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Kaiser Foundation Health Plan
Program Offices

June 17, 2019

Don Rucker, M.D.
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U.S. Department of Health & Human Services
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Washington, DC 20201

Submitted to https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

RE: *ONC Request for Comments on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2*

Dear Dr. Rucker:

Kaiser Permanente appreciates ONC's efforts to fulfill the requirements in Title IV, Section 4003 of the 21st Century Cures Act, to "develop or support a trusted exchange framework and common agreement (TEFCA) among health information networks (HINs) nationally." ONC has set three high-level goals, namely 1) Provide a single "on-ramp" to nationwide connectivity; 2) enable electronic health information (EHI) to securely follow the patient; and 3) support nationwide scalability.

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the U.S., with 12.2 million members in eight states and the District of Columbia.[1] Kaiser Permanente has implemented a secure Electronic Health Record (EHR) system, KP HealthConnect® to support the delivery of healthcare services to our members and to enhance communications among providers.

We are committed to delivering high quality health care through cooperation and collaboration among providers, hospitals, health plan, and our purchasers**.** Our integrated model enables us to

[1]Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

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leverage care coordination and secure technology to provide high-quality clinical care across various settings. We also have given members and patients easy, online access to electronic health information since 2005, providing a comprehensive EHR and web portal tools to securely connect members to their health care teams, their personal health information, and the latest medical knowledge.

We offer the following comments on the above-captioned draft document, published in the ONC website on April 19, 2019.[2]

Background

Draft 2 outlines a set of goals, principles, structural components, relationship definitions, terms and conditions, and technical frameworks that together constitute both the trusted exchange framework and the common agreement intended to enable nationwide exchange of EHI across a 'network of networks' ecosystem. ONC intends the TEFCA to be scalable and to help ensure that HINs, health care providers, health plans, public health, EHR vendors, third party app developers, and others have secure access to health information when and where is needed.

ONC seeks comments on three distinct documents in the TEFCA Draft 2 package:

- The Trusted Exchange Framework (TEF) Draft 2 — The principles, structural components, exchange purposes, and exchange modalities that define the TEF. All HINs would follow the TEF to enable widespread data exchange.
- The Minimum Required Terms and Conditions (MRTCs) Draft 2 —Mandatory terms and conditions that Qualified HINs (QHINs) would agree to follow by signing the proposed Common Agreement. Additional Required Terms and Conditions (ARTCs) would also be defined and incorporated into the Common Agreement.
- The QHIN Technical Framework (QTF) Draft 1 — The functional and technical requirements for exchange between QHINs. ONC intends the QTF to be incorporated by reference in the Common Agreement.

Separately, ONC issued a Notice of Funding Opportunity (NOFO) to select a Recognized Coordinating Entity (RCE) that will be responsible for developing, updating, implementing, and maintaining the Common Agreement and the QTF.

General Comments

Kaiser Permanente has been a leader in national and regional health information exchange (HIE) efforts. We collaborated with the Department of Veterans Affairs and the Social Security Administration in prototyping the Nationwide Health Information Network, co-founded the Care Connectivity Consortium to further develop cross-organization HIE functionality, supported the creation of the Sequoia Project, Carequality, and the eHealth Exchange network, and participated in standards developing organizations (SDOs) to create numerous national standards ONC

[2] www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

adopted for certification of electronic health record systems (EHRs); these standards are used in today's HIEs.

In 2018, Kaiser Permanente exchanged medical records data about 98.8 million times for treatment purposes via existing HINs including eHealth Exchange, regional HIEs, DirectTrust, and multiple Carequality Framework implementers. Overall, 88% of these exchanges were with unaffiliated providers, and approximately 55% of the exchange transactions were for inbound records vs approximately 45% which sent outbound medical records to other authorized entities.

Kaiser Permanente members have used our award-winning patient and member portal since 2002; they accessed it nearly 300 million times in 2018 (189 million times via a mobile platform). Last year, our members also booked almost 6 million appointments online, exchanged more than 26 million secure messages with providers, viewed 47 million lab results online, and submitted nearly 26 million prescription refills for fulfillment. Our members can download a copy of their most recent visit, multiple visits, a summary of their medical record, or their full medical record through the portal. They can also calculate an estimate of plan coverage, deductibles, and out-of-pocket costs for a large array of conditions and procedures. Starting in October 2019, all eligible Kaiser Permanent members will be able to use an API platform based on the HL7 FHIR standards that supports consumer access to the core clinical data set via third party apps, consistent with Stage 3 of the CMS Promoting Interoperability (formerly Meaningful Use) program.

