February 20, 2018

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) is pleased to have the opportunity to submit comments on the Trusted Exchange Framework and Common Agreement (TEFCA) draft released by the Office of the National Coordinator (ONC) on January 5, 2018 for public comment.

CHIME is an executive organization serving more than 2,500 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation. CHIME members are among the nation's foremost health IT experts and have a vested interested in seeing a higher state of interoperability.

As executives charged with ensuring effective, efficient, patient-centered, health information technology implementation and maintenance within and across a broad spectrum of healthcare organizations and health IT providers, CHIME members fully appreciate the value of interoperability. We support ONC's dedication to addressing the challenges which have plagued our collective drive towards greater interoperability. In doing so we also recognize that ONC (must balance or balances) a myriad of

issues identified by various stakeholders, thus preventing a truly seamless experience for both providers and patients. CHIME membership has concerns there are outstanding matters which must be addressed to make meaningful progress on interoperability. These issues are addressed below in the Key Recommendations.

I. Key Recommendations

Below you will find our key recommendations followed by more detailed comments on selected TEFCA provisions.

1. **Given the implications of TEFCA and the number of outstanding policy questions we still have, we urge ONC to offer an additional comment period this year for the public prior to finalizing the TEFCA;**
2. **We request ONC work with the National Institute for Standards and Technology (NIST) to pilot test TEFCA as required by the 21st Century Cures Act;**
3. **The Recognized Coordinating Entity (RCE) should be a broad-based, neutral entity that is a not for profit with multi-stakeholder representation – to include the provider community – on its board;**
4. **The Framework should be structured in such a way as to prevent any entity from monetizing the information aggregated thereby;**
5. **ONC should consider setting minimum expectations for C-CDA responses (e.g., provision as a single C-CDA, de-duplicated, normalized data); and finally**
6. **The Framework's data matching provisions should be modified or expanded to reflect expert input**

II. Timelines & General Construct

A. **Timeline: The TEFCA draft timeline is aggressive and sharply limits thoughtful input by stakeholders.**[1] CHIME understands that the 21st Century Cures Act sets several statutory deadlines for TEFCA development. The TEFCA draft, however, creates an expansive, complex, and rather prescriptive structure that is not amenable to cursory reading or rapid consideration. TEFCA's multiple moving parts and areas of overlap with other elements of national health IT infrastructure and data sharing policies materially increase the difficulty of stakeholder understanding of the Framework (e.g., HIPAA, data exchange standards). **CHIME strongly recommends that ONC use all available administrative mechanisms to create additional opportunities for stakeholder input prior to full-scale, nationwide Framework implementation.**

In addition to a very short comment deadline on the draft Framework, we are also worried about the timing of the forthcoming certification / information blocking rule expected from ONC in April. We have found it hard to offer meaningful comments without a complete picture of the policy landscape. We have heard several concerns from members and other stakeholders that while use of the Framework is voluntary pursuant to the 21st Century Cures Act, that they worry the U.S. Department of Health & Human Services (HHS) could deem providers data blockers if they are not using TEFCA. Additionally, we have not yet heard the feedback the new Health IT Advisory Committee has to offer on the draft and believe it would be prudent to offer sufficient time to gather this input. **We, recommend ONC offer an additional opportunity to comment prior to**

[1] Timeline as used here refers to the implementation timeline as provided by ONC in "A User's Guide to Understanding the Trusted Exchange Framework", page 29. The Guide is available at https://www.healthit.gov/sites/default/files/draft-guide.pdf.

finalizing the Framework and to give ample time for stakeholders to review the forthcoming certification / data blocking rule.

