

June 17, 2019

Donald Rucker, MD
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 Trusted Exchange Framework for the Interoperable Exchange of Electronic Health Information

I. Introduction and Statement of Interest

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Office of the National Coordinator for Health Information Technology's (ONC) Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA), released on April 19, 2019.¹ CHI is supportive of ONC's goals in developing the TEFCA and appreciates the release of a second draft for public comment.

CHI represents a broad consensus of stakeholders across the healthcare and technology sectors. Our mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients' and consumers' experience and health outcomes. We seek to partner with the Department of Health and Human Services (HHS) in realizing the benefits of an information and communications technology-enabled American healthcare system. CHI is committed to advancing an interoperable healthcare continuum enabling the bidirectional flow of necessary health data between provider and patient, as well as between other important stakeholders who have a role in improving care coordination and decision-making.

The efficacy of precision medicine, population health, clinical decision support—and artificial intelligence (AI) driven tools in particular—depend in large part on the availability of massive data sets. The free flow of information and interoperability are, therefore, important and potentially life-saving for patients. CHI is committed to advancing health data interoperability throughout the continuum of care.

¹ <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

ONC's work on the TEFCA comes at an important time. There is no disputing that the lack of interoperability and patient access to health information are preventing timely and informed care coordination and decision-making. Further, electronic health information and educational resources are critical tools that empower and engage patients in their own care. CHI strongly believes that a truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from connected medical devices to general wellness products) with open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector by helping to eliminate information silos, data blocking, and deficient patient engagement. Interoperability must not only happen between providers but also between remote patient monitoring (RPM) products, medical devices, and EHRs. The TEFCA should, in close coordination with other related federal efforts both within and outside of ONC, help America realize this connected care continuum.

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

ONC's efforts pursuant to the 21st Century Cures Act's trusted exchange framework and common agreement provisions are timely. Interoperability must not only happen between providers but also 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. This interoperability allowed the communications technology industry to flourish across the globe. In addition to testing and finding consensus on industry standards, encouraging the voluntary implementation of industry standards to ensure interoperability between EHR systems, medical devices, and healthcare products should be a priority for ONC. 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 Act² (MACRA) provides that incentive in a value-based healthcare environment—one which engages patients, reduces costs, and documents quality metrics.

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. 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.⁶ RM has the potential to positively engage patients dealing with chronic and persistent diseases to improve the management of such conditions.

² Pub. L. 114-10 (2015).

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 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.

We believe ONC shares CHI's vision of a seamless and interoperable healthcare ecosystem leveraging the power of PGHD and 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.”⁷ 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.

⁷ 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 Trusted Exchange Framework and Common Agreement

We appreciate ONC's issuance of the Draft 2 TEFCA for public comment. 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 rulemaking (i.e., key definitions) and clearly explain the relationship between the voluntary TEFCA and the forthcoming mandate to prevent unreasonable information blocking. CHI notes that it provided detailed comments on both ONC's and CMS' proposed rules, and we urge their consideration by ONC in the context of the TEFCA.⁸ CHI also urges ONC to utilize its formal rulemaking process before finalizing the TEFCA to ensure application of adequate federal processes and analyses to this development, to allow for full exploration and development of TEFCA's relationship with the CMS interoperability rules and ONC information blocking rules.

CHI already urged ONC to wait for the completion of the information blocking rulemaking and the subsequent finalization of the TEFCA before publicly announcing the Recognized Coordinating Entity (RCE) funding opportunity. CHI again notes its support for creating a single RCE which will form a single common agreement to which Qualified Health Information Networks (QHINs) may voluntarily agree to abide. We support ONC providing as much insight as possible into what it envisions for the RCE, including 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. 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. ONC should also specify how the TEFCA and the RCE will prevent proprietary data or intellectual property from being exchanged with organizations that might promote anti-competitive market dynamics. To address this issue and others, we strongly encourage ONC to create a multistakeholder board (in addition to ONC oversight) to ensure that diverse perspectives are included in the ongoing development, implementation, and functionality of the TEFCA.

⁸ These comments are accessible at <http://www.connectedhi.com/new-page>.

CHI supports an ONC approach to RCE eligibility consistent with the following:

- 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 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 QHIN or Health Information Network (HIN).

