clearly explain the relationship between the voluntary TEFCA and the forthcoming mandate to prevent unreasonable information blocking.

  CHI believes that further public comment will be needed on the TEFCA, including what pilot testing will be required by the 21st Century Cures Act. These comments should come at a later time to address numerous issues in the current draft of the TEFCA, including those we raise below, and to ensure harmony with the information blocking rulemaking.

- ***Role and characteristics of the Recognized Coordinating Entity (RCE).*** CHI supports the proposal to create a single Recognized Coordinating Entity (RCE) which will form a single common agreement to which Qualified Health Information Networks (Qualified HINs) may voluntarily agree to abide. We note that many details regarding the role the RCE will play remain to be revealed, and we request that ONC provide as much insight as possible into what it envisions for the RCE. It may be helpful for ONC to explain the RCE's role through a series of anecdotes (*e.g.*, what would the RCE do to ensure adherence to relevant interoperability standards?).

  The fairness and objectivity of the RCE and the criteria it uses will be essential to the success of TEFCA, and we support ONC taking continuous steps to ensure the RCE operates appropriately through audits, recurring public solicitations of comments from stakeholders and the public, and other means. While much of the eligibility criteria for the RCE is not defined, the draft TEFCA nonetheless states that ONC will announce the RCE funding opportunity in Spring 2018. Given the concerns we describe above, including process and the need to align with the yet-to-be-finalized information blocking rule, we urge ONC to be flexible with the timing of the RCE opportunity announcement. We encourage ONC to wait until several conditions' precedents are fulfilled, namely the completion of the information blocking rulemaking and the subsequent finalization of the TEFCA, before publicly announcing the RCE funding opportunity.

  CHI further urges ONC to place the following restrictions on RCE eligibility:

  - The RCE must be a 501(c)(3) non-profit entity.
  - The RCE must utilize an independent oversight board that equally and adequately represents the range of stakeholders the TEFCA may impact, (e.g. the provider community, patient/non-covered entity community, and public health community).
  - The RCE must allow a formal and recurring public input and evaluation of its activities. The RCE must publicly release the input it receives from stakeholders as well as the improvement actions it plans to take based on the feedback received.
  - To ensure neutrality, the RCE cannot simultaneously act as a Qualified HIN or HIN.

- ***Scope/eligibility of Qualified HINs and participants under the TEFCA.*** CHI appreciates ONC's vision of the TEFCA and the different stakeholder groups it envisions playing a role in the TEFCA's success. The range of connected health stakeholders we represent should be reassured to know that the RCE, Qualified HINs, and participants will take necessary steps to ensure interoperability of health information. Indeed, the technology that our members create appears to meet the draft TEFCA's definition of a HIN (as well as Qualified HINs, despite ONC's indication that there will be a small number of Qualified HINs). To ensure clarity on the scope of the TEFCA, we strongly recommend as many detailed use cases as possible be added to the TEFCA to explain the vision of the typical flow of information and the role different stakeholder groups. We urge ONC to explore the most frequently envisioned flows under TEFCA, as well as key use cases like efforts to address the opioid crisis. Such use cases should be placed in an appendix to the Common Agreement and incorporated by reference, rather than be written into the Common Agreement. This will allow for streamlined revision and updates to the use cases.

  Further, CHI notes that many ongoing exchanges and networks have improved healthcare information interoperability for the U.S. healthcare system, and we strongly urge the TEFCA to enhance interoperability by leveraging existing exchanges and networks already in operation. While we understand that some programmatic changes will be needed to align an existing exchange or network with the finalized TEFCA, these existing exchanges and networks should qualify as Qualified HINs under RCE oversight without upending current operations and business models.

  Finally, we urge ONC to maintain the voluntary nature of the TEFCA by explicitly stating that parties operating under the TEFCA are protected from being compelled to join a Qualified HIN or HIN by contract. CHI fears that Qualified HINs are potentially tied to insurers with immense market power, which effectually forces them to subscribe to one or more networks that may not demonstrate cutting-edge interoperability, security, or other characteristics.

- ***Reducing compliance burdens on participants and end users.*** We urge ONC to make compliance burdens for participants and end users as low as possible to maximize participation. For example, we urge ONC to consider creating a standardized form to communicate TEFCA compliance to the RCE/ONC.

- ***Interoperability standards and technical frameworks in the Common Agreement.*** We support the utilization of open, consensus standards for interoperability and security. However, we are uncertain how the Interoperability Standards Advisory (ISA) standards and others would be proven and/or certified. We request that the next draft of the TEFCA provide ONC's thinking on these mechanics.

