



June 17, 2019

Submitted Via HealthIT.Gov

Donald Rucker, M.D.
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

RE: Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA),
released on April 19, 2019

Dear Dr. Rucker,

Thank you for the opportunity to respond to the second draft of the Trusted Exchange Framework and Common Agreement that Congress directed ONC to develop under Section 4003 of the 21st Century Cures Act.

The Alliance of Community Health Plans (ACHP) is a national leadership organization bringing together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care. The non-profit, provider-aligned health plans that are ACHP members provide coverage and care in all lines of business for more than 22 million Americans across 34 states and the District of Columbia. ACHP members offer five of the fourteen 5-star rated Medicare Advantage (MA) plans. Overall, 34 MA contracts offered by ACHP members received at least 4-stars in the 2018 star ratings.

ACHP is commenting on the three complementary documents in the updated TEFCA draft:

1. The Trusted Exchange Framework, a set of principles by which health information networks should abide to enable data exchange.
2. The Minimum Required Terms and Conditions that Qualified Health Information Networks voluntarily agree to follow. The Minimum Required Terms and Conditions require:
 - a. Support for a minimum set of exchange purposes for sending and receiving electronic health information, (e.g., Qualified Health Information Networks Targeted Query, Qualified Health Information Networks Broadcast Query, and Qualified Health Information Networks Message Delivery);
 - b. Strong privacy and security protections for all entities that elect to participate, including non-HIPAA entities.

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3. The Qualified Health Information Network Technical Framework, a document that details the technical and functional components for exchange among Qualified Health Information Networks.

The ONC will also award a private sector organization to be the Recognized Coordinating Entity that will have oversight, enforcement, and governance responsibilities for each of the Qualified Health Information Networks who voluntarily adopt the final TEFCA.

ACHP understands that this updated TEFCA package relates directly to health plan requirements in the proposed CMS and ONC patient access and interoperability rules. Accordingly, ACHP appreciates ONC's recognition in the new draft that there are several stakeholders involved, including payers, which must consider how to participate in a Qualified Health Information Networks to best serve consumers. It is important to ACHP member organizations that the TEFCA successfully engage various stakeholders' disparate information systems and recognize varying data needs to create a full and trustworthy patient health record.

Overall, we support ONC's effort to establish a network-of networks policy framework for trusted exchange of health information. ACHP members believe that the trusted exchange of health information through interoperable systems will improve care coordination, care management, and population health. Our members are actively seeking ways to create a more seamless exchange of information with health care providers so that they can better serve plan members and appreciate that this is also an objective of the latest TEFCA draft.

Generally, the TEFCA concept is new to health plans and, consequently, the industry requires more time to consider how to provide constructive feedback to develop a long-term, sustainable approach to nationwide data exchange. **At a minimum, ACHP requests that the Recognized Coordinating Entity to be selected by the ONC, work with stakeholders over time on new use cases and engage the payer community before beginning to operationalize the TEFCA.** It is important that the coordinating entity understand the different issues and concerns that payers have in participating in a Qualified Health Information Network before entering into agreements with Health Information Networks.

Specifically, ACHP believes there are several barriers to the successful implementation of TEFCA:

1. Uneven Health Information Exchange and Health Information Network Geographic Distribution and Sustainability.
2. Non-Transparent Governance Process.
3. Incomplete Privacy and Security Framework.

Uneven Health Information Exchange and Health Information Network Geographic Distribution and Sustainability

As ONC has previously reported, there are differing levels of engagement and operations among state and regional health information exchanges and networks. Currently health plans, including

ACHP members, participate in one, several, or none of these varying types of information exchanges, and have contrasting narratives about their experiences.

ACHP understands that the purpose of the TEFCA is, in part, to standardize Health Information Networks and create the possibility for participants to engage with only one Qualified Health Information Network rather than several. However, it is unclear how this would work for plans operating in multiple states. It is also unclear that there has been an in-depth discussion with regional, community and non-profit payers across the country that need assurances that implementing TEFCA will not interrupt existing Health Information Network / Health Information Exchange efforts. Where local level information exchange is working well, health plans need to know that their participation in a Qualified Health Information Network will be valuable, appropriate and address each region's needs. **ACHP requests that ONC study and report on the various experiences with Health Information Networks and Health Information Exchanges and build on those successes, particularly to ensure that the TEFCA does not prohibit existing innovative models to continue seamlessly on their current trajectory.**

ONC is also aware of the difficulties that health information exchanges face to remain economically sustainable over time. With a voluntary participation principle, and varying degrees of understanding and willingness to share data across competitor and multi-stakeholder entities, it is critical that ONC address more clearly the plan for economic sustainability of Qualified Health Information Networks. **ACHP requests that ONC host a series of roundtables with the health plan community and other stakeholders and issue a report based on those listening sessions that outlines a long-term plan for the financial stability that will support the goals of TEFCA. It is critical that these roundtables happen BEFORE the TEFCA is finalized.**

