

June 17, 2019

Donald Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St. SW, Floor 7
Mary Switzer Building
Washington, DC 20201

Submitted electronically via <https://www.healthit.gov>

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

Dear Dr. Rucker,

OCHIN applauds the Office of the National Coordinator's (ONC's) efforts to further health information exchange (HIE) to improve patient care and coordination through the *Trusted Exchange Framework and Common Agreement Draft 2*. We appreciate the opportunity to submit the following comments, as we recognize and actively support the ONC's TEFCA goal to improve national HIE.

OCHIN is a 501(c)(3) not-for-profit community-based health information technology (HIT) collaborative based in Portland, Oregon. Our collaborative supports health care providers that are treating the nation's most vulnerable patients. OCHIN provides a voice to the safety net patients and their providers across the nation. This population, and the providers who serve them, are chronically underrepresented in the HIE conversation.

As a naturally evolving network of networks that supports over 500 health centers across the country, OCHIN scales health IT services through hosted electronic health records (EHRs), HIE, telehealth services, and other professional services to our members. To provide the highest level of care to this unique patient population, OCHIN has grown to be one of the largest movers of health data in the nation. We share data across 46 states and since 2010 we have shared over 100 million clinical summaries with approximately 1,900 unique health care organizations, demonstrating transcendence of state lines for vulnerable patient communities. We continue to innovate within HIE and expand our partnerships to improve care coordination for extraordinarily complex and vulnerable patients.

[OCHIN's Summary of Comments on the Trusted Exchange Framework \(TEF\) and Common Agreement \(CA\)](#):

OCHIN is a strong proponent of ONC's goal of creating a national HIE framework for improved treatment and care coordination purposes. OCHIN has learned during almost 20 years of moving health care data that successful adoption of HIE by safety net providers occurs when it is simple (easy to use),

valuable (content addresses gaps in care), and low cost (both at a fee level and at a resource level). OCHIN's comments reflect the need for those principles to ensure the success of HIE.

In OCHIN's TEFCA 1.0 comments, we noted the rapid adoption of the national health exchange framework Carequality and of supporting networks such as eHealth Exchange and Commonwell, and strongly encouraged their role in ONC's goal of creating a network of networks. These networks reduce the extent to which health systems and providers must join multiple networks to receive the information they need to care for their patients. We suggested ONC allow these systems to mature, as we hold the belief this framework could meet the TEFCA goals of HIE by providing a single "on-ramp" to nationwide connectivity, enabling electronic health information to securely follow the patient to where and when it is needed, and supporting nationwide scalability, as outlined by ONC.

As ONC maintains its path forward to implement the TEFCA, OCHIN suggests avoiding duplication of the existing scalable frameworks and urges caution so as not to disrupt their natural growth. As currently drafted, the TEFCA would result in the disruption and duplication of current HIE activities, adding extensive additional burden on organizations by requiring a reorganization of their current operations with no funding support. Notably, the need to revise legal agreements that have, in many cases, taken years to be developed and executed in support of large-scale information sharing. In our comments OCHIN expresses concerns with the TEFCA that cause complexity or infeasibility within its implementation.

Finally, OCHIN believes ONC can reformat the TEFCA to meet the current frameworks where they are, by addressing current gaps in national HIE, by expanding EHR implementation in the area of mental health for those practices without 2015 CEHRTs, and by harmonizing national and state HIE regulations.

To Support ONC's TEFCA Goals:

Standardization

- ONC has the opportunity to harmonize the movement and use by providers and patients of external information, thereby improving patient experiences and outcomes, but this must be accomplished in conjunction with a reduction in provider burden. ONC must set national standards for HIE at all levels for "on-ramping" to HIE: state, regional, and local. The current regulatory environment is a major hurdle to information exchange, such as;
 - Where a patient resides on or near a state border and transitions across the border for care, some regional HIEs do not allow the sharing of information across state lines based on state regulations;
 - Security mechanisms required to access HIE portals that are so burdensome due to state regulation, that providers cannot implement automated Single Sign-On (SSO) from their EHR and must manually enter identity, password and a secondary authentication token to see the external data about a patient they are currently treating;

- Regional HIE and State Designated Entities that will not exchange or store data associated with 42 CFR Part 2 because of operational requirements to research data under the ACA that are disrupted by SAMSHA regulations; and
- HIEs that connect with national networks to exchange with federal agencies, often will not allow access to patient data by providers that are connected to those same networks directly in their EHR, increasing cost and slowing adoption of national networks.
- There are over 100 HIE organizations across the country, and they need standards to improve data connectivity. This lack of standardization complicates information exchange, and local HIEs only add to this complexity. The various state standards, regional networks, and EHRs create a fragmented system which prevents seamless HIE. Without the opportunity to connect to national frameworks, providers cannot see the value of participating in regional exchanges or purchasing an EHR system which, although it is affordable, does not connect to the national framework.
- Patient data must be simple to review and incorporate into EHRs for regulation reporting, and events notification. The format must be discrete, codified and not in pdf format or requiring specific portal access. The data must also contain the provider notes, which are often the most useful information during a transition of care.
- Community Information Exchanges create similar complexity and require standardization, especially where they support Community Service Locators to address social determinants of health. With the growth of social determinant information and its inclusion into the EHR, it is vital that ONC use its extensive reach to guide national Record Locator Services standardization. OCHIN, as a national organization, is observing the proliferation of community information exchanges across the country. ONC guidance on standards to drive interoperability is needed to ensure community resources are connected to meet patient social needs at scale.
- TEFCA currently calls for the reformation of all data sharing agreements presently in use by providers and HIEs. Many of these agreements and contracts are burdensome to finalize, at times taking years to draft, negotiate, and complete. To reduce burden on these entities, OCHIN suggests allowing contracts currently in place to remain. Upon their expiration, all subsequent contracts must be reformatted to meet TEFCA requirements. Further, safety net providers require assistance navigating health information exchange contracts. These contracts require extensive administrative resources to navigate the legal complexities for health information exchange with various entities.

