June 17, 2019

Don Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker:

The College of Healthcare Information Management Executives (CHIME) and the Association for Executives in Healthcare Information Technology (AEHIT) are pleased to provide comments to the Office of the National Coordinator for Health IT (ONC) on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2, published on April 19, 2019.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief innovation officers, chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With more than 3,000 members in 51 countries and over 150 healthcare IT business partners, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate the effective use of information management to improve the health and healthcare in the communities they serve. Under the CHIME umbrella, our affiliate organizations AEHIT was launched in 2014. AEHIT's members are healthcare's chief technology officers. Together our members are devoted to improving the healthcare delivery experience for patients.

In Draft 2 ONC lays out three goals for TEFCA: 1) provide a single "on-ramp" to nationwide connectivity; 2) enable electronic health information (EHI) to securely follow the patient when and where it is needed; and 3) support nationwide scalability. ONC says this will be achieved through a common set of principles intended to facilitate trust between different health information networks (HINs) and serve as a single set of "rules of the road" for nationwide electronic data exchange. CHIME and AEHIT support these goals and appreciate ONC's efforts under Draft 2 to further streamline and organize the voluntary framework required by the 21st Century Cures Act. Nonetheless, given this ambitious undertaking, we believe talking some prudent steps now will pay dividends later and will better ensure these goals are realized. Below we have outlined the key points we request ONC consider as they move forward with a trusted framework for data exchange:

1. **Phased Approach:** CHIME and AEHIT strongly support ONC use a phased approach to roll out TEFCA including the use of pilots. Pilots should begin with the three use cases ONC has targeted (targeted query, broadcast query and message delivery).
2. **Sequenced Timelines:** The timetable changes necessary to support TEFCA must be thoughtfully sequenced; otherwise we risk unnecessary administrative burdens and complexity.
3. **Keep TEFCA voluntary:** We believe it is premature to mandate the use of a trust framework for any stakeholders given the number of outstanding operational issues which must be addressed first.
4. **Privacy and Security:** TEFCA policies should be aligned as closely as possible with Health Insurance Portability and Accountability (HIPAA) rules.
5. **Need for Rulemaking:** Given the seismic impact the trust framework is expected to have on our industry, we recommend ONC pursue formal comment and rulemaking.

I. Phased Approach

The 21st Century Cures Act requires that the National Coordinator, in consultation with the National Institute of Standards and Technology (NIST), provide for TEFCA pilot testing. ONC was silent in Draft 1 of TEFCA on NIST pilots, however, ONC has said in Draft 2 that they plan to work with NIST.

Draft 2 ONC discusses their plans for a "phased approach." ONC writes, "Over time, ONC intends to phase in new exchange modalities and Exchange Purposes in the Common Agreement to support additional use cases. A phased approach will allow the industry and potential signatories to adequately prepare to incorporate the necessary standards into their architectures, as well as resolve some of the variation in standards and policies that exist today. ONC intends to work with the National Institute of Standards and Technology (NIST) and the industry on pilots focusing on use cases of the TEF and the Common Agreement." We agree and are pleased to see ONC acknowledge the NIST pilots. CHIME and AEHIT consider pilot testing to be an appropriate and essential step in TEFCA development, especially given the complexity other requirements providers and vendors must meet. Further, we believe this is a prudent course of action prior to engaging the entire country in adherence to a new and untested framework.

ONC's Trusted Exchange Framework (TEF) Draft 2 (under the Minimum Required Terms and Conditions (MRTCs)) calls for supporting a minimum set of exchange purposes for sending and receiving EHI which include: 1) QHIN targeted query; 2) QHIN Broadcast Query; and 3) QHIN Message Delivery. What is less clear, however, is whether ONC plans initial pilot testing beginning with these three uses cases or only testing use cases beyond these initial three. Clarification on this point is needed.

Adding to this, is the fact that the current health information exchanges (HIE) landscape is very disjointed. HIEs are supported with different funding models (i.e., some are state funded vs. privately funded) and there has been consolidation and failure among several over the past several years. Providers are also heavily invested in HIEs – less so from a profit standpoint though and more so from a patient care perspective. Pilots will offer the opportunity for early lessons learned and could reduce unnecessary spending and costs by providing a glidepath to larger scalability.

Finally, we have outstanding questions about how ONC's plans dovetail with existing trust frameworks. Much has been said publicly by ONC about their desire about leveraging existing work underway. Yet, Draft 2 is silent on how they anticipate this will all work together. We worry that, if not properly harmonized, this could slow down interoperability progress and distract from the work that is already underway. Vendors and providers only have so much bandwidth. It will be critical to have a clear path forward.