  CHI also notes its concern with, and lack of confidence in, the presumption in the draft TEFCA that the 2015 ONC Certified EHR Technology (CEHRT) standards will facilitate seamless interoperability amongst each of the TEFCA stakeholder groups. We are also concerned by the lack of discussion about how testing of such interoperability would occur. We do not believe that the CEHRT or meaningful use testing regimes will serve the purpose of validating interoperability capabilities for the TEFCA.

  Finally, we caution ONC against listing specific standards and technical frameworks in the Common Agreement, but urge that such standards be listed in an appendix incorporated by reference into the Common Agreement. We do not think this appendix should reference incomplete or draft standards or technical frameworks. Using this approach, ONC can make necessary alterations and additions to the standards and technical frameworks needed for the TEFCA, without freezing any particular versions into the Common Agreement itself.

- ***TEFCA querying issues.*** CHI shares ONC's expectation that APIs must play a central role in querying to ensure the TEFCA can reach its potential. We appreciate the draft TEFCA's discussion of APIs, and its proposed requirement on Qualified HINs to implement necessary HL7 APIs (and other standards found within ONC's ISA). However, if it does not clarify what is and is not information blocking and related key questions (such as the meaning of "exchange without special effort on the part of the user") and how such capabilities would be attested and/or certified under the TEFCA, an electronic healthcare record vendor will maintain an inappropriate amount of latitude. We reiterate our request that the TEFCA be updated after the information blocking rulemaking concludes, and that further public comment be sought on the TEFCA at that time.

  ONC should recognize that third-party service providers may have different needs and requirements than traditional healthcare stakeholders. ONC should foster the ability of those parties, whether participants or end users, to request information in a broadcast query. CHI fears that 7.1 of the draft TEFCA, which states that Qualified HINs are not required to include individuals as participants or end users, may also apply to a third-party service that acts as an agent for either participants or end users. In practice, 7.1 (as drafted) would exclude entities that are not health providers or health plans from the benefit of a broadcast query, ignoring the innovations available today and those not yet developed by participants and end users. We therefore call on ONC to alter 7.1 to permit third parties that act as agents for individuals as participants or end users to request a broadcast query.

CHI also takes issue with the proposed requirement in the draft TEFCA that queries include all U.S. Core Data for Interoperability (USCDI) Data Categories, and that participants or end users be required to share all USCDI data classes to get information. This requirement appears to force an individual to give up their ability to withhold consent to share private health information to allow patient matching to be accomplished in a query. To address this concern, CHI suggests the TEFCA be updated to permit a querying entity to specify which USCDI data categories it seeks to satisfy the "minimum necessary" provisions in the Health Insurance Portability and Accountability Act (HIPAA) of 1996. We also suggest that 10.1.1 be altered to clarify that third-party agents for participants or end users only be permitted to disclose information in a query transaction when the third-party holds consent to share that information, in order to empower patients.

Further, CHI specifically supports the monitoring of real-time patient alerts and notifications capability as a specific core requirement for Quality HINs. Such a capability is essential to ensure the uptake of remote monitoring digital health tools across healthcare systems.

Finally, CHI notes its concern with the draft TEFCA's omission of discussion regarding liability in the event of algorithmic patient matching errors during the querying process. We believe the TEFCA must address liability for patient matching errors, and urge that the TEFCA absolve liability for parties participating in the TEFCA when good faith and reasonable efforts to meet TEFCA's requirements are made.

- ***Support for robust security and privacy measures in the TEFCA.*** CHI strongly supports the draft TEFCA's proposed principle for the secure exchange of information to ensure integrity, and generally supports the security requirements in Part B of the draft TEFCA. Regarding the text of Principle 6, confidentiality and availability are added to integrity as key tenants of security, which ONC should directly reference in the TEFCA Principle 6. CHI further supports the use of the strongest technical protection mechanisms (TPMs), including end-to-end encryption and multi-step authentication. We urge ONC to include direct endorsement of the strongest TPMs used for securing data integrity, confidentiality, and access. We do, however, highlight that TPM must also be balanced with the potential financial, staff, or other resource burdens on small, solo, and rural provider offices.

  Regarding HIPAA, CHI notes its appreciation for ONC's work with HHS' Office of Civil Rights to align the TEFCA with HIPAA. However, the Draft TEFCA does create some uncertainty as to what can be shared, and how patients would be properly notified of their data's use under HIPAA. We strongly discourage creating a scenario where a party making a query must choose between satisfying the TEFCA's requirement for disclosing data fields and violating HIPAA's "minimum necessary" requirements.

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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