AGENDA

Health Information Technology Advisory Committee
Trusted Exchange Framework Task Force
March 16, 2018, 2:00 p.m. – 3:30 p.m. ET
VIRTUAL

2:00 p.m. **Call to Order/Roll Call**

- *Lauren Richie, Designated Federal Officer (ONC)*

2:05 p.m. **Review Draft Recommendations**

- *Denise Webb, Task Force Co-Chair*
- *Arien Malec, Task Force Co-Chair*

3:25 p.m. **Public Comment**

3:30 p.m. **Adjourn**

Agenda

- Call to Order/Roll Call
  - ***Lauren Richie, Designated Federal Officer (ONC)***
- Review Draft Recommendations
- Public Comment
- Adjourn

Trusted Exchange Framework Task Force
Draft Recommendations

March 16, 2018

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

The Health Information Technology Advisory Committee (HITAC) asked the Trusted Exchange Framework Task Force (TEF TF) to provide your office with recommendations around the Draft Trusted Exchange Framework. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force subject matter experts.

Background

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?

Recommendations

Overarching Recommendations

As part of our deliberations, the TEF TF discussed a number of topics relating to the TEF overall, in addition to the particular questions we were asked to address. Given the overarching nature of these topics, we felt it helpful to provide a set of general recommendations to ONC.

Clarity of Policy Goals

In many areas of the current TEF, the TEF TF found detailed discussion prescribing *how* the RCE and QHINs were to operate, without clarity on *why* they were to operate in this way. When assessing these items, the TF found it difficult to make clear recommendations about alternative policy approaches.

As a particular example among many, when the TF was discussing the QHIN eligibility criteria and how ONC defined "participant neutral" with respect to QHINs, it was not clear *why* ONC made that particular definition; this, in turn, made it difficult for the TF to discuss and recommend policy alternatives.

Recommendation: 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.

Recommendation: 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).

Division of Responsibilities

The TF found many areas where we believe ONC specified specific implementation details that would be more appropriate for the RCE to determine in conjunction with the QHINs, Standards Development Organizations, and Participants.

Given the state of interoperability with respect to many of the Permitted Purposes contemplated by the TEF, the TF believes standards and implementation guidance will undergo rapid cycles of testing and revision. In addition, the optimal set of capabilities delivered by QHINs to enable the articulated policy goals established by the 21st Century Cures Act and ONC will evolve through rapid cycles of trial and real-world feedback.

These cycles of trial, testing, feedback and revision are common to the evolution of interoperability in multiple sectors (see the findings and recommendations of the S&I TF of the HIT Standards Committee (INSERT REFERENCE)).

The API requirements for 2015 Edition Certification and the associated API requirements for MIPS provide a useful model for successful policy given these environmental conditions. By defining functional requirements (policy statements about *what* EHRs were to do) and leaving the implementation details to the private sector and consensus-based standards development organizations, ONC allowed rapid evolution of FHIR, as standardized by HL7, and SMARTonFHIR as profiled by the Argonaut Project. This led to a large and growing ecosystem of EHRs supporting SMARTonFHIR and consumer (including broad consumer technology companies) and provider applications implementing this standard.

In taking this approach, ONC was able to use policy levers to encourage standardization without freezing markets or impeding innovation. At the same time, all stakeholders understood ONC retained multiple options, such as directing standards through regulation, in the event private sector actors were unable to move towards universal standards-based approaches.

The TF believes the ONC should take a similar approach with the TEF.

Recommendation: 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 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: ONC should, in areas of broad~~er~~ concern including those for market or ecosystem development, clearly document key policy outcomes~~, including those for market or ecosystem development,~~ and establish clear checkpoints for evaluating whether additional restrictions on the QHINs or RCE need 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. ~~see the TF recommendations on QHIN participant neutrality.~~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.

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Recommendation: 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 incredibly helpful in providing guidance and interpretation of HIPAA in multiple areas, including interpretation clarifying a patient's broader data access into the readily available form and format of the patient's choosing through ~~for~~ 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.

Commented [WD1]: Mark requested "privacy" be added. I do wonder if this is applicable here in terms of coordinating and harmonizing Federal privacy requirements with commercial standards. Arien please remove if not applicable here.

Commented [WD2]: There was a request to change to "Federal and State" but I agree with Genevieve that the ONC doesn't have any leverage over State's policies and laws that are not in conflict with the Federal policies and laws. Someone also brought up adding something about "moral equivalent of safe harbor." Not sure how that applies to this.