Recommendations:

1. **CHIME and AEHIT strongly support pilot testing and recommend this begin with the initial use cases selected by ONC (targeted query, broadcast query, message delivery); and**
2. **ONC should outline a clear plan for how TEFCA is expected to interplay with existing frameworks.**

II. Sequenced Timelines and Balancing Regulatory Requirements

Combined, ONC and CMS have proposed a staggering number of changes associated with the drive to improving interoperability and patient access to data. We strongly support facilitating better access to patient data and fostering a more interoperable healthcare ecosystem. The past decade beginning with the incentives stemming from the Health Information Technology for Economic and Clinical Health (HITECH) Act have ushered in a sea change in healthcare where most physicians and hospitals are now using EHRs and an increasing number are exchanging data. Yet, we also recognize despite the enormous strides that have been made there is still much work that remains. We worry that pushing to accomplish the policies outlined by the Administration too quickly could result in unintended consequences. Our members instead favor a clear pathway where the timeline for achieving the goals of TEFCA, information blocking, and better patient access to data are thoughtfully sequenced. One of the biggest administrative barriers identified by our members has been shifting health IT timelines and policies.

ONC has identified 2020 as when they plan on releasing the first draft of the Common Agreement. If ONC finalizes their information blocking / certification rule by January 2020 as they have suggested they aim to

do, then vendors would have until January 2022 to begin rolling out products. Based upon the complexity associated with certified product development changes proposed by ONC, we anticipate this would take far longer than 24 months and in fact it would be preferable to have an entirely new Edition of certified technology. We are concerned that the timeline to accommodate these changes, when combined with those associated with updating contracts and trusted exchange onboarding activities, need to be more carefully examined and thoughtfully sequenced. Below we have outlined some of the policies providers and vendors will be expected to meet under proposed CMS and ONC policies.

- **Mandatory Updating of Participant Member Agreements:** Section 7.2.2 of TEFCA Draft 2 calls for each participant to update its Participant Member Agreements to incorporate the mandatory applicable minimum obligations set forth under TEFCA.
  - **ONC proposed timeline:** Eighteen months.
  - **CHIME and AEHIT recommendation:** While we appreciate that ONC added an additional six months onto their initial proposal of 12 months, we believe more time will be needed to amend contracts. We recommend ONC afford at least 36 months.
- **Admission, Discharge and Transfer (ADT):** CMS has proposed requiring hospitals to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another healthcare facility or to another community provider.
  - **CMS proposed timeline:** Presumably as soon as Medicare's CoP are modified following publication of the final rule.
  - **CHIME and AEHIT recommendation:** Ideally this requirement would not be adopted until there is a certification standard to support this, but at the very least we recommend this mandate occur **no sooner** than 36 months from the time the rule is finalized.
- **2015 Edition CEHRT:** ONC has proposed numerous changes to the 2015 Edition.
  - **ONC proposed timeline:** Within 24 months of publication of the final rule.
  - **CHIME and AEHIT recommendation**: Given the complexity associated with the number of proposed changes we believe this warrants an entirely new Edition.
- **EHI Export:** ONC proposes to replace the data export criterion within 2015 CEHRT, which uses the CCDA standard with a standards agnostic approach using a new 2015 Edition revised base certification criterion for electronic health information (EHI) export.
  - **ONC proposed timeline:** Developers would have to roll out the "EHI export" within 24 months of the effective date of the final rule.
  - **CHIME and AEHIT recommendation:** We did not offer a recommended timeline for adoption; rather, we recommended the scope of EHI export is too expansive and should be limited to what is contained in a certified product that is part of the legal medical record.
- **"Gag clauses":** CHIME and AEHIT appreciate ONC's attention to improving transparency around the use of vendor / provider contracts whereby some contracts prohibit a provider from sharing

concerns related to their product. However, the timelines for amending these contracts as proposed by ONC is very short.

- **ONC proposed timeline:** ONC has proposed developers must notify all customers with whom it has contracts within six months of the effective date of the final rule regarding any contract / communication that must be amended pursuant to these new rules where it contravenes what is already in place. Then, annually thereafter vendors would be required to notify customers concerning the need to make changes to contracts. Vendors would have up to 24 months to remove any contravening provisions related to communications.
- **CHIME and AEHIT recommendation:** Again, we appreciate that ONC has recognized the urgency around the need to correct the persistent challenges providers face in this space but, we worry about both providers and vendors' capacity to execute all of the necessary changes in such an abbreviated timeline. We recommend instead that ONC allow up to 60 months instead.