Building on the above and CHI's previous comments offered on Draft 1 of the TEFCA, CHI offers the following comments on the specifics of the Draft 2 TEFCA:

- CHI agrees with ONC that the industry took significant steps to "broaden the exchange of data, build trust frameworks, and develop participation agreements that enable providers to exchange data across organizational boundaries," and that "[a] national exchange agreement must leverage what is working well to encourage and facilitate growth." CHI suggests socialization and leveraging of successful use cases that utilize both CEHRT and other tailored software innovations in combination, should be socialized and leveraged. We support the RCE serving as a clearinghouse for such use cases, and that ONC ensure that such a role is included in the RCE's responsibilities.
- CHI appreciates Draft 2 TEFCA's refined concept of a QHIN. In recent comments to ONC on its proposed information blocking rules, CHI described how ONC's proposed definition of a Health Information Network (HIN) in the context of the information blocking rule be narrowed to include only entities that are an actual network (or formalized component of an actual network) and have an actual operational role and responsibility for the network. We also strongly urged ONC to clarify that passive infrastructure tools used to perform health information exchange functions are excluded from the proposed definition of an HIN. Health care providers use many different passive infrastructure tools (including computers, broadband connectivity, telephones, internal networking technology, and cloud-based service applications) to manage and store health information and facilitate its movement within and beyond their internal systems. Passive infrastructure offerings are commonly acquired and operated under the direction of healthcare providers through contractual arrangements with third-party technology vendors and create the technological platform that provides the baseline information technology environment to meet the health provider's information exchange needs.

We do not believe that Congress intended for ONC to regulate passive infrastructure tools as health information networks. ONC should create an explicit exclusion in the regulatory text to exempt third-party vendors providing passive infrastructure tools used for purposes of health information technology. For instance, cloud-based technology is a passive infrastructure tool that is subject to the Health Insurance Portability and Accountability Act (HIPAA) in its role as a business associate when it stores health data generated by the majority of health care providers and other health care stakeholders. Many cloud providers are developing or have developed APIs based on Fast Healthcare Interoperable Resources (FHIR) standards to share health information as directed by healthcare providers in a manner that is consistent with HIPAA protections or as authorized by patients. This function is significantly distinct from the current understanding of a health information network because the cloud is primarily a destination for obtaining and accessing information rather than an independent broker connecting two unaffiliated parties. Therefore, the mere fact that a passive storage solution enables the authorized exchange of information under the direction of a health care provider through an API should not trigger regulation of the cloud vendor as an HIN.

To avoid the unintended consequence of creating unnecessary regulatory burdens or red tape related to the use of passive infrastructure tools, CHI has urged ONC to amend the proposed definition of a HIN at 45 CFR 171.102 as follows (underlined text being added in):

Health Information Network or HIN =

(1) Means an individual or entity that satisfies one or both of the following –

(a) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

(b) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

(2) Does not mean a third-party vendor of passive infrastructure tools, including cloud-based technology.”

To align and coordinate the TEFCA with the ONC information blocking rules, we, therefore, request that ONC adopt a common definition of a HIN between the TEFCA and ONC information blocking rule consistent with the above.

- Regarding the RCE's responsibility for monitoring QHINs on an ongoing basis and adjudicating noncompliance with the TEFCA up to and including removal of the QHIN from ONC's public directory on HealthIT.gov, we believe that ONC should provide as much detail as possible on the process for notice to a QHIN, and subsequent steps to bring the QHIN into alignment with the TEFCA, that would take place before removal from ONC's public directory.
- In Draft 2 TEFCA, ONC provides that QHINs, Participants, and Participant Members must respond to all requests for electronic health information they receive for any of the Exchange Purposes with the EHI they have available; and that if the Participant stores or maintains EHI, the Participant shall respond by providing all of the EHI it receives in the then applicable U.S. Core Data for Interoperability (USCDI) to the extent that conditions are satisfied. CHI supports the bidirectional exchange of data utilizing standardized formats which facilitate interoperability, including the USCDI. We urge ONC to clarify in the TEFCA that the responsibility for data exchange is scoped to electronic health information captured by the USCDI. Further, we strongly urge ONC to add the Encounter resource/data type to v1 of the USCDI rather than a proposed v2. It provides essential context for the other data types.
- CHI supports ONC requiring that, in addition to requiring the QHINs "file with the RCE a schedule of Fees used by the QHIN relating to the use of the QHIN's services provided pursuant to the Common Agreement that are charged to other QHINs and Participants," that such information also be made publicly available.
- CHI supports ONC's proposal to undertake TEFCA pilot testing with the National Institute of Standards and Technology (NIST). We urge ONC to ensure that this pilot testing builds trust in the privacy and security of patient health information. Further, we believe that such pilot testing should occur in phases, beginning with the exchange of information for treatment and patient access to information.
- CHI strongly supports the draft TEFCA's proposed principle for the secure exchange of information to ensure integrity, and generally supports the security requirements the draft TEFCA. 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 it. 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.

CHI appreciates ONC's seeking comment on "appropriate security controls for Participants or Participant Members in the Common Agreement, specifically regarding EHI received from federal agencies." CHI underscores that HIPAA is outcome-driven, and therefore ONC should provide for flexibility in how TEFCA Participants and Participant Members satisfy HIPAA requirements. For example, CHI strongly supports that adoption and implementation of a security framework (e.g., the NIST Cybersecurity Framework or the Health Industry Cybersecurity Practices) constitute meeting TEFCA security controls. CHI believes that the proposed Section 6.2.4 "Identity Proofing" should be limited to only the first sentence ("Individual Users. Each QHIN shall require that Individual Users with whom it has a Direct Relationship be identity proofed at a minimum of IAL2 prior to issuance of access credentials by the QHIN"); the text following this sentence in the Draft 2 TEFCA only adds ambiguity and we propose that it be deleted.

