The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Trusted Exchange Framework Task Force Final Recommendations

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Charge

- **Overarching charge:** The Trusted Exchange Framework Taskforce will develop and advance recommendations on Parts A and B of the Draft Trusted Exchange Framework to inform development of the final Trusted Exchange Framework and Common Agreement (TEFCA).
- **Detailed charge:** Make specific recommendations on the language included in the Minimum Required Terms and Conditions in Part B, including—
  - **Recognized Coordinating Entity:** Are there particular eligibility requirements for the Recognized Coordinating Entity (RCE) that ONC should consider when developing the Cooperative Agreement?
  - **Definition and Requirements of Qualified HINs:** Recommendations for further clarifying the eligibility requirements for Qualified HINs outlined in Part B.
  - **Permitted Uses and Disclosures:** Feedback on enhancing or clarifying the six (6) permitted purposes and three (3) use cases identified in Part B.
  - **Privacy/ Security:** Are there standards or technical requirements that ONC should specify for identity proofing and authentication, particularly of individuals?

Overarching Recommendations— Clarity of Policy Goals

Recommendation 1: ONC, in the Trusted Exchange Framework, should clearly define policy goals, expressed as clear statements of outcomes ONC wants to enable or outcomes ONC wants to prevent. In areas where ONC believes defining or prescribing particular implementations of policy is critical to national success, we recommend ONC first define the overall policy goals. We also recommend that ONC explain how the Framework operates to enable some of the core national priorities and use cases for interoperability, such as individuals' electronic access and use of their electronic health information, bi-directional access so patients can contribute and doctors have access to patient-generated health data and patient-reported outcomes, and shared care planning by doctors and patients. This will help users of the final Trusted Exchange Framework understand how the Framework works in real-world situations.

Recommendation 2: In areas where clear guidance or documentation for policy requirements already exists and where specific recommendations are desired, ONC should point to the existing guidance or documents rather than duplicate requirements in the TEF and only call out specific exceptions or deviations. Examples include specifics called out in the TEF on cyphers, key lengths, or particular hashing or encryption algorithms, where pointers to appropriate NIST or other guidance is preferable to repeating specific requirements. (These examples, however, are those where the TF would recommend instead deferring details to the RCE.)

Overarching Recommendations – Division of Responsibilities

Recommendation 3: ONC, in the Trusted Exchange Framework, should define policy outcomes and functional requirements and, to the extent possible, refrain from naming particular standards or particular implementation mechanisms. Instead, ONC should charge the RCE, in conjunction with the QHINs, to evolve (through clear milestones involving real-world production use, feedback and refinement) towards named standards, implementation guides, and enabling policies meeting the broad policy goals and functional requirements defined by ONC. If stakeholders do not make clear, timely progress towards defined policy outcomes, ONC should retain the policy levers sufficient to name and direct standards, implementation guides, enabling policies and other mechanisms to address market failure.

Recommendation 4: ONC should, in areas of broad concern including those for market or ecosystem development, clearly document key policy outcomes and establish clear checkpoints for evaluating whether additional guidance for the QHINs or RCE needs to be established.

- As an example, QHIN services should be available for a broad range of actors, including small and independent provider organizations, and the patient. In these areas, rather than defining possibly restrictive criteria on QHINs (see our recommendations on Participant Neutrality), ONC should define key objectives and specific milestones for availability of QHIN services and evaluate the need for additional course correction at those times.

Recommendation 5: ONC should work closely with the RCE and coordinate with other Federal actors in areas where policy clarification or coordinated Federal action are critical enablers of QHIN success. For example, past coordinated actions of ONC and HHS OCR have been helpful in providing guidance and interpretation of HIPAA in multiple areas, including interpretation clarifying a patient's broader rights of data access in the readily available form and format of the patient's choosing through patient-controlled applications based on standards-based APIs. These kinds of interpretation and guidance improve interoperability by expanding the cases where exchange can be reasonably presumed to be in accord with Federal law and regulation. Coordinating and harmonizing Federal information security, privacy and identity assurance requirements with commercial standards will be important to enable broad adoption of interoperability by Federal actors.

Overarching Recommendations—Single On-Ramp

Recommendation 6: ONC should clearly define the role of the QHIN relative to existing forms of exchange and more clearly define the objectives and scope of "a single on-ramp" with respect to the types and capabilities of exchange anticipated to be provided through that single on-ramp.