Finally, the TEFCA draft provides for the RCE to operationalize the proposed Framework and to administer the Common Agreement. Although the eligibility criteria for the RCE are not yet formally defined and are open for comment,[2] the TEFCA draft timeline calls for ONC to announce a competitive funding opportunity in the spring of 2018 to award a single, multi-year Cooperative Agreement to an RCE. **Given the central role of the RCE in the Framework and ONC's intention for multi-year contracting with the RCE, CHIME urges that the RCE selection process be unhurried.**

B. Pilot testing: Pilot testing of TEFCA is not described in the draft Framework or related resource documents. 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.[3,4] CHIME considers pilot testing to be an appropriate and essential step in TEFCA development, especially given the complexity and foreshortened timeline of TEFCA as proposed. We believe this is a prudent course of action prior to engaging the entire country in adherence to a new and untested framework. **CHIME strongly recommends that the National Coordinator promptly share with stakeholders ONC's plan for pilot testing.**

II. General Construct of TEFCA

A. **Framework Scope.** CHIME appreciates the significant amount of thought and time that has gone into the draft Framework and recognize that challenges to addressing interoperability cannot be solved in one fell swoop. What we are grappling with, however, is that the scope of the proposed Framework is exceptionally broad, and worry that the expansive nature of the Framework may simply be too much for the industry to digest, especially in such a short timeframe.

B. **Framework Approach**. We recognize that it was ONC's intent to build from existing work already underway aimed at speeding interoperability as they crafted the TEFCA. That said, the draft agreement creates an entirely new national exchange network and it is not entirely clear to us how this will impact existing agreements but it does appear to require a substantial amount of change processes. ONC has said they anticipate most Health Information Networks (HINs) will be forced to revise their existing participation agreements – which ONC acknowledges - regardless of whether a HIN seeks to function at the QHIN or Participant level under TEFCA. Numerous revisions will consume stakeholder time and resources that already are in short supply and are unlikely to be fully completed before year's end - the time ONC has said TEFCA is expected to be finalized. **We recommend that ONC work collaboratively with NIST as required under 21st Century Cures Act to pilot test TEFCA.**

C. **Framework Inclusiveness.** TEFCA is intended first and foremost to advance interoperability across the health care continuum. Some provider segments, including but not limited to those delivering post-acute care (e.g., skilled nursing facilities, home health agencies), were not included in prior programs that incentivized transition to electronic health records (EHRs). These segments of the healthcare sector continue to lag behind acute care providers in EHR utilization and in certified EHR technology (CEHRT)

[2] The TEFCA draft mentions only that the RCE be "industry-based" and "a private sector organization".
[3] Public Law 114-255, Section 4003(b)(B)(ii)
[4] CHIME recommends embedding US Core Data for Interoperability (USCDI assessment within TEFCA pilot testing.

adoption. Population health management and value-based payment implementation for an aging population and other populations for whom healthcare needs can be more complex, will face continued hurdles until post-acute care and other providers across the healthcare ecosystem reach health IT sophistication levels comparable to those of acute care. **We believe more attention to this facet of the interoperability conversation is warranted and recommend ONC elaborate on their vision for including more provider types.**

D. **Voluntary Framework Consequences.** While CHIME members fully recognize the intrinsic value of interoperability, they nonetheless must be able to put into practice what is being outlined under TEFCA. Therefore, each CIO will find themselves in the spot of determining whether participation makes sense for their organization. Harkening back to our earlier comments around deadlines, our members are worried about how feasible it will be to revise all their data exchange agreements on such a tight timeline. **CHIME is concerned that the complexity and aggressive timeframes could discourage some organizations from participating in TEFCA at least initially.** Also, the critical mass of TEFCA participation necessary for benefit to outweigh burden for most participants has not been discussed nor has ONC shared any projections for TEFCA uptake. Further, the consequences to an organization of not participating are unclear; for example, as noted earlier could choosing not to participate be construed as data blocking? **We recommend ONC clarify how they envision the interface between TEFCA participation and data blocking regulations during the comment period on the data blocking rule. Also, we are unclear about what the impact to providers will be if some HIEs in their region join TEFCA while others do not and request ONC clarify this as well.**

III. Structure and Approach to RCE and QHINs

A. **RCE Construct.** As noted above, the role of the RCE will play a central role in successfully operationalizing the TEFCA. As such, the construct of the RCE will be pivotal. **CHIME feels very strongly that the RCE should be formed under the auspices of a not for profit entity – ideally a 501(c)(3) – and which has a multi-stakeholder board which includes representation from the entire industry including the providers. Further, we also recommend that the RCE should be a neutral entity, meaning, it should not be over-representative of one area of the healthcare sector and should not be created by an entity with a vested stake in one area of the industry.** We also think a scenario whereby the RCE concurrently serves as a QHIN would not be acceptable as it could raise real and / or perceived conflicts of interest.

