



June 13, 2019

Don Rucker, M.D.

National Coordinator Office of the National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
330 C Street, SW
Floor 7
Washington, DC 20201

**RE: Office of the National Coordinator for Health Information Technology Request for
Comments on the Trusted Exchange Framework and Common Agreement Draft 2**

Submitted electronically at <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>

Dear Dr. Rucker:

Thank you for the opportunity to comment on the second draft of the Trusted Exchange Framework and Common Agreement (TEFCA). Centene supports the efforts of the Office of the National Coordinator for Health IT (ONC) to improve the health care experience and outcomes for individuals. We support moving towards greater interoperability, in order to allow individuals to use their data to empower themselves, while preserving their privacy and security.

Founded in 1984, Centene Corporation (hereinafter “Centene”) has established itself as a national leader in the health care services field with over 14 million members across the country. Centene provides health plans through Medicaid, Medicare, Health Insurance Exchanges, TRICARE, and other health solutions through our specialty services companies. For over 30 years, Centene has been committed to transforming the health of the community, one person at a time. We offer a comprehensive portfolio of innovative, flexible solutions that demonstrate our commitment to delivering results for our stakeholders: the federal government, state governments, members and their families, providers, and other health care and commercial organizations.

Centene supports finalizing TEFCA, given its advantages as a model framework for interoperability in terms of promoting standardization and embedding privacy and security protections for consumers’ data. In our comments, we seek greater clarity within the final framework as well as coordination with other federal interoperability policies. We also provide additional context and recommendations for strengthening TEFCA.

DETAILED COMMENTS

Centene supports finalizing TEFCA, codifying this framework in regulation, and moving towards implementation. TEFCA, under the auspices of ONC, has provided a model framework in standardization, privacy, and security protections for protected health information (PHI). In particular, TEFCA has the following advantages that further the goal of improving interoperability and empowering patients while ensuring security of PHI:

- (1) There would be a common rule-bound framework protecting member data with data-use stipulation, extending HIPAA to non-HIPAA entities, and disallowing electronic health information (EHI) use/disclosure outside of the United States;
- (2) These rules would be enforced and monitored by an oversight and governance body known as the Recognized Coordinating Entity (RCE) that could monitor to assure no bad actors threaten the security of the system;
- (3) Data would be collected from the party with the most current, credible information (e.g., clinical data from providers, claims information from plans, etc.);
- (4) There would be greater assurance of standardization on terms and on connectivity;
- (5) User authentication and identity proofing would be embedded safeguards.

Due to the ability for data to flow efficiently and securely between payer, providers, and other key stakeholders, we believe that TEFCA may present a better long-term opportunity to provide consumers with health information than use of Open APIs included in the recent CMS proposed rule.

Our detailed comments are organized in the order in which issues appear in the Trusted Exchange Framework and Common Agreement (TEFCA) Draft 2. Specifically, we will begin by addressing the Minimum Required Terms & Conditions (MRTC) followed by the Qualified Health Information Network (QHIN) Technical Framework. Our specific comments are offered to suggest improvements to the TEFCA with the end-goal of optimization in order to meet consumers' and the industry's needs.

I. Minimum Required Terms & Conditions

Exchange Purposes and EHI Reciprocity

ONC proposes to allow the exchange and use of member EHI by a QHIN, Participant, or Participant Member if the request for EHI is only for one or more of the "Exchange Purposes" and is initiated by "(1) [t]he Participant on its own behalf in accordance with the Participant-QHIN Agreement; or (2) [b]y the Participant on behalf of a Participant Member in accordance with the Participant Member Agreement; or (3) [b]y the Participant for Individual Access Services on behalf of an Individual User with whom it has a Direct Relationship."

Centene supports the enumeration of the ways that an entity may initiate the request for EHI, but we recommend that the use of member EHI be limited to the stated Exchange Purpose or Exchange Purposes provided by the requesting party and that guardrails be put in place to protect

against unauthorized uses. This recommendation accounts for potential EHI requests that may be grounded in pretext. For instance, an entity may justify their EHI request by listing the Exchange Purpose Z, but the entity may utilize the EHI for Exchange Purpose Z along with other data manipulation actions that go beyond their initial stated purpose. These sort of potential actions create an additional set of security and privacy concerns for our members.

Qualified Health Information Privacy, Security, and Patient Safety

TEFCA proclaims that “(e)ach QHIN shall comply with the HIPAA Rules as if they apply to EHI, including but not limited to the Breach notification requirements applicable to Business Associates pursuant to 45 CFR Part 164 Subpart D regardless of whether it is a Business Associate.” Additionally, breach notification requirements are discussed, but TEFCA does not clarify party liability as it pertains to adverse occurrences.

We applaud the fact that the Common Agreement provides the foundation for governing the exchange of data between QHIN-Participant, but we recommend that ONC clarify the attachment of liability upon a breach of a QHIN. In particular, given that each QHIN will be allowed to store the EHI it receives from the Participants for the foreseeable future, we believe that the language in TEFCA should be revised to expressly relieve Participants from liability upon submission of EHI to the QHIN. Addressing the topic of liability in TEFCA is critical since the chance of achieving a free-flowing nationwide exchange of data will be hindered because QHINs and Participants will get bogged down in negotiating the allocation of risks under the Common Agreement. Furthermore, the lack of clarity regarding liability and the omission of a universal standard for risk allocation could leave some Participants or QHINs at a disadvantage relative to their peers, resulting in a potentially lower adoption rate.