With respect to what that definition should be, the TF was split. There were at least three fairly strongly held views, particularly with respect to the role of the QHIN over the next three-year period. Generally, the split followed a passionately held prioritization of two different policy goals:

- **Narrow-focus:** Improving interoperability is sufficiently complicated that ONC, the RCE and QHINs should maximize success by concentrating on a narrow area of focus and should be non-disruptive to existing successful exchange models.

- **Broad-focus:** The benefit of providing a true single on-ramp to providers and patients for a variety of exchange models and types is sufficiently high that the mandate for QHINs should be broad as originally proposed.

The TF does not wish to restrict the evolution of the QHIN model over a longer period of time nor imply QHINs should offer only exchange modalities defined by the Trusted Exchange Framework. Some QHINs and HIT developers may be able to advance capabilities more rapidly for a broader "single on-ramp." However, we recommend the TEF establish priority for floor services over the initial three-year period of the RCE cooperative agreement.

The TF was evenly split on the two policy goals.

Overarching Recommendations—Single On-Ramp, cont'd

Alternative (Narrow-focus) Recommendation 7A: ONC should clearly define the three-year priority to establish a floor capability for the "on-ramp" provided by QHINs to be for query-based exchange and access to EHI. ONC should clearly document that the QHINs will only be serving a subset of the needs of the defined permitted purposes as a floor. Additional exchange needs may be satisfied by QHINs (if they offer exchange services above the floor) and/or by other HINs.

There were two different formulations of the expansive-focus recommendation. Inclusion of these two different formulations should not be taken to imply a majority/minority or plurality/minority split as the broad split was even. Among the members of the TF adopting the more inclusive recommendation, the first formulation below had the broader support.

Alternative (Broad-focus) Recommendation 7B: ONC should clearly define the three-year priority to establish a floor capability for the "on-ramp" provided by QHINs to be for all forms of EHI exchange, including but not limited to query-based exchange and push-based exchange models, including push to public health, referrals and transitions of care access to patient generated health data, electronic orders and results, electronic prescribing and administrative transactions. Note that for some forms of exchange, this may be an "on-ramp" only, and for other forms of exchange, it may be a complete exchange solution.

Alternative (Broad-focus) Recommendation 7C: ONC should clearly define the "on-ramp" provided by QHINs to serve under-served high priority EHI exchange needs to be defined by ONC in the Trusted Exchange Framework, regardless of exchange modality. In particular, QHINs should serve needs for public health and coordinated referrals, as well as query-based exchange, even when those needs require other modalities of exchange (e.g., unidirectional or bidirectional push exchange). Additional exchange needs may be satisfied by individual QHINs (if they offer exchange services above the floor) and/or by other HINs.

Overarching Recommendations—Single On-Ramp, cont'd

Recommendation 8: Should the ONC adopt the inclusive definition of "single on-ramp," ONC should establish in the TEF a process for defining and ensuring that QHINs serve needs established as the national floor for additional modalities of exchange, including unidirectional and push-based exchange. These forms of exchange serve a broad set of purposes for the allowed permitted purposes. For example, bidirectional push is used for coordinated referrals and pushed transactions are used for reportable labs and diseases for public health.

Recognized Coordinating Entity (RCE)

Recommendation 9: ONC should establish eligibility criteria for the RCE, requiring not-for-profit status, a clear sustainability model, and a governance model that balances responsibility among the national interests and the dues-paying members of the RCE. The governance model for the RCE should represent a broad range of perspectives relevant to priority use cases and permitted purposes under the TEF. Given that larger actors are often oversampled, the RCE governance should make special effort to represent smaller actors, particularly smaller practice provider actors, as well as the patient perspective. The governance model for the RCE should deliver transparency and protect against governance or board configurations and operating models that could lead to or be perceived as leading to conflicts of interest. In particular, the RCE governance should not be weighted towards or against particular segments of the provider community (e.g., large or Federal providers), health IT vendors, particular QHINs, etc., and should include ONC representation.

Recommendation 10: ONC should require the RCE, as it works on standards, implementation guidance, profiles and other enabling material to make such material open to the public without restrictions on use or reuse except as necessary to enforce certification marks or other proofs of QHIN compliance with RCE-defined requirements.