We reviewed Draft 2 with this long history of successful HIE experience and our strong support for consumer access to health data. While we support ONC's goals, purposes, and overarching principles for advancing exchange, we strongly recommend that ONC significantly revise the structural, operational, technical, and contractual approach outlined in Draft 2.

Overall, we are concerned that the TEFCA as proposed would adopt a top-down model that would not take advantage of valuable input via the rulemaking process. Over a decade of experience indicates that more flexibility with balanced stakeholder participation will be more successful. A better, more appropriate approach would be for ONC to build on the strong foundation of existing HIN/HIE infrastructure and to promote policies that will empower market-driven solutions for HIE. ONC should focus on removing barriers to exchange and providing strong incentives for participation.

We strongly recommend that ONC consider adopting an open, transparent, participatory governance structure that defines higher-level guardrails, so HINs can operate in a regulatory environment that fosters competition and innovation. To accomplish this, the most effective governance structure would also be flexible and would eliminate or reduce granular, prescriptive, and restrictive terms and conditions. The burden these requirements create would discourage rather than encourage participation in the TEFCA.

The enabling statute gives ONC the option to either support existing models of trusted exchange framework and common agreement or to develop a new one. It is not clear whether ONC considered recognizing and supporting one or more existing initiatives rather than developing one from scratch. National efforts like Carequality represent substantial progress towards

effective HIE that ONC should recognize and support. Existing initiatives can achieve the overall intent of the 21st Century Cures Act and all the goals ONC has outlined for TEFCA and should be recognized. They have demonstrated technical experience, scalability, common agreement acceptance, effective governance, flexibility, credibility, and agility. These are essential characteristics to successfully achieve the goals set forth by the 21st Century Cures Act. We are also confident that consumers can benefit from an approach to HIE that leverages the trusted framework and economic efficiencies these efforts have achieved.

We are concerned with the overly prescriptive and inflexible nature of the required terms and conditions applicable to all QHINs, Participants, and Participant Members. Considering the volume of minimum and additional terms and conditions proposed, the entire health care industry would have to undertake a major effort to update contractual agreements, modify and release Notices of Privacy Practices for consumers, and remediate many other policies and procedures to meet Draft 2 proposed requirements and expectations. The burden of making these changes is unwarranted and material; it should cause ONC to significantly reconsider its proposal.

Rather than attempting to dictate national information exchange policies with restrictive contractual terms and conditions, ONC should consider developing high-level guardrails for the entire HIN and exchange ecosystem that would provide consistent HIE/HIN operations, but in a manner that fosters participation and competition, is flexible and scalable, and promotes innovation. The complex nature of Draft 2's multiple requirements is more likely to discourage participation and create barriers than to improve the flow of data. Thus, we strongly believe that one additional goal of TEFCA should be to empower market-driven solutions in support of HIE.

Lastly, ONC should consider the impact that implementing Draft 2 will have on existing HIEs, HINs, providers, payers, public health entities, vendors, and others. The complexity and cost to operationalize and maintain all required terms and conditions will likely keep a number of these organizations outside of the realm of TEFCA (as proposed), diminishing the value for those that decide to join.

Comments on Specific Sections

Trusted Exchange Framework (TEF) Overview

TEF Principles

ONC describes six principles as part of the TEF, namely: 1) Standardization; 2) Transparency; 3) Cooperation and Non-Discrimination; 4) Privacy, Security and Patient Safety; 5) Access; and 6) Data Driven Accountability.

We recommend ONC add two additional principles: 7) Interoperability – using accredited standards[3]; and 8) Open, Transparent and Participatory Governance. We provide more detailed comments below.

[3] American National Standards, or standards fulfilling all elements of either the ANSI Essential Requirements or the World Trade Organization Agreement on Technical Barriers to Trade.

Common Agreement

Under Draft 2, the Common Agreement would comprise three parts: 1) Minimum Required Terms and Conditions (MRTC); 2) Additional Required Terms and Conditions (ARTC); and 3) Qualified Health Information Network (QHIN) Technical Framework (QTF). Under ONC's guidance, the RCE would be responsible to develop, update, implement and maintain the Common Agreement.

The lack of a participatory and open governance structure in TEFCA leaves primary responsibility and authority over the development, implementation, and decisions about future changes of the entire TEFCA ecosystem to ONC, via the RCE. Most major policy and technical decisions about TEFCA (e.g., decisions to add, modify, eliminate MRTCs and ARTCs) would presumably occur through sub-regulatory actions rather than the public notice and comment process.

We recommend that ONC work with the RCE to establish a participatory governance structure and process, and to ensure that major policy and technical decisions are made through formal rulemaking. All required terms and conditions should be the subject of public comment and stakeholder engagement through this open, balanced and transparent participatory governance process.

