

June 17, 2019

Dr. Donald Rucker
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. S.W.
Washington, D.C. 20201

RE: Office of the National Coordinator for Health Information Technology (ONC); 2019 Draft Two of the Trusted Exchange Framework and Common Agreement (TEFCA)

Dear Dr. Rucker,

UnitedHealth Group (UHG) is pleased to respond to ONC's Draft Two of the Trusted Exchange Framework and Common Agreement (TEFCA) that enables Health Information Networks (HINs) to securely exchange electronic health information (EHI) with each other supporting a wide range of stakeholders.

UHG is a mission-driven organization dedicated to helping people live healthier lives and making our nation's health care system work better for everyone through two distinct business platforms – UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of nearly 310,000 people, including 85,000 clinical professionals, serves the health care needs of 142 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. As America's most diversified health care company serving 25 million patients in 35 markets in the U.S. and five other countries worldwide, we not only serve as one of the nation's most progressive health care delivery organizations, we also serve people within many of the country's most respected employers, in Medicare – serving nearly one in five seniors nationwide – and in one of the largest Medicaid health plans, supporting underserved communities in 31 States and the District of Columbia.

We appreciate ONC's leadership in facilitating broad and secure health information sharing nationwide, and the commitment to identifying future areas of improvement as reflected in the second draft of the TEFCA. A connected, informed, and effective health care system relies on data, actionable insights, care coordination, and value to enable innovation and advance high-quality care. Investments to modernize health care infrastructure, increase utilization of data and information, and deploy proven technology solutions are necessary to empower consumers and care providers, reduce costs, contribute to better health outcomes, and improve the consumer experience.

To achieve these goals, we are advancing end-to-end interoperability through innovative capabilities, including:

- Informing consumers of next best actions by developing a complete, longitudinal, and accurate Individual Health Record that puts a member's health care information at their fingertips;
- Integrating real-time pharmacy benefit and drug interaction alerts into the clinical workflow via PreCheck MyScript®, saving consumers on average \$135 per prescription;
- Referring consumers and clinicians to high-quality Premium Designation providers;

- Engaging consumers and providers with incentives to close gaps in care and proactively manage their health through Rally Health; and
- Aligning payment models to incent value-based care and performance.

We appreciate ONC's commitment to incorporating diverse stakeholder feedback in developing industry standards and best practices in the second draft of the TEFCA. We are aligned with ONC's intent to directly accelerate and simplify interoperable data exchange by aligning health care industry stakeholders around a unified approach to achieving interoperability and facilitating more effective and efficient care coordination through the TEFCA. While the TEFCA second draft furthers these goals in a substantial way, UHG offers specific comments that will improve the TEFCA and better align with interoperability provisions enacted in the 21st Century Cures Act.

We understand that the TEFCA will be a process of development until the Recognized Coordinating Entity (RCE) is selected and capable of carrying out the duties established under ONC. As the TEFCA develops over time, and until the RCE is fully operational, we request that ONC continues to gather industry-wide stakeholder feedback to ensure the single "on-ramp" for nationwide connectivity and scalability outcomes can be realized.

Consistent with our letters and conversations in response to ONC's first draft of the TEFCA, the Information Blocking Proposed Rule, and the Interoperability Standards Advisory (ISA), we offer the following specific recommendations to achieve the TEFCA's stated goals, while fostering advancements to the health system.

The Trusted Exchange Framework (TEF)

UHG supports the concept of a TEF as a means to create a common set of principles designed to facilitate trust between HINs, and by which all HINs should abide in order to enable efficient data exchange. We recommend ONC continue to seek stakeholder engagement as the agency finalizes the TEFCA standardization; transparency; cooperation and non-discrimination; privacy, security, and patient safety; access; and data-driven accountability principles to ensure they are implementable and can deliver EHI exchange effectively.