Recognized Coordinating Entity, Cont'd

Recommendation 11: ONC should develop a set of outcomes-based goals, measures and associated milestones based on expected patient and provider real-world experiences enabled through the TEF and associated RCE activities. The RCE should define a set of satisfaction, user experience and process measures and metrics linked to the outcome goals and measures. Measures and milestones should be defined from the perspective of the desired real-world goals expected to be achieved by the end of year three and then work backwards to interim goals, balancing feasibility and urgency. Outcome goals, measures and milestones should be set based on high-priority use cases (see the TF recommendations on Permitted Uses).

Qualified Health Information Networks (QHINs)

Recommendation 12: ONC should clarify the policy intent in the meaning of "Participant Neutral" and revise the definition and associated qualification criteria for QHINs to better reflect the policy intent. ONC should define a policy goal that the overall ecosystem of QHINs is neutral and accessible to all parties. ONC should use more neutral definitions that do not prevent data holders from offering QHIN services. If ONC desires stronger, more restrictive participant-neutral language, ONC should consider the various ways that prospective QHINs may structure business entities to address possible restrictions.

Consistent with our overall recommendations, the TF felt the description of the broker model was too detailed. It would be more helpful to establish a functional description of the experience to be achieved by providers and patients, and let the RCE and QHINs work out the operational details. As currently described, the specified broker model could be too "chatty" and inefficient in actual practice.

Qualified Health Information Networks, Cont'd

Recommendation 13: ONC should define a set of functional requirements documenting the outcomes of using a QHIN from the perspective of a provider or patient. For example, ONC might define a functional requirement that a provider or patient should receive all known locations where a patient's data might be found and the content of data to be found at those locations, regardless of the technology vendor or QHIN used by the end location of data.

The TF discussed the proposals for QHIN fees. The goal of the TEF QHIN fee requirements is to establish reasonable and non-discriminatory fees for QHIN-to-QHIN interchange pricing. In particular, to allow uniform access to all permitted purposes across QHINs, the draft TEF requires QHINs to establish a QHIN-to-QHIN price of zero for some permitted purposes (patient access, public health, benefits determination) and cost-basis fees (Attributable Costs) for the other permitted purposes required under the TEF.

At the same time, the draft TEF establishes a duty to respond for permitted purposes both on QHINs and, through flow-down terms, on Participants. The combination of zero or cost basis fees and duty to respond for permitted purposes creates a market situation where actors can receive data at a low cost that they otherwise might have paid for, by establishing a QHIN to serve those actors.

As an example, the Social Security Administration might establish or participate in a QHIN for Federal actors. Although SSA is otherwise willing to pay for electronic exchange, because of the relative value of electronic exchange to paper-based chart retrieval, handing, and abstraction; through the TEF fee structure, SSA could request and receive the same data through the Federal QHIN with no fees needed to be paid to the end provider organizations or the QHINs that facilitate exchange. Because these kinds of uses currently provide business models and incentives to provider organizations and the HINs that support them, the combination of zero or cost-basis fee structure for QHIN-to-QHIN exchange and the duty to respond may change the market for exchange in profound ways.

Because some of the broader regulatory context for the 21st Century Cures Act has yet to be published by ONC and other HHS offices, centers and agencies, and because our recommendations on Permitted Uses recommends a scaled roll-in, this may be market-distorting in some instances.

Qualified Health Information Networks, Cont'd

Recommendation 14: ONC should establish through the TEF the combination of zero or cost-basis QHIN-to-QHIN fee requirements with the duty to respond by QHINs, Participants and End Users only on QHIN-intermediated access that is required for all Participants and End Users and for uses that are reciprocal (where both sides of the exchange benefit and participate). ONC should understand that zero or cost-basis QHIN-to-QHIN fee structures combined with duty to respond for permitted purposes will significantly shape market dynamics and increase the incentive for organizations to opt out of participation in the TEF.

The Attributed Costs calculation has the potential to distort pricing and provide a disincentive to create efficient services. As an example, if one QHIN invested R&D capital in projects to create more efficient services, the QHIN would not be able to recoup the benefit of that increased efficiency through increased margin, because the Attributed Costs for providing the more efficient service have decreased. The counterpart who is highly inefficient, by contrast, benefits from reduced R&D expenses with no penalty for inefficiency. The QHIN-to-QHIN fee structure should instead be uniform. The RCE should use mechanisms that provide appropriate incentives to reduce cost structures over time. For example, reverse auction mechanisms have been used in similar areas to establish market-appropriate fee structures. The TF noted that QHIN-to-QHIN fees need to be for well-defined Service Level Agreements (that is, it should not be acceptable for a QHIN to meet defined fee structures by being slower than peers).