Cost

- Affordability is a critical necessity for participation in TEFCA. As a voluntary program, it is vital to keep costs down for those participating in TEF, and to make the onboarding of those without 2015 CERHT feasible. High participation is vital to the success of the TEF and providing financial support and incentives to participate will improve HIE rates, and therefore patient care and outcomes.

- To ensure financial sustainability, TEFCA must provide guidance on operational capacity long-term without additional funding.
- OCHIN suggests providing initial subsidies to bring those left out of Meaningful Use up to 2015 CEHRTs. Some of these providers still operate using paper records.
- We also request more explanation from ONC as to how fees are charged by Participants and Participant Members under the Common Agreement.

Safety Net Voice

- For TEFCA to truly improve the current HIE framework, it must solve for all providers, including independent providers, primary care, safety net, rural health, behavioral health, and small providers. Safety net providers' complex patients are not accounted for in the TEFCA. This field of care experiences the lowest rates of patient matching and comorbidities requiring an easily exchangeable patient record between a variety of providers and community services. TEFCA has the potential to solve the issues for these entities which the current framework cannot, increasing the value of this national framework through cross-sector inclusion. The risk burden of these providers must be taken into account.

Feasibility Concerns

- OCHIN has concerns about the feasibility of some aims of TEFCA. These are outlined below:
 - Technical Components: Data Segmentation for Privacy (**DS4P**) and Consent Management in a distributed model are problematic, both from an operational and standards viewpoint. OCHIN recognizes the goal of narrowing the approach to security labeling but the DS4P implementation guide is focused on HL7 C-CDA and does not address FHIR. We also have no knowledge of real adoption of DS4P at scale in clinic practices and have concerns regarding the productivity impact to providers of requiring tagging of individual data elements. Adoption of Consent2Share has gone through no formal consensus-based review process and SAMHSA is not providing ongoing support for their technical specification. OCHIN has also seen adoption of this solution in small regional HIEs and nothing at a scale that addresses operational concerns at a national level. OCHIN recommends that implementation of DS4P and Consent2Share be delayed until a more formal consensus-based review has been made and the operational impact to providers is understood. We believe more practical approaches can emerge as privacy policies across 42 CFR Part 2 and HIPAA are harmonized.
 - Safe harbor: TEFCA proposes to extend HIPAA privacy and security regulations to all TEFCA participants, even those who are non-covered entities (NCEs) or business associates under law. However, NCEs not participating in TEFCA are still required to receive HIPAA-covered data, making HIPAA covered entities vulnerable to legal action. This lack of safe harbor is a concern expressed by OCHIN in our Information Blocking and Interoperability comments. As TEFCA does not provide any additional safety

mechanisms to this process, it remains necessary to clarify when liability releases in this transfer statutorily, and ONC provides that opportunity here. It is also necessary to clarify who is required (if any entity) to determine whether the NCE is a good or bad actor prior to the data being transferred. It is reasonable to assume some providers have the bandwidth to make this determination, but small and safety net providers do not have the staff or budget to allow for this research and potential liability. It is critical to protect providers from legal and punitive consequences of simply following regulatory requirements, despite being aware of the potentially hazardous consequences to patients who have agreed to direct their data to a particular actor. Aside from implementing strong restrictions on the use of patient data by NCEs, patient education and provider protections are vital, especially for providers and entities operating with minimal margins and supporting the safety net which has a lower rate of medical comprehension and higher vulnerability. Ideally, the Information Blocking Rules, the Interoperability Rules, and TEFCA will serve as the national roadmap and align around patient and provider protections.

- Query Method: The proposed query method requires the respondent to compile the returned electronic health information prior to responding to the primary care provider request, with an unintended effect of causing it a likely delay in response to the query. Under the common circumstances of a 15-minute patient appointment, this time lag removes all value from this query system and will likely result in providers opting out of this time-consuming process. Similarly, the response to a patient query of records that has an elongated response will result in consumer dissatisfaction and could result in limited consumer engagement in applications. A faster alternative is required prior to this system being implemented, or patient outcomes will decline over time. OCHIN recommends that responses be sent to the requesting system as they are available and not after all responses are compiled. OCHIN has experience in requesting documents from organizations that compile a CDA response from multiple downstream PHI repositories and have seen times extend up to 10 minutes.
- Identity Proofing: When Identity Proofing is tied to User Authentication requirements, rural providers are often at a grave disadvantage in implementation. Rural providers often use P.O. boxes for mailing addresses, which are not accepted by federally approved credential service providers (CSPs), as has been our experience in the implementation of Electronic Prescribing of Controlled Substances (EPCS). OCHIN recommends ONC and CMS create a workgroup to understand the requirements for this system and differentiate between Identity Proofing of “Individual Practitioners” as opposed to “Organizational Identity” proofing for hospitals. The Drug Enforcement Administration (DEA) requirements for identity proofing differ in the EPCS implementation of multifactor authentication at a state level and this leads to an increased burden on providers, as states allow hospitals to utilize organizational identity proofing with requiring ambulatory practices to implement individual identity proofing. Ideally, Organizational Identity Proofing will be permitted regardless of the type of provider or the size of their facility.

Conclusion

We thank ONC for providing the opportunity to comment on the second draft of the TEFCA. OCHIN is eager to assist ONC in advancing our national interoperability agenda.

Please contact Jennifer Stoll at stollj@ochin.org should you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jennifer Stoll".

Jennifer Stoll
EVP, Government Relations and Public Affairs