- **FHIR:** ONC proposes to adopt FHIR Release 2 as the baseline standard for a new application programming interface (API) standard, citing that it is widely adopted.
  - **ONC proposed timeline:** ONC has only proposed 24 months to transition to Release 2.
  - **CHIME and AEHIT recommendation:** We recommended that ONC select Release 4 instead and provide at least three years from the time the final rule is published for vendors and providers to move to FHIR to achieve FHIR fluency under Release 4.

In addition to the aforementioned policies providers will be adopting, our members continue to remind us of the numerous existing requirements that they are still implementing. As part of the move to value and driving better clinical decision-making, our members are in the midst of adopting high value initiatives such as incorporating social determinants of health, as well as, changes stemming from the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which includes the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models. In addition to MACRA, providers are undergoing an overall transition from the fee-for-service world to the world of value. The complexity for even large, better resourced providers is still staggering when it comes to meeting the Stark, anti-kickback (AKS) and Federal Trade Commission requirements for operating clinically integrated networks. We look forward to the CMS and Office of Inspector General (OIG) requirements under review at the Office of Management and Budget (OMB) on Stark and AKS exemptions and safe harbors, which we hope will bring some regulatory simplification to clinically integrated networks.

Finally, CHIME and AEHIT support electronic prescribing of controlled substances (EPCS), a requirement that was codified in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Transitioning clinicians to EPCS as mandated under Section 2003 of the SUPPORT Act by the statutorily required date of January 1, 2021 will also require software upgrades and clinical workflow redesign for many.

Taken together, it is clear that providers have a full plate, thus sequencing the timing associated with more changes around technology adoption must be considered.

Recommendation: CHIME and AEHIT recommend ONC take into consideration, as they move forward with TEFCA, the numerous changes vendors and providers will be grappling with related to existing and new policy requirements. Establishing timelines and premature requirements could cripple interoperability progress and establish unnecessary administrative burdens on our industry if the timetable is not adequately sequenced.

III. Voluntary Framework

ONC and CMS have both made recommendations or expressed intentions to require participating in a trusted health information exchange network for some stakeholders and are considering requiring even more. Specifically, ONC sought comment in its information blocking / certification proposed rule on whether vendors of certified products should be required to participate in trusted health information exchange network to demonstrate they are not information blocking. Concurrent to this CMS proposed in their interoperability / patient access rule requiring Medicare Advantage plans, Medicaid managed care plans, CHIP managed care entities and QHP issuers in FFEs to participate in trust networks in order to improve interoperability. And, they are also considering requiring Innovation Center models to participate in a trusted health information exchange network. As the agency considers further changes to the Promoting Interoperability program, they have also said they are considering encouraging hospitals to engage in certain activities focused on interoperability, which could include participation in a health information network that is part of TEFCA.

CHIME and AEHIT believe it is entirely premature to consider requiring participation in TEFCA when the framework has not been finalized, the Recognized Coordinating Entity (RCE) has not been selected, and the number and makeup of the Qualified Health Information Networks (QHINs) remains unknown. We also understand that Draft 2 is designed to serve as a blueprint and that a final Common Agreement won't be released until the Recognized Coordinating Entity (RCE) is established. We appreciate this; however, we believe requiring stakeholders to participate without first initiating pilots to test out the new trust framework could create a series of unintended consequences the least of which is additional administrative complexity. There are simply too many proof-points (i.e. exchanging data that exceeds electronic protected health information, managing consent, and financial viability) that must be established first before the framework should be widely deployed, let alone mandating participation.

Recommendation: We recommend against mandatory participation in TEFCA at this time. Instead, we recommend the focus should be on establishing the RCE and pilot testing.