B. **QHINs.** QHINs will serve essential functions under the draft Framework. We have several questions around how the QHINs will function which makes it challenging to offer substantive feedback. First, we are unclear how the QHINs are expected to be financially viable. ONC appears to assume that a limited number of applicants will seek and / or achieve QHIN status, but this assumption is not explicitly stated or discussed. QHINs appear to have substantial overhead expenses and large volumes of non-revenue-generating required transactions to be recouped through a limited menu of allowable fees. Additionally, storage capacity and bandwidth availability expectations for QHINs also appear to be quite high, especially related to data repository functions and broadcast queries, but no estimates or minimum requirements are provided in the draft Framework. QHIN liability exposure for patient data matching errors could also prove to be substantial. It is thus unclear to us since QHINs are not permitted to charge fees to end users for data queries, how they will be able to recoup incurred costs. **We recommend ONC elaborate on how they envision QHINs remaining financially viable.**

IV. Query-Related Issues

A. **Query Processing.** As noted above, CHIME members have questions and concerns related to query processing demands that will be placed upon QHINs (e.g., capacity and bandwidth) and worry about the substantial capacity that will be entailed to ensure the transaction audit trail necessary simply to maintain database integrity. Projecting bandwidth requirements is challenging given the uncertainties of TEFCA uptake. However, one statewide health information exchange currently handles over two million admission, discharge, and transfer (ADT) messages monthly for a population that includes about 1/50th of the US total population. Assuming this exchange were a prototypical statewide QHIN, under TEFCA this could lead to a projected nationwide QHIN transaction volume of 100 million per month (2 million/state/month x 50 states). Also, because the bulk transfer standard that will apply to population-level queries is not yet available from HL7, the added processing demand cannot be estimated. Similarly, estimation of demand induced through use of application programming interfaces (APIs) is impossible to project since release of the associated Fast Healthcare Interoperability Resources (FHIR) standards are still pending. **CHIME has considerable reservations about inclusion in the TEFCA draft standards that have not been finalized (e.g., bulk transfer, FHIR). Incorporating pilot testing into TEFCA rollout could provide important opportunities for making adjustments as relevant new or updated standards become available.**

B. **Query Responses**. A robust national process for making queries and providing responses could contribute substantially to improving the quality and cost outcomes of healthcare, with increasing impact potential as value-based care models proliferate. Consolidated Clinical Document Architecture (C-CDA) is currently the dominant vehicle for query response delivery, and **CHIME urges ONC to consider setting minimum expectations for C-CDA responses (e.g., provision as a single C-CDA, de-duplicated, normalized data).** Response standard-setting is consistent with the Standardization Principle #1 of the draft Framework. APIs are anticipated to become common mechanisms for query submissions and responses and may ultimately replace C-CDA as the dominant vehicle. Setting relevant minimum expectations should similarly be considered for APIs. **The potential for improved outcomes through the query process will not be realized if query responses do not reliably and routinely deliver needed patient information.**

   CHIME members place very high value on the incorporation of query responses into clinician workflow with little or no clinician action required, allowing clinicians to focus attention on the patient rather than on EHR maintenance while delivering care. The 21st Century Cures Act indeed directs ONC to define interoperability to mean (among other things) that information be exchanged without "special effort on the part of the user." And, the law also calls for enhanced certification requirements to accommodate this. As far as we can tell the draft Framework does not address this topic, and it appears that this effort will be left to EHR vendors. CHIME is thus concerned about how an optimized interface between the query process and clinician workflow will occur.