Non-Transparent Governance Structure

ACHP member organizations are concerned that the TEFCA structure, as proposed, will not meaningfully engage participants in policy, operational and technical decisions. In its proposed interoperability rule, CMS requires plans to participate in a Trusted Exchange Network, but ONC presents the TEFCA as a voluntary guidance document. In fact, participating in TEFCA is not a voluntary choice, at least according to CMS. We urge ONC to create an open participatory governance process and structure, including the creation of a TEFCA Oversight Board with balanced representation.

We are also concerned that the updated TEFCA is an overly complex and prescriptive set of rules over the entire Health Information Network / Health Information Exchange ecosystem. The new TEFCA appears to create barriers to organic innovation and collaboration with its top-down approach and lack of open and participatory governance.

Because of these more basic issues, ACHP declines to comment on the 15 specific inquiries in the new TEFCA. Instead, ACHP concurs with prior commenters that ONC should not specify particular standards or implementation mechanisms in the Common Agreement.

ACHP respectfully requests that the ONC and the Recognized Coordinating Entity work with private industry stakeholders to develop the technical framework and other parameters

that eliminate the prescriptive, burdensome required terms and conditions, and instead create guardrails for Health Information Exchange participants to operate in a manner that fosters competition, is flexible and promotes innovation. This is particularly necessary on items that lack industry solidarity, such as how to best identity proof and authenticate patient records, which are critical to the overall objectives of creating reliable and complete health care information.

Incomplete Privacy and Security Framework

As ACHP stated in its comment letters on the proposed interoperability rules, it is essential that we maintain public trust in the electronic exchange of health data as we modernize the system. ACHP member organizations agree that better access to information will help avoid mistakes and wasteful spending and otherwise improve the quality of care. Despite the obvious value in making information more available through Qualified Health Information Networks, there is a substantial level of concern about the privacy and security of this information.

We believe ONC should align TEFCA with HIPAA requirements and state laws, and work with the FTC to develop privacy oversight for non-HIPAA covered entities that participate in TEFCA. We are concerned that the TEFCA is establishing privacy and security requirements under contractually required terms and conditions that are above and beyond those defined by HIPAA and other federal and state laws, and are being applied to Qualified Health Information Networks, Participants and Participant Members, many of which are covered entities.

Indeed, modernizing information exchange and the growing number of relationships with non-HIPAA entities require a fresh analysis of privacy and security practices. Patient matching, authentication and identity proofing, and linking policy objectives with technical processes are known barriers to the functionality and secure exchange of electronic health information. ACHP appreciates that several of these issues are addressed by the draft TEFCA; however, health plans' particular issues – including immature data standards for interoperability and differing viewpoints on patient matching solutions – have yet to be addressed.

Finally, we note that the TEFCA encourages individuals to exercise a “Meaningful Choice” about whether to share their data. This appears to be an all or nothing action covering all personal health data exchange under the TEFCA. ACHP requests that ONC consider allowing a more nuanced approach than this blanket action, which may not allow individuals to distribute their own data in the manner and to the extent that they wish. The existing language may also cause confusion with existing federal and state data-sharing consent rules.

ACHP requests that TEFCA be implemented only at a time when these and other barriers to interoperability and privacy issues have been completely resolved and necessary guidance issued to the industry.

Conclusion

ACHP member organizations are proactively seeking ways to create a more seamless exchange of information with health care providers, public health agencies and other entities, so that we can

better serve plan members. We appreciate federal agencies such as ONC issuing guidelines and general parameters for the operation of new health information exchange infrastructures that will advance this worthy goal. At the same time, we ask that the Administration avoid a highly-regulated, top-down approach to Health Information Networks and Health Information Exchanges that already exist and are working well. To accomplish this difficult work of “right-sizing” regulatory approaches to a complex system, we recommend that the ONC and CMS work with stakeholders directly to avoid reinventing a wheel where it is unnecessary and counterproductive to do so.

Thank you for the opportunity to comment on the TEFCA draft. We look forward to serving as a resource to ONC as we continue to focus on this important issue. At your availability, ACHP and its members would welcome the opportunity to meet with you and your staff, along with your colleagues at CMS, to further discuss operationalizing TEFCA implementation. If you have questions or require additional information, please contact Michael Bagel, ACHP’s Director of Public Policy, at mbagel@achp.org.

Sincerely,

A handwritten signature in cursive script that reads "Ceci Connolly".

Ceci Connolly
President and CEO
Alliance of Community Health Plans