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National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
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Submitted electronically at: https://www.regulations.gov/

Dear Dr. Rucker:

Thank you for the opportunity to provide comments on Draft 2 of the Trusted Exchange Framework and Common Agreement (TEFCA).

The Alliance for Nursing Informatics (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in practice today. We have reviewed the draft and offer our comments as nursing stakeholders.

ANI strongly endorses the goal of TEFCA to support interoperability by enabling nationwide exchange of electronic health information (EHI) across disparate health information networks. ANI previously provided recommendations on the first draft, including emphasis on a person-centered and do-no-harm focus, clear roles for individuals in partnerships with the entire healthcare team in the health information exchange (HIE) ecosystem and the representation of nurses and consumers in TEFCA and USCDI workgroups. Building on these recommendations, ANI strongly endorses many of the proposed updates in this second draft, including the improved definitions of the roles of Participants, Participant Members, and Individual Users, and the expanded exchange modalities and purposes.

Having reviewed the Trusted Exchange Framework Draft 2, the Minimum Required Terms and Conditions Draft 2, and the QHIN Technical Framework (QTF) Draft 1, we offer two **overarching recommendations** to the Office of the National Coordinator (ONC) to promote achievement of the key 21st Century Cures provisions:

1. **Engage Nurses and Consumers as key stakeholders and ensure their representation in TEFCA and USCDI FACA Workgroups**

2. **Emphasize a person-centered approach in the implementation of TEFCA**

Our detailed rationale, and more responses to specific requests for comment, are included below.

1. Engage Nurses and Consumers as key stakeholders and ensure their representation in TEFCA and USCDI FACA Workgroups

As the largest of the healthcare professions,[1] working on the frontlines of healthcare across the care continuum, nurses play a substantial role in the design, collection, exchange and use of electronic health information. Following our comments on TEFCA draft 1, we were happy to see a nurse serve on the U.S. Core Data for Interoperability Task Force in 2018. This task force has now been retired, and at present there is no nursing representation on either the current NPRM U.S. Core Data for Interoperability Task Force or the Trusted Exchange Framework Task Force. ANI reiterates the recommendation that nurses, as key stakeholders, be represented in TEFCA and USCDI FACA Workgroups. We also believe that the Recognized Coordinating Entity (RCE) should include a stakeholder board to broadly represent the stakeholder community, including nursing. This is important since the topics and issues that the RCE will be addressing require input and collaboration from the entire healthcare community. ANI offers professional nursing informatics expertise, including assistance in identifying qualified nurse informatics experts to serve on stakeholder boards, task forces and workgroups, and providing letters of support for nursing experts to serve in these roles.

ONC should also assure the selection of consumer advocates to serve on the TEFCA and USCDI FACA Workgroups and the RCE stakeholder board.

2. Emphasize a person-centered approach in the implementation of TEFCA

Evidence shows that the successful adoption of any new technology hinges on highly usable and easy to use solutions.[2] A growing body of evidence indicates that usability issues related to current electronic health information systems contribute to adverse patient outcomes and increased clinician burden.[3] Similarly, consumer-facing technology such as patient portals, are underutilized due to accessibility and usability issues.[4] With this in mind, ONC should emphasize a person-centered approach in

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[1] Institute of Medicine (US) Roundtable on Evidence-Based Medicine, "Healthcare Professionals," in *Leadership Commitments to Improve Value in Healthcare: Finding Common Ground: Workshop Summary* (Washington, D.C.: National Academies Press (US), 2009), https://www.ncbi.nlm.nih.gov/books/NBK52843/.

[2] William R. King and Jun He, "A Meta-Analysis of the Technology Acceptance Model," *Information & Management* 43, no. 6 (September 1, 2006): 740–55, https://doi.org/10.1016/j.im.2006.05.003.

[3] Alexander K. Ommaya et al., "Care-Centered Clinical Documentation in the Digital Environment: Solutions to Alleviate Burnout," *NAM Perspectives*, January 29, 2018, https://doi.org/10.31478/201801c; Nancy Staggers et al., "Nursing-Centric Technology and Usability A Call to Action," *Computers, Informatics, Nursing: CIN* 33, no. 8 (August 2015): 325–32, https://doi.org/10.1097/CIN.0000000000000180; Lotte N. Dyrbye et al., "Burnout Among Health Care Professionals: A Call to Explore and Address This Underrecognized Threat to Safe, High-Quality Care," *NAM Perspectives*, July 5, 2017, https://doi.org/10.31478/201707b; Susan McBride et al., "Statewide Study to Assess Nurses' Experiences With Meaningful Use-Based Electronic Health Records," *Computers, Informatics, Nursing: CIN* 35, no. 1 (January 2017): 18–28, https://doi.org/10.1097/CIN.0000000000000290.