C. **Medication, Allergy & Problem Lists:** In discussing the draft Framework's Security and Patient Safety Principle, ONC proposes that QHIN Participants be required to ensure that each patient's clinical record contains up to date medication, allergy, and problem lists before responding to queries about that patient. **CHIME strongly encourages ONC to eliminate this requirement**. CHIME members find ONC's expectation to be unrealistic if

not impossible for Participants to meet, since patients may move among care organizations and their movement is not reliably captured in real-time by all of the involved organizations. Further, resource limits preclude initiating "forever tracking" for all patients by each and every organization that has ever touched those patients and treating clinicians already are held accountable for considering up-to-date medication, allergy, and problem information in treatment decision-making.

V. Data Access-related Issues

A. Data matching. In prior comments on various ONC initiatives, CHIME has repeatedly emphasized the central importance of accurate patient identification and data matching. CHIME encourages ONC to go beyond basic demographics by seeking input about industry best practices (e.g., ADT feeds blended with probabilistic algorithms and analytics applied in advance of query receipt) and experiences of Record Locators. Lessons learned should be sought from a diverse group of entities, including high-stakes information holders whose repositories have been corrupted or breached (e.g., credit bureaus, government employee databases). We have the following specific recommendations: 1**) The Framework's data matching provisions should be modified or expanded to reflect expert input; 2) ONC should consider adding real-time patient alerts and notifications capability as a specific core requirement for QHINs; 3) ONC should propose principles for monitoring of QHIN data matching performance by the RCE with ONC oversight; and 4) CHIME members would welcome in the near future a frank and transparent discussion for stakeholders led by ONC about reporting of and liability for the data matching errors that will inevitably occur.**

B. **HIPAA & expanded patient data access.** The Trusted Exchange Framework (TEFCA) summary specifically states that it supports four outcomes, including the following (page 7):

> *4. The health IT community has open and accessible API to encourage entrepreneurial, user focused innovation to make health information more accessible and to improve EHR usability.*

While this statement is accompanied by the generic statement that this will be accomplished "in compliance with applicable HIPAA Rules' requirements", very little information is offered to explain the nature and scope of the implementation process. By way of example, as noted within the documentation, existing providers and payers tend to have policies and procedures in place to protect the PHI and, where necessary, electronic health information they actually create. These procedures include the protection of data internally and the protection of data shared with business associates through business associate agreements.

However, third party entities tend to have no such policies and procedures in place, as they do not create the PHI or EHI. Instead, they would presumably utilize the PHI and/or EHI created by the providers and payers without any of the limitations contained within business associates agreements. Absent such limitations, it is difficult to ascertain how the privacy rights of consumers would be protected. Theoretically, the third parties could leverage the available data to profit off of consumers without compensating the consumers for such use. Even worse, the third parties could develop applications that would force consumers to pay to access their own health data.

We believe it is extremely important that the Trusted Exchange Framework be structured in such a way as to prevent any entity from monetizing the information aggregated thereby. Utilizing the Framework as a profit-making enterprise will dis-incentivize data sharing amongst participants and will undermine the goals and objectives laid out in the 21st Century Cures Act.

C. **Managing Consent policies for data access and sharing.** CHIME appreciates that the TEFCA draft clearly stipulates that individual choices about access to and sharing of their data be provided at no cost and be respected. It appears that ONC anticipates that consent management will be managed at the QHIN level but few details are provided. The process of verifying consent by all QHIN participants and the maintenance of individual consent choice records in a nationwide data exchange environment offers considerable challenges. CHIME encourages ONC to outline principles as soon as possible for QHIN involvement, RCE monitoring, and ONC oversight of data-sharing consent. The frequency with which consent choices must be updated should also be addressed by ONC to balance currency, accuracy, and administrative burden. Boundaries and approaches for QHIN handling of the complexity superimposed by varying state privacy laws and regulations deserves full consideration. **We recommend ONC clearly address how they anticipate consent to be managed under TEFCA.**