The TEFCA remains voluntary with no mandates to participate as a Qualified Health Information Network (QHIN), Participant, or Participant Member today, and therefore we recommend ONC clarify either via the TEFCA or in the Final Information Blocking Proposed Rule whether any organizations will be required to participate going forward, or how incentives or mandates will be used to drive adoption. Additionally, ONC should provide additional information to affected entities regarding how the TEFCA aligns with the information blocking provisions within ONC's Information Blocking Rule.

Scalability Challenges

The TEFCA is designed as a network-of-networks model, attempting to stitch together numerous regional, State, and other HINs into a nationwide architecture. There are some significant challenges to scalability with this model.

Last-mile integration with Electronic Medical Record (EMR) systems is still challenging, as EMR vendors have implemented standards in different ways and will continue to store data in a federated model. While standards like Fast Healthcare Interoperability Resources (FHIR) are gaining adoption, differences in implementation still cause normalization issues. Given that each HIN may only store fragments of a patient's data without a centralized record location, and given that the U.S. lacks a national patient identifier, it will be difficult for the TEFCA to provide a complete, accurate, and longitudinal view of a patient across all the various HINs due to reliance on patient matching techniques which are not completely accurate. We are also concerned about the scalability and performance of the broadcast-based query exchange modality outlined in the QHIN Technical Framework (QTF).

In the absence of a national patient identifier, ONC could establish the capability to provide a longitudinal, complete, and accurate record of a patient across all HINs. ONC should also establish private-sector partnerships to implement national global record locator, consent management, and identity management services within the TEFCA.

Fees

In the Agreements and Fee Schedules, ONC states that "each QHIN shall file with the RCE a schedule of Fees used by the QHIN relating to the use of the QHIN's services provided pursuant to the Common Agreement that are charged to other QHINs and Participants." We are concerned the multi-layered structure of the TEFCA could increase the existing prices for health information exchange, raising overall national health care costs. ONC should establish capped, reasonable fees that do not contribute to unnecessary costs for exchanging clinical data. We recommend ONC and the RCE monitor the pricing models proposed by QHINs and establish what the reasonable fees could include. We also recommend ONC and the RCE gather diverse industry stakeholder input as they set the fees that may be charged and determine which are reasonable. A transparent process for stakeholder input will be crucial with regard to fees, as the TEFCA should avoid adding more costs to health information exchange.

We recommend that all QHINs adopt the same fee structure to simplify the costs of data exchange, and reduce administrative efforts in reconciling different fees charged by different QHINs for the same services. Additionally, we recommend that any change in fees be implemented for all QHINs at the same time to provide predictability and stability to stakeholders. We agree with ONC's position that no fee can be charged for individual access services, and that no fees can be charged for secondary uses of EHI by another QHIN.

Example QHIN Exchange Scenarios - Specified & Alternative Standards for QHIN Exchange Network Query

UHG notes that the QTF categorizes FHIR as an emerging alternative standard and not a mandatory functionality for QHINs. We believe that QHINs must be able to exchange data by using FHIR Application Program Interface (APIs) in order to ensure efficiency and consistency across the health care industry. We ask ONC to clearly specify that FHIR is a basic, mandatory functionality for QHINs in order to eliminate any ambiguity regarding what standards are allowed. Clearly stating that the standard is FHIR will allow for the TEFCA to more seamlessly conform to the ONC Information Blocking Rule and set consistent expectations among all stakeholders exchanging EHI, allowing the health system to focus its IT development resources on moving to FHIR. We recommend that any interoperability standards that are required or promoted to operationalize QHIN data exchange in the TEFCA be the same as those specified in the ONC Information Blocking Final Rule.

No EHI Used or Disclosed Outside the United States

UHG believes the Common Agreement's Minimum Required Terms & Conditions (MRTCs) regarding the prohibition on QHINs from using or disclosing EHI outside the United States should only apply to QHINs and not to Participants or Participant Members. Many entities that would be defined as Participants or Participant Members, such as hospitals and health systems, may already be using offshore IT services. Given that they are the owners of the EHI, they should be able to make the best decisions that are appropriate for their activities. We strongly encourage ONC to not expand the scope of this restriction as it would adversely impact business operations used to manage health and health care for millions of individuals. In addition, providers will need access to an individual's EHI that may be stored or managed offshore. The off-shoring restrictions should only apply to activities performed within the scope of acting as a QHIN, with non-QHIN activities explicitly excluded from the Common Agreement.