[4] Caroline Lubick Goldzweig et al., "Electronic Patient Portals: Evidence on Health Outcomes, Satisfaction, Efficiency, and Attitudes: A Systematic Review," *Annals of Internal Medicine* 159, no. 10 (November 19, 2013): 677–87, https://doi.org/10.7326/0003-4819-159-10-201311190-00006; Ronald Dendere et al., "Patient Portals Facilitating Engagement

implementation, employing rigorous testing and continuous evaluation for interoperability and usability. ANI reiterates previous recommendations of using participatory research to decrease efforts of accessing health information, and building on existing evidence of successful patient engagement in health data:

- 'Individual' should be used instead of 'patient'.

- In areas where the individual right of access is discussed, this language should also include an individual's personal representative or caregiver. The term "caregiver" should at least include an unpaid family member, foster parent, or other unpaid adult who provides in-home monitoring, management, supervision, or treatment of a child or adult with a special need, such as a disease, disability, or the frailties of old age.

Nurses, as the most trusted patient advocate,[5] are in key roles to continue to support education for individuals and family caregivers, including their empowerment for personal health data access, aggregation and exchange. We also recognize new education approaches are needed to support individuals and their family caregivers to understand how their EHI is exchanged, and their rights and responsibilities for Consumer Directed Exchange.

Comments on the QHIN Technical Framework	
Request for comment	**ANI Comments and recommendations**
#1: Should the QTF specify additional standards or approaches for securing QHIN Exchange Network transactions (e.g. OASIS Web Services Security47)?	ANI recommends that any standards specified be aligned with current national standardization efforts.
#2: What specific elements should a SAML assertion for User Authentication include?	*See previous comment
#3: Should QHINs be required to transmit other authorization information (e.g., user roles, security labels) in addition to Exchange Purpose and any information required by IHE XUA? What specific elements should a SAML assertion include?	Yes, at a minimum, user roles and unique provider identifiers should be included in transmitted authorization information
#6: The IHE XCA profile is content-agnostic; it enables queries for documents based on metadata about the document but not the contents of the document itself. Therefore, the XCA profile does not necessarily support more	HL7 standards, including the HL7 FHIR framework, will be most inclusive as a standard for QTF. We reiterate our previous comments to ensure that recommended standards align with current national standardization efforts and that

With Inpatient Electronic Medical Records: A Systematic Review," *Journal of Medical Internet Research* 21, no. 4 (April 11, 2019): e12779, https://doi.org/10.2196/12779.

[5] "For the 17th Year in a Row, Nurses Top Gallup's Poll of Most Trusted Profession," AHA News, January 9, 2019, https://www.aha.org/news/insights-and-analysis/2019-01-09-17th-year-row-nurses-top-gallups-poll-most-trusted-profession.

granular queries for discrete data (e.g., a request for all clinical documents about a patient that contain a specific medication or laboratory result). Comments are requested on other appropriate standards to consider for implementation to enable more discrete data queries, such as emerging IHE profiles leveraging RESTful APIs and/or use of HL7 FHIR.	they are representative of the entire healthcare team across the care continuum.
#7: The IHE XCPD profile only requires a minimal set of demographic information (i.e., name and birth date/time). Should QHINs use a broader set of specified patient demographic elements to resolve patient identity? What elements should comprise such a set	The demographic information related to name/gender should include any historic change to the information over time. This addresses gender or name transitions for the individual and is aligned with the SOGI (Sexual Orientation Gender Identity) items consistent with the 2019 ISA Reference Edition[6].
#8: There are many possible approaches to Patient Identity Resolution, each with its own benefits and risks. For example, a centralized index of patient identity information may be more efficient for resolving patient identities across disparate communities, but also poses a greater risk to privacy if the system is compromised. Federated approaches may be less susceptible to external threats like cyberattacks, but harder to scale across many communities. Recognizing that new technologies and business entities with robust identity matching solutions may disrupt traditional approaches, should the QTF specify a single standardized approach to Patient Identity Resolution across QHINs?	The QTF should specify a recommended standardized approach to patient identity resolution across QHIN. Recommendation of a single standardization approach can limit unnecessary variation in the approach and potentially enhance the time frame to achieving a single standard.
#9: Different communities tolerate different degrees of risk with respect to accurately matching patient identities. Should QHINs meet a minimum performance standard (e.g., a minimum acceptable matching accuracy rate) over a specified time period? Likewise, different algorithmic techniques for matching patient identities use different approaches and must be tuned to the applicable patient population and continuously refined over time. Should QHINs measure and report on the performance of the	Transparency in the performance of an algorithmic technique can lead to improvements in the algorithm. It also provides data to decision makers who may falsely rely on algorithmic techniques without full knowledge of the performance or comparison with more successful techniques available.