QHINs, Participants, Participant Members, and Individual Users

The TEFCA should ensure that participation is open to all, and that participants should not be able to exclude certain groups and entities. We are concerned about the potential increase in participating fees to join QHINs and Participants (when a Participant in a QHIN is an HIE or a HIN). We are also concerned with QHINs and some Participants (e.g. HIEs, HINs) having direct relationships with individual users. These individual users may be overshadowed by other larger and more complex participants of the QHIN, and the QHIN might not be able to appropriately address individual user needs.

Exchange Modalities, Exchange Purposes, and Phased Approach

QHINs will be required to support a minimum set of exchange modalities and exchange purposes. ONC proposes three types of exchange modalities: 1) QHIN-to-QHIN Targeted Queries; 2) Broadcast Query from one QHIN to many QHINs; and 3) QHIN Message Delivery.

From our perspective, exchange modalities fall into the following domains: 1) "Push" (message transmission) and "Pull" (data query) modes; 2) Pushes and Pulls involving a single individual or a population; 3) Pushes and Pulls done with one specific QHIN (one-to-one exchange) or with multiple QHINs at the same time (broadcast exchange or one-to-many); and 4) "Publish/ Subscribe" in which authorized recipients may receive filtered event notifications. This construct eliminates the presumption that there are "only" three exchange modalities to support, which misses the critical interdependencies between the key elements of exchanges about an individual/multiple individuals and exchanges between single/multiple QHINs.

We recommend ONC use these domains to define exchange modalities and require QHINs to support all of them. This approach will encourage innovation yet maintain guardrails that can

flexibly support all modalities for individuals and organizations, including publish/subscribe, targeted and broadcast query, push (data, notification), and pull data.

With respect to how Draft 2 addresses exchange purposes, we are concerned that identifying selected subsets of purposes (such as benefit determination or utilization management) will unnecessary increase the complexity of the system. TEFCA should support all exchange purposes (Treatment, Payment, and Health Care Operations as defined in HIPAA as well as Public Health, Research, etc.) and QHINs should be free to support all these purposes.

ONC intends, over time, to phase in new exchange modalities and exchange purposes. Stakeholder engagement will be critical to the success of a phased approach. Therefore, as noted earlier, we recommend that ONC adopt an open, transparent, and participatory governance process to guide and determine how to implement updates and modifications in phases.

Common Agreement Relationship to HIPAA Privacy and Security
We applaud ONC's attempt to incorporate various HIPAA requirements into the TEFCA. However, rather than selecting only some but not all HIPAA requirements to include in TEFCA, and applying them differently to QHINs, Participants, and Participant Members, we recommend ONC fully align TEFCA with HIPAA Privacy and Security requirements and apply all requirements as appropriate to all participants in TEFCA (except individual users).

We have several specific concerns about the proposed Common Agreement that present potential conflicts with current applicable law, including:

Meaningful Choice:
Kaiser Permanente is concerned that some of the Common Agreement requirements would go beyond what HIPAA currently permits. Specifically, the meaningful choice requirement, which applies to QHINs, Participants, and Participant Members, would create a new level of consent or authorization that would apply to both uses (internal to an organization) and disclosures (external to organizations). This new requirement might also apply, incidentally, to exchanges within members of an Organized Health Care Arrangement (OCHA) which are generally exempt under HIPAA from consent requirements for TPO purposes. We recommend that OCHAs be specifically addressed in the final TEFCA and that exchanges between members of an OHCA be exempt from this and all other TEFCA requirements. Consumers/individuals should be able to exercise meaningful choice under current applicable law (federal and state). At this time, we recommend that ONC limit meaningful choice to disclosures, and to allowing individuals to opt out of having their health information exchanged via the TEF.

Written Privacy Summary:
We also recommend that the Written Privacy Summary be offered to individuals be the same in content and process as the Notice of Privacy Practices required under HIPAA. Under proposed TEFCA terms, the Written Privacy Summary is supposed to be modeled on the ONC Model Privacy Notice, with additional information. Yet, another part of this section of Draft 2 states that QHINs must comply with all HIPAA regulations (which include a Notice of Privacy Practice).

Breach Notification:
We support the breach notification provisions in TEFCA, which are consistent with HIPAA breach notification regulations. ONC should also recognize – expressly within the TEFCA – that many entities that participate in the TEFCA also must comply with additional federal and state breach notification requirements beyond HIPAA, including providing notices to individuals (even if the QHIN does NOT have a direct relationship with the individual), to state attorneys general, and to others.