IV. Privacy and Security

Overall, we appreciate that ONC has devoted more attention to both privacy and security issues. We nonetheless still have concerns with how the Common Agreement interacts with HIPAA. **Our members are still confused by the overall interplay between HIPAA, data blocking policies and TEFCA.** These concerns are akin to the ones we expressed in our earlier comments to ONC on their proposed data blocking rule. We continue to believe it is imperative that TEFCA and HIPAA are aligned. We have outlined some of the more pressing concerns below:

- **Electronic Health Information (EHI):** Similar to the concerns we expressed in our comments in response to ONC's information blocking proposal, we have concerns with the way EHI has been defined. The 21st Century Cures Act does not define EHI and like the questions we raised in our earlier comments on information blocking, we worry that the definition ONC has put forward under TEFCA is too expansive. ONC defines EHI in Appendix 2 of Draft 2 as:

  Electronic Protected Health Information, and any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in "electronic media," as defined at 45 CFR § 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

  We are concerned that requiring providers to create new policies beyond HIPAA aimed at offering patients a "meaningful" opportunity to consent, erects more challenges than solutions and will create unnecessary administrative burdens and complexity for providers. Providers are already very accustomed to working with HIPAA requirements and this wording creates a confusing and separate set of rules. Further, rather than creating new policies, a better approach would be to have providers leverage any opportunity under HIPAA (i.e., check in) when seeking consent.

  For example, as evidenced by this statement in the Draft - "all QHINs, Participants, and Participant Members who provide Individual Access Services must publish and make publicly available a written notice describing their privacy practices regarding the access, exchange, Use, and Disclosure of EHI. This notice should mirror ONC's Model Privacy Notice and include information an explanation of how an Individual can exercise their Meaningful Choice and who they may contact for more information about the entity's privacy practices" – it is clear providers will now need to manage two different sets of privacy practices.

Additionally, to our earlier point for the need for a sequenced timetable, numerous contracts will need to be renegotiated as a result of the new amount of data that will be exchanged under the definition of EHI. Today contracts refer to protected health information (PHI), therefore each will need to be scrubbed; we consider these changes to be fairly significant.

Recommendation: Any policies which supplant HIPAA or create unintended conflicts must be carefully examined. At the very least, ONC should create a crosswalk that clearly depicts where there is overlap and where new policies will be required.

- **"Meaningful Choice" / Consent management:** We appreciate the need for patients to be able to decide how their information is shared. ONC has defined the term to mean, "an Individual's choice with respect to the Use or Disclosure of EHI in the context of the applicable Framework Agreement that is: (i) made with advance knowledge as provided by the written privacy summary described in Sections 6.1.5, 7.6, or 8.6, as applicable; (ii) not used as a condition for receiving medical treatment or for discriminatory purposes; and (iii) revocable on a prospective basis if an Individual gives written notice to a QHIN, Participant, or Participant Member." We foresee a number of challenges, however in operationalizing the "Meaningful Choice" as proposed.

    1. **Treatment, payment and healthcare operations:** Under HIPAA providers are permitted to share patient information related to treatment, payment and healthcare operations (TPO) without a patient's consent. On page 17 ONC writes, "Given the anticipated increased access in EHI exchange through the Common Agreement, it is critical that Individuals have the opportunity to understand and make informed choices about where, how, and with whom their EHI is shared." ONC goes on to state that QHINs, Participants, and Participant Members must "provide Individuals with the opportunity to exercise Meaningful Choice to request that their EHI not be Used or Disclosed via the Common Agreement, except as required by Applicable Law. Participants and Participant Members are responsible for communicating this Meaningful Choice up to the QHIN who must then communicate the choice to all other QHINs. This choice must be respected on a prospective basis." **Given HIPAA does not require providers seek consent prior to sharing data related to TPO, we believe it would set up two different and competing standards if providers will be required under TEFCA to seek consent for TPO-related data and non-TPO-related data. We request ONC elaborate on how they envision providers manage these two separate processes.**
    2. **State policies on consent and revocation of consent:** As ONC notes, this must occur in accordance with "Applicable Law" and requires the ability for patients to be able to revoke their consent prospectively. The challenge we have identified is most states have stricter

consent laws than HIPAA and each one is different. This continues to create a number of challenges and complexity that is still very hard to manage under today's technology. TEFCA does nothing to make this easier and cannot solve the issue of stricter state policies. In fact, with added data exchange as called for under TEFCA these problems are only going to be exacerbated. For example, managing patient consent for those in border states or those living in two different states through the year (i.e., snowbirds) will be even more complicated than it is today. Further, technology is still not at the point where it can easily flag charts to allow them to segregate the chart by these types of requirements (i.e. revocations or varying state laws). While there are some interfaces that help with state laws, the overall complexity is very hard to manage. **CHIME supports a patient's right to decide how their information is used. However, there are constraints outside our members' control that must be addressed in order to make this work.**

3. **Terminology:** The term "meaningful choice" raised questions for our members. What this is really addressing is consent management, a term widely recognized by providers and others in the industry. We are worried adding a new term will create unneeded confusion. **We recommend ONC rename "meaningful choice" to "consent management."**

Recommendation: Meaningful Choice policies should exclude TPO data.