D. **Opioids** CHIME members share HHS' concerns with the growing epidemic which is sweeping our nation and which claimed than 42,249 people in 2016, according to the Centers for Disease Control (CDC). In fact, CHIME recently launched *a new* Opioid Task Force aimed at bringing our expertise with technology use to help tackle this complex problem. CHIME members report that their respective organizations are each suppressing some sensitive information and limiting data-sharing within their own systems; principles for the Framework about sensitive information standardization could perhaps be developed by ONC by surveying CHIME members and other stakeholders about their experiences and perceived best practices. **We recommend consideration of the opioid use case be used by ONC to serve as a proxy for issues shared by a broader category of "sensitive information" (e.g., genetic testing results, gender identity interventions).**

E. **Sharing Substance & Mental Health Information:** Appropriate standards for query responses and methods for integrating responses into clinician workflows when sensitive information is being exchanged may differ from those discussed above for routine queries. Use of APIs during sensitive information exchange cannot be evaluated until the FHIR standards are available and API security challenges are addressed. Because the issues surrounding sensitive information transfer are myriad and complex, and because some of our members have expressed their intention to end all their participation agreements should sensitive information sharing become mandatory under TEFCA, we recommend ONC exclude this type of information under TEFCA for the near term. **We also recommend that ONC work closely with the Substance Abuse and Mental Health Services Administration (SAMHSA) who have oversight for HIPAA and 42 CFR Part 2 rules governing consent for mental and substance abuse information sharing, and the Office for Civil Rights (OCR) to address misalignment with HIPAA.**

F. **Prescription Drug Monitoring Programs (PDMPs):** PDMPs generally fall under the purview of state medical licensing or pharmacy governance boards**; CHIME recommends that ONC engage these boards as stakeholders to participate in ONC's opioid use case discussion.** CHIME notes that a national effort is already underway to link PDMPs. The National Association of the Boards of Pharmacy (NABP)

oversees and manages "PMP Interconnect", the only existing national network for State-based PMPs.[5] PMP Interconnect allows participating states to access PDMP data from other participants. Agreements between states and the NABP may place limits on how the states can provide access to PDMP data to entities outside PMP Interconnect yet maintain states' ability to access data via the PMP Interconnect network. Finally, complete data capture of a patient's opioid history may extend outside traditional sources of PHI (e.g., transitional housing, emergency medical services records), further complicating data exchange.

VI. Security

We appreciate the attention ONC has placed in the security provisions outlined in the draft Framework. We believe in a trusted ecosystem in which secure data and information can move freely between systems, modalities, continuums of care, and ultimately provide better patient quality outcomes. The draft Framework starts aligning organizations to share data in a manner in which is secure and validated. Specifically, we support the need for strong authentication and validated identity proofing prior to access and disclosure of data and CHIME is an avid supporter of the NIST Cybersecurity Framework (CSF).

TEFCA further defines the minimum technical standards needed to ensure a secure infrastructure to transmit data leveraging more industry-accepted standards. We generally support the minimum standards, particularly a minimum floor of IAL2 being set for end user identity proofing. We also support the NIST 800-63-3, in which addresses identity proofing, identity authentication, and the strength of assertion in a federated environment. This all said, we worry that the requirements may be hard for smaller providers to meet and we urge ONC to take this into consideration. The two-factor authentication requirements may simply be too onerous and expensive for smaller providers. We also received feedback that the privacy and security requirements represent an expansion of the DEA requirements for identity proofing and provisioning for e-prescribing of controlled substances.

VII. Conclusion

CHIME appreciates the opportunity to comment on this body of work and looks forward to continuing to lend the voice of members who play such an integral role is using technology to facilitate better patient care. Should you have any questions about our letter please contact Mari Savickis, vice president, Federal Affairs at msavickis@chimecentral.org.

Sincerely,

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[5] For more information, see https://nabp.pharmacy/initiatives/pmp-interconnect/.