Minimum Security Requirements:
ONC should make TEFCA security requirements fully consistent with the administrative, physical, and technical safeguards required under HIPAA to protect the confidentiality, integrity, and availability of health information. ONC should avoid adding to, modifying, or omitting HIPAA security requirements; such requirements should apply equally to QHINs, Participants, and Participant Members (except individual users).

No EHI Used/Disclosed Outside the U.S.:
While consumers control whether/how to use or disclose their EHI outside the U.S., the TEFCA must also allow situations when the best interest of the individual prevails, if the individual is unable to make such decision on his/her own. ONC should not set a blanket prohibition in the MRTCs, rather adopt terms and conditions that allow for appropriate flexibility in defined cases.

Security Labeling:
We are concerned about the adoption of security labeling under the TEFCA, as this technology, while promising, is still not mature enough for industry-wide implementation. Without sufficiently mature automation the proposed security labeling would impose a significant burden on clinicians and clinical data system environments. Thus, we recommend that the adoption of security labels be postponed and adopted through future modifications of the ARTCs. Similarly, we are concerned that data segmentation use across these exchange modalities is inadequately supported by Consent2Share, which is proposed by ONC. Consent2Share is not a recognized national standard, and only supports the security controls required by 42 CFR Part 2, a regulation currently under review by SAMHSA.

Trusted Exchange Framework Principles

Principle 1 - Standardization
We support the principle of adherence to industry and federally-recognized technical standards, policies, best practices, and procedures. However, the TEFCA is not clear about the process for deciding final standards adoption or who will participate in those decisions. As mentioned earlier, such decisions should be done through an open, transparent, and participatory process among stakeholders.

We recommend that TEFCA-adopted standards should comprise only accredited American National Standards or consortia consensus standards that meet all provisions of the World Trade Organization's (WTO) Technical Barriers to Trade Agreements or the ANSI Essential Requirements.[4] ONC should promulgate unaccredited implementation guidance for these

[4] per the National Technology Transfer and Advancement Act (NTTAA) and OMB circular A-119.

standards, such as data specifications for government quality measures, only through sub-regulatory publications that can be updated when needed.

Principle 2 - Transparency
We support the open and transparent conduct of all exchanges and operations under TEFCA. We believe transparency is a critical principle, and it should go beyond QHINs (the narrow focus of this principle) to encompass the entire governance and operational implementation of TEFCA.

Principle 3 – Cooperation and Non-Discrimination
We agree with the basic premises of this principle – to collaborate with stakeholders across the continuum of care to exchange EHI, even when a stakeholder may be a business competitor. However, we believe cooperation and non-discrimination should also apply to access to TEFCA There should be non-discriminatory practices regarding member interested in participating in QHINs and Participants.

Principle 4 – Privacy, Security and Safety
We also support the principle to exchange EHI securely and in a manner that promotes patient safety, ensures data integrity, and adheres to privacy policies. We also reiterate the importance of fully aligning privacy and security requirements under TEFCA with those required by HIPAA, as we recommend above.

Principle 5 – Access
Individuals and their authorized caregivers should have easy access to their EHI. We recommend ONC apply this principle to entities' ability to access health information of individuals when necessary and appropriate.

Principle 6 – Population-Level Data
We agree it is critical to ensure that TEFCA supports the ability to access and exchange multiple records for a cohort of individuals at one time to enable population health management. However, rather than identifying this as a 'principle' in TEFCA, ONC should explicitly include it in supported exchange modalities and purposes, and accredited standards should be adopted to enable it. Furthermore, there should be no limit on the number of records that can be exchanged at a time (Draft 2 proposes a maximum of 30 at a time).

Additional Principles Recommended
We recommend that ONC consider including two additional principles:

- ***Principle of Interoperability***: Promote the use of accredited standards and technologies that support interoperable exchange of individual and population level information.

- ***Principle of Open, Transparent and Participatory Governance***: Establish a governance structure that is open, transparent, participatory, and ultimately responsible for decision making on all TEFCA matters.

Minimum Required Terms and Conditions (MRTCs)

Definitions

As we commented in response to ONC's recent Proposed Rule on certification and information blocking,[5] we strongly recommend ONC use PHI as defined under HIPAA, rather than proposing the more expansive definition of EHI. Alignment of these definitions is critical because the health care industry has implemented HIPAA privacy and security protections consistent with the PHI definition for 15 years. A new, expanded definition would impose significant implementation and compliance burdens on covered entities and create confusion about how to treat information under the different definitions.