- **No EHI Outside the U.S. (Section 2.2.11):** Under Section 2.2.11 ONC dictates that no QHINs may disclose EHI outside the U.S. except as required by "applicable laws" and in certain cases such as a patient requesting data be sent outside the U.S. Further, no cloud-based services will be permitted to be physically located outside the U.S. While we recognize that ONC's intents may be rooted in patient privacy and security, from an operational standpoint this could make things difficult for several providers. First, it exceeds what is required under HIPAA; second many providers have international affiliates; and third some electronic health records (EHRs) are hosted overseas. If this provision is retained it will require some providers to maintain two systems to bifurcate data which is domestic vs data that needs to be shared internationally. This will create unnecessary administrative burdens.

  Recommendation: We recommend striking provision 2.2.11 and again allowing providers to rely on existing HIPAA practices. We also recommend ONC clarify if by "applicable laws" this is intended to include the European Union's General Data Protection Regulation (GDPR).

- **Other Legal Requirements (Section 6.1.4):** Under Section 6.1.4 in the Privacy section, ONC writes that to the degree, "Applicable Law requires that an Individual either consent to or approve the Use or Disclosure of his or her EHI to the QHIN, then each QHIN that has a Direct

Relationship with the Individual shall not Use or Disclose such EHI in connection with the Common Agreement unless the QHIN has obtained the Individual's consent, approval or other documentation with respect to such Uses or Disclosures consistent with the requirements of Applicable Law." If each QHIN must maintain copies of consent, federating each QHIN to maintain this will create potential for disclosure conflicts across QHINS at the patient level.

- **Recommendation: We recommend that consent disclosure should be standardized across the QHIN network(s) to support participant access to minimum necessary EHI from every participant that hasn't been selectively excluded through patient consent.**

- **Breach Reporting (Section 6.1):** Under Section 6.1 concerning breach notifications ONC writes, "Each QHIN further shall notify, in writing, the RCE and the following to the extent that they are affected by the Breach: other QHINs, Participants, Participant Members, and Individuals with whom the QHIN has a Direct Relationship. Such notice shall be provided without unreasonable delay in accordance with this Section and Applicable Law." It's unclear however what the specific timeline is. HIPAA requires breach reporting occur within 60 days of when the breach is discovered; ideally there should be alignment with this policy.

  Recommendation: ONC should clearly articulate a timeline around breach reporting and we recommend it be consistent with HIPAA.

  Demand for Compulsory Disclosures (Section 6.1.3): Under Section 6.1.3 ONC writes, "If the QHIN is requested or required…to Disclose any EHI, then the QHIN shall provide…prompt written notice of the request to the Participant, Participant Member, or Individual with whom the QHIN has a Direct Relationship that contributed the EHI so that the Participant, Participant Member or Individual may seek an appropriate protective order." It is also unclear from the Draft what ONC's envisioned timeframe is for this.
  Recommendation: ONC should clearly articulate a timeline around Demand for Compulsory Disclosures. This should also align with HIPAA.

- **Identity Proofing (Section 7.9):** Under Section 7.9 on identify proofing ONC calls for requiring Participant Members be identity proofed at IAL2 prior to issuance of access credentials.

  Recommendation: CHIME and AEHIT support IAL2 as the level of identity proofing, a standard supported by NIST.

V. **Need for Rulemaking**

In speaking with our members, we believe ONC should engage in formal rulemaking for the trust framework as the impact to the economy will be large. While the Cures Act deems compliance with the trust framework to be voluntary, as noted earlier CMS and ONC have already called for making participation mandatory. By our estimations the work to comply with TEFCA will well exceed $100 million, the threshold for having a "significant" impact on the economy.

Recommendation: We believe, given the significant impact to the economy the trust framework policies will have, that the more prudent and fair approach is for ONC to undertake formal comment and rulemaking.

VI. **Conclusion**

CHIME and AEHIT appreciate the opportunity to comment. Please contact Mari Savickis, vice president, federal affairs, at mari.savickis@chimecentral.org with any questions you may have.

Sincerely,

Russell Branzell, FCHIME, CHCIO
CEO & President, CHIME

Clint Perkinson
Director, Information Technology
Vice Chair, AEHIT