June 17, 2019

Comment Letter to the Office of National Coordinator on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dr. Donald Rucker
National Coordinator for HIT
Office of National Coordinator
U.S. Department of Health and Human Services
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Washington, DC 20201

RE: Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2

Dear Dr. Rucker:

On behalf of the HealthShare Exchange, data aggregator and facilitator of bidirectional exchange in the Delaware Valley Region, we appreciate the opportunity to comment on the proposed Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. HSX links the electronic medical record (EMR) systems of different hospital health systems and other healthcare providers — and the claims data of healthcare insurers — to make this information accessible at inpatient and outpatient points of care (including medical practice offices) and for care management. HSX services provide recent clinical care information, and alert providers and health plans to care events.

The HSX Membership currently includes hospitals and health systems, independent ambulatory practices, behavioral health organizations, health plans, and post-acute care organizations (see section 7.0 for more details on the HSX Membership) which amount to connecting to 8.8 million patients and 14,000 doctors in the region. This means that HSX has successfully captured clinical data for approximately a third of the combined census population of Pennsylvania, New Jersey, and Delaware and connected to over 25% of the entire physician population in the state of Pennsylvania. HSX constantly works to expand its geographic reach into New Jersey, Delaware, and Central Pennsylvania to better support the region's traveling patient population.

HSX's integration and bidirectional exchange is based on a foundation of:
- Interoperability- This enables the large amount of healthcare providers in the region to be able to actively communicate: HSX is able to connect to over 30+ Electronic Medical Record systems

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- Standardization for bidirectional exchange and data aggregation- This enables the passage of timely, meaningful, actionable clinical information directly to providers within their individual workflow.
- Establishment of trust within the community- HSX established a legal framework to enable health information sharing and maintains strong relationships with the vested community represented by its Board of Trustees and several committees and workgroups.

The HSX strategy for innovation is centered around the HSX MarketStreet Platform, which expands the interoperability described above to include consumer-directed exchange of information. HSX MarketStreet empowers individual consumers to securely control and share their personal health information. This enables several enhancements including care coordination and management alerts for patients, families and caregivers; the capture of consumer-supplied data such as Advance Directives/Medical Orders for Life Sustaining Treatment (MOLST); in-home monitoring; and surveying of social determinants of health and health risk assessments.

Through the above, HSX very much requires non-HIPAA entities exchanging electronic health information to be bound by provisions which align with the safeguards of HIPAA standards.

These pillars, the HSX approach to establishing a trusted community asset, and HSX's strategy for innovation strongly align with the approach contained within the TEFCA Drafts, which is further detailed later in this commentary. *HSX, as a community-development-driven asset, fully anticipates applying to become a Qualified Health Information Network to better support its membership and the patients and members they serve.*

HSX believes that a strong board of trustees or governing entity should be involved with the initiative during its implementation and operations. HSX would like to be considered for representation on such a board as industry leaders in the field.

Recommendations for the Challenges Found in TEFCA Draft 2

There are significant challenges with the TEF and the Common Agreement which are detailed with recommendations below:

1. The need for substantial development of the technical requirements within the Qualified Health Information Network Technical Framework.

The technical framework utilizes standards not aligned with the forward movement and direction of the industry, with arguably an outdated approach to exchange. HSX has

concerns that querying standards, found also within the eHealthExchange and the Sequoia Project have been slow to uptake, had significant time out issues, and are not seamlessly integrated within the physician's workflow.

HL7's FHIR standard enables better integration with the EMR, easily enables minimum necessary standards, and should be the technical standard utilized for exchange.

The method of patient matching is not specified or defined. HSX recommends that rather than having each entity agree upon, consistently capture, and consistently share a core set of demographic data each time personal health information is requested to accurately match individuals, there is a clearly defined method for patient matching along with a delineated process for addressing problems with matches when they arise. In other words, a patient matching mechanism with proven reliability should be utilized such as IHE standards XCPD. For example, HSX has had significant success by matching on a series of demographic elements after applying logical standardization methods (e.g. 'St.' being transformed to 'Street' for matching purposes) with a minimum threshold set to confirm patient identities.

The technical framework within the Common Agreement needs significant specification definitions as crucial processes, such as User Authorization nor Authentication, are not entirely fleshed. HSX recommends that these processes should align with the established OAuth 2.0 standards.

2. The TEF's Exchange Purposes have not been tested nationally.

While the exchange purposes are expansive and have the potential to be a valuable asset, the approach to the use cases have not been tested at the national scale.

HSX recommends that a defined data governance and provenance solution be applied to the data being shared throughout the QHINs and the extended networks. Each data element should be tagged with the exchange purposes that the individual (the consumer) and/or the data provider has acquiesced to, to ensure that the privacy of the individual is maintained. The HL7 FHIR standard does enable this identification within their resource management.

3. The large amount of responsibilities allocated to the Recognized Coordinating Entity (RCE) as the designated authority of the TEF

The RCE will have a large set of responsibilities and large amount of authority within the program, with limited funding to accomplish this. The RCE, being tasked with finalizing crucial elements of the program, may take more than a year to establish the requirements within the agreement as well as establish the mechanisms to ensure compliance for the

requirements within the agreement. The potential time it could take for the RCE to get established coupled with the lack of funding is a cause for concern. The RCE needs to be initiated in short order with a clear financial sustainability model in order for TEF to be successful.

Therefore, HSX recommends that the funding be increased OR components of the RCE's responsibilities be divided.

4. The reliance on voluntary admission to the program.

To encourage participation, HSX recommends establishing an incentivization program or to closely relate and align with the Centers for Medicaid & Medicare Services Department of Health and Human Services proposed rule, CMS-9115-P. For those entities with established successful systems in place, the existing program and exchange should be sufficient to satisfy the key aims within the TEF.

5. No identified business model for sustainability for the RCE and QHIN.

There is no established methodology for sustaining the program's functionality, accommodating the appropriate support for the RCE's and QHIN responsibilities, and ensuring that compliance is met with all of the TEF and the CA's requirements.

Final Conclusions

HSX strongly agrees with the core foundation of the TEF and indicates its inclination to apply for to become a Qualified Health Information Network. HSX strongly recommends expediting the deployment of the initiative. The need for a national method of trusted exchange for a variety of exchange purposes within the industry has been strongly established. Beyond the above recommendations and considerations, ONC should consult with industry experts in developing the additional details and requirements of TEFCA and connect those entities with the RCE for the remaining conversations of the initiative.

Thank you for the opportunity to review and comment concerning the proposed framework. If you have any questions, please feel free to contact Martin Lupinetti at martin.lupinetti@healthshareexchange.org

HealthShare Exchange

Thank You,

DocuSigned by:

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