Qualified Health Information Networks, Cont'd

Recommendation 15: ONC should provide the RCE the authority to employ mechanisms to ensure QHIN-to-QHIN fees are uniform for like services at like performance SLAs and should encourage the RCE to adopt mechanisms, such as auctions, that prevent against inappropriate price increases and provide appropriate incentives for QHINs to reduce cost structures for QHIN-to-QHIN exchange over time.

The TF noted that zero-cost QHIN-to-QHIN fees decrease incentives on Participants and End Users of QHIN services to develop and use those services efficiently. Accordingly, the TF believes zero-cost QHIN-to-QHIN exchange fees should be limited only to Individual Access.

Recommendation 16: ONC should limit, under the TEF, zero-cost-basis QHIN-to-QHIN exchange solely to Individual Access purposes (as defined and limited following TF recommendations under Permitted Uses and Disclosures).

Permitted Uses and Disclosures

Recommendation 17: ONC should clearly define "Individual Access," consistent with HIPAA (45 CFR 164.524), such that aggregator-based access on behalf of the individual is differentiated from the individual acting on their own. Fee restrictions and duty to respond should be restricted to the case where the patient is requesting access to view, download, use or transmit data to an entity or application or utility that the patient manages and subsequent data donation should be optional and under the patient's control.

Recommendation 18: ONC should make it clear the duty to respond that is an obligation on other Participants and End Users is not an obligation on individuals. Individually-controlled services should be able to make data available for query (one possible model would be a health record bank) but should not be required to do so; and should they make data available, the choice of response should be up to the patient.

Policies and standards for individual access to a patient portal have been developed and are in moderate scale use (for example, SMARTonFHIR-based access). However, when broad-scale individual access cross-provider and other data holder queries are made, data respondents are not the organizations that have performed identity assurance and authentication sufficient to minimize the possibility of breach when releasing data to the individual. The policy requirements and standards enablement (for example, the format and meaning of Oauth2 requests in a patient request use) for these cases are under limited scale pilot have not been formalized sufficiently for broad scale usage.

Permitted Uses and Disclosures, Cont'd

Recommendation 19: ONC should ensure stakeholders (such as the RCE, Standards Development Organizations and public/private consortia) test and evolve standards, implementation guidance, profiles (for example, to provide information about the level of identity assurance used in standards such as OAuth2) and accompanying policies that are sufficient to enable broad-scale individual access, within a timeframe sufficient to meet the policy goals for individual access and other permitted purposes.

The TF applauds and strongly endorses the requirement for treatment-based access. This is a well-tested area and has many exemplars in practice.

Other permitted uses and disclosures have had only pilot-based use or use only through proprietary exchange. The TF believes these uses require active production testing and refinement prior to broad scale use. The TF clarifies that it makes this recommendation based on relative standards and policy readiness, not based on relative need or policy importance.

Permitted Uses and Disclosures, Cont'd

Recommendation 20: ONC should require Individual Access and Treatment permitted uses and disclosures, with those purposes of use defined as per HIPAA. Other uses and disclosures require broader scale testing and require additional standards and policies, and subsequently should be phased in as testing, standards and implementation guidance development, and policy clarification are sufficient for broad-scale national deployment. Of course, this should not preclude a QHIN, HIN, or Participant from enabling the other permitted uses.

Although the particulars of the USCDI are outside of the charter for this TF, we noted that the USCDI needs to be evolved in conjunction with permitted uses and disclosures and needs to be aligned to the particulars of each use. That alignment needs both to address the use of additional data for the particular use case and limitations on data supplied to address HIPAA minimum necessary standards and local policy requirements. As examples:

- The current US Core Data Set, as enabled through the Consolidated CDA, is insufficient to meet all the data needs for the Social Security Administration disability benefits determination use.
- Many public health agencies both require more data than is supplied in the US Core Data Set and are limited by policy from collecting data outside of the data needs sufficient for the particulars of the public health reporting need.