[6] https://www.healthit.gov/isa/sex-birth-sexual-orientation-and-gender-identity

algorithm(s) they rely on (e.g., by calculating precision, recall, etc.)?	
#10: Recognizing there are different ways to implement Record Location services, should the QTF specify a single standardized approach across QHINs?	Yes, a recommended standardized approach will provide guidance from an authoritative source.
#11: Should the QTF require QHINs to implement Directory Services? Recognizing there are many possible approaches for implementing Directory Services, should the QTF specify a single standardized approach? If QHINs implement Directory Services, which entities should be included in directories? Should directories be made publicly accessible?	A recommended standardized approach will provide guidance from an authoritative source. Directories should be inclusive of all licensed clinical care team members and come from an authoritative source providing a single unique identifier for each provider. We suggest consideration of the NCSBN ID as the unique identifier for nurses.[7] Directories should be publicly accessible supporting the role of the consumer in access to health information.
#12: Future drafts of the QTF will specify a format for Meaningful Choice notices communicated between QHINs. Which standard/format should the QTF specify? What information should be included in a Meaningful Choice notice (e.g., should a notice include patient demographic information to enable QHINs to resolve the identity of the Individual that exercised Meaningful Choice)?	Use of HL7 as the standard format will be most inclusive as a standard for QTF. The meaningful choice notice should include patient demographic information to enable QHINs to resolve identity of individuals exercising meaningful choice.
#13: In addition to enabling Meaningful Choice, the Common Agreement requires QHINs to collect other information about an Individual's privacy preferences such as consent, approval, or other documentation when required by Applicable Law. Should the QTF specify a function to support the exchange of such information through the QHIN Exchange Network? Which standards and/or approaches should the QTF specify for this function?	Privacy preferences as well as consent should be supported as a function of information exchange through the QHIN Exchange Network. Without exchanging this key information, confidentiality and privacy are at risk, which may jeopardize confidence by the consumer in the exchange of their health information. Privacy and consent preferences, as directed by the consumer, are dynamic and will change over time.
#14: QHINs may participate in a variety of activities and transactions involving First Degree Entities and/or internal operations, including receiving and processing Query and Message Delivery Solicitations, performing Patient Identity	Changes to key demographic information should be auditable. In addition, deletions to key diagnosis or test results should be identified as auditable events. Audit information should include the user making the change as well as the

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[7] Nursing Knowledge Big Data Science Health IT Policy Workgroup (2018), "Advocating for a Unique Nurse Identifier" https://www.himss.org/library/identifying-unique-nurse-identifier.

Resolution, performing Record Location, sending EHI, receiving EHI, performing queries, granting/revoking access credentials, etc. Future versions of the QTF may specify a list of events a QHIN must record involving First Degree Entities and/or internal operations. Which activities and transactions should the QTF specify as auditable events? What information should the QHIN record about each event?	date, time, system location or system owner of the change or deletion. New information added to demographics, diagnoses, or test results should also be auditable, as well as changes in patient privacy policies consumer consent.
#15: Should the QTF specify a consistent set of error messages for interactions between QHINs? Which error messages should the QTF specify? Should the QTF specify a consistent format for error messages?	Failure to match identity, failure to update or append a record, transaction failure errors should be specified. HL7 formatting would provide a consistent method of communicating these errors.

ANI appreciates the opportunity to offer our comments to advance interoperability, with broad ranging implications to the health of the US population. We are available and interested in supporting future public responses on these important healthcare issues.

Sincerely,

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The Alliance for Nursing Informatics (ANI), cosponsored by AMIA & HIMSS, advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represents more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in practice today. Contact ANI.