We support ONC requiring QHINs, Participants, and Participant Members to comply with the HIPAA Breach notification requirements "regardless of whether or not they are a Covered Entity or Business Associate," as well as requiring QHINs to "notify the RCE, as well as other QHINs, Participants, Participant Members, and Individual Users who may have been affected by the Breach without unreasonable delay."

CHI further supports enabling individuals to exercise Meaningful Choice (free of charge) to request that their EHI not be used or disclosed via the Common Agreement, except as required by law. We believe it would be helpful for ONC to develop a detailed listing of when Meaningful Choice can and cannot be applied, taking into consideration both federal and state laws. CHI requests that ONC create a safe harbor for QHINs, Participants, and Participant Members to be held harmless when they share an individual's EHI when the individual has provided contradictory consent decisions. Further, in the event that contradictory individual decisions exist, ONC should also clarify whether the 'No' decision takes precedence over other 'Yes' decisions.

- Some realities may make realizing the vision of the TEFCA difficult—for example, patient data may be stored in a decentralized manner and the United States currently does not permit for the use of a national patient identifier—making an accurate picture of a patient's health hard to evaluate. Such factors will also likely impact the success of the QHIN Technical Framework (QTF). In the absence of a national patient identifier, CHI suggests that ONC establish a capability that provides a longitudinal, complete, and accurate record of a patient across all HINs, which would be created through the private-sector partnership model (addressing record locator implementation, consent management, and identity management).

- CHI further notes its support for transparency to patients in how and why their data is being collected and used. The TEFCA can and should play a role in advancing this important concept. For example, CHI supports the TEFCA requiring in the Participant Minimum Obligations that Participants that are API technology suppliers attest to key multistakeholder consensus guidelines including the Xcertia App Privacy Guidelines,⁹ the FTC’s Mobile Health App Developers Best Practices,¹⁰ the CARIN Code of Conduct,¹¹ or the ONC Model Privacy Notice.¹²
- CHI urges 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. Non-use of the TEFCA should not be taken as an indication of violating ONC information blocking rules. This aspect of the TEFCA should be clearly confirmed by ONC in both the final TEFCA and ONC’s final information blocking rules.
- CHI urges ONC to make compliance burdens for participants and end users as low as possible to maximize participation. For example, we support ONC creating a standardized form to communicate TEFCA compliance to the RCE/ONC. For example, we urge ONC to distinguish between HIPAA authorization for an individual (where that individual is required to sign a form in order to have data sent to another covered entity) and the individual’s right of access (where they can request access to data for their own use or through a non-covered entity such as a third-party app).
- ONC’s Draft 2 TEFCA QTF categorizes FHIR as an emerging alternative standard and not a mandatory functionality for QHINs. We support the utilization of open, consensus standards for interoperability and security – particularly the use of the FHIR standard Release 4 and HL7 U.S. Core FHIR Implementation Guides. CHI requests that ONC clarify that support of FHIR is mandatory functionality for QHINs, which should also align with the approach taken in the ONC information blocking rules (and we urge for the same approach to interoperability standards to be taken across the ONC information blocking rule and the final TEFCA). We support ONC clarifying how the Interoperability Standards Advisory (ISA) standards and others would be proven and/or certified.

CHI also notes its concern with, and lack of confidence in, the presumption in the draft TEFCA that the 2015 ONC CEHRT standards will facilitate seamless interoperability amongst each of the TEFCA stakeholder groups. We do not believe that the CEHRT or meaningful use testing regimes will serve the purpose of validating interoperability capabilities for the TEFCA.

⁹ <https://xcertia.org/app-privacy-survey/>.

¹⁰ <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices>.

¹¹ <https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/>.

¹² <https://www.healthit.gov/sites/default/files/2018modelprivacynotice.pdf>.

Finally, we again caution ONC against listing specific standards and technical frameworks in the Common Agreement and note our support for listing such standards 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.

- 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 2 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, therefore, 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 health care stakeholders. ONC should foster the ability of those parties, whether participants or end users, to request information in a broadcast query. CHI supports permitting third parties that act as agents for individuals as participants or end users to request a broadcast query.

CHI also supports the TEFCA permitting a querying entity to specify which USCDI data categories it seeks to satisfy the "minimum necessary" provisions in HIPAA, and 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 QHINs. Such a capability is essential to ensure the uptake of remote monitoring digital health tools across healthcare systems.

- CHI supports ONC's proposed 18-month implementation timeframe which would commence once the TEFCA is final and published. We also advise that recurring updates be made by the RCE for QHINs during this phase-in period and develop an operational procedure moving forward.

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,

A handwritten signature in black ink, appearing to read "B. Scarpelli", written in a cursive style.

Brian Scarpelli
Senior Policy Counsel

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