February 16, 2018

Donald Rucker, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729-D
Washington, DC 20201
Submitted electronically to exchangeframework@hhs.gov

Subject – Comments on the Draft Trusted Exchange Framework and Common Agreement (TEFCA)

Dear Dr. Rucker:

We are writing on behalf of the Association of Public Health Laboratories (APHL). APHL represents state and local governmental health laboratories in the United States. APHL members monitor, detect, and respond to health threats. APHL works to strengthen laboratory systems serving the public’s health in the United States and globally. We are writing in regard to ONC’s request for comments on the draft Trusted Exchange Framework and Common Agreement (TEFCA).

APHL plays an additional unique role in public health for which TEFCA is very relevant. APHL operates the APHL Informatics Messaging Services (AIMS) Platform, the pre-eminent public health shared services messaging platform that has been developed with assistance from the Centers for Disease Control and Prevention, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology and others. The platform supports Meaningful Use compliant data exchange and transformation services for public health and increasingly for clinical care to connect to public health. AIMS currently receives up to 9 million messages per month and is working with over 160 data exchange partners.

In the AIMS context, APHL sees TEFCA as not only an important initiative, but, indeed, as a critical one for the support of public health nationally. AIMS has been playing a central role in supporting electronic laboratory reporting (ELR) and is now working to operationalize electronic Case Reporting (eCR) and other important public health initiatives. AIMS offers a single, consistent, secure interface for clinical care and Electronic Health Records (EHRs) to connect to public health agencies. But as AIMS strives to support the needs of the clinical care and public health communities, it is challenged to meet the trust, financial, and technical challenges of establishing and maintaining all of these electronic connections.

The Potential of the TEFCA

There is great promise for APHL and public health in the concept of the TEFCA. In the nation’s developing electronic health infrastructure, AIMS needs to electronically connect with many public health and healthcare entities to fulfill its mission. TEFCA offers AIMS the promise of a “single on-ramp” to connect to this electronic health infrastructure. Theoretically, AIMS could
connect to just one Health Information Network (HIN) and exchange data with those who are connected to other networks through a “network of networks” model. The TEFCA “single on-ramp” could help:

- eliminate the costs of connecting to many different networks;
- eliminate costly point-to-point data use negotiations and agreements;
- reduce individual system interfaces;
- allow the use of provider identity proofing and authentication provided by others; and
- allow the use of provider directories provided by others.

We commend ONC for including public health as a permitted purpose for health information exchange in the TEFCA and for the “flow down” of this permitted purpose from the Common Agreement, through the Qualified Health Information Networks (QHINS), through their Participants, and ultimately to the End Users. This permitted purpose could be highly significant in enabling data exchange and eliminating unsustainable point-to-point data use agreement needs.

We also strongly support the principles of exchange specified in Part “A” of the Trusted Exchange Framework, the vision for using data beyond those that are in EHRs, and that there should be no query charges for public health.

**A Significant Obstacle to the TEFCA Potential**

Events that initiate public health reporting, however, begin in healthcare, laboratories, and other related health organizations. The vast majority of public health transactions are, resultantly, of an “unsolicited push” nature. Of the 25 million message exchanges that AIMS now supports, one hundred percent are pushed. All of the planned exchanges with clinical care for electronic case reporting (eCR) are of an unsolicited push nature as well. Public health and AIMS cannot, as some have suggested, “move to query” for these core transactions because they do not even know that the events exist before a push transaction acts as notification. Without push transactions almost all of the TEFCA potential will not be achievable for AIMS or public health.

- Public health needs a core, required, push use case to take advantage of the TECFA potential
- TEFCA should express “flow down” requirements for the push use case in the Common Agreement, through the QHINs, through the Participants, and to the End Users

ONC has stated that its charge from Congress in the 21st Century Cures act is “ensuring full network-to-network exchange of Electronic Health Information (EHI) through a trusted exchange framework and common agreement (TEFCA).” Including a required push use case is central to fully accomplishing network-to-network exchange and this important mission.

ONC has also indicated that push was not included in this draft because “Direct is functioning very well.” But Direct and other existing push networks do not meet basic TEFCA expectations. AIMS has some experience with Direct, but Direct does not connect to other networks. Nor do Direct and DirectTrust eliminate the need for negotiated Data Use Agreements (DUAs) among participants. An additional DUA is still necessary because public health is not a permitted purpose in the DirectTrust agreement. There are, in fact, no permitted purposes in the
DirectTrust agreement as it focuses more on the authentication and authorization aspects of trust.