Defining "Single On-Ramp"

The TF struggled with connecting the ambitious and far-reaching language used by ONC, defining a goal for the QHINs to work together to provide a "single on-ramp"to Electronic Health Information, and the specific exchange models described for the QHINs (i.e., point-to-point or targeted query, brokered or broadcast query, and population-level query). In areas including public health and coordinated end-to-end referrals, the TF noted there are important ecosystem needs that are not met through HINs and are not addressed through the described capabilities of the QHIN. At the same time, there are interoperability needs that are currently well served through existing HINs. These needs, including administrative transactions, electronic prescribing, and increasingly Direct-based exchange and electronic resulting and, in some cases, electronic ordering may be significantly disrupted if the mandate of QHINs is overly broad in the short term, such that the mandate of QHINs causes a business model struggle between existing and new actors.

At the same time, the TF believes over the long term it may be possible to evolve to a "single on-ramp" particularly for newer services based on new exchange models.

Recommendation: 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:

- 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.
- 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 and expansive.

The TF does not wish to restrict the evolution of the QHIN model over a longer period of time ~~r~~or imply ~~that~~ QHINs should offer only exchange modalities defined by the Trusted Exchange Framework as some QHINs and EHR developers may be able to advance capabilities more rapidly for a broader "single on-ramp". However~~Instead~~, we recommend ~~that~~ the TEF establish priority for floor services over the initial ~~a~~ three ~~-~~year period of the RCE cooperative agreement.

[NOTE: ~~Assign~~ presuming the following "majority/minority" survives voting. Otherwise, will go with 50% ~~or~~ "plurality/minority" labels to these recommendations ~~and see if we can eliminate one based on voting~~]

~~-~~**Majority Recommendation:** 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 ~~will be served by~~ as a floor ~~need by the QHINs~~. Additional exchange needs may be satisfied ~~by satisfied~~ by QHINs (if they offer exchange services above the floor) and/or by other HINs.~~, with other needs satisfied by other HINs.~~

Minority Recommendation: 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, 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.

Minority Recommendation: 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.,~~a~~ unidirectional or bidirectional push exchange). Additional exchange needs may be satisfied by ~~satisfied~~ individual QHINs (if they offer exchange services above the floor) and/or by other HINs.

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Commented [WD3]: Struggled with this sentence so flipped it to active voice.

Commented [WD4]: TF asked what is the definition of this and what is priority? It was suggested that uses cases for permitted purposes would need to be prioritized and sequenced [by the RCE/QHINs]

~~**Recommendation:** ONC should clearly define 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, 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.~~

Recognized Coordinating Entity:

As noted above in our Overarching Recommendations, the TF believes ONC should defer and assign many of the operating decisions and detailed guidance for overall architecture and orchestration, standards, interoperability guidance, profiles, and metrics to the RCE, working in conjunction with the QHINs. Accordingly, the RCE should have strong capabilities in health care interoperability.

The TF believes the RCE should be broadly trusted, above reproach, transparent, and open. Governance of the RCE should represent a broad range of perspectives, including the patient, and not be overly weighted to large health systems, Federal providers, users of particular Health IT, a particular QHIN or set of QHINs, and should have sufficient protections against activities that would lead to or be perceived as leading to conflict.

At the same time, depending on the particular sustainability model used, the RCE may need to provide appropriate ~~, the TF believes the likely sustainability model for the RCE is through dues paid by the QHINs, who should therefore have a~~ fiduciary oversight ~~role~~ for funding members ~~for~~ of the RCE.

The TF believes the RCE role ~~may~~ might not match exactly any of the existing governance actors, and that the RCE selected by ONC ~~may~~ might represent a merged or reconfigured version of one or more established actors. The TF believes ONC may wish to look at successful governance outside of health care.

Recommendation: ONC should establish eligibility criteria for the RCE, requiring not-for-profit status, a clear sustainability model, and a governance model that balances responsibility between the national interests and the dues--paying members of the RCE. The governance model for the RCE should represent a broad range of ~~of provider perspectives (keeping in mind that definition of "provider" relevant to the 21st Century Cures Act is broad and expansive) as~~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 provider practice 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 conflict. In particular, the RCE governance should not be weighted towards or against

Commented [WD5]: Mark had a suggestion to point ONC to the gap analysis done last summer on organizations that may be eligible to be the RCE. A few individuals suggested we recommend ONC look at governance models outside healthcare, such as the NTSB, UL Labs…

particular segments of the provider community (e.g., large or Federal providers), health IT vendors, particular QHINs, etc.; and should include representation from ONC.