Permitted Uses and Disclosures, Cont'd

Recommendation 21: ONC should work with stakeholders to align USCDI with the particular needs for each permitted purpose and exchange use case, both to address additional data that may need to be collected, and to address data exchange limitation to minimum necessary standards.

The Social Security (SSA) Disability Determination use is well established and the TF applauds inclusion of this use case as a permitted purpose. However, as noted in our recommendations for the QHIN-to-QHIN fee structure, those fee requirements conflict with SSA's established fee structure, under which SSA is authorized to pay a per record access fee.

Recommendation 22: ONC should work with stakeholders to resolve the fee disparities for the SSA disability determination use case.

For purposes of use beyond Individual Access and Treatment, please see the TF comments on QHIN fee structures for TF concerns about the combination of duty to respond and zero or cost-basis QHIN-to-QHIN fee requirements on the evolution of markets and assumption of fees.

The TF found that Payment use was too broadly defined in the draft document to be useful. Payment-based uses include claims attachment, medical necessity and utilization management, risk adjustment and others yet to be defined. Some of these uses require individual member-level data access (e.g., query for utilization management), others require population-level data access. Population level queries for payer-based use cases may require member filtering and other mechanisms to address policy requirements when patients move between payers and plans. In many cases, payer/provider data query have additional contractual requirements and the relationship between payers and providers could be substantively affected by an affirmative duty to respond under the TEF.

Permitted Uses and Disclosures, Cont'd

Recommendation 23: ONC should clearly define sub-purposes of use under the broad Payment permitted purpose, and define the policy objectives. ONC should work with the RCE to establish enablement, including standards, implementation guidance, policy guidance, and profiles for each of the permitted purposes for which duty to respond is required.

With respect to population-based query, the TF made a distinction between population access by providers and provider-aligned organizations (such as clinically integrated networks or accountable care organizations) and access by other organizations, including payers.

For provider-based HIPAA operations uses that allow data aggregation across covered entities such as quality measurement or ACOs evaluating physician performance, the TF applauds inclusion of this use as a permitted purpose. In addition, as this case meets the requirement of reciprocity and alignment of value, the combination of duty to respond and cost-basis fees are not market distorting.

However, standards and policy enablement in this area are early and evolving, and the TF believes this use is not ready for broad-scale adoption.

The TF notes that use of population data by other actors, including payer use for payer-based quality measurement (e.g., HEDIS measures) and especially payer use for evaluating physician performance, have many of the same market and contractual issues noted under the recommendations for payment.

Recommendation 24: ONC should work with standards development organizations and public-private stakeholders (for example, the Argonaut Project and/or the DaVinci Project) to define, test, collect feedback and refine standards for population-based query for provider-oriented value-based-care uses. ONC should work with HHS OCR and other stakeholders to align standards with policy requirements to ensure the standards can be used in practice. ONC should delay implementation of these uses until appropriate testing can be performed.

Privacy/Security

Recommendation 25: ONC should not demand universal requirements to collect and honor individual consent for HIPAA permitted purposes. ONC should assign requirements in this area to the RCE to address which should consider successful implementations that allow flowing/assigning these requirements to the organizations (for example, provider organizations) that are closest to the patient and to obligations established under state and local law and regulation.

Patient education on rights and responsibilities, particularly for the patient application side of the HIPAA-FTC legal boundary concerning their data is critical. The ONC has created important resources in the model privacy notice.

Requirements for patient matching and linking are being evolved in practice. There is sufficient background already provided by ONC in a variety of reports as well as the ONC playbook.

Recommendation 26: ONC should provide existing background to the RCE but not otherwise constrain requirements for patient education and patient matching. ONC, HHS OCR and other relevant actors should establish appropriate guidance and interpretative background regarding the rights of patients with respect to patient -generated health data that flows to covered entities or other actors participating in exchange, including through the TEF and QHINs.

With respect to the detailed requirements for identity assurance, for certificates, cyphers and the like, the TF points back to our overarching recommendations that ONC point back either to established policy or assigning the details to the RCE to address. The TF notes many of the issues involved in individual identity assurance are federated to the responsible organization; therefore, organizational identity assurance is critical to define.

The TF wishes to note there are additional topics relative to exchange, access, use, privacy and security that were outside the TF charter. Except as discussed in these recommendations, the TF only addressed topics as requested by ONC.

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