There are some potential roles for query in support of public health, but these roles are largely in areas that supplement, or add to, core push functions. The query opportunities can also bring complexities and challenges including when data are accessed.

- HIPAA, and at times State and Local laws, limit the data that public health agencies can access. Under HIPAA's “minimum necessary” provision, public health should only receive data necessary to meet a specific purpose
- It should be clarified in TEFCA and in the US Core Data for Interoperability (USCDI) that only necessary USCDI data should be shared for some purposes

There are also challenges for QHINs to aggregate some public health data so that they may be queried. And while we support progress in advancing the promise of broadcast queries, the effort and challenges of reconciling data from many different sources should not be underestimated.

**TEFCA Policy Issues**

All levels of government have specific responsibilities for public health. Many of the nation’s public health programs are carried out by government agencies whether they are managing an emerging infectious disease outbreak, preventing illness and chronic diseases, or monitoring other health trends. Through TEFCA, ONC is delegating some responsibilities to a private sector Recognized Coordinating Entity (RCE). As this delegation is happening, it is important that ONC ensure that public health responsibilities are still attended to and that core public health needs, like push reporting capabilities, are a required part of the minimum terms and conditions for trusted exchange. Cooperative agreements can be weak management tools and it is important that the governance and management of the RCE itself include public health representation.

There are other policy issues that still need to be worked through. While we support the TEFCA concept for individuals to submit a “request for no data exchange” for many use cases, individuals should not be able to withdraw from legally mandated public health reporting. TEFCA needs to develop a differentiation between optional and mandatory information exchange. We believe that the inclusion of a push use case with directed routing of data can be one way to help develop this differentiation.

- Individuals cannot “opt-out” of public health reporting that is mandated by State and Local statutes
- A public health permitted purpose for health information exchange needs to clearly represent public health authorities to receive critical data when they are needed

We also believe that more work needs to be done to reconcile the TEFCA with jurisdiction-specific consent and data sharing rules. Communication about how the TEFCA concepts are reconciled with the very complicated legal and regulatory environment nationally will be an important part of TEFCA’s success.
TEFCA Standards and Scale

AIMS has significant experience developing interoperability in environments like those that TEFCA describes. Participating systems and organizations are separated from each other by one or more intermediary and one or more networks. The data exchange participants don’t usually know each other. And the scale of total connections defines a rigor for standards specification that is not usually present in point-to-point connections. With the caveats identified above, we support the concept of the USCDI, but note that interoperability needs more than high-level data element identification to succeed in this TEFCA environment.

Public health uses implementation guidance for HL7 2.X messages and CDA documents to align connections between systems for data exchange of specific data in support of specific functions. These standards and specifications take time to develop and time to implement. Because many organizations cannot afford to change standards frequently, consideration should be given to both the timeframe allowed to implement new standards and the timeframe for eliminating the support of old standards. Overlapping support for both the new and the old standards is usually needed. Citing specific standards in regulation has been unwieldy. It is not clear that citing specific standards in a Common Agreement will be an agile approach either, but somehow additional standards need to be identified for other functions including public health.

- Public health needs additional message and document standards to be supported for the TEFCA
- A timeframe of twelve months is not adequate for identifying when everyone must support new standards. Even longer timeframes should be considered for when old standards should no longer be supported.

On behalf of public health, APHL has endeavored to work with Standards Development Organizations (SDOs) to develop implementation guidance, messages, documents, testing infrastructure, and data element specifications to help drive interoperability at scale. With clinical care now working at comparable scale, public health needs more support to work collaboratively with clinical care, to be an effective electronic data trading partner, and be fully effective in nationwide interoperability.

We applaud TEFCA’s progress in establishing provider directories that AIMS can rely upon for secure data exchange. We hope that ONC soon considers the needs for standards so that these directories can be used to also communicate out to providers as well.

Thank you very much for the opportunity to comment on the Trusted Exchange Framework and Common Agreement. We look forward to working with ONC to fully realize the potential of this critical initiative.

With best regards,

Scott J. Becker, MS
Executive Director