Recommendation: 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.

The TF discussed how ONC should judge the success or failure of the RCE and what interim milestones might be considered. The TF felt the RCE should be judged primarily based on outcomes-based measures and the real-world success of interoperability. That is, the TEF and the RCE will be judged successful if providers and patients adopt and receive services through QHINs that address the policy goals in the 21st Century Cures Act. Secondary measures should be satisfaction or survey-based, measuring the perceptions (including the user experience of interoperability) primarily of patients and providers, and secondarily of Health IT developers and QHINs. Process-based measured should be viewed as leading indicators of eventual outcome and satisfaction-based success. Because of the complexity of this effort, outcome, satisfaction and process measures should be defined with the end in mind, and working backward to satisfy the twin constraints of ~~realism~~ feasibility and policy urgency.

Recommendation: ONC should develop a set of outcomes-based 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 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 ~~realism~~ feasibility and urgency. Outcome measures and milestones should be set based on high-priority use cases (see the TF recommendations on Permitted Uses).

Qualified Health Information Networks

The TF discussed the meaning of "Participant Neutral" provided in the in the definition of QHIN on page 28 of the TEF. The TF had a great difficultly untangling the policy intent of the language from the mechanics of the language itself. We understood the language "none of the exchanges of EHI by or on behalf of the Qualified HIN include the Qualified HIN itself (whether directly or indirectly) as one of the parties" to preclude, for example, an EHR or a large provider or pharmacy organization, from establishing a QHIN serving its members or users. We had difficulty both with the language itself and with the policy intent behind the language. Here are two examples:

- It is not clear how an EHR vendor running a QHIN is including "itself" when it returns data from the providers who use the QHIN technology
- ~~Many~~ Some existing vendor-specific exchanges are in fact run by separate not-for-profit entities governed by the provider organizations who use the technology.

~~We speculate the intent of the language is to ensure the largest EHR technology vendors do not lock up the market with products that are proprietary on the vendor interface side (though open to cross-QHIN exchange) and therefore create a market issue where 80% of the market is locked out to prospective QHINs and the 20% remaining is the most difficult to wire.~~

Consistent with our overall recommendations that ONC document policy goals, it would be helpful to understand the underlying policy goals intended in the meaning of "Participant Neutral.".

The TF endorsed a policy goal that the ecosystem of QHINs be neutral and accessible to all relevant parties. At the same time, the sense of the TF was that restrictive language would prevent business models that might otherwise offer significant value to the health care ecosystem.

Recommendation: 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.

Recommendation: 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 ~~net effect~~goal of the TEF QHIN fee requirements is to establish ~~common carrier~~reasonable and non-discriminatory fees ~~requirements~~ for QHIN-QHIN pricing~~s~~. In particular, to allow uniform access to all permitted purposes across QHINs, the draft TEF requires QHINs to establish a QHIN-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 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, handling, 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-QHIN exchange and the duty to respond may change the market for exchange in profound ways.

~~-~~Because some of the broader enabling content 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.

When exchange requests and responses are reciprocal, this kind of common exchange model would be helpful. ~~-~~As examples, treatment-based uses which benefit patients and provider organizations are clearly established in the 21st Century Cures Act as subject to information blocking penalties. Accordingly, all provider organizations will need to enable access ~~,~~ ~~presumably through QHINs,~~ to avoid information blocking penalties. Although the TEF and QHIN participation are voluntary, it would be ideal if active participation in exchange enabled by QHINs established a reasonable basis for assuming conformance to relevant information blocking rules. (The TF acknowledges exact details here are speculative, pending final rules on information blocking.) These kinds of access benefitting patient and providers and are required of all provider data holders are appropriate for common ~~carrier~~ requirements combining cost-basis fee structures and duty to ~~.~~respond.