We are concerned that the definition of HIN includes "an individual," not just an entity. Also, the definition refers to HINs as an entity that "defines business, operational, technical, *or other conditions or requirements* for enabling access, exchange, *or use* of EHI between or among two or more unaffiliated individuals or entities" (italicized text for emphasis). This definition is too broad and could unintentionally encompass entities that would not otherwise be considered HINs (e.g., entities that define operational requirements for use of EHI). We recommend narrowing the HIN definition as follows: "defines business, operational or technical conditions or requirements for enabling access or exchange of EHI between or among two or more unaffiliated individuals or entities".

Initial Application, Onboarding, Designation, Operation of QHINs

Kaiser Permanente is very concerned with the granularity and prescriptive nature of the terms and expectations of QHINs. Section 2.2 details every function, action, role, responsibility, limitation, option, and operation of a QHIN. We recommend that this entire section be revised to focus on defining higher-level, reasonable guardrails for QHIN operations that can foster competition, flexibility, and innovation.

Permitting a QHIN to have direct relationships with individuals is likely to result in constraining the QHIN's resources and limiting its ability to effectively serve Participants and Participant Members in support of HIE. There is also a risk that the QHIN would not be able to appropriately address individual user needs, in which case individuals would be overshadowed by large, more complex participants of the QHIN,

Data Quality and Minimum Necessary Provisions

Draft 2 would apply Minimum Necessary provisions to QHINs for any requests, uses or disclosures of EHI, but appears to ignore exceptions to minimum necessary provisions under HIPAA, for example, when the purpose is Treatment. As we have recommended above, fully aligning Draft 2 with HIPAA will be essential to eliminating conflicts with applicable law.

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[5] Kaiser Permanente response to *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule* **[RIN 0955-AA01]**, filed June 3, 2019, www.regulations.gov.

Participant and Participant Member Minimum Obligations
As we note above in comments regarding QHIN operations, we are equally concerned that the level of detail and the prescriptive nature of the terms and expectations proposed for Participants and Participant Members will result in significant disruptions in current operations, burdensome processes to modify and update current agreements, and potential unintended patient safety effects due to the complexity and restrictive nature of these terms and conditions. Rather than addressing all of the functions, actions, roles, responsibilities, limitations, options, and operations of a Participant and a Participant Member, ONC should refocus the TEFCA on defining appropriate guardrails for Participants and Participant Members that can also foster competition, flexibility, and innovation.

Individual Rights and Obligations
As proposed, Draft 2 would require all entities that voluntarily agree to join and participate in TEFCA to use Identity Assurance Level 2 (IAL2, two-factor authentication), as defined by NIST Special Publication 800-63A, for all individual users and by all QHINs, Participants, and Participating Members. The level or kind of identity proofing that is appropriate for clinician users accessing many records as part of their job is fundamentally different from the identity proofing that is appropriate for individual members and patients who may access only parts of their own records via a portal system. We are concerned that proposed TEFCA requirements ignore this critical distinction and therefore we strongly recommend that the level of identity proofing (e.g., a "Real ID" -level versus "any government picture ID" -level) should be commensurate with the inherent risks.

We recommend that the proposed Summary of Disclosures of EHI in TEFCA be fully aligned with the current HIPAA accounting for disclosure requirements and follow the Office for Civil Rights (OCR) guidelines on the topic. As proposed, this provision does not seem to consider current named exclusions from disclosure accounting.

Qualified Health Information Network Technical Framework

This section of Draft 2 covers the functional and technical requirements that a HIN needs to fulfill in order to be considered a QHIN under the Common Agreement, as well as the technical underpinnings for QHIN-to-QHIN exchange.

Overall, we are concerned with the high volume and extreme level of detail of the requirements included in this section, and the unduly prescriptive (and restrictive) nature of the technical specifications that would be required of QHINs. It is likely that the volume and complexity of requirements will be a significant barrier that will prevent and discourage, rather than encourage, QHIN participation.

The cost of implementation will also be passed to participants and participant members, making it more expensive to participate in TEFCA. As we recommended above, ONC should reconsider these requirements and focus on establishing high-level guardrails that define the framework within which QHINs, Participants, Participant Members and Individual Users engage in achieving interoperable HIE.

Conclusion

Kaiser Permanente looks forward to continuing to work with ONC to improve the nation's HIE ecosystem and establish an effective public-private trusted exchange framework for the U.S. We appreciate your willingness to consider our comments. Please feel free to contact me at (510)-271-5639 (email: jamie.ferguson@kp.org) or Lori Potter at 510-271-6621 (email lori.potter@kp.org) with any questions or concerns.

Sincerely,

Jamie Ferguson
Vice President
Health IT Strategy and Policy