Meaningful Choice

We agree with ONC's proposal that QHINs, Participants, and Participant Members must provide

individuals with the opportunity to exercise Meaningful Choice free of charge, by requesting that their EHI not be used or disclosed, via the Common Agreement. We understand that Participants and Participant Members are responsible for communicating individuals' Meaningful Choice decision to the QHIN, who must then communicate the choice to all other QHINs within five (5) business days.

We have some concerns that the Meaningful Choice process may be difficult to operationalize because an individual's EHI may reside with various Participants or Participant Members, who may have received contradictory consent decisions from the same individual. Because this requirement may be difficult to implement in all situations, we request that ONC create a safe harbor for QHINs, Participants, and Participant Members to be held harmless when they share an individual's EHI when the individual has provided contradictory consent decisions. This is necessary because each QHIN may not have visibility into the consent decisions held by other QHINs. Until consent from each data source is consistent and reconciled among all QHINs without inconsistencies, penalties should not be applied. Further, there must be clear workflow expectations established with respect to exchanging consent between QHINs, particularly in situations where one QHIN has received a 'no' decision and others have received a 'yes' decision. In this situation, ONC should clarify whether an individual's one 'no' will overrule all affirmative consents.

Implementation Timeline

UHG supports the 18 month timeframe given to implement changes after an updated, Final Common Agreement or TEF is published. We note that exchange entities will need to support the prior and the new Common Agreement versions simultaneously for a period of time, therefore we request ONC to clarify how frequently the RCE plans to update their requirements. We request a routine scheduled update allowing QHINs to plan for required changes.

QHIN Technical Framework

UHG supports implementing the U.S. Core Data for Interoperability (USCDI) as the basic data set for exchange, but we would encourage those that can go above USCDI for data exchange do so and continue advancing additional exchange use cases and services.

As such, ONC and the RCE should look to industry private-sector initiatives that are actively providing frameworks and standards for the exchange, integration, sharing, and retrieval of EHI including the HL7 FHIR Accelerator Program and the FHIR at Scale Taskforce (FAST). ONC and the RCE should remain engaged with these and all stakeholders as ONC and the RCE work toward a functional framework. In future versions of USCDI there is the potential that data types could be added for inclusion in USCDI that could include proprietary data, or data that is intellectual property – such as negotiated provider rates. We note that the MRTCs do not specifically call out intellectual property, and suggest that this important issue be addressed in a transparent way with stakeholder input. ONC should describe how the TEFCA and the RCE will prevent proprietary data or intellectual property to be exchanged to organizations that might promote anti-competitive market dynamics.

Recognized Coordinating Entity

We look forward to working with the selected RCE whose role is to realize the vision of the TEFCA. We understand the RCE responsibilities include establishing semiannual public listening sessions for industry stakeholders to provide feedback to the Common Agreement, QHIN Technical Framework, and other initiatives. We note that the RCE will be given authority to oversee, manage, and govern the Common Agreement and it is not clear how this organization will make decisions that impact diverse industry stakeholders, and how private-sector organizations will have input to the development and evolution of the Common Agreement. Our expectation is that ONC will have strict oversight of the RCE and final approval of the Common Agreement and the QTF. We recommend establishing a multi-stakeholder Board in addition to ONC oversight, to ensure that diverse perspectives are included in the ongoing development, implementation and functionality of the TEFCA.

As always, UHG welcomes the opportunity for constructive discussion and collaboration as part of this comment process, and we look forward to sharing any additional data or information that further ONC's goals of advancing interoperability and ending information blocking.

Sincerely,

A handwritten signature in black ink, appearing to read "John Santelli", with a long horizontal flourish extending to the right.

John Santelli
Chief Information Officer
UnitedHealth Group