However at the present time, the market for payment-based uses (including, for example, data retrieval to enable risk adjudication for MA plans) or benefits determination are under rapid development. As payers differentially benefit from information access for risk adjustment, the market has developed with a payer fee structure. ~~Common carrier~~Cost-basis fee structures and a duty to respond to payment-based purposes of use would inevitably either shift cost to providers who are obligated to respond to queries and to establish query infrastructure for treatment uses or reduce the incentive for provider and QHIN participation in the TEF. ~~Two-sided markets are common for information exchange in other industries and shifting the side of the market required to bear the cost and obligation of exchange may cause market distortions.~~

Recommendation: ONC should establish through the TEF the combination of ~~common carrier~~zero or cost-basis QHIN-QHIN fee ~~-~~requirements with the duty to respond by QHINs, Participants and End Users only on QHIN-intermediated access that is ~~actually required~~required for all providers and ideally for uses that are reciprocal in nature where both sides of the exchange equally benefit and are equally likely to query and respond. ~~Should ONC expand common carrier requirements in other areas, ONC should line up other policy levers (for example, information blocking penalties) to align market value (for example, compliance with information blocking) with the cost borne to enable information exchange services.~~ ONC should understand that ~~common carrier~~zero or cost-basis QHIN-QHIN fee structures combined with duty to respond for permitted purposes will significantly shape market dynamics.

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 inter-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 a~~A~~uction mechanisms have been used in similar areas to establish market-appropriate fee structures~~could be used to ensure inter-QHIN fees are reasonable and minimal~~.

Recommendation: ONC should provide the RCE the authority to employ mechanisms to ensure inter-QHIN fees are uniform for like services 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 inter-QHIN exchange over time.

Permitted Uses and Disclosures

The TF applauds and strongly endorses the requirement for Individual Access. At the same time, the TF recognizes this is an emerging space, and policy and standards requirements are not

clearly established. The TF believes individual access (e.g., access to EHI through an individually controllable account) should be cleanly separated from aggregator-based access (e.g., where data is accessed by a data aggregator for secondary purposes via a proxy through an individual access request) for the purposes of fee restrictions and duty to respond. Note the TF acknowledges patients have the right to donate or otherwise use their data as they choose which may involve actors that are not governed by HIPAA but would be subject to FTC regulations.

Recommendation: ONC should clearly define "Individual Access" 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 ~~cause~~ case where the patient is requesting access to supply data to an application or utility that the patient manages and subsequent data donation should be optional and under the patient's control.

Recommendation: ONC should make it clear the duty to respond is on providers not individuals. Individually controlled services should be able to make data available for query (through a health record bank or similar structure) 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. However, individual access to broad-scale cross-provider query uses are under active pilot and policy requirements and standards enablement (for example, the format and meaning of Oauth2 requests in a patient request use) have not been established.

Recommendation: ONC should task the RCE to test and evolve standards and policies sufficient to enable broad-scale individual access. Standards should align with the policy and security requirements established for individual access.

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.

Recommendation: 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 later.

The Social Security (SSA) Disability Determination use is well established and the TF applauds inclusion of this use case as a permitted purpose. However, the QHIN fee requirements conflict with SSA's established fee structure, under which SSA is willing to pay a per record access fee. In addition, the USCDI is not currently sufficient to meet SSA's current data needs.

Recommendation: ONC should work with stakeholders to align USCDI with SSA's data needs for disability determination and to resolve the fee disparities.

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 common carrier fee requirements on the evolution of markets and assumption of fees.

The TF found that Payment use was too broadly defined 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 (e.g., HEDIS measures). 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 open data access and a duty to respond.

Recommendation: 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 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 common carrier requirements 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 payer use of population data for payer-based quality measurement (e.g., HEDIS measures) and especially for evaluating physician performance have many of the same market and contractual issues noted under the recommendations for payment.

Recommendation: ONC should work with standards development organizations and public-private stakeholders (for example, ~~such as~~ 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 and Security

With respect to the issues of individual choice to participate in information exchange, the TF noted that both so-called "opt-in" (a default presumption not to consent to HIPAA permitted purposes unless consent explicitly is granted and "opt-out" (a default presumption to consent unless explicitly withdrawn) have the same real-world outcome where large majorities (95%) choose to participate when choice is meaningfully presented to the individual. A presumption of non-consent drives significant administrative burden.

Successful real-world exchanges defer these issues to the provider organizations who are in the best position to comply with local requirements and policies. For example, electronic prescribing medication history requests carry a true/false assertion that is ultimately set in the EHR by the provider organization.

Recommendation: 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 provider organizations.

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: ONC should provide existing background to the RCE but not otherwise constrain requirements for patient education and patient matching.

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.

References

[API TF RECOMMENDATIONS]
[S&I TF RECOMMENDATIONS]
[Privacy and Security TF Informed Choice RECOMMENDATIONS]
[ONC PLAYBOOK]

Public Comment

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press "*1" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Task Force and made part of the Public Record.

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Health IT Advisory Committee

Trusted Exchange Framework Task Force

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