HIPAA, Exchange Purposes, and Non-Covered Entities

The manner in which the enumerated exchange purposes, as they apply to entities that utilized a QHIN under TEFCA, relate to the privacy and security protections required by HIPAA is ambiguous. For instance, under TEFCA, the Exchange Purpose of “Business Planning and Development” is defined as “conducting business planning and development activities of a Covered Entity as described in subsection (5) of the definition of health care operations at 45 CFR § 164.501...[,] [which includes the following][:] conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies.”¹ Coupled with the obligation that “the Common Agreement requires non-HIPAA entities, who elect to participate in exchange, to be bound by certain provisions that align with safeguards of the HIPAA Rules” makes the applicability and potential enforcement thereof ambiguous.

Centene agrees that data use protections are needed to allow for the exchange of health information in a frictionless manner and agree that HIPAA should be extended to participating non-covered entities such as third party application developers. However, it is unclear how

¹ 45 C.F.R § 164.501(5).

HIPAA would be enforced with non-covered entities. In particular, we seek clarification on the HIPAA data use, privacy safeguards, and enforcement mechanisms for non-covered entities.

No EHI Outside the United States

As currently constructed, TEFCA would prohibit QHINs from using or disclosing EHI outside of the U.S. “except to the extent that an Individual User requires his or her EHI to be used or disclosed outside of the United States”. It requires that QHINs only use cloud-based services physically located in the U.S., and EHI be stored in the U.S. and “not be transferred to or located in any other countries or jurisdictions.”

Centene agrees with the premise behind the requirement, but we seek further clarification on the topic. One question is whether ONC intends for this restriction to apply to the QHINs only or apply to the Participants as well. Another potential question is whether this restriction is intended to prohibit the viewing of EHI by a Participant’s service providers outside the U.S. even when the data remains located on hardware physically located in the U.S. We recommend that the language in TEFCA be modified or an exemption be provided to permit offshore viewing of EHI by a Participant’s affiliates and service providers for the data stored in the U.S. This is particularly relevant for U.S. health plans with an international presence.

Qualified Health Information Fees

ONC proposes that a QHIN must “use reasonable and non-discriminatory criteria and methods in creating and applying pricing models if it charges any fees or imposes any other costs or expenses on another QHIN.” Centene agrees with the proposed safeguards, but we recommend that the language in TEFCA be revised to better define what constitutes a “reasonable” and “non-discriminatory” fee. Operationally, QHINs and other players may take advantage of this ambiguity, which may encourage market consolidation thus culminating in an upward trend in fees given that players can use their pricing power in a post-consolidation market. We seek clarification on what constitutes a “reasonable” and “non-discriminatory” fee. For instance, linking the fees to inflation is a possible guardrail to protect against an artificially-inflated trend in fees.

Another concern that Centene has corresponds to the “[n]o Fees for Individual Access Services” language embedded in TEFCA. On the surface, the requirement may seem broad given that “[n]otwithstanding anything to the contrary set forth in the Common Agreement, a QHIN may not charge another QHIN any amount for a QHIN Query or QHIN Message Delivery for the Exchange Purpose of Individual Access Services.” A potential issue that may arise centers around whether a QHIN will be required to provide individual access services à la carte or if it could bury the cost for individual access services in the cost that it charges for other services, such as when the QHIN requires Participants to purchase additional services alongside the individual access services.

Security Labeling of EHI

ONC is considering a security labeling requirement for sensitive protected data (e.g. substance use disorder information). We seek clarification on the process and labeling of pertinent EHI, such as Part 2 SUD data and ways to safeguard the data to prevent unauthorized data use. For instance, clarification is needed on the ways in which an entity can transmit member EHI to a QHIN in such a manner as to safeguard the data to prevent unauthorized data use or whether this information could be sent to the QHIN absent the member's specific intent. Another point of clarification needed is whether and to what extent the ONC seeks to permit the use or disclosure of Part 2 SUD data in ways that are not currently permitted under existing regulations.

Definition of EHI

As currently constituted, TEFCA defines "Electronic Protected Health Information, and any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in "electronic media," as defined at 45 CFR § 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

While Centene acknowledges that members should be able to access their health care data, we are concerned about the incorporation of price information into the definition of EHI. In a previous letter to ONC, we expressed support for the recent recommendation from ONC's Health Information Blocking Technical Advisory Committee (HITAC) to decouple price transparency from the information blocking proposed rule and to charge a taskforce with further study of the issue to be codified in future rulemaking. In fact, the disclosure of payment information may have a negative impact as it pertains to overall health care costs, including those borne by consumers. The FTC believes that disclosure of this "information among competing providers likely would undermine the effectiveness of selective contracting, a key mechanism used by health plans to drive down health care costs and improve overall value in the delivery of health care services."²

II. Qualified Health Information Network (QHIN) Technical Framework

Centene urges the ONC to work with HHS to harmonize the use of TEFCA as a mechanism to achieve interoperability. By adopting the technical standards and data security/privacy approach included in TEFCA, there would be standardization of data exchange and protections for PHI. We support finalizing the TEFCA framework guidance, codifying this framework in regulation, and moving towards implementation of OAuth 2.0 with OIDC with language that distributes the security risk cited above to ONC to adequately protect both Centene and our memberships' health information. Centene believes that protecting our members' privacy and securing their health care information are paramount. As such, we suggest that CMS and ONC favor the use of the combined OAuth 2.0 and OIDC in conjunction with building on the TEFCA structure to

² Federal Trade Commission. (2015, June 29). Amendments to the Minnesota Government Data Practices Act Regarding Health Care Contract Data, 4. Retrieved from: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf

further security and privacy safeguards to ensure that the number of bad actors are minimized while protecting health information.

Thank you for the opportunity to comment. We would be happy to serve as a resource and partner to ONC on any of the issues we outlined in this letter. If you have questions or need more information, please contact me at patti.barnett@centene.com or 314.349.3086.

Sincerely,

A handwritten signature in cursive script that reads "Patti Barnett".

Patti Barnett
Vice President, Health Policy
Centene Corporation